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SENATE

{ REPORT
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LETHAL DRUG ABUSE PREVENTION ACT

OCTOBER 6 (legislative day, October 2), 1998.—Ordered to be printed

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

REPORT

together with

ADDITIONAL AND MINORITY VIEWS

[To accompany S. 2151]

The Committee on the Judiciary, to which was referred the bill (S. 2151) to amend provisions of chapter 13 of title 21, United States Code, amending the Controlled Substances Act to clarify Federal law to prohibit the dispensing or distribution of a controlled substance for the purpose of causing or assisting in causing the suicide or euthanasia of any individual, 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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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 “Lethal Drug Abuse Prevention Act of 1998”.

SEC. 2. FINDINGS; PURPOSES.

(a) **FINDINGS.**—Congress finds that—

(1) the use of certain narcotics and other drugs or substances with a potential for abuse is strictly regulated under the Controlled Substances Act;

(2) the dispensing and distribution of certain controlled substances only by properly registered practitioners only for legitimate medical purposes are permitted under the Controlled Substances Act and implementing regulations;

(3) the dispensing or distribution of controlled substances to assist suicide or euthanasia are not legitimate medical purposes and are not permissible under the Controlled Substances Act;

(4) the dispensing or distribution of certain controlled substances for the purpose of relieving pain and discomfort are legitimate medical purposes and are permissible under the Controlled Substances Act;

(5) inadequate treatment of pain, especially for chronic diseases, 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 those 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, including that of assisting suicide or euthanasia, affect interstate commerce.

(b) **PURPOSES.**—The purposes of this Act are—

(1) to provide explicitly that Federal law is not intended to allow the dispensing or distribution of any controlled substance with the purpose of causing, or assisting in causing, the suicide or euthanasia, of any individual; and

(2) to encourage practitioners to prescribe, dispense, distribute, and administer controlled substances as medically appropriate in order to relieve pain and discomfort, by reducing unwarranted concerns that their registration to prescribe controlled substances will thereby be put at risk, if there is no intent to assist in causing a patient’s death.

SEC. 3. LETHAL DRUG ABUSE PREVENTION.

(a) **ADDITIONAL GROUND FOR DENIAL OF REGISTRATION.**—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

“(i) The Attorney General shall determine that registration of an applicant under this section is inconsistent with the public interest if—

“(1) during the 5-year period immediately preceding the date on which the application is submitted under this section, the registration of the applicant under this section was suspended or revoked under section 304(a)(4); or

“(2) the Attorney General determines, based on clear and convincing evidence, that the applicant is applying for the registration with the intention of using the registration to take any action that would constitute a violation of section 304(a)(4).”.

(b) **SUSPENSION OR REVOCATION OF REGISTRATION.**—

(1) **IN GENERAL.**—Section 304(a) of the Controlled Substances Act (21 U.S.C. 824(a)) is amended—

(A) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively; and

(B) by inserting after paragraph (3) the following:

“(4) has intentionally dispensed or distributed a controlled substance with the purpose of causing, or assisting in causing, the suicide or euthanasia of any individual, except that this paragraph does not apply to the dispensing or distribution of a controlled substance—

“(A) for the purpose of alleviating pain or discomfort (even if the use of the controlled substance may increase the risk of death), so long as the controlled substance is not also dispensed or distributed for the purpose of causing, or assisting in causing, the death of an individual for any reason;

or

“(B) for the purpose of carrying out a sentence of death under Federal or State law;”.

(2) **CONFORMING AMENDMENT.**—Section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)) (as redesignated by paragraph (1) of this subsection) is amended by inserting “other” after “such” the first place the term appears.

(c) 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) ASSISTED SUICIDE.—

“(A) FINDINGS.—

“(i) IN GENERAL.—Prior to any proceeding under paragraph (1), where an order to show cause may be based on subsection (a)(4) for denial, revocation, or suspension of registration, the Attorney General shall make a finding that the applicant or registrant—

“(I) has dispensed or distributed a specific controlled substance that was directly responsible for the death of an individual; and

“(II) did not dispense or distribute the specific controlled substance as medically indicated.

“(ii) CONSULTATION.—In making any finding under clause (i)(II), the Attorney General may consult with the Secretary of Health and Human Services, as the Attorney General, in consultation with the Secretary, determines to be appropriate.

“(B) BURDEN OF PROOF.—At any proceeding under paragraph (1), where the order to show cause is based on subsection (a)(4) for denial, revocation, or suspension of registration, the Attorney General shall have the burden of proving, by clear and convincing evidence, that the practitioner’s intent was to dispense or distribute a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual. In meeting such burden, it shall not be sufficient to prove that the registrant knew that the use of the controlled substance may increase the risk of death.

“(C) REQUEST FOR REVIEW BY MEDICAL ADVISORY BOARD ON PAIN RELIEF.—At any proceeding under paragraph (1), where the order to show cause is based on subsection (a)(4) for denial, revocation, or suspension of registration, the practitioner may request, within 30 days after the receipt of the order to show cause, that the Medical Advisory Board on Pain Relief review, in accordance with paragraph (3), the administrative record of such proceeding as it relates to subsection (a)(4).

“(3) MEDICAL ADVISORY BOARD ON PAIN RELIEF.—

“(A) IN GENERAL.—The Secretary of Health and Human Services, in consultation with the Attorney General, shall by regulation establish a board to be known as the Medical Advisory Board on Pain Relief (referred to in this subsection as the ‘Board’).

“(B) MEMBERSHIP.—

“(i) IN GENERAL.—Subject to clause (ii), the Secretary of Health and Human Services, in consultation with the Attorney General, shall appoint the members of the Board—

“(I) from among individuals who by reason of specialized education or substantial relevant experience in pain management, are clinical experts with knowledge regarding standards, practices, and guidelines concerning pain relief; and

“(II) after consultation with the American Medical Association, the American Academy of Pain Medicine, the American Pain Society, the American Academy of Hospice and Palliative Medicine, the National Hospice Organization, the American Geriatrics Society, and such other entities with relevant expertise concerning pain relief, as the Attorney General determines to be appropriate.

“(ii) PROHIBITION.—No member of the Board may be an officer or employee of the Federal Government.

“(C) DUTIES OF BOARD.—If, in accordance with paragraph (2)(B), an applicant or registrant requests a review by the Board of the record of a proceeding under paragraph (1), the Board shall review the administrative record of such proceeding as it relates to subsection (a)(4) and issue to the Secretary of Health and Human Services and the Attorney General an advisory opinion as to whether the dispensing or distribution of the controlled substance at issue in the proceeding was for the purpose of alleviating pain or discomfort in a manner that does not constitute a violation of subsection (a)(4). The opinion of the Board under this subparagraph shall be part of the administrative record and shall be considered by the Attorney General

in determining whether to deny, revoke, or suspend the registration involved.

“(D) COMPENSATION OF MEMBERS.—Each member of the Board shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Board.

“(4) NO ADDITIONAL INVESTIGATIVE AUTHORITY.—Nothing in section 303(i), subsection (a)(4) of this section, or this subsection may be construed to provide the Attorney General with any additional investigative authority in any State, to the extent that the law of the State prohibits assisted suicide or euthanasia.”.

SEC. 4. DESIGNATION OF LIAISON.

Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall designate an officer of the Department of Health and Human Services to serve as a liaison between the Secretary of Health and Human Services and the Attorney General in carrying out this Act and the amendments made by this Act.

SEC. 5. DIVERSION CONTROL FEE ACCOUNT.

Notwithstanding any other provision of law, for purposes of section 111(b) of the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations, Act, 1993 (21 U.S.C. 886a), the operation of the diversion control 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), (c)(2), and (c)(3) of section 304 of the Controlled Substances Act (21 U.S.C. 824), as amended by this Act.

SEC. 6. APPLICABILITY; CONSTRUCTION.

(a) APPLICABILITY.—The amendments made by this Act shall apply with respect to any controlled substance dispensed or distributed on or after the date of enactment of this Act.

(b) CONSTRUCTION.—Nothing in this Act or amendments made by this Act shall be construed to imply that the dispensing or distribution of a controlled substance before the date of enactment of this Act for the purpose of causing, or assisting in causing, the suicide or euthanasia of any individual is or is not a violation of the Controlled Substances Act (21 U.S.C. 801 et seq.).

(c) INCORPORATED DEFINITIONS.—In this section, the terms “controlled substance”, “dispense”, and “distribute” have the meanings given those terms in section 102 of the Controlled Substances Act (21 U.S.C. 802).

I. PURPOSE AND SUMMARY

This legislation is intended to provide explicit clarification that the dispensing or distribution of controlled substances to assist with a suicide, that is, certain narcotics and other drugs or substances with a potential for abuse, is not a legitimate medical purpose and thus is not permissible under the Federal Controlled Substances Act. At the same time, the legislation is proposed in order to encourage medical practitioners to continue to prescribe, dispense, distribute and administer controlled substances as medically appropriate in order to relieve pain and discomfort. As the bill notes, inadequate treatment of pain is a serious public health problem affecting hundreds of thousands of patients a year.

Thus, this legislation is premised on the principle that the Controlled Substance Act contemplates use of controlled substances to alleviate human pain and suffering and that this purpose cannot be turned on its head by allowing controlled substances to become intentional agents of death.

Under the Lethal Drug Abuse Prevention Act, as amended, Congress finds that the strict regulation of controlled substances allows the dispensing and distribution of 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 legitimate medical purposes, relieving pain and discomfort, both before and after enactment of S. 2151.

The Lethal Drug Abuse Prevention Act requires the Attorney General to determine that the registration of an applicant (most commonly a physician, retail pharmacy, hospital/clinic or teaching institution) is inconsistent with the public interest in either of two cases. In the first, the Attorney General would make the determination if the applicant's registration has been suspended or revoked in the past 5 years because the applicant intentionally dispensed a controlled substance to cause or assist in causing a suicide. In the second case, if the Attorney General determines that the applicant intends to use the registration in connection with an assisted suicide. In the second case, the Department of Justice's determination must be based on a "clear and convincing evidence" standard.

Prior to starting any action to investigate a suspected assisted suicide, the Attorney General must make two findings. First, she must make an evidentiary-based finding that the registrant had dispensed or distributed a controlled substance which was directly attributable to the death of an individual. Second, she must find that the registrant did not use the controlled substance as medically indicated in accordance with this Act.

These two provisions were inserted by the Committee as a "screen," to make certain that the Drug Enforcement Administration does not undertake unwarranted investigations which might have the dual negative effects of impeding proper pain management as well as unnecessarily subjecting registrants to the time-consuming and costly proceedings with serious implications for the registrant and the community served by the registrant, especially in small, rural single practitioner towns.

The requirement that the Department of Justice make these two findings prior to any investigation, combined with the "clear and convincing evidence" standard cited above, attempts to allay fears that enactment of S. 2151 would provide the DEA with unreasonable, expanded authority which could result in innocent practitioners be unjustly charged. Rather, this Act explicitly affirms, which was not done in the Controlled Substances Act, the need for practitioners to use pain medications as medically indicated, in fact, even if the use of those medications may increase the risk of death.

As a further safeguard, the amended bill makes explicit that nothing in this legislation shall be construed to grant the Attorney General additional investigative authority in any State, to the extent that the law of the State prohibits assisted suicide or euthanasia.

This Act—consistent with the existing framework of the Controlled Substances Act—contemplates a strong relationship between the Department of Justice and the Department of Health and Human Services (HHS), so that HHS may serve as the Drug Enforcement Administration's chief medical adviser in carrying out

this Act. For example, S. 2151, as amended, requires that within one month of enactment the Secretary of HHS designate an officer to serve as a liaison with the Attorney General in implementing the Act.

In addition, the bill requires HHS (in consultation with the Department of Justice) to establish a Medical Advisory Board on Pain Relief which may be used by any applicant subject to license revocation proceedings to review the administrative record and provide guidance on whether the controlled substance had been used for a legitimate medical purpose. The bill enumerates the type of membership envisioned for the Board, including individuals who are by reason of specialized education or substantial relevant experience in pain management considered clinical experts in pain relief and practice. The Board shall be operated consistent with the Federal Advisory Committee Act and will be funded from the Diversion Control Fee Account, consistent with that account's traditional use in connection with registration issues.

Finally, the bill includes language to make certain that the amendments to the Controlled Substances Act made therein will apply only with respect to any controlled substance dispensed or distributed on or after the date of enactment.

II. BACKGROUND AND NEED FOR THE LEGISLATION

The ability of modern medicine to extend life has moved far from the 16th century, when Montaigne observed: "To die of old age is a death rare, extraordinary, and singular * * * a privilege rarely seen."

As science yields its astounding, life-extending discoveries, our Nation faces the stark reality that many of its citizens will develop chronic, often painful conditions such as arthritis, or perhaps acute, life-threatening diseases such as cancer.

Medicine's ability to treat these illnesses and extend life brings with it new challenges, including the task for providing the best care and treatment for our loved ones as they move toward the end of life.

A number of recent events have sparked a national debate over the tremendously intertwined moral, legal and ethical issues surrounding end-of-life care, and more specifically, the idea of physician-assisted suicide. Several converging factors have raised our national consciousness with respect to end-of-life issues, including two recent Supreme Court cases on assisted suicide, *Vacco v. Quill*¹ and *Washington v. Glucksberg*², enactment of Oregon's Measure 16 (the "Death with Dignity Act"),³ and Presidential signature of the Assisted Suicide Funding Restriction Act of 1997 (P.L. 105-12).⁴ America's conviction that physicians are healers is underscored by the fact that 36 States outlaw assisted suicide under criminal law, and nine others do so through common law.⁵

¹ 117 S.Ct. 2293 (1997).

² 117 S.Ct. 2258 (1997).

³ Or. Rev. Stat. §§ 127.800-127.995.

⁴ The Assisted suicide Funding Restriction Act of 1997, 111 Stat. 23, April 30, 1997.

⁵ Merritt, Dick; Fox-Grage, Wendy; and Rothhouse, Marla of the National Conference of State Legislatures, and Lynn, Joanne; Cohn, Felicia; and Forlini, Janet Heald of The Center to Improve the Care of the Dying, The George Washington University, "State Initiatives in End-of-

In 1997, the Congress voted overwhelming by a 99–0 vote in the Senate, and a decisive 398–16 vote in the House of Representatives, to adopt the Assisted Suicide Funding Restriction bill, which safeguarded from legal challenge the long-standing Federal practice which barred the use of Federal funds to assist in suicide or euthanasia. The bill, which was signed into law by President Clinton on April 30, 1997 (Pub.L. 105–12), prohibits the use of appropriated funds to provide or pay for any health care item or service or health benefit coverage for the purpose of causing or assisting to cause the death of any individual.

Shortly after enactment of P.L. 105–12, on July 25, 1997, the Chairmen of both the House and Senate Judiciary Committees wrote to Drug Enforcement Administrator 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, despite enactment of any State laws which might appear to be in conflict.

As noted in the July, 1997, letter to Mr. Constantine,⁶ under existing regulations (21 CFR 1306.04), a controlled substance must be

Life Care: Policy Guide for State Legislators”, National Conference of State Legislatures, 1998, p. 40.

⁶Hon. HENRY J. HYDE,
Congress of the United States,
Washington, DC.

THOMAS A CONSTANTINE,
Administrator, Drug Enforcement Administration,
Washington, DC.

DEAR MR. CONSTANTINE: As chairmen of the House and Senate Judiciary Committees we write seeking the Drug Enforcement Administration’s view as to whether delivering, distributing, dispensing, prescribing, filling a prescription, or administering a controlled substance with the deliberate intent of assisting in a suicide would violate the Controlled Substance Act, applicable regulations, rulings, or other federal law subject to DEA enforcement, notwithstanding the enactment of a state law such as Oregon’s Measure 16 which rescinds state penalties against such prescriptions for patients with a life expectancy of less than six months.

Drugs used to assist in a suicide include such controlled substances as amobarbital, codeine, diazepam, flurazepam, glutethimide, chloral hydrate, hydromorphone, meprobamate, methyprylon, meperidine, methadone, morphine, phenobarbital, secobarbital, and pentobarbital. Derek Humphrey, *Final Exit: The Practicalities of Self-Deliverance and Assisted Suicide for the Dying* (Hemlock Society 1991), at 117–120. Under existing regulations, a prescription for a controlled substance “must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. Sec. 1306.04. Case law indicates “that the physician must have some therapeutic purpose to prescribe lawfully.” George J. Annas, “Death By Prescription: The Oregon Initiative,” *New Eng. J. of Med.* 1240, 1242 (Nov. 3, 1994).

The Health Care Financing Administration has stated that physician-assisted suicide is not “reasonable and necessary” to the diagnosis and treatment of disease or injury and is therefore barred from reimbursement under Medicare. See enclosed letter of May 1, 1996 from Debbie I. Chang, Director of HCFA’s Office of Legislative and Inter-Governmental Affairs. The American Medical Association, the American Nurses Association, the American Psychiatric Association, and at least 43 other national specialty and state medical societies have condemned assisted suicide, stating that it has “[l]ong [been] viewed as outside the realm of legitimate health care” and is “fundamentally incompatible with the physician’s role as healer * * *.” See Briefs of Amici of the American Medical Association, *et al.*, at 4–5, in *Washington v. Glucksberg*, No. 96–110 (U.S.) and *Vacco v. Quill*, No. 95–1858 (U.S.), citing Code of Medical Ethics, sec. 2.211 (App. 11a).

In our view, assisting in a suicide by prescribing or filling a prescription for a controlled substance cannot be a “legitimate medical purpose” under DEA regulations, especially when the practice is not reasonable and necessary to the diagnosis and treatment of disease and injury, legitimate health care, or compatible with the physician’s role as healer.

As you know, this is an area of special interest to the Congress. On March 20, the House Commerce Committee, by a 45–2 vote, approved legislation (H.R. 1003) to pro-

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used “for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” Drugs reported to be used in assisted suicide include such controlled substances as amobarbital, codeine, diazepam, flurazepam, glutethimide, chloral hydrate, hydromorphone, meprobamate, methyprylon, meperidein, methadone, morphine, phenobarbital, secobarbital, and pentobarbital.⁷

A panoply of National and State medical associations have condemned the practice of assisted suicide, both in testimony to the Congress and in briefs accompanying the *Vacco* and *Washington cases*. Indeed, as noted in the Assisted Suicide Funding Restriction Act of 1997, while the Federal Government provides financial support for the provision and payment of healthcare services, assisted suicide, euthanasia, and mercy killing have been criminal offenses throughout the United States. That position is enjoined by the Federal Health Care Financing Administration, which has 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.⁸

In response to the letter of Chairmen Hyde and Hatch, the Drug Enforcement Administration undertook a serious review of case law, legal briefs, law review articles, and State laws related to assisted suicide. Citing that study, in a November 5, 1997 response,⁹

hibit any use of federal funds, programs or facilities to perform or advocate assisted suicide. The bill was approved by the full House of Representatives on April 10 by a vote of 398-to-16, by the Senate on April 16 by a vote of 99-to-0, and signed by the President on April 30. Clearly Congress would have a serious concern were any federal agency to construe the intentional prescribing of lethal drugs for suicide as a legitimate medical practice. Therefore, we would be grateful for your prompt response.

Sincerely,

ORRIN HATCH,
United States Senator.

HENRY HYDE,
United States Representative.

⁷ Humphrey, Derek, “Final Exit: The Practicalities of Self-Deliverance and Assisted Suicide for the Dying,” Hemlock Society, 1991, pp. 117–120.

⁸ Letter of May 1, 1996 from Debbie I. Chang, Director of the Office of Legislative and Intergovernmental Affairs, Health Care Financing Administration.

⁹ U.S. DEPARTMENT OF JUSTICE,
Drug Enforcement Administration,
Washington, DC.

Hon. ORRIN G. HATCH,
U.S. Senate,
Washington, DC.

DEAR SENATOR HATCH: Thank you for your letter of July 29, 1997. In that letter, you requested the Drug Enforcement Administration’s (DEA) view as to “whether delivering, distributing, dispensing, prescribing, filling a prescription, or administering a controlled substance with the deliberate intent of assisting in a suicide would violate the Controlled Substances Act (CSA), applicable regulations, rulings, or other federal law subject to DEA enforcement, notwithstanding the enactment of a state law such as Oregon’s Measure 16 which rescinds state penalties against such prescriptions for patients with a life expectancy of less than six months.”

I apologize for the delay in responding to you. As you know, the CSA authorizes DEA to revoke the registration of physicians who dispense controlled substances without a legitimate medical purpose. Historically, DEA’s experience with the phrase “without a legitimate medical purpose” has focused on cases involving physicians who have provided controlled substances to drug addicts and abusers. The application of this phrase to cases involving physician-assisted suicide presented DEA with a new issue to review.

Since receiving your inquiry, my staff has carefully reviewed a number of cases, briefs, law review articles and state laws relating to physician-assisted suicide, including the documents referenced in your letter. In addition, my staff has conducted a thorough review of prior administrative cases in which physicians have dispensed controlled substances for other than a “legitimate medical purpose.” Based on that review, 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 of a “legitimate

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,” Mr. 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 letter¹⁰ from Attorney General Janet Reno which overturned the DEA position.

medical purpose.” As a result, the activities that you described in your letter to us would be, in our opinion, a violation of the CSA.

Because physician-assisted suicide would be a new and different application of the CSA, a number of issues remain unresolved. For example, suspicious or unnatural deaths require a medico-legal investigation. The first priority in such an investigation would be a comprehensive forensic inquiry by a state or local law enforcement agency, which is traditionally supported by the efforts of a medical examiner, forensic pathologist, and/or coroner. At the conclusion of this stage of the inquiry, the evidence often is submitted to a grand jury or similar process for a determination of potential criminal liability of the person who assisted in the death.

This initial determination as to the cause of death is not DEA’s responsibility. Rather, DEA would have to rely on the evidence supplied to us by state and local law enforcement agencies and prosecutors. If the information or evidence presented to DEA indicates that a physician has delivered, distributed, dispensed, prescribed or administered a controlled substance with the deliberate intent of assisting in a suicide, then DEA could initiate revocation proceedings on the grounds that the physician has acted “without a legitimate medical purpose.”

In addition to moving to revoke a physician’s registration for dispensing controlled substances “without a legitimate medical purpose,” please also be aware that the CSA provides a number of other grounds upon which DEA might revoke the registration of a physician who assisted in a suicide. For example, DEA will revoke the registration of any physician whose state license to practice medicine has been revoked for assisting suicide. Similarly, DEA has authority to revoke the registration of any physician whose acts in assisting a suicide result in a conviction under state controlled substances laws.

DEA must examine the facts on a case-by-case basis to determine whether a physician’s actions conflict with the CSA. If the facts indicate that a physician has acted as set forth in your letter, however, then DEA would have a statutory basis to initiate revocation proceedings.

I trust that this response addresses your inquiry. If you have any further questions, please feel free to contact me.

Sincerely,

THOMAS A. CONSTANTINE,
Administrator.

¹⁰ OFFICE OF THE ATTORNEY GENERAL,
Washington, DC.

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

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

The Oregon Act was approved by Oregon voters on November 8, 1994, and went into effect on October 27, 1997. The Act provides for a detailed procedure by which a mentally competent, terminally ill patient may request to end his or her life “in a humane and dignified manner.” *O.R.S. § 127.805*. The procedure requires, for example, that the patient’s competence and the voluntariness of the request be documented in writing and confirmed by two witnesses, *see id.* § 127.801(1), that the patient’s illness and competence and the voluntariness of the request be confirmed by a second physician, *see id.* § 127.820, and that the physician and patient observe certain waiting periods, *see id.* §§ 127.840, 127.850. Once a request has been properly documented and the requisite waiting periods have expired, the patient’s attending physician may prescribe, but not administer, medication to enable the patient to take his or her own life. As a matter of state law, physicians acting in accordance with the Oregon Act are immune from liability as well as any adverse disciplinary action for having rendered such assistance.

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Writing on June 5, 1998, General Reno said, "The Department has reviewed the issue thoroughly and has concluded that adverse ac-

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

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

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

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

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

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

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

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

Sincerely,

JANET RENO.

tion against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA.”

General Reno’s letter appeared to be, in part, a response to an October 8, 1997 action by the U.S. Supreme Court to deny *certiorari* in the case of *Lee v. Oregon*¹¹ which removed the final barrier to implementation of Oregon’s Death With Dignity Act. The Death With Dignity Act allows terminally ill Oregon residents, those who are determined to have fewer than 6 months to live, to request from their attending physician a prescription for drugs to end their life. The Oregon Act requires a 15-day waiting period, three requests from the patient, one of which must be in writing, and a second physician’s opinion. The Oregon measure does not permit lethal injection, mercy killing, or active euthanasia, but makes clear that actions taken in accordance with the law do not constitute suicide, mercy killing or homicide.¹²

In her letter, General Reno related that the Department had conducted a thorough and careful review of the issue of whether the CSA authorizes adverse action against a physician who prescribes a controlled substance to assist in a suicide in compliance with Oregon law, and concluded that the CSA “does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law.” In rendering that decision, General Reno noted that it applied to a narrow set of conditions and in compliance with certain detailed procedures (e.g. those in the Oregon law) and concluded that “adverse action under the CSA may well be warranted in other circumstances: for example, where a physician assists in a suicide in a State that has not authorized the practice under any conditions, or where a physician fails to comply with State procedures in doing so.”

Amplifying further on General Reno’s views, Joseph N. Onek, Principal Deputy Associate Attorney General, testified before the Senate Committee on the Judiciary on July 31, 1998 that their lengthy legal analysis of existing law concluded that the DEA is not authorized to take action against physicians who are in compliance with the laws of their own States regarding physician-assisted suicide.

Mr. Onek testified that the Department had based its conclusion on the legislative history of the Controlled Substances Act and the actual language of the Act which he said provided no evidence that the Congress intended to delegate to the DEA the right to decide whether State-approved physician-assisted suicide constituted a legitimate medical purpose. He contrasted that decision with the instance of the use of marijuana for medical purposes, as authorized in at least two States. In that instance, according to Mr. Onek, Congress has specifically extended the national control of the CSA by acting to place marijuana specifically on the list of Schedule I controlled substances, which have no currently accepted medical use.

Enactment of S. 2151 will resolve the divergence of opinion between the DEA and the DoJ and is intended to clarify that the

¹¹ 107 F.3d 1382 (9th Cir. 1997) cert. denied, 66 U.S.L.W. 3282.

¹² *Oreg. Rev. Stat.* §§ 127.800–127.995.

Controlled Substance Act does apply on a national basis to cases of assisted suicide, State law notwithstanding. While some have expressed concern about any legislative effort which might appear to override State laws, it is important to note that the Federal Government has asserted for decades its appropriate role in regulating substances of abuse, including the Federal Controlled Substances Act which was enacted in 1970 as a national statute to set uniform standards governing the use of drugs with a high potential for abuse. The Committee has approved S. 2151 consistent with the national nature of the Controlled Substances Act, which does not envision variances in law from State to State with respect to drugs with a high potential for abuse.

III. SECTION-BY-SECTION ANALYSIS

Following is a section-by-section analysis of the Chairman's substitute as ordered reported by the Committee on September 24, 1998:

Section 1. Short title

Entitles the Act the "Lethal Drug Abuse Prevention Act of 1998."

Section 2. Findings; purposes

Makes a series of findings about 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, the need for improved treatment of pain, and the fact that dispensing and distributing such drugs affects interstate commerce. Relates the purposes of the bill to: (1) provide explicitly that Federal law does not allow the dispensing or distribution of a controlled substance to cause or assist a suicide or euthanasia; and (2) encourage the use of such substances when medically appropriate to relieve pain and discomfort.

Section 3. Lethal drug abuse prevention

Adds a new subsection (I) to section 303 of the Controlled Substances Act ("Registration Requirements") to require the Attorney General to determine that registration of an applicant is inconsistent with the public interest in either of two cases: (1) when the registration has either been revoked or suspended in the past 5 years because the registrant intentionally dispensed or distributed a controlled substance to cause or assist in a suicide or euthanasia; or (2) when the Attorney General determines (based on a clear and convincing evidence standard) that the applicant intends to use the registration to cause or assist in a suicide.

Amends section 304 ("Denial, Revocation or Suspension of Registration") to add to the list of factors the Attorney General considers in suspending or revoking a registration a new consideration (304(a)(4)) of whether the registrant has intentionally dispensed or distributed a controlled substance with the purpose of causing or assisting in causing the suicide or euthanasia of any individual.

Makes clear that prior to commencing any action under the new section 304(a), the Attorney General must find that the registrant dispensed or distributed a specific controlled substance which was directly responsible for the death of an individual, and that the reg-

istrant did not dispense or distribute the controlled substance as medically indicated. The term “medically indicated” refers to the use of a controlled substance where the use of such substance is reasonable and necessary for the treatment of a patient and is not consistent with intentionally causing the death of the patient. The Attorney General may consult with the Secretary of HHS as she deems appropriate in making such a finding. HHS is required to appoint an individual or office which will serve as the principal liaison in carrying out the Act.

Clarifies that the new 304(a)(4) does not apply to dispensing and distributing controlled substances to alleviate pain or discomfort (even if it may increase the risk of death) or to carry out a death sentence. 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 suicide or euthanasia.

The Secretary of Health and Human Services and the Attorney General will establish a “Medical Advisory Board on Pain Relief.” The membership is appointed after consultation with pain relief experts and will be drawn from individuals with experience in pain management and relief. A practitioner subject to investigation under 304(a)(4) may request that the Medical Advisory Board on Pain Relief review the administrative record of the proceeding and issue an opinion to the Attorney General on whether the dispensing or distribution of the controlled substance at issue was for the purpose of alleviating pain or discomfort consistent with 304(a)(4).

Makes explicit that nothing in these amendments to the Controlled Substances Act shall be construed to grant the Attorney General additional investigative authority in any State to the extent that the law of the State prohibits assisted suicide or euthanasia.

Section 4. Designation of liaison

Requires the Secretary of Health and Human Services to designate an officer to serve as liaison with the Attorney General.

Section 5. Diversion control fee account

Clarifies that, because the activities under this legislation are consistent with the Drug Enforcement Administration’s registration activities under current law, agency activities, including review board activities, pursuant to this bill are to be reimbursed under the diversion control fee account.

Section 6. Applicability; construction

Explains that the changes in the bill apply with respect to any controlled substance dispensed or distributed after date or enactment. Clarifies that the Act does not change current law prior to enactment with respect to the use of a controlled substance in an assisted suicide or euthanasia.

IV. LEGISLATIVE HISTORY AND VOTES IN COMMITTEE

S. 2151, the “Lethal Drug Abuse Prevention Act of 1998” was introduced on June 9, 1998 by Senators Don Nickles, Trent Lott and

11 other Senators.¹³ On July 31, 1998, 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, its interrelationship with State law, and the role of the Drug Enforcement Administration in the regulation of controlled substances. The Committee heard testimony from three panels of witnesses, including Members of Congress, representatives of the Administration, and public advocates expert in end-of-life care issues.

In the first panel, Senator Nickles testified that the sole purpose of the legislation is to clarify that assisted suicide is not a “legitimate medical purpose” under the Controlled Substances Act and that, therefore, federally-controlled substances cannot be prescribed or dispensed for that purpose. Enactment of the Lethal Drug Abuse Prevention Act of 1998 will ensure that Federal authorization to prescribe DEA-regulated drugs does not include the authority to prescribe such drugs to cause a patient’s death, Senator Nickles explained.

Also on panel one, Senator Ron Wyden strongly opposed S. 2151. He testified that he believes the underlying message of S. 2151, with which he completely disagrees, is that Congress can better decide what is best for the people than the voters in Oregon. 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 less aggressively comfort patients in intractable pain.

As the final witness in the first panel, Senator Gordon Smith explained he believed assisted suicide is an issue of conscience, not a States’ rights issue, but rather an issue of what the law should be with respect to life. He outlined his own experience with the law as an Oregon State Senator and a member of its Health Care and Bioethics Committee, as well as his experiences as a lay bishop visiting the sick, elderly and the dying. Senator Smith argued that the bill should eliminate any retroactive prosecution of doctors in Oregon, and it should more fully define a high tolerance for aggressive palliative care.

Testifying for the Administration on the second panel were Joseph N. Onek, Principal Deputy Associate Attorney General, U.S. Department of Justice, and Thomas A. Constantine, Administrator, Drug Enforcement Administration. Mr. Onek testified that, although the President is against physician-assisted suicide and any Federal support of it, he believes S. 2151 is flawed in many ways. He raised three principle objections to the legislation: First, that he believed it would compromise the DEA’s core mission of preventing drug abuse and the diversion of controlled drugs; second, that the bill might inappropriately involve DEA in decisions about the use of pain medication and lessen the cooperation the agency receives from the medical community; and third, that the legislation could “intimidate” physicians from providing adequate palliative care.

¹³S. 2151 is currently sponsored by Senators: Nickles; Lott; Coats, Inhofe, Helms, Murkowski, Grams, Faircloth, Bond, Enzi, Sessions, Hazel, Coverdell, Smith (NH), Lieberman, Brownback, Craig, Abraham, Santorum, Allard, Grassley, DeWine, Kyl, and Hutchinson.

DEA Administrator Constantine related the analysis used to develop his November 5, 1997 response to Congress, concluding that while he believed the DEA has authority with respect to the use of controlled substances in an assisted suicide, the agency would make any decision to initiate a revocation on a case-by-case basis after a careful review of the facts.

The third panel of witnesses consisted of experts who deal with end-of-life issues and physician-assisted suicide. As the first witness in this panel, Dr. Ralph Meich, a professor of pharmacology at Brown University, and the founder of the Rhode Island Cancer Initiative, expressed his support of S. 2151 stating that it clarifies important ethical and legal distinctions between appropriate medical use of therapeutic drugs for pain control in palliative care and lethal misuse of such drugs to accomplish assisted suicide. Dr. Meich also believes that the use of the controlled substances regulated by this legislation should be subject to DEA regulation.

Dr. Joanne Lynn, president of the Americans for Better Care of the Dying, and representing the American Geriatrics Society, expressed her opposition to the bill. She testified that it is her belief that this bill will have a deleterious effect on pain management of the chronically ill. She fears this legislation will have the unintended consequence of increasing pain suffered by the terminally ill by deterring physicians from prescribing adequate doses of scheduled pain management drugs.

The next witness, Dr. Walter Hunter, medical director of the South Oakland County Hospice of Michigan, testified in support of the legislation, stating that his bill will not interfere with his ability, as a hospice physician, to deliver palliative care. Dr. Hunter argued that increased scrutiny of treatment practices by the DEA will only improve the quality of care by his colleagues. Hospice care serves as an alternative to the need for physician-assisted suicide by providing proper palliative care to the terminally ill which Dr. Hunter believes will not survive if legalization of assisted suicide occurs.

Dr. Harold S. Sox, Jr., president of the American College of Physicians (ACP)-American Society of Internal Medicine (ASIM), testified in opposition to the proposed legislation. Dr. Sox argued that the ACP-ASIM opposes S. 2151 primarily because they fear that physicians who aggressively prescribe pain medication could face disciplinary proceedings under the new act. Dr. Sox said this will result in a reluctance of physicians to effectively treat pain.

Andrew Batavia is an Associate Professor of the Health Services Administration Program with the School of Policy and Management in the College of Urban and Public Affairs at Florida International University. He testified in opposition to S. 2151 because he believes such legislation violates basic Republican principles of federalism, sound legislation, regulatory restraint, and fairness. He argued that S. 2151 supersedes the right of Oregon citizens who have had two elections deciding the policy of assisted suicide in their State, and as a result the Federal Government should not preempt this law.

As the final witness, Gayle Hafner of Not Dead Yet (NDY), testified in support of S. 2151. Ms. Hafner argued that there have been years of medical discrimination against people with disabilities and

therefore categorically opposes physician-assisted suicide. NDY believes that quality of life in disabled people is underestimated by many doctors and that doctors often prey on the fears of newly disabled people and sway them into making a so-called choice for death decisions.

The bill was considered by the full committee in an executive session on September 24, 1998, where the committee voted 11–6 to report the bill as amended to the Senate. Voting in favor were Senators Thurmond, Grassley, Specter, Thompson, Kyl, DeWine, Ashcroft, Abraham, Sessions, Biden and Hatch, and in opposition were Senators Leahy, Kennedy, Kohl, Feinstein, Feingold and Torricelli.

The House companion bill, H.R. 4006, was introduced on June 5, 1998 by Judiciary Committee Chairman Henry Hyde and Representative James Oberstar. The Subcommittee on the Constitution approved the bill, as amended on July 22, 1998. The full committee ordered it reported on August 4, 1998.

The Committee met to consider the bill on Thursday, September 24, 1998. Senator Hatch offered a substitute amendment which was agreed to by unanimous consent. The bill was ordered favorably reported, as amended, by a rollcall vote of 11 yeas to 6 nays, as follows:

YEAS	NAYS
Thurmond	Leahy
Grassley (by proxy)	Kennedy (by proxy)
Specter (by proxy)	Kohl (by proxy)
Thompson	Feinstein
Kyl (by proxy)	Feingold (by proxy)
DeWine	Torricelli
Ashcroft (by proxy)	
Abraham	
Sessions	
Biden	
Hatch	

V. EXPLANATION OF LEGISLATION AND COMMITTEE VIEWS

The Lethal Drug Abuse Prevention Act of 1998 is intended to clarify Federal law with respect to the use of controlled substances in cases of assisted suicide and euthanasia, and at the same time highlight the concern of Congress that medical professionals be encouraged to provide appropriate palliative care for those in chronic pain. The Committee is aware that criticisms have been raised that this legislation will have unintended consequences which might inappropriately reduce the level of care that the terminally ill might receive. The Committee believes that many of these criticisms are based on erroneous information, an unfair reading of the provisions, or an analysis of the bill prior to adoption of the Chairman's substitute.

A. SCOPE OF THE BILL

One key misconception about S. 2151 is that it is intended to eradicate all assisted suicide, a misunderstanding frequently cited by opponents of the bill. Indeed, the testimony of the Justice De-

partment before this Committee was replete with such references. At that hearing, Mr. Onek testified that:

The proposed revision of the Controlled Substances Act through S. 2151 would not necessarily accomplish the intended effect of banning all assisted suicides, as there are several plausible means of assisted suicide or euthanasia which do not involve the use of controlled substances.¹⁴

The Principal Deputy Associate Attorney General also told the Committee the legislation is:

Likely to be ineffective in preventing physician-assisted suicide, because, in fact, physician-assisted suicide does not require the use of controlled substances. Furthermore, in the real world, most terminally ill patients already have an ample supply of such substances to use in conjunction with an assisted suicide effort. In short, just as the DEA is, in our view, the wrong agency to deal with this issue, the Controlled Substances Act is the wrong vehicle.¹⁵

The Committee is not so ignorant as to believe that this legislation will thwart all suicides or assisted suicides. Nor is the bill intended to do so. Indeed, no amount of regulation could accomplish that purpose. Instead, the purpose of S. 2151, as highlighted above, is to ratify the uniform, national nature of the Controlled Substances Act, to clarify that its provisions intended to regulate drugs with a potential for abuse apply equally in all states.

B. FEDERALISM

Another erroneous criticism of the bill is that it usurps the power of States to enact legislation, a power which is reserved under the 10th amendment to the Constitution. Related to that argument is the allegation that the bill is intended to overturn the Oregon Death with Dignity Act. Again, these allegations appear to be based more on fear than reality.

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. The CSA is achieving its purpose of imposing that nationwide system of controls to reduce the potential for drugs to be abused, while at the same time improving pain care. In 1970, when the Controlled Substances Act was enacted, 70 percent of the drug-related emergency room visits were caused by legitimate drugs. By 1990, that figure had fallen to 20 percent.

While as a matter of general principle, the Federal Government should defer to the States wherever and whenever possible, there are a myriad of areas in which there is a need for over-arching Federal supremacy. For example, on numerous occasions, the Congress has affirmed and then reaffirmed the Federal Food, Drug and Cosmetic Act as the Nation's principal regulatory authority over one-quarter of the Nation's consumer goods. Similarly, given the devastating national problem of illicit drug use, the Controlled Sub-

¹⁴Testimony of Mr. Joseph N. Onek before the Senate Committee on the Judiciary, July 31, 1998.

¹⁵Testimony of Joseph N. Onek before the Committee on the Judiciary, July 31, 1998.

stances Act itself finds, “The illegal importation, manufacture, distribution, and possession improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.” The Committee views enactment of S. 2151 as entirely consistent with that Federalism principle.

It is difficult to see how a 50-state, crazy quilt approach to the regulation of controlled substances can adequately protect the health of the American public. Using controlled substances as agents not for bona fide medical purposes, but instead to extinguish life, flies in the face of Hippocrates’ great teaching: “First do no harm.”

Under the CSA, the Drug Enforcement Administration has become the Nation’s chief steward in the prevention of abuse of controlled substances. The Committee believes that this amendment to the CSA will unambiguously empower DEA, in close consultation with HHS and other medical experts, to take action against those who would flaunt the CSA and use controlled substances to effectuate the ultimate harm.

C. PALLIATIVE CARE

The Committee also wishes to take this opportunity to address the criticism that this legislative effort will thwart legitimate pain treatment, by encouraging a “climate of fear” in which practitioners will err on the side of safety by not dispensing or distributing adequate medication. This trepidation has been echoed by a number of organizations opposing the legislation.

Representatives of the pain care community, in particular, expressed concern in two areas: That the bill would allow the Drug Enforcement Administration to undertake unwarranted investigations too easily; and that these investigations might be both time-consuming and costly, and result in unwarranted revocation of a license. In fact, mindful of this trepidation, the Committee undertook a serious effort to change the legislation and insert safeguards which are intended to provide practitioners with the peace of mind that legitimate medical practice will not be threatened. The Committee is extremely cognizant of those concerns, and took a number of steps to make certain that the bill which was reported created a favorable climate for palliative care.

The Committee wishes to reassure medical practitioners that Congress encourages the use of palliative care, and particularly the legitimate use of Controlled Substances to treat painful, chronic diseases or terminal illnesses. The Chairman’s substitute makes a number of needed corrections which it hopes will serve as that encouragement. For example, the bill clarifies that prior to commencing any investigation of suspected assisted suicide, the Attorney General must make two specific findings that the registrant: (1) dispensed or distributed a specific controlled substance which was directly responsible for the death of an individual; and (2) did not dispense or distribute the specific controlled substance as medically indicated as set forth in this Act. The Committee inserted these provisions as a filter, to prove to the medical community that the DEA would not undertake any investigations under this legislation unless there were good cause for such an investigation.

The Committee was also mindful of the concern that any investigation, once undertaken, is a serious event which, if not handled appropriately, has the potential of harming patient care and damaging the careers of registrants. Accordingly, the Committee has also inserted another safeguard to make certain that practitioners operating within the bounds of legitimate medical practice need not fear government intervention. The Chairman's mark adopted by the Committee includes the House-reported language (H.R. 4006) which places the burden on the Attorney General in actions to revoke, deny, or suspend a registration because of suspected suicide assistance to prove (by a clear and convincing evidence standard) that the registrant intended to assist a suicide.

As a final safeguard, the bill includes language in section 304(a)(4) making clear that its provisions do not apply in cases in which the distribution or dispensing of the controlled substance was for the purpose of alleviating pain or discomfort, even if the use of the controlled substance might increase the risk of death, so long as the drug was not used for the purpose of causing the death of an individual. In combination, these are extremely high hurdles which the Committee believes will serve to ensure that only those who intend to assist in a suicide are subject to the provisions of the legislation.

D. ROLE OF THE DEA IN PAIN MANAGEMENT

The Committee has also inserted language to address the concerns raised by the Administration that, in the words of Mr. Onek, "this legislation will embroil the DEA in decisions about the use of pain medication for terminally ill patients which it is poorly equipped to make. Indeed, the legislation's call for a rather anomalous new pain relief board underscores the DEA's relative lack of expertise in this area."

We wish to note that, under current law and regulation, the DEA is required to make regular judgments about whether registrants are using controlled substances for legitimate medical purposes. Indeed, in the words of the DEA Administrator, "the CSA authorizes DEA to revoke the registration of physicians who dispense controlled substances without a legitimate medical purpose."¹⁶ In fact, the DEA has provided the Committee with a statement of policy¹⁷ which notes that the agency relies on the medical community itself, through its state licensing authorities and recognized experts, for the definitions and standards of medical practice. In the words of DEA:

Medical experts are currently reevaluating some basic but long held beliefs concerning the extended use of narcotic substances for chronic pain. This has generated a need to more effectively define and standardize practice guidelines in this sensitive area of pain management as well as a need to update educational efforts for physicians concerning the pharmacology of narcotic analgesics, pain

¹⁶Letter to Senator Hatch and Rep. Hyde from Mr. Thomas A. Constantine, November 5, 1997.

¹⁷"Statement of Policy for the Use and Handling of Controlled Substances in the Treatment of Pain," Drug Enforcement Administration (undated).

management and addiction, as well as diversion and patient scams.

DEA encourages the development of pain management practice guidelines and educational programs by medical boards to better define acceptable medical practice for the management of pain with controlled substances. Practice guidelines which reflect currently acceptable standards and treatment modalities will prove invaluable in helping a physician form his medical judgment in making pain management decisions, and in allaying any fear of adverse consequences from licensing boards or investigative agencies when none is justified. Practice guidelines assist everyone concerned in better defining the elements of legitimate pain treatment, thereby providing the courts and licensing boards a sound and definitive basis to judge instances which clearly fall outside acceptable norms.

It is clear that decisions concerning the adequacy or appropriateness of a particular form of medical treatment rest entirely with the medical experts. Consequently, DEA believes that continued involvement of its representatives in the ongoing dialog with the medical community should continue.

Indeed, those who aver that it is not the responsibility of the DEA to insert itself into either State licensing activities or private medical practice with respect to pain management may be surprised to learn that the DEA has a long record of active involvement with the medical community in this regard. As recent examples, this year, the DEA participated in a July 21, 1998 workshop with the University of Wisconsin Pain Policy Studies Group, the American Pain Society, and the Alliance of States with Prescription Monitoring Programs. The workshop was designed to foster an exchange of ideas on pain management. The DEA has also participated in a March, 1998 Symposium on Pain Management with the Federation of State Medical Boards meeting, and a January, 1998 Conference on Pain Management.

It is also noteworthy that the DEA has worked within the pain community to reinforce that the agency's mission envisions legitimate use of controlled substances for pain relief. In 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."¹⁸ Similarly, in 1990, the DEA also said:

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 Adminis-

¹⁸"Guidelines for Prescribers of Controlled Substances: A Joint Statement of the Drug Enforcement Administration and the DEA/Practitioners Working Committee," Physician's Manual, Drug Enforcement Administration, rev. March 1990, p. 24.

tration that these controlled substances should be prescribed, dispensed, or administered when there is a legitimate medical need.¹⁹

E. ROLE OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Despite this long record of the Drug Enforcement Administration, the Committee has inserted explicit language to address concerns raised about the agency's experience and expertise in determining legitimate medical uses of controlled substances by making the Department of Health and Human Services a more integral part of the medical advisory board process, allowing a practitioner under investigation to request examination of the case by the medical advisory board, and enhancing the membership of the committee to reflect consultation with such experts as the American Medical Association, the American Academy of Pain Medicine, the American Pain Society, the American Academy of Hospice and Palliative Medicine, the National Hospice Organization, the American Geriatrics Society, and other entities with relevant expertise on pain relief.

During consideration of this legislation, the Department of Justice wrote to Senator Hatch²⁰ and suggested that a better way to avoid assisted suicides is to develop consensus guidelines on the appropriate use of controlled substances for terminally ill patients. In that letter, the Department of Justice suggested that a board be charged with developing those guidelines and with recommending how the guidelines should be enforced.

The Committee rejects this bureaucratic response, noting that formation of a committee will not take any concrete steps toward the goal of stopping assisted suicides, a goal which the President has stated he shares. The problem with the Justice Department suggestion is that a mere study delays implementation of what we have already shown to be the correct policy: That the Federal Government should not be involved in any way in assisting suicides. Indeed, the Committee believes that the preferable approach is contained in S. 2151, as amended. That is, the DEA will continue to enforce the Controlled Substances Act's provisions requiring legitimate medical use of controlled substances, while at the same time continuing to work within the medical community to further its understanding of pain management practices.

The Committee notes that, in addition to the Advisory Board chaired by HHS, the Committee has included language which makes clear that the Department of Justice may consult with HHS before commencing any investigation under this Act so that HHS may provide any needed medical judgment to DEA. Having built in these safeguards, the Committee believes that S. 2151, as ordered reported, obviates many of the concerns raised by the pain community and by the Administration.

¹⁹ Ibid, p. 21.

²⁰ Letter of September 16, 1998 from L. Anthony Sutin, Acting Assistant Attorney General to Senator Orrin G. Hatch.

F. INVESTIGATIVE AUTHORITY OF THE DRUG ENFORCEMENT ADMINISTRATION

A fact neglected to be mentioned in this debate is that under current law, the Drug Enforcement Administration has the authority to regulate physician prescribing patterns, and to the extent that is a deterrent to effective pain management, the bill would not exacerbate the situation. The Committee intends to monitor the situation closely to make certain that, whether under current law or the law as modified by S. 2151, Drug Enforcement Administration practices do not discourage the legitimate use of controlled substances for palliative care.

Nevertheless, the Chairman's mark also included language in section 4(c)(4) providing that nothing in the amendments to the Controlled Substances Act contained therein may be construed to provide the Drug Enforcement Administration with any additional investigative authority in any State, to the extent that the law of the State prohibits assisted suicide or euthanasia. This rule of construction simply makes clear that the intent of these amendments is not to supplant State efforts to enforce existing State laws against assisted suicide or euthanasia. Many States already have laws against assisted suicide; medical practitioners in those States are likely to have participated in enactment of those laws and understand the procedures involved and the standards applied. Presumably, the DEA will take the efficacy of those State laws into account as it assigns its scarce enforcement resources.

This rule of construction is intended in part to allay the fears of those health care practitioners, in States with existing prohibitions in State law, that DEA might interpret this bill as a new mandate to open up overzealous Federal investigations that could duplicate or interfere with State efforts in this area. Nothing in this rule of construction will diminish the authority of the DEA to investigate and take necessary enforcement actions in any State. Consistent with the efficient administration of justice, every practitioner in every state will be treated equally under this new Federal law.

G. DEATH PENALTY

Section 3(b)(1)(B) of the bill, as amended, makes clear that nothing in this legislation will interfere with the ability of states or the Federal Government to carry out the death penalty. The Committee added this provision because at least one of the drugs commonly used in lethal injection, sodium thiopental, is a controlled substance, and the Committee wished to make clear that the DEA should not refuse to grant a registration under this Act to an applicant who will carry out a sentence of death under Federal or State law.

In that regard, the Committee cites the 1985 Supreme Court decision of *Heckler v. Cheney* in which some prisoners duly convicted of capital crimes in the States of Texas and Oklahoma sought to avoid the death penalty on grounds that the FDA had not approved any drugs as safe and effective for causing death. In upholding FDA's discretion not to intervene in this case—which was decided without any dissenting opinions—then-Justice Rehnquist wrote:

The fact that the drugs involved in this case are ultimately to be used in imposing the death penalty must not lead this Court or other courts to import profound differences of opinion over the meaning of the eighth amendment to the Constitution into the domain of administrative law.

In filing his concurrence, Justice Brennan noted:

I adhere to my view that the death penalty is in all circumstances cruel and unusual punishment under the 8th and 14th amendments * * *. My concurrence here should not be misread as an expression of approval for the use of lethal injections to effect capital punishment as an independent matter. The Court is correct, however, that “profound differences of opinion over the meaning of the 8th amendment” should not influence our consideration of a question purely of statutory administrative law.

The Committee notes that these Justices, while holding completely opposite views on capital punishment, nevertheless agreed that this Constitutional battle should not be fought out in administrative statutes and that is exactly what section 3(b)(1)(B) of the bill makes clear.

H. CRIMINAL LIABILITY

The Committee also wishes to acknowledge the concern expressed that health care providers may incur a new criminal liability under this bill. The Controlled Substances Act—like its cousin the Federal Food, Drug, and Cosmetic Act—contains in parallel a series potential criminal and civil sanctions. That is not changed in this bill.

Both the DOJ and DEA have a degree of discretion and flexibility in relegating minor violations to civil penalties or even formal or informal warnings. For more serious violations involving knowing and intentional possession or distribution of controlled substances, the statute contemplates more severe penalties. In fact, section 401 of the Act specifies certain criminal penalties if certain amounts of certain types of drugs are involved.

A major sanction in the bill against those facilitating suicides is revocation or denial of DEA registration. Although this sanction, no doubt a heavy tool, is civil in nature, it provides a strong incentive under the bill for health care personnel not to engage in the practice of assisting suicides. We are confident this formidable civil sanction of loss of a DEA registration number would act to limit the situations in which DEA and DOJ believed that these more rigorous, criminal penalties should be applied.

I. MULTIPLE USERS OF SINGLE REGISTRATIONS

The Committee also wishes to address the concern raised by certain registrants, such as hospitals or pharmacies, that the action of one of their licensees (e.g., residents or pharmacists) could result in the revocation of the facility’s registration. Currently, the Controlled Substances Act holds the registrant responsible for the action of its employees. That is, each pharmacist who might dispense,

or each resident who might prescribe, is not registered by the DEA, only the pharmacy or hospital would be. The amendments to the Controlled Substances Act do not, and should not, change any accountability system that is working.

We are aware that some have suggested exempting pharmacists or hospitals from this legislation. It is important to note that pharmacists and the hospital personnel who dispense and administer controlled substances are an important part of the healthcare team. Their extensive knowledge of drug actions and side effects adds another layer of patient protection from the potential catastrophic consequences of powerful prescribed medications. Arbitrarily reducing their responsibility by allowing them to look the other way, as some have suggested, could harm patients. Nevertheless, the Committee intends to monitor this situation closely and will take action should it find that the registration system hinders the ability of patients to receive adequate pain care from health care professionals.

J. PATIENT CONFIDENTIALITY

Finally, some physicians have suggested to the Committee that language be included to address confidentiality concerns with respect to any investigations DEA might undertake pursuant to this act. The Committee feels compelled to note that the Congress has already given the DEA investigative authority to enforce the Controlled Substances Act, and that authority already allows the agency to use colleague and patient interviews to investigate reported violations of the Controlled Substances Act. This bill authorizes no new actions which are intended to violate patient confidentiality.

More importantly, the Committee has inserted a safeguard which should limit the number of cases in which confidentiality concerns could arise. The bill requires that before the DEA undertakes an investigation of a possible assisted suicide, the Attorney General must make a finding that the registrant prescribed, dispensed, or administered the specific controlled substance which was directly responsible for the death. This provision will assure that the DEA investigates legitimate concerns. Killing a person is a serious matter, and any deaths by other than natural causes must be taken seriously and investigated accordingly. Therefore, law enforcement personnel, including the DEA, must have the ability to conduct interviews as appropriate. Again, this bill does not change the agency's current authorities with respect to investigation of violations of the Controlled Substances Act.

VI. COST ESTIMATE

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate and section 404 of the Congressional Budget Act of 1974, the committee provides the following cost estimate prepared by the Congressional Budget Office:

U.S. CONGRESS,
 CONGRESSIONAL BUDGET OFFICE,
 Washington, DC, October 2, 1998.

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 S. 2151, the Lethal Drug Abuse Prevention Act of 1998.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Mark Grabowicz (for Federal costs), Lisa Cash Driskill (for the state and local impact), and Matthew Eyles (for the private-sector impact).

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

S. 2151—Lethal Drug Abuse Prevention Act of 1998

Summary: S. 2151 would make it a violation of the Controlled Substances Act of 1970 to distribute or dispense a controlled substance to assist in suicide or euthanasia. Persons who violate the bill's provisions could face revocation of their license to prescribe controlled substances. The legislation would direct the Secretary of Health and Human Services, in consultation with the Attorney General, to establish the Medical Advisory Board on Pain Relief to assist in resolving disputes over the dispensing of controlled substances in certain instances of assisted suicide or euthanasia.

CBO estimates that implementing S. 2151 would not result in any significant cost to the federal government. Because enactment of S. 2151 could affect direct spending and receipts, pay-as-you-go procedures would apply to the bill; however, CBO estimates that the amounts involved would be less than \$500,000 a year.

S. 2151 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would have no impact on the budgets of State, local, or tribal governments. The bill would impose a new private-sector mandate as defined in UMRA, but the direct costs imposed by the mandate would fall well below the statutory threshold established in UMRA (\$100 million in 1996, adjusted annually for inflation).

Estimated costs to the Federal Government: Enacting the bill would increase administrative costs of the Drug Enforcement Administration (DEA) and the Department of Health and Human Services in cases of assisted suicide or euthanasia that involve controlled substances. Under the bill's provisions, any such costs, including those relating to the Medical Advisory Board on Pain Relief, would be funded from user fees that are deposited into the diversion control fee account. Such outlays would constitute direct spending. CBO anticipates very few of these cases, however, so the amount of additional spending would be negligible.

If an individual's license to dispense controlled substances is revoked, the DEA could seize any such substances in his or her possession. Thus, enacting S. 2151 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 in the same year. Thus, the change in direct spending from the assets forfeiture fund would match any increase in revenues to that fund.

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 S. 2151 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: S. 2151 contains no intergovernmental mandates as defined in UMRA and would have no impact on the budgets of state, local, or tribal governments. Although Oregon citizens voted to legalize doctor-assisted suicide for terminally ill patients, S. 2151 would not preempt that law. It would, however, make it legal for doctors to assist in suicide or euthanasia using drugs governed by the federal Controlled Substances Act.

Estimated impact on the private sector: S. 2151 would impose a new private-sector mandate, as defined in UMRA. The bill would prohibit medical practitioners from intentionally dispensing or prescribing controlled substances for the purpose of assisting the suicide or euthanasia of an individual.

Under current law, medical practitioners who are licensed by state medical boards must also register with the Attorney General through the DEA if they intend to dispense or prescribe controlled substances. Practitioners may now lose their federal registration to dispense those substances if the Attorney General, after considering specific factors, determines that the registration would not be in the public interest. Intentionally dispensing or prescribing controlled substances to assist or facilitate a suicide or euthanasia is not included in that list of factors, but under the provisions of S. 2151, it would be grounds for suspending or revoking a practitioner's federal license. In addition, controlled substances possessed by practitioners whose licenses have been revoked or suspended based on the bill's provisions would be subject to government seizure.

CBO estimates that the direct costs of the mandate on federally registered practitioners would fall well below the statutory threshold in UMRA. In all states except Oregon, medical practitioners may not legally assist in the suicide or euthanasia of an individual. Moreover, one recent study indicates that only a small percentage of physicians who provide care for dying patients—about 6 percent—have actively helped patients die. Thus, the number of medical practitioners potentially affected by the prohibition would be small.

Estimate prepared by: Federal Costs: Mark Grabowicz; Impact on State, Local and Tribal Governments: Lisa Cash Driskill; Impact on the Private Sector: Matthew Eyles.

Estimate approved by: Robert A. Sunshine, Deputy Assistant Director for Budget Analysis.

VII. 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 S. 1301 will not have significant regulatory impact.

VIII. ADMINISTRATION VIEWS

U.S. DEPARTMENT OF JUSTICE,
OFFICE OF LEGISLATIVE AFFAIRS,
Washington, DC, July 30, 1998.

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

DEAR MR. CHAIRMAN: As the Committee prepares to consider S. 2151, the "Lethal Drug Abuse Prevention Act of 1998," we write to provide the views of the Department of Justice on the bill. We look forward to working with you on this legislation.

The President is opposed to assisted suicide and any Federal support for it. As such, he is open to working with you and other interested Members of Congress on this complex but extremely important issue. Having said this, the Administration believes that S. 2151 represents a flawed approach to the sensitive area of Federal regulation of medicine. We are fully cognizant of the general authority of the Drug Enforcement Administration (DEA) to regulate physicians' activities that facilitate the abuse or diversion of controlled substances. However, we are concerned that the insertion of the DEA into the role of overseer of the practice of medicine in the unique circumstances of suffering, terminally ill patients would inevitably divert agency attention away from the core mission of strictly controlling Schedule I drugs and preventing the abuse, diversion of and trafficking in all scheduled drugs.

Determination of whether a practitioner's conduct which results in a patient's death—either in a specific instance or in general—is "an appropriate means to relieve pain" is far afield from the DEA's role, as envisaged by Congress and as carried out by the agency, under the original legislative rubric of the Controlled Substances Act (CSA). The medical, scientific, ethical, and related aspects of the practice of medicine at the end of life would involve DEA in issues in which it has no particular expertise. The use of a peer review board of pain management experts would lend needed consultation on the merits of any case, but the very necessity for such a board is evidence of the poor fit between the task DEA is being asked to undertake and its central expertise. Moreover, as noted below, the board's insertion in the context of a contested administrative proceeding could well complicate rather than elucidate matters surrounding physician-assisted suicide.

In addition to the above-noted concerns, the proposed revision in the Controlled Substances Act through S. 2151 would not necessarily accomplish the intended effect of banning all assisted suicides, as there are several plausible means of assisted suicide or euthanasia that do not involve the use of controlled substances. Typically, a controlled substance is used as a sedative; a non-controlled substance is used to actually bring about death. Thus, the CSA offers at best only a partial fix. If amendments to the CSA

force physicians to use non-controlled substances to assist a patient to hasten as desired death, a procedure that would not explicitly be banned by the CSA, it will not save lives, but merely will increase the amount of pain suffered by those taking their lives.

The limitations of this proposed ban on assisted suicide are apparent by examining the plausible scenario of a patient who has legally obtained a controlled substance from a physician for palliative purposes without disclosing an intent to commit suicide. Once that patient has decided to end his or her own life, they would need only to employ the services of a second physician, who would agree to assist in the suicide so long as the patient agrees to self medicate. As long as the second physician does not “dispense or distribute” a controlled substance, it is difficult to imagine how they could be subject to a revocation action under the proposed changes to the CSA. Moreover if the bill were modified broadly to reach those who merely assist in a suicide, including by providing their patients with truthful information, it would likely invite serious constitutional challenges.

In addition to the foregoing concerns, the proposed bill raises several technical concerns. First, Sec. 3(a) would amend 21 U.S.C. § 823 to require denial of registration, as inconsistent with the public interest, of any application for registration that had either been revoked within the preceding five years under § 824(a)(4) or for which there is “clear and convincing evidence” that it is sought “with the intention of using the registration” to assist a suicide or commit euthanasia. This latter provision may be unworkable. We are concerned that it is not practical to determine in advance an applicant’s “intent” as to how he/she will use a registration; much less can this be determined by clear and convincing evidence. Certainly, few if any applicants will seek the controlled registration with assisted suicide as a primary intended use; even fewer would admit as much on an application. For most physicians, whether they use controlled substances for this purpose will depend on the circumstances, which cannot be foreseen in advance.

There is an apparent inconsistency between Sec. 3(a) stating a new basis for action against a practitioner’s registration under § 824(a)(4), and Sec. 3(c), setting forth the responsibility of the new “Medical Review Board on Pain Relief” to issue an option under new § 824(c)(3)(C)(i). Under the latter, the Board would review, for appropriateness as a means to relieve pain, “any potential action” (as opposed to “intended” action) by an applicant. Review of “potential” action to even more speculative than “intended” action. Moreover, this section does not mention the clear and convincing evidence standard; it is not clear whether a different level of proof is intended.

The new Board would afford a peer review process to any practitioner aggrieved by a show cause order under 21 U.S.C. § 824(c) proposing to take adverse action against a practitioner’s registration in light of physician-assisted suicide. This provision would for the first time inject a regulatory peer review process into the quasi-judicial administrative discipline process. The Board’s opinion would be “admissible” in any show cause hearing, but would it be binding in effect? If the DEA went against the Board’s decision, either in favor of or against the physician, what would be the likely

result on appeal? We think this Board—undoubtedly a well-intended innovation designed to give the physician a fair hearing—unnecessarily creates a myriad of different issues.

Finally, in Sec. 4, the language includes a statement that the amendment does not imply that the dispensing of a controlled substance before the date of enactment was not a violation of the CSA. In light of the Attorney General's letter of June 5, 1998, to you, concluding that "adverse action against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be authorized by the CSA," we recommend a neutral construction regarding the effect of this amendment (*e.g.*, "Nothing in this Act or the amendments made by this Act shall be construed to express an opinion as to whether the dispensing or distribution of a controlled substance before the date of enactment of this Act * * *").

Thank you for this opportunity to provide our views on this important matter. The Office of Management and Budget has advised that there is not objection from the standpoint of the Administration's program to the presentation of this report.

Sincerely,

L. ANTHONY SUTIN,
Acting Assistant Attorney General.

U.S. DEPARTMENT OF JUSTICE,
OFFICE OF LEGISLATIVE AFFAIRS,
Washington, DC, September 16, 1998.

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

DEAR MR. CHAIRMAN: We responding to your letter of September 9, 1998, to Mr. Joseph Onek, Principal Deputy Associate Attorney General, regarding S. 2151, the "Lethal Drug Abuse Prevention Act of 1998." We regret the delay in responding.

The President is committed to working with you, Senator Leahy, and Members on and off the Judiciary Committee to help develop approaches to curtail assisted suicide. As you know, this position is consistent with his longstanding opposition to assisted suicide and his support for the Assisted Suicide Funding Restriction Act last year. As such, he has requested that the Justice Department and the Department of Health and Human Services work collaboratively with you and other Members of Congress on this issue.

The President, however, is concerned that S.2151 will have unintended adverse consequences, which cannot adequately be remedied in the limited time remaining in this Congress. The negative impact S.2151 could have on the provision of pain relief medications for our nation's terminally ill is of particular concern to the Administration, as it is to virtually every major medical organization in the nation. These organizations share the President's abhorrence and opposition to assisted suicide, but, with very few exceptions, oppose the Lethal Drug Abuse Prevention Act.

There is broad consensus that the American medical system does a poor job of providing palliative care to terminally ill patients and, in particular, that it fails to provide effective pain management. As

a result, many patients unnecessarily suffer excruciating pain and some patients—in pain or fearing future pain—seriously consider suicide (physician assisted or otherwise).

Health care experts in this field strongly believe that S. 2151 exacerbates this problem. The legislation authorizes the DEA to impose serious civil penalties against physicians who dispense controlled substances to assist a patient suicide. The legislation may also authorize the imposition of criminal penalties on such physicians. Virtually all potent pain medications are controlled substances. Thus, physicians who dispense these medications to ease the pain of terminally ill patients could well fear that they could be the subject of a DEA investigation whenever a patient's death can be linked to the use of a controlled substance.

The Lethal Drug Abuse Prevention Act is designed to address physicians' fears by prohibiting sanctions as long as physicians do not dispense the controlled substance with the intent of causing death. However, 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 relationships with the patient and the patient's family.

It is precisely the fear of a DEA investigation that creates the potential to inhibit physicians from providing adequate paid medication to terminally ill patients. In response, physicians may under-medicate patients, patients may suffer unnecessary pain and, as a result of increased incidence of great pain amongst the terminally ill, patient suicides—physician assisted or not—may increase. Such an outcome would be far more than ironic; it would be tragic. Understanding this, the American Medical Association, the American Nurses Association, the National Hospice Organization and many other respected national health organizations strongly oppose S. 2151.

We believe that the better way to avoid assisted suicides is to develop consensus guidelines on the appropriate use of controlled substances for terminally ill patients. Such guidelines would be designed to be sufficiently clear that a physician who followed them would be free from any fear of sanctions. The board charged with developing these guidelines would have representatives of doctors, nurses, consumers, theologians, ethicists, and law enforcement officials and would report back to the Congress and the Administration in a specified period of time. The board also could provide recommendations on the most appropriate entity to enforce these guidelines, as well as the authority and responsibility such an entity should have.

Clearly, any board charged with developing guidelines for this area should be carefully chosen. If we pursued this approach, we would want to determine a mutually acceptable appointment process. If you find this advisory board concept acceptable, which would be one way of coming closer to a consensus approach, we would be pleased to work with you to establish—through legislation or, if legal and appropriate, by Executive Action—any such entity.

The Administration believes that working together we can develop an appropriate way to address this important issue. We look forward to working with you in the future. The Office of Manage-

ment and Budget has advised that there is not objection from the standpoint of the Administration's program to the presentation of this report. If we may be of additional assistance, we trust that you will not hesitate to call upon us.

Sincerely,

L. ANTHONY SUTIN,
Acting Assistant Attorney General.

IX. ADDITIONAL VIEWS OF SENATOR ORRIN G. HATCH

I join with my colleagues in condemning the practice of assisted suicide. To me, assisted suicide is morally and ethically reprehensible, an abhorrent practice which our society can ill-afford to see as a viable alternative to compassionate care and treatment. Indeed, the Congress spoke out overwhelmingly on this issue last year, when we passed the Assisted Suicide Funding Restriction Act by a vote of 99–0. I see S. 2151 as a logical extension of that vote. It is a measure that is fully consistent with that great teaching of the Hippocratic Oath: “First do no harm,” which is a central tenet of Western medicine.

I am keenly aware that some in the medical community have expressed opposition to this legislation because they believe that it will discourage practitioners from the legitimate use of pain medication. In considering this legislation, I have consulted with a number of health care experts from Utah, including Dr. Sharon M. Weinstein, the new Director of Palliative Care for the renowned Huntsman Cancer Center at the University of Utah, Dr. Joseph Simone, from the Huntsman Center, Dr. Michael Ashburn, Director of the University of Utah’s Pain Management Clinic, and Dr. Allan Nelson, representing Intermountain Health Care in Salt Lake.

These eminent experts in palliative care have voiced the concerns about the unintended negative effects of this legislation on treatment of patients, and I am very sympathetic to their arguments. Both as Chairman of this Committee, and as a representative from the State of Utah, I have worked diligently to accommodate those who expressed those concerns.

We have changed the bill significantly to address those fears and strengthen the safeguards against unwarranted actions. First, we have clarified that prior to commencing any investigation of a suspected assisted suicide, the Attorney General must make a finding that the registrant dispensed or distributed a specific controlled substance which was directly responsible for the death of an individual. Second, before any investigation, the Attorney General must find that the registrant did not dispense or distribute the specific controlled substance as medically indicated consistent with this Act. Third, we have included the House-reported language which places the burden on the Attorney General in actions to revoke, deny or suspend a registration because of suspected suicide to prove (by a clear and convincing evidence standard) that the registrant intended to assist a suicide. Fourth, the bill, along with last year’s Assisted Suicide Funding Restriction Act (which called upon the Department of Health and Human Services to make educational grants improving end-of-life care) will make clear the congressional intent to improve pain care while preventing assisted suicide. In addition, in response to concerns raised by the medical

community and the Administration, we have added language bringing HHS more into the process.

I am aware this language does not completely satisfy those who oppose this bill. As this bill moves to the floor, I pledge to continue to work with medical experts to address their fears about this legislation, if any of these medical groups choose to do so. In fact, as I have publicly stated, I will go one step further. As Chairman of this Committee, I pledge that when this bill is enacted, as I believe it will be, if the DEA takes any actions which threaten the use of pain medication for legitimate medical purposes, I will work with the medical community to remedy those problems, whatever they may be.

While I do sympathize with those who genuinely fear an unintended consequence from this legislation, I am hopeful they will read the revised draft with an open mind, in full cognizance of Drug Enforcement Administration's abundant current-law authority to regulate controlled substances. My ultimate concern is twofold: that we not incrementally, state-by-state, embark down a path to undercut the powerful tools of the Controlled Substances Act to prevent drug diversion; and that we continue to recognize at a Federal level that assisted suicide is wrong.

In closing, it is important to note that there are many other steps to prevent practitioner-assisted suicide. The Secretary of Health and Human Services should expeditiously move forward with the suicide prevention provisions in the bipartisan Suicide Funding Restriction Act of 1997. That Act authorizes the Secretary to fund research projects and training programs intended to reduce the rate of suicide including assisted suicide. Furthermore, the same legislation authorizes the Secretary to fund demonstration projects to reduce restrictions to hospice care.

As an additional measure, the Secretary should be authorized to require as a condition of participation in Medicare that facilities, physician groups and health maintenance organizations measure the quality of end-of-life palliative care and take steps to remedy problems which are found, including poor use of pain medications by practitioners. Finally, the Secretary in cooperation with the Attorney General should determine whether alleged reduction in hospice enrollment resulting from efforts to reduce fraud and abuse in Medicare has adversely affected end-of-life palliative care.

I look forward to working with my colleagues—both those who have supported S. 2151, and those who have opposed it—to address the myriad pain care and end-of-life issues in a comprehensive manner. Those steps, however, do not negate the need to address the Controlled Substances Act clarification in separate legislation which should move forward expeditiously.

ORRIN G. HATCH.

X. MINORITY VIEWS

INTRODUCTION

As noted by Andrew I. Batavia, Special Assistant to Attorney General Dick Thornburgh during the Bush Administration, at the Senate Judiciary Committee hearing on S. 2151, “[t]he Lethal Drug Abuse Prevention Act:”

I am a Republican, because I believe the Republican Party is the party of principles. It is because I believe in the principles of the Republican Party that I strongly oppose this legislation. The Lethal Drug Abuse Prevention Act is legislation that, in my view, violates basic Republican principles of federalism, sound legislation, regulatory restraint and fairness.¹

We, along with more than 50 national health organizations (most of which strongly oppose physician-assisted suicide), share the view of Mr. Batavia. Although we, like the majority, are troubled by physician-assisted suicide, we see this bill as an unnecessary encroachment on State medical boards’ traditional regulatory role which may ultimately cause thousands of terminally ill patients to suffer needlessly and could lead to an increase in the number of assisted suicides.

The States are effectively dealing with the issue of physician-assisted suicide

S. 2151 is a serious violation of the basic tenets of federalism. Medical practice has always been regulated by the States under their traditional police powers; physician-assisted suicide is no different. Currently, physician-assisted suicide is illegal in 45 States (36 by statute; nine under common law).² In one State, Oregon, the citizens approved by referendum “[t]he Death with Dignity Act,” which provides for physician-assisted suicide under very limited and highly regulated circumstances.³ Moreover, at least 20 States have established commissions or task forces to examine end-of-life care issues, including physician-assisted suicide.⁴ Clearly, the States have made a concerted effort to address this issue intelligently and thoroughly. This Federal bill will not enhance the regulation of physician-assisted suicide. On the contrary, S. 2151 is at

¹Andrew I. Batavia, Testimony Before the Senate Judiciary Committee, July 31, 1998, at 93, lines 10–16.

²Merrit, Dick; Fox-Grage, Wendy; and Rothouse, Marla of the National Conference of State Legislatures, and Lynn, Joanne; Cohn, Felicia; and Forlini, Janet Heald 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.

³Or. Rev. Stat. §§ 127.800–127.995.

⁴End-of-Life Care: Policy Guide at 3.

best superfluous and at worst, extremely harmful to the States' ongoing efforts in this area.

Although the majority argues that this bill is designed to mend a "50-state, crazy quilt approach to the regulation of controlled substances,"⁵ it is readily apparent that S. 2151 was drafted and is being moved forward not in an effort to deal with controlled substances, but rather in a direct attempt to starkly limit the scope of the Oregon referendum and physician-assisted suicide in that State. Indeed, the majority points to the Oregon referendum, two recent Supreme Court cases on assisted-suicide, *Vacco v. Quill*⁶ and *Washington v. Glucksberg*,⁷ and the Presidential signature of the "Assisted Suicide Prevention Act"⁸ as key events precipitating the introduction of this bill.⁹ In fact, these two Supreme Court rulings held that the States, not the Federal Government, should determine how best to address the issue of physician-assisted suicide, and the Assisted Suicide Prevention Act did not address this issue in outlawing the use of Federal funds for the practice of physician-assisted suicide.

S. 2151's efforts to usurp the rights of Oregon's citizens' to deal with the issue of physician-assisted suicide on a State level is indefensible. It is certainly ironic that the majority, which promotes itself as the party of State's rights, would choose to overrule a State law when it contradicts national Republican policy.

S. 2151 will have a chilling effect on palliative care and may increase the demand for physician-assisted suicide

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.¹⁰ A study of 13,625 elderly patients living in Medicare/Medicaid certified nursing homes found that 26 percent of residents with daily pain received no medication for pain.¹¹ This study also found that pain is most prevalent among nursing home residents with cancer; that pain is often left untreated, especially in African-Americans and older patients.¹²

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 and appropriate doses of controlled substances due to a fear of unjust and unwarranted investigations and possible revocations of their Federal registrations. Indeed, physicians will have good reason to be troubled, because under S. 2151, the investigations will not be conducted by the State medical review boards which, since the passage of the Controlled Substances Act, have managed the responsibility of overseeing appropriate pain management. Instead, the investigations will be carried out by the Drug Enforcement Administration (the "DEA") which, as noted

⁵Majority Views at 32.

⁶117 S. Ct. 2293 (1997).

⁷117 S. Ct. 2258 (1997).

⁸P.L. 105-12.

⁹Majority Views at 32.

¹⁰"The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment," *The Journal of the American Medical Association*, Vol. 274, 1591-98 (1995).

¹¹Bernabie, R. et al., "Pain Management in Elderly Patients with Cancer," *The Journal of the American Medical Association*, Vol. 279, 1877-1882 (1998).

¹²*Id.*

by Principal Deputy Attorney General Joseph N. Onek, would “embroil the DEA in decisions about the use of pain medication for terminally ill patients which it is poorly equipped to make.”¹³

A nationwide study of cancer physicians demonstrated a “reluctance to prescribe” opioids due to concern about “excessive regulations” which were viewed as barriers to effective cancer pain management.¹⁴ In addition, 71 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.¹⁵ And 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 one-third reporting that their patients may be suffering from neglected, treatable pain.¹⁶ We do not believe that doctors’ and pharmacists’ ability to request a hearing with the proposed Medical Advisory Board on Pain Management would adequately resolve their concerns and counteract this potential chilling effect. This is especially true because these medical practitioners can only request a hearing with the Board, which merely issues an advisory opinion, after any such investigation has begun.

In the end, S. 2151 will not stop physician-assisted suicide. A physician could easily circumvent this law and still assist a suicide by prescribing a non-controlled substance, an over-the-counter drug, or common chemicals such as carbon monoxide or potassium (which Jack Kevorkian uses). Rather, the bill may have the perverse effect of increasing the demand for assisted suicide. As S. 2151 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 patients who are forced to suffer will increase. These same patients, unable to handle the severity of their pain, will more likely turn to assisted suicide; the ultimate consequence we all want to protect against.

We recognize that the issue of physician-assisted suicide is a difficult moral, ethical, and legal question that our society must confront. We believe, however, that this matter is best left to the States which have demonstrated that they can effectively and comprehensively address this issue. When the Federal Government prematurely supplants its views for those of the States, as the majority attempts to do with S. 2151, there is a definite chance of unintended consequences. The unintended consequences in this case are that palliative care will be diminished and patients will suffer needlessly. In addition, the bill may even lead to an increase in assisted suicides. Moreover, S. 2151 is likely to be wholly ineffective

¹³ Joseph N. Onek, Testimony Before the Senate Judiciary Committee, July 31, 1998, at 28, lines 15–17.

¹⁴ Von Roenn, J; Cleeland, C.S., et al., “Results of Physicians’ Attitudes toward Cancer Pain Management Survey,” Proceedings of the American Society of Clinical Oncology, Vol 10, 326 (1991).

¹⁵ New 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, January, 1998.

¹⁶ Skelly, F.J., “Fear of Sanctions Limits Prescribing of Pain Drugs,” American Medical News, 19 (August 15, 1994).

in curtailing physician-assisted suicides. We see no reason to accept these negative repercussions when the bill will deliver little to no positive results.

The established medical community strongly opposes the Hatch substitute to S. 2151

Over 50 national and State-based organizations, most of which oppose the practice of physician-assisted suicide, oppose the revised S. 2151 because of concerns related to pain management and the negative effect it will have on palliative care. Other concerns raised by these groups include the bill's override of the role of State medical licensure boards and interference with the goals of hospice and comfort care; the DEA's expanded role in determining the necessary and reasonable use of drugs; and the potentially onerous DEA investigatory process. We ask that a complete list of these organizations be included in this report.

COALITION TO IMPROVE PAIN MANAGEMENT

PAIN PATIENTS

American Chronic Pain Association
 American Pain Foundation
 American Society for Action on Pain
 National Foundation for the Treatment of Pain
 Pain Relief 2000
 Reflex Sympathetic Dystrophy Syndrome Association of America
 Triumph Over Pain Foundation

PHYSICIANS

American Academy of Pain Medicine
 American Academy of Family Physicians
 American Association for Geriatric Psychiatry
 American College of Physicians-American Society of Internal Medicine
 American Geriatrics Society
 American Medical Association
 American Medical Directors Association
 American Society of Anesthesiologists
 American Association for the Study of Headache
 Society of Critical Care Medicine

NURSES

American Nurses Association
 American Society of Pain Management Nurses
 Hospice and Palliative Nurses Association
 Oncology Nursing Society

PHARMACISTS

Academy of Managed Care Pharmacy
 American Association of Colleges of Pharmacy
 American College of Clinical Pharmacy
 American Pharmaceutical Association

American Society of Consultant Pharmacists
 American Society of Health-System Pharmacists

CANCER

American Alliance of Cancer Pain Initiatives
 American Cancer Society
 American Society of Clinical Oncology
 Cancer Care, Inc.
 Leukemia Society of America
 National Alliance of Breast Cancer Organizations
 National Coalition for Cancer Survivorship
 Susan G. Komen Breast Cancer Foundation
 US TOO Prostate Cancer Organization
 Y-ME National Breast Cancer Organization

HOSPICE AND END-OF-LIFE CARE

American Academy of Hospice & Palliative Medicine
 Americans for Better Care of the Dying
 Choice in Dying
 Delaware Hospice and Palliative Care Organization
 National Hospice Organization
 New Jersey Hospice and Palliative Care Organization
 Oregon Hospice Association

RELATED ORGANIZATIONS

AIDS Action
 American Academy of Pain Management
 American Pain Society
 Delaware Association for Home & Community Care
 Delaware Ecumenical Council on Children and Families
 Federation of State Medical Boards
 National Health Council
 National PACE Association
 Pain Care Coalition

While the Coalition to Improve Pain Management appreciates the effort of Senate Judiciary Committee Chairman Orrin Hatch and staff to attempt to improve S. 2151, the “Lethal Drug Abuse Preventive Act”, we cannot support the Substitute. This broad group of health care organizations is firmly opposed to the Hatch Substitute Amendment, which was passed by the Senate Judiciary Committee on September 24, because it would have a devastating impact on the legitimate treatment of pain and symptoms at the end of life.

Despite changes to the original bill, the Substitute does not address the serious concerns raised by the more than 50 groups representing millions of patients in severe intractable pain and virtually every aspect of the American health care system—physicians, pharmacists, hospices, nurses and pain specialists—that provides care for dying people and other pain sufferers.

Specifically, while the Hatch Substitute made minor changes to the procedural aspects of the bill, it retained

the major objectionable provisions of S. 2151. The Substitute Amendment does not address the underlying concerns about DEA investigations, the triggers for those investigations, and numerous other problems with the original bill. The Substitute Amendment would: (1) result in more Americans in pain because fear of DEA investigations mandated by this bill will deter physicians from prescribing and pharmacists from dispensing pain medicines, and (2) increase the demand for suicide by making access to adequate pain care more difficult—severe and chronic pain is a leading cause of suicide.

End-of-life care, physician-assisted suicide and improved pain management are too complex to address in a bill written in the last days of a congressional session. Such a bill will have lasting and severe consequences.

These Organizations oppose the Hatch Substitute Amendment to S. 2151. Please vote no!

S. 2151 IS BEING RUSHED THROUGH THE SENATE

We are gravely concerned that this legislation, which will have a significant impact on medical practices and end-of-life care across the nation, is being rushed through the Senate. Senator Nickles introduced S. 2151, the “Lethal Drug Abuse Prevention Act” on June 9, 1998. A hearing was held on July 31, 1998, the last day before the Senate began its August recess.

At the executive mark up of S. 2151, on September 24, 1998, after significant debate, several Senators, including Senators Leahy, Biden, Torricelli and Thompson, asked the Chairman to delay a vote on the bill for at least one more week so they could have additional time to review the Chairman’s substitute language which had been circulated the day before. Instead of delaying the vote on this bill, the Committee proceeded to pass the bill by an 11-6 vote. We are especially concerned that Senators have had very little time to discuss the ramifications of the revised S. 2151, including the fact that no hearings have yet been held on this version of the bill. We are also concerned that this revised legislation is still opposed by over 50 national and State-based medical and hospice organizations. These organizations include the American Medical Association, the American Nurses Association, American Association of Colleges of Pharmacy, American Cancer Society and the American Academy of Hospice and Palliative Care. We intend to ensure that Senators, both on and off the Committee, have adequate time to investigate fully the ramifications of this legislation before being asked to vote on it in the full Senate. As the Coalition to Improve Pain Management has noted: “End-of-life care, physician-assisted suicide and improved pain management are too complex to address in a bill written in the last days of a congressional session. Such a bill will have lasting and severe consequences.”

CORRESPONDENCE BETWEEN THE JUDICIARY COMMITTEE AND THE ADMINISTRATION

In July 1997, and again in October 1997, Senator Hatch and Representative Hyde, writing on behalf of the Senate and House Judiciary Committees, asked the Administrator of the DEA, Thom-

as Constantine, whether the prescribing or dispensing of 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 the “delivering, dispensing or prescribing [of] a controlled substance with the intent of assisting a suicide would not fall under any current definition a ‘legitimate medical purpose.’”

On June 5, 1998, Attorney General Reno issued a letter on the Oregon referendum. The statement rejected the DEA position, as expressed in its November 1997 letter, by concluding that a physician or pharmacist, who assisted with a suicide in full compliance with the Oregon referendum, was not in violation of the CSA. Attorney General Reno reasoned that Congress, in the CSA, did not intend 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.” Attorney General Reno also reiterated that the President continues to oppose assisted suicide and Federal support for it.

If enacted, this bill would override the Department of Justice’s position on this issue, and for the first time, empower the DEA to regulate and investigate doctors and pharmacists directly regarding their use of controlled substances for the purposes of pain relief.

THIS BILL IS A DIRECT AFFRONT TO STATES’ WELL ESTABLISHED
POWER TO REGULATE MEDICAL PRACTICES

The majority claims that S. 2151 will 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 will accomplish.

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 letter of June 5, 1998, 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 State criminal or medical board proceedings. In our view, not only should the DEA not have an independent investigatory power into allegations of the misuse of pain management drugs, it is also a power the DEA cannot handle. When asked during a Committee hearing whether the DEA can discern between

an appropriate dosage of drugs and one intended to kill, 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.¹⁷

Moreover, the Principal Deputy Associate Attorney General, Joseph N. Onek testified that:

[T]his legislation will embroil the DEA in decisions about the use of pain medication for terminally ill patients which it is poorly equipped to make. Indeed, the legislation's call for a rather anomalous new pain relief board underscores the DEA's relative lack of expertise in this area.¹⁸

The Supreme Court has also suggested that the issue of physician-assisted suicide should be left to the States. In two decisions cited by the majority, *Vacco v. Quill*¹⁹ and *Washington v. Glucksberg*,²⁰ the Court upheld State laws on assisted suicide and declined to federalize the issue by recognizing a fundamental right to assisted suicide. Justice O'Connor, in her concurring opinion in *Glucksberg*, concluded:

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 * * * in the first instance."²¹

The Supreme Court's denial of certiorari in a case that challenged the Oregon referendum—*Lee v. Oregon*²²—further demonstrates the Court's belief that the issue of assisted suicide is best left to the States.

In addition, the American public overwhelmingly agrees that assisted suicide should be handled by the States. The results of a national opinion survey released in July 1998 show that:

76 percent of the respondents agree that "[i]t is not appropriate for Congress to get involved in regulating legal drugs prescribed by doctors for their patients."²³

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.²⁴

¹⁷Testimony of Mr. Thomas Constantine before the Senate Committee on the Judiciary, July 31, 1998 at p. 55, lines 5–13.

¹⁸Testimony of Mr. Joseph Onek before the Senate Committee on the Judiciary, July 31, 1998 at p. 28, lines 14–19.

¹⁹117 S.Ct. 2293 (1997).

²⁰117 S.Ct. 2258 (1997).

²¹*Washington v. Glucksberg*, 117 S.Ct. 2303 (1997) (citations omitted).

²²107 F.3d 1382 (9th Cir. 1997), cert. denied, 66 U.S.L.W. 3282.

²³Survey by GLS Research of Los Angeles.

²⁴*Id.*

Despite the majority's statements to the contrary, S. 2151 appears, in large part, to have been drafted to override Oregon's Death With Dignity Act. It is worth noting that before there was a State law permitting assisted suicide, Congress declined to take any action "clarifying" the CSA and its stance towards the use of controlled substances for assisted suicide.

THE HISTORY OF THE OREGON DEATH WITH DIGNITY ACT

While most States have engaged in the debate over physician-assisted suicide and decided to prohibit its practice, Oregon is the only State to date to have passed a law permitting the practice.

Following Oregon's long standing tradition of public referenda, the State held two public referenda votes on the issue of physician-assisted suicide. The Oregon Death with Dignity Act was first passed 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 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 Act provides for a comprehensive and detailed procedure by which a patient determined to be mentally competent and terminally ill may request assistance to end his or her life "in a humane and dignified manner." Under the Oregon law, the physician is required to provide extensive documentation, including that the patient has requested assistance in ending his or her life three times. 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 the patient is a capable adult with a terminal illness and who 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 they want to engage in physician-assisted suicide, the patient must self administer the lethal dose.

Within days of the second successful referendum, the Drug Enforcement Administration issued an opinion in which it declared it had the authority under the Controlled Substances Act to prosecute physicians in Oregon, who in compliance with Oregon law, prescribe drugs at the request of a terminally ill patient. However, on June 5, 1998, in a letter narrowly written in the context of Oregon's law, the Attorney General determined that the DEA did not have such authority under the Controlled Substance Act. In that letter the Attorney General stated:

There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice.

The Attorney General also noted in this letter:

Even more fundamentally, there is no evidence that Congress, in the CSA, intended to assign DEA the novel role of resolving the "earnest and profound debate about the morality, legality and practicality of physician-assisted

suicide,” *Washington v. Glucksberg* * * * simply because that procedure involved the use of controlled substances.

In September 1998, Oregon released information concerning the first 10 cases of assisted suicide. Two of these individuals died before taking the medication prescribed for them. Of the 10 individuals, five were men and five were women. In all but one case, cancer was the terminal diagnosis.

WE SHARE THE CONCERNS OF THE MEDICAL COMMUNITY REGARDING
THIS LEGISLATION

S. 2151 will discourage effective and necessary palliative care

This bill will 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. Opioids are the major class of analgesics used in the management of moderate to severe pain because of their effectiveness, ease of establishing an appropriate dose and favorable risk to benefit ratio.²⁵ Opioids, however, are also classified as a controlled substance under the CSA. The DEA, therefore, will have the ability to interfere in the physician-patient and/or pharmacist-patient relationship to determine why they are prescribing or dispensing this medication. This will inevitably lead to physicians and pharmacists not prescribing or dispensing or perhaps under-prescribing opioids in an effort to escape unnecessary bureaucracy and potentially harmful investigations.

Overly bureaucratic regulation of pain management drugs has already been demonstrated to discourage effective palliative care. The Institute of Medicine (IOM) published a report in 1997 entitled “Approaching Death: Improving Care At The End of Life,” which stated “studies have repeatedly indicated that a significant proportion of dying patients and patients with advanced disease experience serious pain, despite the availability of effective pharmacological and other options for relieving most pain.” In addition, the IOM stated that controlled substance laws may obstruct good care, due to specific provisions or fear and misunderstanding surrounding legal requirements. “Pain prescribing laws stand out in this regard and, in the view of the [End-of-Life] Committee, warrant revisions to minimize discouragement of effective pain management.”

In addition, numerous studies have also demonstrated that government regulations are one of the barriers to effective pain treatment. For example:

A 1998 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 prescribing and could lead to (disciplinary) proceedings;”

A 1990 *Journal of Pain and Symptom Management* article stated that one-quarter of State medical licensing and disciplinary board members surveyed were unaware that prescribing

²⁵The 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, March, 1994 pp. 49-60.

opioids for an extended period for cancer patients was both legal and acceptable medical practice;²⁶

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;²⁷ and

A nationwide study of cancer physicians showed “reluctance to prescribe” opioids and concern about “excessive regulations” as barriers to cancer pain management. Doctors’ concerns were greatest in States with triplicate prescription programs.²⁸

These studies point to the need for less regulation. S.2151 would cause the opposite result.

S. 2151 would provide a level of unprecedented federal intrusion into the practice of medicine, while not addressing the underlying need that may cause some patients to seek physician-assisted suicide. The literature and medical practitioners themselves repeatedly point to the need for better provider and patient education concerning pain management and a regulatory environment in which providers do not fear investigations that might ruin their professional reputations.

In addition, any DEA investigation will be quite intrusive, because it will 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 health care providers have pointed out and as was discussed in the Department of Justice’s testimony before the Committee, in the real world, most terminally ill patients already have an ample supply of such substances on hand to use in any suicide effort. The DEA, therefore, will not be able to make an objective determination based upon the drug and dosage the patient had on hand. Rather, the DEA will be forced to determine the intent of 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. As noted by the Justice Department:

The Lethal Drug Abuse Prevention Act is designed to address physicians’ fears by prohibiting sanctions so long as physicians do not dispense the controlled substance with the intent of causing death. However, 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.²⁹

²⁶Joranson, D.E. Federal and State Regulation of Opioids. *Journal of Pain and Symptom Management* 5 (1990) S12–23.–

²⁷Bernabei R., et al. Pain Management in Elderly Patients with Cancer. *JAMA*, June 17, 1998: 279: 1877–1882.–

²⁸Von Roenn J., Cleeland, CS, et al. Results of Physicians’ attitudes toward cancer pain management survey. *Proceedings of the American Society of Clinical Oncology* 109 1991, 326.

²⁹Letter of L. Anthony Sutin, Acting Assistant Attorney General, to Orrin G. Hatch, September 16, 1998.

S. 2151 may further expand the DEA's authority over the practice of medicine

This bill could be interpreted to expand the DEA's authority over the medical profession beyond its purported purpose. 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 states that the term "medically indicated" as used in this bill refers to the use of a controlled substance where the use of such substance is "reasonable and necessary" for the treatment of a patient and is not consistent with intentionally causing the death of the patient. If this statement is true, the DEA's authority could be interpreted to go beyond examining the intent of the provider and the appropriate use of the drug. The DEA could now also examine what is "reasonable and necessary" in the care of the patient which is a very different kind of determination than one of appropriate use. The CSA was never intended to be used by the DEA as a source of authority to make the medical determination of what is a reasonable and necessary use of drugs for patient care beyond the narrow scope of preventing the diversion of or illegal trafficking in drugs.

The medical advisory board on pain relief is not a sufficient safeguard to protect against the potential harms of S. 2151

Proponents of the bill believe the Medical Advisory Board on Pain Relief (the Board or Advisory Board) would provide an adequate shield for health care providers because these physicians and pharmacists could request that the Board review their case after they have been notified that they are subject to a DEA investigation. Unfortunately, the Board's review is likely to be too little, too late. The Board only issues advisory opinions and can only be brought into the process *after* an investigation has already begun. In addition, the organizations to be named to this Board oppose this legislation and were not consulted in the drafting of the bill. Finally, the pharmacists are alarmed because the Board does not include any representation by pharmacists.

The majority also states that the Department of Health and Human Services (HHS) would serve as the chief medical advisor for the DEA in implementing this legislation. However, the actual legislation provides no specific responsibilities for the liaison and its input appears to be non-binding. The Chairman's additional language requiring such a liaison with HHS in itself is a determination that the DEA currently lacks the expertise necessary to determine the intent or the reasonable and necessary use of the drugs in question.

The Attorney General cannot make a finding without an investigation

The majority argues that this revised bill provides another layer of protection to physicians and pharmacists by requiring the Attorney General to make a finding that a physician or pharmacist has dispensed or distributed a specific controlled substance which was directly responsible for the death of an individual before a DEA investigation can be commenced. It is unclear to us, however, how

the Attorney General can make such findings without first conducting some sort of potentially intrusive investigation.

S. 2151 is not necessary to insure the uniform application of the Controlled Substances Act

The majority states 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 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.

State medical boards are the proper forum for governing pain management practices

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

S. 2151 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 provider's intent. This conflicts with the mission of State 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 and superfluous federal enforcement mechanism.

According to the Federation of State Medical Boards (FSMB), in cases where the inappropriate prescribing of controlled substances is determined, the State medical boards require a physician to surrender his or her DEA certificate as part of the disciplinary action taken and notify the DEA of such action. The surrendering of the DEA certificate may be only one of the conditions imposed upon the physician and if the physician fails to comply with all the terms of the disciplinary action, the board may then revoke the physician's medical license.

Under the current system, all physicians are subject to peer review while licensed. Hospitals, other health care 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 de-

signed 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, State 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 State 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.

S. 2151 will interfere with the goals of hospice and comfort care

In 1997, 3200 hospices cared for nearly a half-million 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 the patient can maintain the highest quality of life during their remaining days.

In Oregon, as a result of the physician-assisted suicide debate and the State's law which requires physicians and their patients to discuss options other than physician-assisted suicide, use of hospice care has increased significantly. Oregon's rapidly increasing use of hospice care demonstrates the public's need for information concerning alternatives to physician-assisted suicide and the overall need for improvements in end-of-life care.

S. 2151 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. S. 2151 does not address these serious concerns, and in the opinion of an overwhelming number of physicians, pharmacists, hospice providers, nurses and pain patients, will only exacerbate the problems of pain management and hinder the ongoing evolution of the fields of palliative care and pain management.

CONCLUSION

Physician assisted-suicide is a disturbing practice which 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 this bill, S. 2151, will do little to stop or even reduce the practice.

Indeed, the majority, under the guise of amending the Controlled Substances Act, 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 will discourage appropriate, palliative care and may actually increase the demand for physician-assisted suicide.

If the majority wishes to effectively 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, patients largely 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, S. 2151 will exacerbate these problems.

We, therefore, cannot support this bill.

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

XI. 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. 2151, as reported, are shown as follows (existing law which would be omitted is enclosed in bold brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman type):

UNITED STATES CODE

* * * * *

TITLE 21—FOOD AND DRUGS

* * * * *

CHAPTER 13—DRUG ABUSE PREVENTION AND CONTROL

Subchapter I—Control and Enforcement

PART A—INTRODUCTORY PROVISIONS

* * * * *

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

* * * * *

§ 823. Registration requirements

MANUFACTURERS OF CONTROLLED SUBSTANCES IN SCHEDULES I AND II

(a) The Attorney General * * *

* * * * *

PRACTITIONERS DISPENSING NARCOTIC DRUGS FOR NARCOTIC TREATMENT; ANNUAL REGISTRATION; SEPARATE REGISTRATION; QUALIFICATIONS

(g) Practitioners * * *

* * * * *

APPLICANTS FOR DISTRIBUTION OF LIST I CHEMICALS

(h) The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that reg-

istration 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 802(39)(A)(iv) of this title. In determining the public interest for the purpose 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) *The Attorney General shall determine that registration of an applicant under this section is inconsistent with the public interest if—*

(1) *during the 5-year period immediately preceding the date on which the application is submitted under this section, the registration of the applicant under this section was suspended or revoked under section 304(a)(4); or*

(2) *the Attorney General determines, based on clear and convincing evidence, that the applicant is applying for the registration with the intention of using the registration to take any action that would constitute a violation of section 304(a)(4).*

§ 824. Denial, revocation, or suspension of registration

GROUND S

(a) A registration pursuant to section 823 of this title 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—

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) *has intentionally dispensed or distributed a controlled substance with the purpose of causing, or assisting in causing, the suicide or euthanasia of any individual, except that this paragraph does not apply to the dispensing or distribution of a controlled substance—*

(A) for the purpose of alleviating pain or discomfort (even if the use of the controlled substance may increase the risk of death), so long as the controlled substance is not also dispensed or distributed for the purpose of causing, or assisting in causing, the death of an individual for any reason; or

(B) for the purpose of carrying out a sentence of death under Federal or State law;

[(4)] (5) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such *other* section; or

[(5)] (6) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of Title 42.

A registration pursuant to section 823(g) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g) of this title.

LIMITS OF REVOCATION OR SUSPENSION

(b) the Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

SERVICE OF SHOW CAUSE ORDER; PROCEEDINGS

[(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 823 of this title, 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. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(2) *ASSISTED SUICIDE.*—

(A) *FINDINGS.*—

(i) *IN GENERAL.*—*Prior to any proceeding under paragraph (1), where an order to show cause may be based on subsection (a)(4) for denial, revocation, or suspension of registration, the Attorney General shall make a finding that the applicant or registrant—*

(I) has dispensed or distributed a specific controlled substance that was directly responsible for the death of an individual; and

(II) did not dispense or distribute the specific controlled substance as medically indicated.

(ii) *CONSULTATION.*—*In making any finding under clause (i)(II), the Attorney General may consult with the Secretary of Health and Human Services, as the Attorney General, in consultation with the Secretary, determines to be appropriate.*

(B) *BURDEN OF PROOF.*—At any proceeding under paragraph (1), where the order to show cause is based on subsection (a)(4) for denial, revocation, or suspension of registration, the Attorney General shall have the burden of proving, by clear and convincing evidence, that the practitioner's intent was to dispense or distribute a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual. In meeting such burden, it shall not be sufficient to prove that the registrant knew that the use of the controlled substance may increase the risk of death.

(C) *REQUEST FOR REVIEW BY MEDICAL ADVISORY BOARD ON PAIN RELIEF.*—At any proceeding under paragraph (1), where the order to show cause is based on subsection (a)(4) for denial, revocation, or suspension of registration, the practitioner may request, within 30 days after the receipt of the order to show cause, that the Medical Advisory Board on Pain Relief review, in accordance with paragraph (3), the administrative record of such proceeding as it relates to subsection (a)(4).

(3) *MEDICAL ADVISORY BOARD ON PAIN RELIEF.*—

(A) *IN GENERAL.*—The Secretary of Health and Human Services, in consultation with the Attorney General, shall by regulation establish a board to be known as the Medical Advisory Board on Pain Relief (referred to in this subsection as the “Board”).

(B) *MEMBERSHIP.*—

(i) *IN GENERAL.*—Subject to clause (ii), the Secretary of Health and Human Services, in consultation with the Attorney General, shall appoint the members of the Board—

(I) from among individuals who by reason of specialized education or substantial relevant experience in pain management, are clinical experts with knowledge regarding standards, practices, and guidelines concerning pain relief; and

(II) after consultation with the American Medical Association, the American Academy of Pain Medicine, the American Pain Society, the American Academy of Hospice and Palliative Medicine, the National Hospice Organization, the American Geriatrics Society, and such other entities with relevant expertise concerning pain relief, as the Attorney General determines to be appropriate.

(ii) *PROHIBITION.*—No member of the board may be an officer or employee of the Federal Government.

(C) *DUTIES OF BOARD.*—If, in accordance with paragraph (2)(B), an applicant or registrant requests a review by the Board of the record of a proceeding under paragraph (1), the Board shall review the administrative record of such proceeding as it relates to subsection (a)(4) and issue to the Secretary of Health and Human Services and the Attorney General an advisory opinion as to whether the dispensing or distribution of the controlled substance at issue in the

proceeding was for the purpose of alleviating pain or discomfort in a manner that does not constitute a violation of subsection (a)(4). The opinion of the Board under this subparagraph shall be part of the administrative record and shall be considered by the Attorney General in determining whether to deny, revoke, or suspend the registration involved.

(D) COMPENSATION OF MEMBERS.—Each member of the Board shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day (including travel time) during which such member is engaged in the performance of the duties of the Board.

(4) NO ADDITIONAL INVESTIGATIVE AUTHORITY.—Nothing in section 303(i), subsection (a)(4) of this section, or this subsection may be construed to provide the Attorney General with any additional investigative authority in any State, to the extent that the law of the State prohibits assisted suicide or euthanasia.

