

Assisted Suicide File 0

"Assisted Suicide Funding Restriction Act of 1997"

- The Assisted Suicide Funding Restriction Act of 1997, Pub. L. No. 105-12 (April 30, 1997), bans the use of federal funds to pay for or promote assisted suicide. The central restriction in the Act is phrased in the following terms: "[N]o funds appropriated by Congress for the purpose of paying (directly or indirectly) for the provision of health care services may be used" (1) to provide, (2) to pay for, or (3) to pay for health benefit coverage including any "item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing." Sec. 3(a).
- The only provision of the Act that restricts the actual furnishing of services (as distinguished from funding) is applicable only to federal employees and to services provided in federal facilities. That provision states that "no such item or service may be furnished for the purpose of causing" death by assisted suicide, and applies to items and services furnished (1) "by or in a health care facility owned or operated by the Federal government," or (2) "by any physician or other individual employed by the Federal government to provide health care services within the scope of the physician's or individual's employment." Sec. 3(c).
- Nothing in the Act authorizes the federal government to take adverse action against a private physician for assisting in a suicide in a non-federal facility.

"Assisted Suicide Funding Restriction Act of 1997"

- The Assisted Suicide Funding Restriction Act of 1997, Pub. L. No. 105-12 (April 30, 1997), bans the use of federal funds to pay for or promote assisted suicide.
- The Act does not have any effect on the Controlled Substances Act (CSA), and nothing in the Act is inconsistent with the conclusion that the CSA was not intended to authorize DEA to take adverse action against a physician who assists in a suicide in compliance with state law.
- Congress found in section 2(a)(3) of the Act: "Because of recent legal developments, it may become lawful in areas of the United States to furnish services in support of such activities [assisted suicide, euthanasia, and mercy killing]."
- In his signing statement, President Clinton stated: "The restrictions on the use of funds contained in [section 5(a)(3)], properly construed, will allow the Federal Government to speak with a clear voice in opposing these practices." 1997 U.S.C.C.A.N. 58 (April 30, 1997). He was addressing a portion of the Act ensuring that federal funds "not be used to subsidize legal assistance or other forms of advocacy in support of legal protection for assisted suicide, euthanasia, or mercy killing." Id. He proceeded to emphasize that the First Amendment required a narrow construction of this provision as covering only activities with the purpose of advocating assisted suicide, and not those providing "forums for the free exchange of ideas." Id.
- Nothing in President Clinton's signing statement is inconsistent with the conclusion that the CSA was not intended to authorize DEA to take adverse action against a physician who assists in a suicide in compliance with state law, or with the conclusion that such adverse action is unwarranted for reasons unrelated to opposition to assisted suicide (such as federalism concerns).

## Oregon Initiative Procedure

- The Oregon Constitution provides that "[t]he people reserve to themselves the initiative power, which is to propose laws . . . and enact or reject them at an election independently of the Legislative Assembly." Or. Const. art. IV, § 1(2)(a). The Oregon Death With Dignity Act was enacted through the initiative process.
- The legislature apparently has the authority to repeal an act passed by initiative just as it can repeal an act passed by the legislature itself. Although neither the Constitution nor statutes specifically address repeal of initiatives, the Oregon Supreme Court has stated that "the Legislative Assembly, when convened, may amend or repeal a law passed by the people." State ex rel. Carson v. Kozer, 270 P. 513, 514 (Or. 1928).
- However, the Oregon legislature apparently has never repealed an initiative. Out of 99 voter-approved initiatives since 1904, the Secretary of State reports that none has been repealed by the legislature. Portland Oregonian, March 1, 1997, p. D1. "Many legislators consider it heresy to override the will of the people." Id.
- After efforts in the legislature to repeal Oregon's Death With Dignity Act failed last year, an initiative to repeal the Act was placed before voters. Voters rejected the repeal initiative on November 4, 1997.

# PAIN CARE COALITION

*A National Coalition for Responsible Pain Care*

July 31, 1998

The Honorable Henry J. Hyde  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Hyde:

Improving end-of-life care is a priority for the Pain Care Coalition. In its attempt to prevent certain behavior, H.R. 4006, the *Lethal Drug Abuse Prevention Act*, will have a detrimental effect on end-of-life care and seriously harm existing patient care. Rather than passing the proposed legislation, therefore, the Pain Care Coalition urges Congress to engage in a meaningful and thoughtful debate on this complex issue.

Many patients with terminal illnesses suffer debilitating pain every day. The foundation of good end-of-life care for these patients includes appropriate pain relief. Unfortunately, as recently noted by the Institute of Medicine, pain is currently under-treated, in part due to existing laws and regulations.

Patients in severe pain require a variety of necessary services for pain control. Options include the use of medications, such as narcotics, medical procedures, and other non-medicinal interventions. One of the means to control pain in some individuals is the use of narcotics, at dosages varying depending upon the clinical circumstances. We are concerned that H.R. 4006 will exacerbate the under-treatment of pain.

Faced with the potential investigation by the Drug Enforcement Agency, the majority of physicians will be fearful to prescribe pain-relieving narcotics, even to those patients in need. In its current form, this bill could have a damaging effect by limiting one key element of appropriate patient care, particularly in those patients who suffer from terminal illness.

An additional concern is that the bill threatens a patient's right to privacy, because any government review of a physician's actions would require the physician to disclose details of the patient care that should be held in the strictest confidence.

The Pain Care Coalition opposes physician-assisted suicide. However, we are writing to express our opposition to H.R. 4006 in its current form. We stand ready to work with Congress as it undertakes the critical task of improving end-of-life care.

The Pain Care Coalition is a national coalition which advocates for responsible pain care policies at the federal level and was founded by concerned organizations representing the interests of pain care professionals and their patients. Constituent members of the Coalition represent a broad spectrum of physicians and other health care professionals involved in the diagnosis and treatment of patients suffering from pain, biomedical and related researchers, and professionals studying the effectiveness of diagnostic and therapeutic approaches to eradication or lessening of pain.

Thank you for your consideration.

Sincerely,

Joel R. Saper, M.D.  
Chair

# PAIN CARE COALITION

*A National Coalition for Responsible Pain Care*

July 31, 1998

The Honorable Orrin G. Hatch  
United States Senate  
Washington, DC 20510

Dear Senator Hatch:

Improving end-of-life care is a priority for the Pain Care Coalition. In its attempt to prevent certain behavior, S. 2151, the *Lethal Drug Abuse Prevention Act*, will have a detrimental effect on end-of-life care and seriously harm existing patient care. Rather than passing the proposed legislation, therefore, the Pain Care Coalition urges Congress to engage in a meaningful and thoughtful debate on this complex issue.

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The Pain Care Coalition opposes physician-assisted suicide. However, we are writing to express our opposition to S. 2151 in its current form. We stand ready to work with Congress as it undertakes the critical task of improving end-of-life care.

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Thank you for your consideration.

Sincerely,

Joel R. Saper, M.D.  
Chair



**APhA**

**American  
Pharmaceutical  
Association**

2215 Constitution Avenue, NW  
Washington, DC 20037-2985  
(202) 628-4410 Fax (202) 783-2351  
<http://www.aphanet.org>

*The National Professional  
Society of Pharmacists*

July 27, 1998

The Honorable Henry J. Hyde  
2110 Rayburn House Office Building  
Washington, D.C. 20515

Dear Representative Hyde:

The American Pharmaceutical Association (APhA), the national professional society of pharmacists, has profound concerns about the patient care implications of the Lethal Drug Abuse Prevention Act of 1998, HR 4006. While the bill is intended to halt health professional involvement in assisted suicide, in reality it would have a significant negative unintended impact on patient care and on the practice of pharmacy.

Our concerns with the bill arise from the chilling effect of new regulatory requirements for the use of controlled substances. The new requirements of HR 4006 will have the same negative impact that other regulatory requirements have had—a decrease in the prescribing and use of controlled substances. This often occurs because prescribers fear prosecution for overuse of controlled substances when their patients require large doses to control chronic pain. Discouraging controlled substance use will hurt patients in pain. Pain management is already generally inadequate, and controlled substances are one of the best weapons doctors and pharmacists have in fighting chronic pain. Attached please find two summaries of the scientific literature supporting these contentions.

We know from these studies that further intimidation of health professionals will worsen the already substantial problem of poor pain management in our country. While it may be difficult to understand—and hard for health professionals to admit—study after study has concluded that pain management in the United States health care system is abysmal. It is particularly inadequate when it comes to managing the pain of the elderly and minorities.

This bill is no solution to assisted suicide, and will worsen the real problem: poor end of life care. By leaving more patients in uncontrolled pain, H.R. 4006 may *encourage* demand for assisted suicide from thousands of dying patients, even if it does prevent a handful of patients from using this option in a State where it is legal. This is a poor trade-off and poor public policy.

APhA would welcome the opportunity to discuss this bill with you. Please contact Susan C. Winckler of my staff at 202/429-7533 should you need more information. Thank you.

Sincerely,

John A. Gans, PharmD  
Executive Vice President

Enclosures

cc: Susan C. Winckler, RPh, Director, Policy & Legislation



**APhA**

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Pharmaceutical  
Association**

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*The National Professional  
Society of Pharmacists*

## **When Regulation Hurts: Undermining Good Pain Management**

**Physicians have been disciplined for legitimate prescribing of opioid analgesics.**

Nowak R. Cops and Doctors: drug busts hamper pain therapy.

*The Journal of NIH Research* 4 (1992), 27-28.

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 committee, *warrant revisions to minimize discouragement of effective pain management.*" [Emphasis supplied] National Academy of Sciences. Institute of Medicine, 1997. "Approaching Death: Improving Care at the End of Life". \*

In cases where large quantities of opioids are needed by an individual, health care workers may be reluctant to prescribe or dispense opioids if they feel there is a possibility of their professional license being suspended or revoked by regulators, even though the medical need for such drugs can be substantiated. World Health Organization Expert Committee. Cancer pain relief and palliative care. Geneva, Switzerland: WHO, 1990.

A nationwide study of cancer physicians showed "reluctance to prescribe" opioids and concern about "excessive regulations" are barriers to cancer pain management. Doctors' concerns were greatest in States with triplicate prescription programs. Von Roenn J, Cleeland CS, et al. Results of physicians' attitudes toward cancer pain management Survey. *Proceedings of the American Society of Clinical Oncology* 10 (1991), 326.

71% of physicians surveyed in New York State reported they do not prescribe effective medication for cancer pain if such prescriptions would require them to use a special state-monitored prescription form for controlled substances—even when the medication is legal and medically indicated for a patient. 82% utilize drugs not requiring a triplicate form, even when an alternative drug is otherwise indicated, due to concern about regulatory scrutiny. 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. \*

69% of California physicians surveyed stated the risk of disciplinary action made them more reluctant to use opioids in pain management. One-third reported that their patients may be suffering from neglected, treatable pain. Skelly FJ. Fear of sanctions limits prescribing of pain drugs. *American Medical News*, August 15 (1994), 19.

Prescriptions for controlled (Schedule II) drugs decreased by 60% one year after imposition of a State triplicate prescription law for controlled substances, at a 1200-bed teaching hospital in Texas. [See last entry, page 2 for further explanation of "schedules."] Sigler K, Guernsey B, et al. Effect of a triplicate prescription law on prescribing of Schedule II drugs. *American Journal of Hospital Pharmacy* 41 (1984), 108-111. \*

One-quarter of State medical licensing and disciplinary board members surveyed were unaware that prescribing opioids for an extended period for cancer pain is both legal and acceptable medical practice. Joranson DE. Federal and State regulation of opioids. *Journal of Pain and Symptom Management* 5 (1990), S12-23.

54% of physicians surveyed in a University of Wisconsin Study reported that due to concern over regulatory scrutiny they will reduce drug dose or quantity, or reduce the number of refills, or choose a drug that appears on a lower Controlled Substances Act "schedule." [Please see last entry, below, for further explanation.] Weissman D, Joranson D, et al. Wisconsin physicians' knowledge and attitudes about opioid analgesic regulations. *Wisconsin Medical Journal* 90 (1991), 671-675.

68% of Texas physicians responding to a statewide survey stated that they believed the Texas State Board of Medical Examiners influences pain treatment to some degree or to a great degree. Ralston RL. Texas physicians' perceptions of regulatory barriers to adequate pain treatment. University of Texas at Houston Health Sciences Center, unpublished M.P.H. thesis (1995).

In July 1993, Indiana abolished its triplicate prescription program, noting the program was not considered to be a cost-effective means of reducing drug diversion and abuse, and citing concerns about possible negative effects the program had on appropriate prescribing and patient care. Angarola RT, Joranson DE. Recent Developments in pain management and regulation. *American Pain Society Bulletin* 1994: 4(1), 9-11.

Controlled substances are "scheduled" under the Federal Controlled Substances Act (CSA) according to their potential for dependence and abuse. Those with the greatest dependence/abuse potential and no currently accepted medical use are classified in "Schedule I." "Schedule II" includes the opioids and opiate derivatives. [Source: Section 202 of CSA]. 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. These are generally the drugs of choice for pain management in terminal patients. The 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).

\* Denotes a study referenced in the testimony of Calvin H. Knowlton, RPh, MDiv, PhD, before the House of Representatives Committee on the Judiciary Subcommittee on the Constitution, July 14, 1998.



## **End of Life Pain Management: A Public Health Crisis** **“Undertreatment of pain and other symptoms of cancer is a serious and neglected public health problem” – National Cancer Institute, 1990**

50% of patients experience moderate to severe pain at least half the time in their last days of life. [Source: A controlled trial to improve the care for seriously ill hospitalized patients: The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT). *JAMA*. 1995 (274): 1591-1598.]

A large, four-State study found 81% of over 600 physicians in five hospitals reported “the most common form of ‘narcotic abuse’ in the care of the dying is undertreatment of pain.” [Source: Solomon MZ, et al. Decisions near the end of life: professional views on life-sustaining treatments. *American Journal of Public Health*. 1993 (83): 14-23.]

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. [Source: Bernabei R, et al. Pain Management in Elderly Patients with Cancer. *JAMA*. June 17, 1998;279:1877-1882.]

Physicians in training still demonstrate deficiencies in their knowledge about the pharmacology and bioequivalency of opioids. When asked to convert an intravenous dose of morphine to an equivalent dose of a controlled-release preparation, 75% calculated a dose that was less than one-third the correct dose. [Source: Mortimer JE, Bartlett NL. Assessment of knowledge about cancer pain management by physicians in training. *Journal of Pain and Symptom Management*. 1997 (14,1): 21-28.]

The majority of cancer patients experience significant pain during their illness. Most cancer pain can be readily managed with oral analgesic therapy. However, cancer pain is often undertreated because of poor communication between physicians and patients and inadequate training of physicians in pain management. [Source: Rhoades DJ, Grossman SA. The management of cancer pain. *Maryland Medical Journal*. 1997 (46): 141-6.]

Pain control for cancer patients is a significant problem in health care. Lack of expertise by clinicians in assessing and managing cancer pain is an important cause of inadequate pain management. Only 58% of young physicians evaluated were judged competent in clinical cancer pain assessment; many were judged not to be competent in the assessment or the management of the severe pain of a hypothetical patient. [Source: Sloan PA, et al. Cancer pain assessment and management by housestaff. *Pain*. 1996 (67): 475-81.]

Fear of cancer pain is one of the primary reasons patients request euthanasia. Persistent pain interferes with patients' quality of life and this, in turn, influences a patient's choice about suicide or physician-assisted suicide. There is evidence pain almost always undermines the quality of life for patients and that pain relief appears to improve quality of life.” [Source: Foley KM. The relationship of pain and symptom management to patient requests for physician-assisted suicide. *Journal of Pain and Symptom Management*. 1991(6): p.294.]

# THE AMERICAN GERIATRICS SOCIETY

770 LEXINGTON AVENUE, SUITE 300, NEW YORK, NY 10021 TELEPHONE: (212) 308-1414 FAX: (212) 832-8646

LINDA HIDDEMAN BARONDESS  
Executive Vice President

July 27, 1998

The Honorable Henry J. Hyde  
Chairman, House Committee on the Judiciary  
2138 Rayburn House Office Building  
Washington, DC 20515-1315

Dear Representative Hyde:

On behalf of the American Geriatrics Society (AGS), an organization of over 6,000 health care professionals dedicated to the health and well-being of older persons, I am writing to express our opposition to H.R. 4006, the "Lethal Drug Abuse Prevention Act."

This bill would authorize the Drug Enforcement Agency (DEA) to revoke a physician's license to prescribe controlled substances if the physician "intended" to cause a patient's death. The DEA would become responsible for investigating allegations of wrongdoing and determining "intent."

While its goal is to prevent physician-assisted suicide -- a goal the AGS shares -- we believe the bill will have the unintended effect of creating additional barriers for patients needing relief of severe pain. Many physicians are already reluctant to prescribe adequate pain relief for fear of violating existing pain-prescribing laws. A 1997 Institute of Medicine study said that "drug-prescribing laws, regulations and interpretations by state medical boards frustrate and intimidate physicians," resulting in under-treatment of pain. In fact, the bill may prompt an increased demand for assisted suicide from patients whose pain has become unbearable.

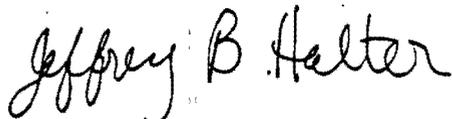
Further, since many lethal agents are not "controlled substances" and would be unaffected by this bill, it would not even be effective in preventing physician-assisted suicide.

Unrelieved pain is a critical problem in this country, as a number of recent studies have documented. One study showed that 50% of terminally ill patients experience moderate to severe pain at least half the time in their last days of life (SUPPORT, 1997), and a 1998 study of elderly cancer patients in nursing homes found that one-fourth of all patients in chronic pain received no pain medication at all.

To address this issue, the AGS just released the first clinical practice guidelines that focus specifically on pain management in older Americans. These guidelines urge regulatory agencies to change existing policies to improve access to narcotics for patients in pain.

Instead of pursuing this proposal, we urge you to work on federal efforts to improve end-of-life care. If dying patients receive the care and pain relief they need, the demand for suicide would be greatly diminished.

Sincerely,

A handwritten signature in cursive script that reads "Jeffrey B. Halter".

Jeffrey B. Halter, MD  
President



# NATIONAL HEALTH COUNCIL

July 21, 1998

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**Mitchell R. Steiner**  
American Paralytic Association

The Honorable Jim Sensenbrenner  
United States House of Representatives  
2332 Rayburn House Office Building  
Washington, DC 20515

Dear Representative Sensenbrenner:

The National Health Council represents forty of the Nation's leading patient-based which serve more than 100 million individuals with chronic diseases and/or disabilities. The National Health Council is concerned that efforts to expand the authority of the federal government to regulate the dispensing of pain medication under the Controlled Substance Act may undermine the care of patients with serious and life-threatening conditions. Therefore, we urge you to move cautiously as you consider the Lethal Drug Abuse Prevention Act of 1998, HR 4006, and carefully examine all its potential consequences.

Over the last decade, care for persons at the end-of-life and for those who experience severe, chronic pain has evolved dramatically. When pain is adequately controlled, and people are assured that that they are not a burden on their loved ones, this period of life can be one of physical comfort and of emotional and spiritual value.

However, it remains a tragedy that some patients with serious illnesses seek an early death. It should be our responsibility to understand this desire and to remedy the absence of competent, comprehensive care which leads too many patients to consider assisted suicide necessary. Many more patients, than the current rate of one in five, must have access to palliative care and comprehensive pain management. Programs should be required at medical and nursing schools on state-of-the-art care for the dying and their families. And, hospitals and nursing homes must provide quality end-of-life care.

We appreciate your concerns regarding assisted suicide. No patient should believe they only have one choice when confronting illness and pain. We must work together to make the delivery of compassionate end-of-life care available to all Americans. The National Health Council, therefore, encourages you to examine this issue carefully and seek other means to accomplish our mutual goal of providing good, compassionate care to our most vulnerable patients.

Sincerely,

Myrl Weinberg, CAE  
President

# American Medical Association

Physicians dedicated to the health of America



1101 Vermont Avenue, NW  
Washington, DC 20005

## Statement

to the

**Subcommittee on the Constitution  
Committee on the Judiciary**

**U.S. House of Representatives**

**Re: H.R. 4006, the "Lethal Drug  
Abuse Prevention Act of 1998"**

**Presented by Thomas R. Reardon, MD**

**July 14, 1998**

Division of Legislative Counsel  
202 789-7426

**Statement**  
**of the**  
**American Medical Association**  
**to the**  
**Subcommittee on the Constitution**  
**Committee on the Judiciary**  
**U.S. House of Representatives**

**H.R. 4006, the "Lethal Drug Abuse Prevention Act of 1998"**

**Presented by: Thomas R. Reardon, MD**

**July 14, 1998**

The American Medical Association (AMA) appreciates the opportunity to present its views to the Subcommittee on the Constitution of the House Judiciary Committee regarding H.R. 4006, the "Lethal Drug Abuse Prevention Act of 1998."

The AMA is sympathetic to the concerns that have motivated the introduction of this measure. We agree with the sponsors that physician-assisted suicide is ethically incompatible with the physician's role as healer. Yet the AMA, after considerable internal consideration, has decided that we must oppose the bill before the Subcommittee today. That decision is based on a disagreement over means, rather than ends.

We understand that the sponsors are attempting to assure that no controlled substances are available to persons seeking suicide. In fact, however, we fear the "real world"

consequences of the bill would be to discourage the kind of appropriate aggressive palliative care that can dissuade patients in pain from seeking just such an early death. Recent promising advancements in the care of people at the end of life could be set back dramatically, to the detriment of patient care. In addition, the AMA believes that expanding the DEA's authority in this matter would be an unacceptable federal intrusion over matters of state law regarding the practice of medicine.

### **Pain Management**

Care for persons at the end of life and for those who experience severe, chronic pain has evolved dramatically in the last decade. Educational efforts within both the public and private sectors have intensified, reflecting a growing appreciation of the need for aggressive palliative treatment that addresses not only the physical suffering, but the psychological, social and spiritual distress that accompany terminal illness and intractable, chronic pain.

The dilemma physicians face when prescribing controlled substances for their patients suffering intractable pain can be better understood through a discussion of what is known as the "double effect." In some instances, administration of adequate pain medication will have the secondary effect of suppressing the patient's respiration, thereby hastening death. The distinction between this action and assisted suicide is crucial. The physician has an obligation to provide for the comfort of the patient. If there are no alternatives but to increase the risk of death in order to provide that comfort, the physician is ethically permitted to exercise that option. In this instance, the physician's clinical decision is guided by the intent to provide pain relief, rather than the intent to cause death. This

distinguishes the ethical use of palliative care medications from the unethical application of medical skills to cause death.

The past failure of many states to expressly permit this practice generated reluctance among physicians to prescribe adequate pain medication. The potential for legal or licensure action against the physician created additional uncertainty when controlled substances were prescribed in large amounts for patients with intractable pain. This uncertainty chilled the physician's ability to effectively evaluate and control their terminally ill patients' pain and suffering through the appropriate prescription and administration of opiates and other controlled substances. Proponents of assisted suicide cited a fear of prolonged suffering and unmanageable pain as a rationale for their position. Patients need to feel -- as much as is possible -- a sense of control over their medical condition; the availability of controlled substances for aggressive pain control must be among the options we can offer them. Lacking this, patients may easily turn to more desperate measures; adding the specter of DEA authority would only exacerbate their concerns and fears.

These concerns prompted physicians and their patients to demand change and the response was an exciting expansion of educational efforts that appears to be culminating in meaningful legislative, regulatory and guideline activity across the nation. Fifteen states have passed carefully crafted laws that grant immunity from licensure discipline for physicians who prescribe opiates to treat intractable pain.<sup>1</sup> Several others have regulations

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<sup>1</sup> California, Colorado, Florida, Minnesota, Missouri, Nevada, North Dakota, Ohio, Oregon, Rhode Island, Texas, Virginia, Washington, West Virginia and Wisconsin. (National Conference of State Legislatures (NCSL), July 1, 1998)

concerning intractable pain.<sup>2</sup> According to the Pain and Policy Studies Group at the University of Wisconsin Comprehensive Cancer Center, medical licensing boards in twenty-five states have adopted guidelines to improve or establish palliative care/intractable pain programs.<sup>3</sup> In May of this year, the Federation of State Medical Boards approved a model state guideline for the proper use of controlled substances in the treatment of intractable and end-of-life pain.

In its April, 1998, report, "Suicide Prevention: Efforts to Increase Research and Education in Palliative Care," the U.S. General Accounting Office (GAO) cites several current federal initiatives related to palliative care. The "Assisted Suicide Funding Restriction Act of 1997" included an amendment to section 781 of the Public Health Service Act, expanding the program support available through the Department of Health and Human Services' (HHS) Health Professional Educational Research Program to palliative care and suicide prevention topics.

The GAO report also cites several HHS agencies' funding of complementary projects investigating appropriate palliative care techniques and treatment approaches. Such funding includes over \$82 million in research conducted at the National Institutes of Health (NIH) to advance biomedical knowledge of pain management and assess patient outcomes regarding pain. The Agency for Health Care Policy Research (AHCPR) issued guidance in 1994 on management of cancer pain that offered recommendations on palliative therapies

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<sup>2</sup> Alabama, Arkansas, Iowa, Louisiana, Nevada, New Jersey, Oregon and Texas. (NCSL, July 1, 1998)

<sup>3</sup> Alaska, Arizona, California, Colorado, Florida, Georgia, Idaho, Iowa, Massachusetts, Maryland, Minnesota, Montana, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, and Wyoming. (NCSL, July 1, 1998)

used to ease or relieve pain. HCFA has supported multiple demonstration projects in the states to address palliative care options among medically vulnerable populations. We commend this GAO report to the Subcommittee's attention.

Outside of government, the AMA's Institute for Ethics, in collaboration with the Robert Wood Johnson Foundation, has helped to lead the way in educating physicians on how to better care for the dying through its nationwide initiative, *Education for Physicians on End-of-Life Care (EPIC)*. Multiple private foundations, professional associations and non-profits have funded an important array of palliative care investigations whose results are just now beginning to change the way such care is rendered.

We cite these many initiatives and educational efforts to demonstrate that the medical and health care community has responded to a need. The horror with which Americans responded to Jack Kervorkian's so-called "mercy" killings catapulted us all into action to find ways to improve our care for terminally ill patients in a humane and ethical manner. We urge this Subcommittee as strongly as we know how to resist the temptation to undo this hard work by creating a new federal watchdog to second-guess treatment decisions. The sponsors appear to be responding to a specific situation in Oregon and seeking ways to short-circuit what most of us would characterize as an unethical medical practice. But by choosing this route, they may well harm the very people who they are trying to help, not only in Oregon, but in every other state in the Union.

Physicians write potentially lethal prescriptions every day. A hundred tablets of Dilaudid, prescribed legitimately for pain control, can be used by the patient to cause death. This is

out of the physician's direct control, but could raise concerns under this bill. Further, under the terms of H.R. 4006, aggressive drug therapies for pain management will become automatically suspect. Physicians are only human and will go to great lengths to avoid a Department of Justice investigation... as would anyone. A Department of Justice investigation, which under the terms of this bill could be instigated by any individual, could result in a physician's (1) loss of federal DEA license for prescribing controlled substances; (2) exclusion from participation in the Medicare and Medicaid programs; and (3) possible criminal prosecution. There is no question but that H.R. 4006 would affect physician decision-making and have the perverse effect of chilling appropriate palliative care.

### **The Proper Roles of State and Federal Government**

It is difficult to reach any other conclusion but that H.R. 4006 is a federal attempt targeted specifically at undermining the will of the people of the state of Oregon. No federal action is needed; the states are addressing the issue of assisted suicide through their legislatures, their medical boards and their courts. According to the National Conference of State Legislatures (NCSL), 36 states currently explicitly criminalize assisted suicide through statute.<sup>4</sup> Another nine states criminalize assisted suicide through common law.<sup>5</sup> Three – North Carolina, Utah and Wyoming – abolished the common law of crimes and do not statutorily criminalize assisted suicide. Ohio's Supreme Court has ruled that assisted suicide is not a crime (October, 1996). Of all the states, only Oregon permits physician-

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<sup>4</sup> Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Virginia, Washington and Wisconsin. (NCSL, July 1, 1998)

<sup>5</sup> Alabama, Idaho, Maryland, Massachusetts, Michigan, Nevada, South Carolina, Vermont and West Virginia. (NCSL, July 1, 1998)

assisted suicide, having legalized the act through a 1994 voter ballot initiative, which was upheld by the U.S. Court of Appeals for the Ninth Circuit on March 3, 1997, after legal challenge. Oregonians had a second chance to vote by referendum on the "Death With Dignity Act" on November 4, 1997, which was again supported by almost 60% of ballots cast.

On November 5, 1997, prompted by concerned legislators and others, the DEA Administrator asserted the authority, under the federal Controlled Substances Act (CSA), to suspend or revoke a physician's DEA license for prescribing controlled substances for the purpose of assisting a suicide, even where, as in Oregon, assisted suicide is permitted by state law. While he acknowledged that this would be a "new and different application of the CSA," he cited his authority as flowing from the provisions of the Act that provide criminal penalties for physicians who dispense controlled substances beyond "the course of professional practice."<sup>6</sup> The Act also provides for suspension or revocation of a physician's DEA license if he or she has engaged in such criminal conduct or other "conduct which may threaten the public health or safety."<sup>7</sup> The Administrator deemed any physician's participation in invoking Oregon's assisted suicide law as not constituting "the legitimate practice of medicine."

Attorney General Janet Reno issued a Department of Justice Statement on June 5, 1998, disagreeing with the DEA Administrator's conclusion, declaring that "an adverse action by the DEA against a physician in full compliance with the Oregon statute would not be

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<sup>6</sup> 21 U.S.C. 802 (21)

<sup>7</sup> 21 U.S.C. 823(f)

authorized under the CSA.” The Department reviewed both the plain language of the statute, as well as its legislative history, and found that neither supports the Act’s application to physicians who are in compliance with the state law. The opinion continues:

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 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 AMA concurs with this interpretation. Any other reading makes the DEA an arbiter of the practice of medicine. This is an unacceptable conclusion. It is the state legislatures, through the police powers, that determine the scope of medical practice. State medical boards are universally authorized by their state statutes to investigate reports of improper prescribing as possible evidence supporting suspension or revocation of a physician’s license to practice medicine. This is the proper purview of the state.

The creation of a new expert review panel within the Department of Justice does not overcome physicians’ objection to this unprecedented intrusion of the federal government into the practice of medicine. In fact, it increases our concerns. At first blush, this “Review Board,” comprised of members of our own profession, with the AMA even deferred to regarding membership, would seem to be just the answer to our quandary. The fact is, though, that state medical licensing boards already exist to, in part, oversee the prescribing

practices of physicians. They are comprised of "individuals, who by reason of specialized education... are clinical experts with knowledge regarding standards, practices, and guidelines concerning pain relief" as part of their larger scope of expertise in patient care. The extra review board within the Justice Department is both redundant and unnecessary, and would be a direct usurpation of legitimate state authority by the federal government.

### Conclusion

We do not think the sponsors of H.R. 4006 intend for these consequences to flow from their proposal. We believe they share the same values expressed by the AMA in its unalterable opposition to physician-assisted suicide. We ask the sponsors to take another look at the means they have selected and ask if there isn't another way to accomplish our mutual goal that would not endanger that very vulnerable population we are all trying to help.

The AMA thanks the Subcommittee for its consideration of our views.



July 10, 1998

The Honorable Henry Hyde  
U.S. House of Representatives  
Washington, DC 20515

Dear Chairman Hyde:

The Judiciary Committee is currently considering H.R. 4006, *The Lethal Drug Abuse Prevention Act of 1998*, which you recently introduced. The National Hospice Organization (NHO), which represents over 90% of America's hospices and thousands of hospice care professionals, hospice patients and their families, has formally taken the position that we do not support assisted suicide or voluntary euthanasia. **Nevertheless, the National Hospice Organization opposes H.R. 4006. The bill proposes the wrong answer to the question of how we should protect and help people in such pain that they seek help to commit suicide. And it will have the unintended effect of increasing the suffering of many terminally ill Americans by chilling the use of many drugs effective in controlling pain.**

#### Summary of the Bill

H.R. 4006 seeks to prevent assisted suicide by amending the Controlled Substances Act. The bill would authorize the DEA to suspend or revoke the federal prescription license of a physician who "intentionally dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, [a] suicide. . ." The bill attempts to prevent interfering with physicians who use controlled substances "to alleviate pain" by creating an exception for such use. It also creates a "Medical Review Board on Pain Relief" to allow physicians, accused of violating the law, to show that their use of a controlled substance was "an appropriate means to relieve pain." Finally, the bill asks the Attorney General to appoint this review board after consulting with several organizations, including NHO.

#### NHO's Reasoning for Opposing H.R. 4006

In 1997 America's 3,200 hospices cared for nearly one half million terminally ill Americans. Hospices neither hasten nor delay death but rather provide comprehensive and compassionate care by addressing the physical, psychological, social and spiritual needs of the dying patient and his or her family. One of the main goals of hospice care is aggressively fighting the patient's pain through a variety of means, including controlled substances such as morphine and other opioids, so that the patient can maintain the highest quality of life during the time that remains. **H.R. 4006 will interfere with achieving the goals of hospice and should be rejected for the following reasons.**

Adding a federal sanction and a federal review board on top of the existing state regulatory structure will cause confusion and anxiety and dilute the beneficial effects that such model guidelines can have for terminally ill patients in severe pain.

**The Legislation Does Not Address the Needs of the Patient**

If the ultimate goal of Congress is to help the terminally ill person in despair, this legislation does not address the needs of those patients. It only makes the delivery of compassionate end-of-life care more difficult. Furthermore, it could simply drive assisted suicide farther underground by encouraging the use of non-controlled substances or encouraging patients to seek assistance from non-physicians.

It is not uncommon for the doctors, nurses, social workers, chaplains and other hospice professionals to see new patients in so much physical, emotional and spiritual pain that they request help to commit suicide. But the appropriate response to such a request is intensive palliative care. Because hospice is about maximizing the quality of patients lives and alleviating their pain and symptoms, hospice provides patients this clearly better option. Thus they can complete their lives as comfortably as possible while they and their families come to closure on the many complex problems that a pending death brings forth.

**Conclusion**

Instead of trying to prevent assisted suicide by threatening doctors with license revocation, the National Hospice Organization encourages Congress to engage in a dialogue with us on how you can promote broader access to hospice care for the more than one million terminally ill Americans who die every year. Your participation in such a dialogue will ultimately lead to reducing the demand for assisted suicide. Please feel free to contact me or our Director of Public Policy and General Counsel, John Giglio, at 703-294-4434 for additional information.

Thank you for your consideration of our views.

Sincerely,



Karen Davie  
President





July 13, 1998

The Honorable Orrin Hatch  
U.S. Senate  
Washington, DC 20510

Dear Mr. Chairman:

We understand that the Judiciary Committee may soon consider S. 2151, *The Lethal Drug Abuse Prevention Act of 1998*, recently introduced by Senator Nickles. The National Hospice Organization (NHO), which represents over 90% of America's hospices and thousands of hospice care professionals, hospice patients and their families, has formally taken the position that we do not support assisted suicide or voluntary euthanasia. **Nevertheless, the National Hospice Organization opposes S. 2151. The bill proposes the wrong answer to the question of how we should protect and help people in such pain that they seek help to commit suicide. And it will have the unintended effect of increasing the suffering of many terminally ill Americans by chilling the use of many drugs effective in controlling pain.**

#### Summary of the Bill

S. 2151 seeks to prevent assisted suicide by amending the Controlled Substances Act. The bill would authorize the DEA to suspend or revoke the federal prescription license of a physician who "intentionally dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, [a] suicide. . ." The bill attempts to prevent interfering with physicians who use controlled substances "to alleviate pain" by creating an exception for such use. It also creates a "Medical Review Board on Pain Relief" to allow physicians, accused of violating the law, to show that their use of a controlled substance was "an appropriate means to relieve pain." Finally, the bill asks the Attorney General to appoint this review board after consulting with several organizations, including NHO.

#### NHO's Reasoning for Opposing S. 2151

In 1997 America's 3,200 hospices cared for nearly one half million terminally ill Americans. Hospices neither hasten nor delay death but rather provide comprehensive and compassionate care by addressing the physical, psychological, social and spiritual needs of the dying patient and his or her family. One of the main goals of hospice care is aggressively fighting the patient's pain through a variety of means, including controlled substances such as morphine and other opioids, so that the patient can maintain the highest quality of life during the time that remains. **S. 2151 will interfere with achieving the goals of hospice and should be rejected for the following reasons.**

Adding a federal sanction and a federal review board on top of the existing state regulatory structure will cause confusion and anxiety and dilute the beneficial effects that such model guidelines can have for terminally ill patients in severe pain.

**The Legislation Does Not Address the Needs of the Patient**

If the ultimate goal of Congress is to help the terminally ill person in despair, this legislation does not address the needs of those patients. It only makes the delivery of compassionate end-of-life care more difficult. Furthermore, it could simply drive assisted suicide farther underground by encouraging the use of non-controlled substances or encouraging patients to seek assistance from non-physicians.

It is not uncommon for the doctors, nurses, social workers, chaplains and other hospice professionals to see new patients in so much physical, emotional and spiritual pain that they request help to commit suicide. But the appropriate response to such a request is intensive palliative care. Because hospice is about maximizing the quality of patients' lives and alleviating their pain and symptoms, hospice provides patients this clearly better option. Thus they can complete their lives as comfortably as possible while they and their families come to closure on the many complex problems that a pending death brings forth.

**Conclusion**

Instead of trying to prevent assisted suicide by threatening doctors with license revocation, the National Hospice Organization encourages Congress to engage in a dialogue with us on how you can promote broader access to hospice care for the more than one million terminally ill Americans who die every year. Your participation in such a dialogue will ultimately lead to reducing the demand for assisted suicide. Please feel free to contact me or our Director of Public Policy and General Counsel, John Giglio, at 703-294-4434 for additional information.

Thank you for your consideration of our views.

Sincerely,



Karen Davie  
President



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H.R. #, S. #

Sec. #. Study on Pain and Symptom Management

(1) IN GENERAL - The Secretary of Health and Human Services shall arrange for a study to design a strategy for analyzing clinical and legal aspects of pain and symptom management.

(2) ITEMS TO BE INCLUDED IN THE STUDY--. Among other items, the study shall---

1. Review and report on the intended purpose of achieving a balance between drug abuse control and ensuring medication availability for medical purposes, including the use of opioid analgesics (narcotic drugs) for pain management, as expressed in relevant international drug control treaties to which the USA is a party, and the Controlled Substances Act;

2. Review the legislative history and report on how the Controlled Substances Act was intended to divide responsibility for decisions concerning a) law enforcement and b) medical and scientific matters between the Department of Justice and the Department of Health and Human Services;

3. Review and report on the findings and recommendations from a) research which has addressed the inadequate management of pain in the USA, focusing on the underuse of opioid analgesics which are controlled under the Controlled Substances Act; b) research which evaluates the barriers to pain management including regulatory barriers and concerns of health professionals about being investigated, c) federal and state reports relating to inadequate management of pain, regulatory barriers, and concerns about investigation;

4. Report on any efforts at the federal and state level especially by government agencies to address regulatory barriers to pain treatment, ways to improve pain treatment, and professionals' concerns about regulatory investigations.

(3) REPORT.—The Secretary shall submit to Congress, not later than <sup>1 year</sup>~~2 years~~ after the date of the enactment of this Act, a report on the study. Such report shall address the items described in paragraph (2) and shall include recommendations with respect to strengthening the quality of pain management.

(4) ARRANGEMENTS FOR STUDY.--The Secretary shall request the National Academy of Sciences or the National Institutes of Health, acting through appropriate units, to submit an application to conduct the study described in this subsection. If either agency submits an acceptable application, the Secretary shall enter into an appropriate arrangement with that agency for the conduct of the study. If they do not submit an acceptable application to conduct the study, the Secretary may request one or more appropriate nonprofit private entities to submit an application to conduct the study and may enter into an appropriate arrangement for the conduct of the study by the entity which submits the best acceptable application.

June 5, 1998

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

Dear Mr. Chairman:

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

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

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

correspondence supporting a contrary conclusion.

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

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

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

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

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



[Judiciary Homepage](#)

May 11, 1998

MEMORANDUM TO THE PRESIDENT

FROM: Bruce Reed  
Charles Ruff

SUBJECT: Assisted Suicide Legislation

The Justice Department has determined that the Drug Enforcement Administration (DEA) has no authority under the Controlled Substances Act (CSA) to take adverse action against physicians who assist patients in ending their lives by prescribing controlled substances pursuant to Oregon's "Death with Dignity Act." The Department conducted its legal analysis in response to letters sent by Senator Hatch and Congressman Hyde urging the Department, through DEA, to invoke the CSA against physicians who assist in patient suicide under the Oregon law.

The Justice Department has completed draft letters to Congressman Hyde and Senator Hatch explaining its legal conclusions. The letters will not be forwarded to Congress until we have developed a roll-out strategy, including a position on federal legislation prohibiting physician-assisted suicide.

As you will recall, the Catholic Health Association (CHA) has informed us that Hatch and Hyde are prepared to introduce legislation amending the CSA in the event the Attorney General concludes that the CSA does not authorize the DEA to pursue physicians who assist patients in committing suicide. They may even introduce this legislation before receiving the Department of Justice's opinion letter. In assessing the possible options for responding to Hatch's and Hyde's likely initiative, we held meetings within the White House and with the Departments of Justice and Health and Human Services (including the FDA).

Justice believes that the Administration should not support the Hatch/Hyde proposal. Justice thinks that DEA's approach to enforcing the narcotics laws is inconsistent with the kind of sensitivity that would be needed in pursuing doctors who are assisting terminally ill patients to commit suicide. Justice is also concerned with the resource drain on the DEA if that agency were tasked with enforcement duty. Justice also worries that this new task would damage DEA's relationship with the medical profession, on which it often relies in pursuing narcotics law violations.

The Justice Department also cites principles of federalism in support of its position against a legislative change. The federal government has deferred to the states as the primary regulators of the medical profession. Especially on such a hotly contested issue as assisted

suicide, Justice believes there is good reason to continue this tradition of deference to local decisionmaking.

HHS/FDA concurs with Justice's position, stressing especially the historic deference given to states in regulating the medical profession. HHS/FDA also worries that a new federal law authorizing the federal government to take adverse action against doctors who assist their patients to commit suicide would exacerbate the problem of physicians' underprescribing pain medications for terminally ill patients.

Your longstanding opposition to the practice of assisted suicide is not necessarily inconsistent with the agencies' positions. You could argue that assisted suicide is wrong, but that it is not a matter that should be handled by federal narcotics agents. Or more broadly, you could argue that it is not a matter to be dealt with by the federal government at all, but instead should be left to state and local decisionmaking. Nor is last year's "Assisted Suicide Funding Restriction Act" inconsistent with a refusal to support a legislative change. The Funding Restriction Act bans the use of federal funds to pay for or promote assisted suicide. Nothing in the Act authorizes the federal government to take adverse action against a private physician for assisting in a suicide in a non-federal facility.

We detail below four options for responding to the expected Hyde/Hatch initiative. These options are: (1) support the Hyde/Hatch legislation; (2) oppose the Hyde/Hatch DEA approach, but suggest openness to alternatives and work with Hatch and Hyde to develop a better bill; (3) engage in a "Kick the Can" strategy, suggesting openness to alternatives, but attempting to ensure that no congressional action is taken; and (4) oppose the Hyde/Hatch legislation outright.

1. **Endorse Hyde/Hatch Legislative Alternative.** After the Justice Department's legal interpretation is released, we could endorse the expected introduction of the Hatch/Hyde legislation authorizing the DEA to pursue criminal actions against physicians prescribing medications for assisted suicides.

#### **Pros**

- Appears consistent with your longstanding opposition to assisted suicide.
- Avoids inevitable conflict with the Congress, where the Hatch/Hyde legislation is likely to be popular.

#### **Cons**

- Conflicts with historic practice of allowing states to regulate the medical profession, and does so with regard to a hotly contested and emotional issue on which local decisionmaking may be particularly appropriate.

- Places authority to act against doctors in an agency ill-equipped to perform this function, in a way that could interfere with the agency's primary mission.
- Ignores danger, noted by many physicians' groups and even the Catholic Health Association, that a federal law of this kind will lead doctors to under-medicate terminally ill patients for fear of federal prosecution.

2. **Oppose Hatch/Hyde legislation, but suggest openness to alternatives.** Under this option, you would welcome the intent of the Hatch/Hyde bill, based on your longstanding opposition to assisted suicide, but raise concerns about using federal drug agents and resources to address this issue. You would advise Republicans of ways to implement the intent of their legislation in a more workable fashion, perhaps suggesting alternative enforcement agencies (such as FDA) or alternative enforcement mechanisms (such as reducing Federal support for Medicaid for states permitting assisted suicide). You would try seriously to find common ground with the Republicans on a workable legislative alternative to DEA enforcement.

#### **Pros**

- Appears consistent with your longstanding opposition to assisted suicide and shows that you are seriously concerned about this issue.
- Takes an approach that recognizes the problems with using DEA resources and agents to address this issue.

#### **Cons**

- Assumes that we can develop a workable alternative approach, when we may not be able to do so. For example, direct regulation of doctors through HHS/FDA also raises serious issues, and enforcement mechanisms directed toward states, such as reduction of Medicaid dollars, would raise widespread protests of federal micro-management and intrusion.
- Raises expectations that a legislative solution can be achieved, when it may be virtually impossible to reach consensus.

3. **"Kick the Can" Strategy.** Under this option, you would also express openness to addressing this issue through federal legislation, but rather than trying to reach agreement, you would attempt to forestall legislative action. You would try to delay long enough to allow the medical groups, states, and others to communicate that federal approaches in this area are ill-advised. These objections could make Congress conclude that it does not have time to draft thoughtful legislation this year.

#### **Pros**

- Allows you to reiterate your strong position against assisted suicide, while preventing problematic federal legislation.
- Provides sufficient time to air the many issues surrounding assisted suicide legislation, perhaps even educating physicians and the public about the problem of undermedicating terminally ill patients

#### **Cons**

- May make us look indecisive and weak.
- May be viewed with skepticism on the Hill and make us vulnerable to the charge that we are trying to have it both ways.

4. **Oppose Hatch/Hyde legislation outright.** Under this option, you would tell the Hill that, although you believe that assisted suicide is immoral, you cannot support legislation that intrudes on state responsibility over this issue and diverts limited law enforcement resources for this purpose.

#### **Pros**

- Takes a strong position consistent with agency views on the undesirability of federal legislation in this area; respects federalism principles; protects law enforcement priorities; and prevents further undermedication of patients due to physicians' fear of criminal prosecution.

#### **Cons**

- May appear inconsistent with your longstanding opposition to assisted suicide.
- Risks major confrontation with the Congress, which almost certainly will pass federal legislation over your objection.

The Departments of Justice and Health and Human Services support Option 4 and strongly oppose Option 1. Of the middle options, they would prefer Option 3 to Option 2. The Counsel's office agrees with the agencies: Chuck believes both that the DEA should not regulate medical practice and that federal legislation in this area conflicts with federalism principles. The DPC agrees that federal legislation in this area makes little sense, but believes that the "Kick the Can" strategy may be the best way to prevent it; the DPC therefore recommends Option 3.

1. **Endorse Hyde/Hatch Legislative Alternative.** After the Justice Department's legal interpretation is released, we could endorse the expected introduction of legislation authorizing the DEA to pursue criminal investigations of physicians prescribing medications for assisted suicides.

**Pros**

- Appears consistent with our stated public position of opposition to assisted suicide.
- Avoids inevitable conflict with the Republican Congress and "right-wing" side of party.

**Cons**

- Raises important and potentially extremely problematic precedent for the establishment of a major Federal regulatory role over medical practice, a responsibility that has historically been the province of the states.
- According to physicians' groups and even the Catholic Health Association, a Federal law in this area will increase the well documented problem of undermedicating terminally ill patients as physicians become even more afraid of prescribing pain control medications that could make them vulnerable to prosecution by the Federal Government.

2. **Oppose Hatch/Hyde legislation outright.** Concurrent with the expected introduction of the Hatch/Hyde bill, communicate to the Hill that, while you find assisted suicide to be an abhorrent practice (as illustrated by your enactment of the Anti-Assisted Suicide Act of 1997), you cannot support legislation that diverts limited law enforcement resources from the DEA for this purpose. Moreover, you would underscore that you believe it would be ill-advised to pass a new, precedent-laden Federal bill that was extremely intrusive to state oversight over the regulation over the patient/doctor relationship.

**Pros**

- Sends a clear signal of opposition, a position that is consistent with that advocated by both HHS and Justice.
- Does not further confuse or frighten doctors, who are already seriously undermedicating terminally ill patients because of their fear of being prosecuted or at least publicly criticized for hastening death inappropriately.

- Could avoid a time-consuming and likely unproductive negotiating process with the Hill over Federal legislation that is extremely difficult to envision resulting in a rationale, desirable policy outcome.

#### **Cons**

- Appears inconsistent with historic position in opposition to assisted suicide.
- Risks major confrontation with the Republicans and virtually all representatives of the "religious right."

### **3. Oppose DEA (likely Hatch/Hyde) approach, but suggest openness to alternatives.**

Welcome the intent of the Republican DEA bill, but raise the same concerns outlined in option 2. Advise Republicans that we believe that there may be other ways to implement the intent of their legislation in a more workable fashion. In this context, we could suggest alternative enforcement agencies (such as FDA) and enforcement mechanisms, (such as reducing Federal support for Medicaid for states that are engaged in this Euthanasia process). By definition, this process would be designed to seriously attempt to find some common ground with the Republicans and the Governors to sincerely developing a workable legislative alternative to DEA enforcement.

#### **Pros**

- Seems consistent with your historic "assisted suicide" position.
- Shows we are seriously concerned about this issue; so much so that we are willing to help develop legislation that addresses the "rationing" fears that many conservative Americans have.
- Would take an enforcement approach that does not tap into limited DEA resources or rely on DEA enforcement agents (who might not be sensitized to this most sensitive of issues).

#### **Cons**

- May excessively raise expectations that a legislative solution can be achieved when, in fact, it may be virtually impossible to reach consensus.
- Relying on a financial enforcement mechanism like reduction of Federal Medicaid matching (or something like highway) dollars would be strongly opposed by the states as micro-management and as an inappropriate Federal intrusion of states rights and responsibilities.

4. **"Kick the Can" Strategy.** The last option is to take the same "openness to addressing issue" public position on the bill that was outlined in option 3, but participate in a process that is explicitly designed to conclude in non-action. Such an approach would presume a drawn-out process that allows the time for the medical groups, states, and others to communicate to all sides that Federal approaches in this area don't work and are ill-advised. At the very least, the opponents would raise serious enough objections to conclude that we do not have time to draft thoughtful Federal legislation this year.

#### **Pros**

- Would allow the process and the affected parties be the most influential participants to achieving closure on this controversial issue -- not us.
- Would allow us to reiterate our strong position against assisted suicide in a way that does not result in legislation that creates as many or more undesirable precedences and problems than it solves.
- Would allow the time for all the issues on this controversial issue to be aired; might even help educate physicians and the public at large about the very real and serious under-medication for terminally ill problem.

#### **Cons**

- Could make us look indecisive and weak.
- Could be viewed with skepticism on the Hill and make us vulnerable to charge that we are trying to have it both ways.

A handwritten signature in black ink, appearing to read "Debra K. [unclear]", located at the bottom left of the page.

Assisted Suicide File

# A Change of Heart on Assisted Suicide

By Diane E. Meier

**A** recent survey, which I co-wrote, found that doctors are often asked by their patients for help in dying, but seldom honor these requests.

Some years ago, I believed that doctor-assisted suicide should be legalized and that terminally ill people in great pain deserved more control over the circumstances of their death.

It is true that terminally ill patients sometimes find themselves in truly unbearable circumstances. But after caring for many patients myself, I now think that the risks of assisted suicide outweigh the benefits.

Proponents of doctor-assisted suicide say that strict regulations can reduce the chances of abuse and pro-

tect the most vulnerable from feeling coerced. But rules would be difficult, if not impossible, to enforce. For instance, Oregon, the only state to legalize assisted suicide, has guidelines that mandate the following:

- *A patient must be mentally alert.* It is the rare dying patient, particularly if elderly, who remains consistently capable of rational deliberation about medical alternatives. Intermittent confusion, anxiety and depression are the rule rather than the exception, inevitably clouding judgment.

- *A patient must be within six months of death.* Abundant evidence shows that accurately predicting when patients are going to die doesn't become possible until just days before death. The guidelines assume that such a prognosis is possible and deny the uncertainty inherent in such predictions.

- *A doctor must certify that the patient's decision is not coerced.* This is an impossible task, given the financial and other burdens that seriously ill patients pose to their families. Indeed, legalizing assisted suicide is co-

ercive in and of itself. Society would no longer promote the value of each life, and instead sanction an expedient death rather than continued care and support.

The push to legalize doctor-assisted suicide could not come at a worse time. Spiraling health costs and our

If this kind of care were available to every patient, it would certainly reduce, if not eliminate, the desire for a hastened death. But legalizing assisted suicide would become a cheap and easy way to avoid the costly and time-intensive care needed by the terminally ill. It could be seen as an appealing alternative when resources are stretched and family members and doctors are exhausted. The terminally ill patient could feel subtle and not-so-subtle pressure to opt for suicide. Our society should not be reduced to offering patients a choice between inadequate care and suicide.

The proposed guidelines for assisted suicide are well-meaning, but unrealistic and largely irrelevant to the reality faced by the dying. While I have had patients whose desire to die was compelling and understandable, such patients are few. The distress of the last days, when it occurs, can be effectively treated with analgesics and sedatives. Although we have the knowledge and tools to reduce suffering near the end of life, we are debating instead whether it should be legal for doctors to hasten death. □

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As doctors, we  
have a reason  
to be wary.

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aging population have led to radical changes in how care is financed, with doctors and hospitals rewarded for doing less for their patients. Seriously ill people need help easing their pain, time to talk to their doctor, answers to their questions and reasonable attempts to prolong their life when death is not imminent.

FRIDAY, APRIL 24, 1998

The New York Times

*Diane E. Meier is an associate professor of geriatrics and director of the Palliative Care Initiative at the Mount Sinai School of Medicine.*

Assisted Suicide Bill

II

105TH CONGRESS  
2D SESSION

# S. 2151

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, euthanasia, or mercy killing of any individual.

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## IN THE SENATE OF THE UNITED STATES

JUNE 9, 1998

Mr. NICKLES (for himself, Mr. LOTT, Mr. COATS, Mr. INHOFE, Mr. HELMS, Mr. MURKOWSKI, Mr. GRAMS, Mr. FAIRCLOTH, Mr. BOND, Mr. ENZI, Mr. SESSIONS, Mr. HAGEL, and Mr. COVERDELL) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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## A BILL

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, euthanasia, or mercy killing of any individual.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Lethal Drug Abuse  
5 Prevention Act of 1998".

6 **SEC. 2. FINDINGS; PURPOSES.**

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

1 (1) the use of certain narcotics and other dan- 1  
2 gerous drugs is generally prohibited under the Con- 2  
3 trolled Substances Act; 3

4 (2) under the Controlled Substances Act and 4  
5 implementing regulations, an exception to this gen- 5  
6 eral prohibition permits the dispensing and distribu- 6  
7 tion of certain controlled substances by properly reg- 7  
8 istered physicians for legitimate medical purposes; 8

9 (3) the dispensing or distribution of controlled 9  
10 substances to assist suicide is not a legitimate medi- 10  
11 cal purpose and should not be construed to be per- 11  
12 missible under the Controlled Substances Act; 12 s

13 (4) the dispensing or distribution of certain 13  
14 controlled substances for the purpose of relieving 14 C  
15 pain and discomfort is a legitimate medical purpose 15 b  
16 under the Controlled Substances Act and physicians 16  
17 should not hesitate to dispense or distribute them 17 e  
18 for that purpose when medically indicated; and 18 u

19 (5) for the reasons set forth in section 101 of 19 if  
20 the Controlled Substances Act (21 U.S.C. 801), the 20  
21 dispensing and distribution of controlled substances 21  
22 for any purpose, including that of assisting suicide, 22  
23 affects interstate commerce. 23

24 (b) PURPOSES.—The purposes of this Act are— 24

1 (1) to provide explicitly that Federal law is not  
2 intended to license the dispensing or distribution of  
3 a controlled substance with a purpose of causing, or  
4 assisting in causing, the suicide, euthanasia, or  
5 mercy killing of any individual; and

6 (2) to encourage physicians to prescribe con-  
7 trolled substances as medically appropriate in order  
8 to relieve pain and discomfort, by reducing unwar-  
9 ranted concerns that their registration to prescribe  
10 controlled substances will thereby be put at risk, if  
11 there is no intent to cause a patient's death.

12 **SEC. 3. LETHAL DRUG ABUSE PREVENTION.**

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

16 “(i) DENIAL OF REGISTRATION.—The Attorney Gen-  
17 eral shall determine that registration of an applicant  
18 under this section is inconsistent with the public interest  
19 if—

20 “(1) during the 5-year period immediately pre-  
21 ceding the date on which the application is submit-  
22 ted under this section, the registration of the appli-  
23 cant under this section was revoked under section  
24 304(a)(4); or

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

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6       (b) SUSPENSION OR REVOCATION OF REGISTRA-  
7 TION.—

6  
7

8           (1) IN GENERAL.—Section 304(a) of the Con-  
9 trolled Substances Act (21 U.S.C. 824(a)) is amend-  
10 ed—

8  
9 St  
10

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

11  
12

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

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14

15           “(4) has intentionally dispensed or distributed a  
16 controlled substance with a purpose of causing, or  
17 assisting in causing, the suicide, euthanasia, or  
18 mercy killing of any individual, except that this  
19 paragraph does not apply to the dispensing or dis-  
20 tribution of a controlled substance for the purpose of  
21 relieving pain or discomfort (even if the use of the  
22 controlled substance may increase the risk of death),  
23 so long as the controlled substance is not also dis-  
24 pensed or distributed for the purpose of causing, or

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1 assisting in causing, the death of an individual for  
2 any reason;”.

3 (2) CONFORMING AMENDMENT.—Section  
4 304(a)(5) of the Controlled Substances Act (21  
5 U.S.C. 824(a)(5)) (as redesignated by paragraph (1)  
6 of this subsection) is amended by inserting “other”  
7 after “such”.

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

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

12 “(c) PROCEDURES.—

13 “(1) ORDER TO SHOW CAUSE.—After any hear-  
14 ing under paragraph (2), and before”; and

15 (2) by adding at the end the following:

16 “(2) MEDICAL REVIEW BOARD ON PAIN RE-  
17 LIEF.—

18 “(A) IN GENERAL.—The Attorney General  
19 shall by regulation establish a board to be  
20 known as the Medical Review Board on Pain  
21 Relief (referred to in this subsection as the  
22 ‘Board’).

23 “(B) MEMBERSHIP.—The Attorney Gen-  
24 eral shall appoint the members of the Board—

1	“(i) from among individuals who, by	1
2	reason of specialized education or substan-	2
3	tial relevant experience in pain manage-	3
4	ment, are clinical experts with knowledge	4
5	regarding standards, practices, and guide-	5
6	lines concerning pain relief; and	6
7	“(ii) after consultation with the Amer-	7
8	ican Medical Association, the American	8
9	Academy of Hospice and Palliative Medi-	9
10	cine, the National Hospice Organization,	10
11	the American Geriatrics Society, and such	11
12	other entities with relevant expertise con-	12
13	cerning pain relief, as the Attorney Gen-	13
14	eral determines to be appropriate.	14
15	“(C) DUTIES OF BOARD.—	15
16	“(i) HEARING.—If an applicant or	16
17	registrant claims that any action (or, in	17
18	the case of a proposed denial under section	18
19	303(i)(2), any potential action) that is a	19
20	basis of a proposed denial under section	20
21	303(i), or a proposed revocation or suspen-	21
22	sion under subsection (a)(4) of this sec-	22
23	tion, is an appropriate means to relieve	23
24	pain that does not constitute a violation of	
25	subsection (a)(4) of this section, the appli-	

1 cant or registrant may seek a hearing be-  
2 fore the Board on that issue.

3 "(ii) FINDINGS.—Based on a hearing  
4 under clause (i), the Board shall make  
5 findings regarding whether the action at  
6 issue is an appropriate means to relieve  
7 pain that does not constitute a violation of  
8 subsection (a)(4). The findings of the  
9 Board under this clause shall be admissible  
10 in any hearing pursuant to an order to  
11 show cause under paragraph (1)."

12 **SEC. 4. CONSTRUCTION.**

13 (a) IN GENERAL.—Nothing in this Act or the amend-  
14 ments made by this Act shall be construed to imply that  
15 the dispensing or distribution of a controlled substance be-  
16 fore the date of enactment of this Act for the purpose of  
17 causing, or assisting in causing, the suicide, euthanasia,  
18 or mercy killing of any individual is not a violation of the  
19 Controlled Substances Act (21 U.S.C. 801 et seq.).

20 (b) INCORPORATED DEFINITIONS.—In this section,  
21 the terms "controlled substance", "dispense", and "dis-  
22 tribute" have the meanings given those terms in section  
23 102 of the Controlled Substances Act (21 U.S.C. 802).

Assisted Gov *5*  
Total Pages: *5*

LRM ID: RJP304

EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
Washington, D.C. 20503-0001

Wednesday, July 29, 1998

LEGISLATIVE REFERRAL MEMORANDUM

URGENT

TO: Legislative Liaison Officer - See Distribution below  
FROM: *Janet R. Forsgren* Janet R. Forsgren (for) Assistant Director for Legislative Reference  
OMB CONTACT: Robert J. Pellicci  
PHONE: (202)395-4871 FAX: (202)395-6148  
SUBJECT: JUSTICE Report on HR4006 Lethal Drug Abuse Prevention Act  
DEADLINE: NOON Thursday, July 30, 1998

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: Senate Committee on the Judiciary is holding a hearing on similar legislation on Friday, July 31st. In addition, the House Committee on the Judiciary is scheduled to markup HR 4006 next week. DEADLINE IS FIRM.

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*Letter*

*needs clearance*





U. S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

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

Dear Mr. Chairman:

As the Committee prepares to consider H.R. 4006, as amended by the Subcommittee on the Constitution, I write to provide the views of the Department of Justice on this bill. We appreciate this opportunity to provide comments and look forward to working with you as the bill progresses through the legislative process.

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 H.R. 4006 represents a flawed approach to the sensitive area of Federal regulation of medicine. We are particularly concerned that the insertion of the Drug Enforcement Agency (DEA) into the role of overseer of the practice of medicine would inevitably divert agency attention away from the core mission of strictly controlling Schedule I drugs and preventing the 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 of the Controlled Substances Act through H.R. 4006 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 a 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 flaws of this proposed ban on assisted suicide are visibly 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. 2(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. 2(a), stating a new basis for action against a practitioner's registration under § 824(a)(4), and Sec. 2(c), setting forth the

responsibility of the new "Medical Advisory Board on Pain Relief" to issue an opinion 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 is 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 difficult issues.

Finally, in Sec. 3, 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 comments. The Office of Management and Budget has advised that there is no objection from the standpoint of the Administration's program to presentation of this report.

Sincerely,

Anthony L. Sutin  
Acting Assistant Attorney General

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

will want you to become involved as well next week, by meeting with Daschle and Lott and pressing for negotiations. We will give you a memo soon on our suggestions for handling such negotiations.

3. **Health -- Patients' Bill of Rights Legislation:** Rep. Ganske told Rep. Dingell this week that at least five Republicans have decided to co-sponsor the Dingell/Gephardt patients' bill of rights legislation. The announcement of these Republican co-sponsors, which is expected to come as early as next week, should greatly increase the pressure on the Republican House caucus to support acceptable patients' rights legislation. (We have heard that a Republican House task force is also drafting legislation in this area, but currently intends to include certain "poison pill" provisions involving limitations on medical malpractice suits and expansions of multi-employer welfare associations.) We are reaching out to Reps. Ganske and Dingell to determine if we can set up a meeting next week between you and the new Republican co-sponsors. Such an event almost certainly would receive significant press attention.

4. **Health -- Assisted Suicide:** A recent study on assisted suicide in the New England Journal of Medicine found that only about three percent of physicians have ever prescribed medications to hasten the death of a terminally ill patient and only about five percent have ever administered injections to do so. The study also found, however, that 36 percent of physicians would write lethal prescriptions and 24 percent would administer lethal injections if such actions were legal. This widely reported study could intensify efforts in Congress to enact legislation to prohibit doctors from assisting their patients to commit suicide. As you recall, Sen. Hatch and Rep. Hyde are prepared to introduce such legislation in the event that the Justice Department opines that the Controlled Substances Act, as currently written, does not prohibit these practices. The Justice Department intends to issue such a decision in about two weeks. We will send you a memo next week that outlines options for responding to Hatch's and Hyde's likely initiative.

5. **AIDS -- Needle Exchange:** As we expected, your needle exchange decision provoked strong criticism from both ends of the political spectrum. On the one side, AIDS advocates and your Advisory Council on AIDS expressed great disappointment that we decided not to release federal funds. DPC, the AIDS office, and others in the Administration have reached out to the AIDS community to explain our decision and explore ways of working together on related initiatives involving HIV prevention and drug treatment. We are also attempting to develop an appropriate way of marking the one-year anniversary of your HIV vaccine initiative. On the other side, Republican members of Congress attacked you for releasing scientific findings that needle exchange can reduce HIV transmission without increasing drug use. Sen. Coverdell introduced legislation to prevent the Secretary from ever releasing federal funds for needle exchange programs, and Rep. Hastert introduced even more extreme legislation that would deny federal funds to any entity using *its own funds* for this purpose. We will work with Legislative Affairs to oppose these initiatives.

6. **Education -- D.C. Vouchers:** The Republican House leadership currently intends to bring a D.C. voucher bill to the House floor next week. DPC, Legislative Affairs, and the

-- Sixty four percent had driven a car while drunk or drugged; 50 percent had been involved in a domestic dispute while drunk or high; and 35 percent had consumed as much as a fifth of a gallon of alcohol in a single day.

**5. Crime -- COPS:** The COPS Office will announce on Thursday \$58 million in hiring grants to 285 police departments to fund about 900 additional officers. This announcement will put the total number of officers funded through the COPS Program at over 72,000.

**6. Health -- Patients' Bill of Rights I:** Rep. Gephardt is insisting that the Democratic Leadership's version of patients' rights legislation include whistleblower protections for hospital employees. Although we are sympathetic to these protections, we believe their addition to the bill would diminish the prospect of passing legislation this year. Rep. Dingell believes equally strongly that including whistleblower protections would be a strategic mistake, because they would prevent Blue Dog Democrats like Reps. Stenholm, Tanner, and Barry from supporting the bill. Indeed, Dingell has said that he would reconsider his decision to be the bill's lead sponsor in the House -- still further decreasing the chance of Congressional action -- if these provisions were added. We will continue to work with Gephardt, Dingell, and the Blue Dogs to see if compromise language can be developed. The Democrats are currently scheduled to introduce their bill as early as Wednesday.

**7. Health -- Patients Bill of Rights II:** Larry Stein and Chris Jennings had a good meeting on Thursday with Rep. Norwood, the Republican sponsor of patients' rights legislation in the House. Norwood believes there is strong bipartisan support in the House to pass this legislation, and wants to work with us to achieve this goal. We agreed that we should aim to pass a bill by July, and that the House would have to act first to put pressure on the Senate. Norwood said he would continue to support a strong enforcement scheme for patient protections, in part because he thinks such a scheme is necessary to maintain the backing of the AMA and consumer groups. He also indicated that he and his Republican colleagues would oppose any provisions mandating insurance plans to provide certain benefits.

*For  
Gephardt*

**8. Health -- Children's Health Implementation:** HHS will announce the approval of Ohio's and California's children's health program next week. Because of the size and strength of these programs, we may want to highlight their approval at the White House, possibly with the Vice President participating in your absence. Also within the next ten days, HHS will make a decision on whether to approve New York's children's health proposal. New York's application has a controversial provision involving provider taxes that may lead HHS to disapprove it. The plan also takes insufficient steps to ensure that federal dollars not substitute for health insurance currently covered by the private sector.

**9. Health -- Assisted Suicide Law:** We met this week with representatives of the Catholic Health Association (CHA) to discuss the Justice Department's likely ruling that doctors in Oregon who assist their terminally ill patients to commit suicide, in conformance with state law recently enacted through referendum, do not violate the federal Controlled Substances Act



**DRAFT**

FDA TALKING POINTS ON PHYSICIAN ASSISTED SUICIDE

206  
833

- The FDCA prohibits causing the introduction or delivery for introduction into interstate commerce of any new drug for which the necessary FDA approval has not been obtained. While each time an FDA-approved drug is promoted for an unapproved purpose, it becomes an unapproved new drug for that purpose, we know that physicians do prescribe approved drugs "off-label."
- FDA generally relies on States to regulate physicians who prescribe approved drugs for off-label uses. FDA has only very rarely brought enforcement actions against physicians, and, in fact, there is legislative history to the effect that the FDCA is not intended--at least not directly--to regulate the practice of medicine.
- The suits brought by FDA have almost exclusively involved physicians who have promoted, sold, or distributed, with a sufficient interstate nexus, drugs or devices that are unapproved for any purpose--not physicians engaged in the ordinary practice of medicine who merely recommend or prescribe a particular approved drug for an unapproved use.
- FDA has only very rarely attempted to bring an enforcement action against a physician who was prescribing approved drugs off-label, and those few cases have involved physicians who were widely promoting the off-label use.
- Regulating physician conduct in assisted suicide in a State that permits the practice would be an inappropriate use of the Agency's authority. FDA's core function is the public health mission of regulating foods and medical products. The current debate about the morality of physician-assisted suicide is not an issue that can be resolved by science or according to ordinary public health principles.
- FDA's decision not to act against States' use of drugs for lethal injection--a similarly morally contentious issue--has been upheld by the Supreme Court.

FDCA:

- Interstate Commerce - causing introduction of unapproved drug
- Drugs are approved for specific uses. Misbranded drugs.

Prohibited Act



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

JAN - 7 1998

The Honorable Tom Bliley  
Chairman, Committee on Commerce  
House of Representatives  
Washington, D.C. 20515-6115

Dear Mr. Chairman:

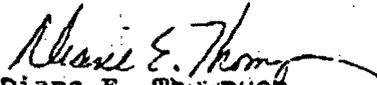
This is in response to your letter of September 19, 1997 requesting the Food and Drug Administration's (FDA) views regarding use of a controlled substance in assisted suicide and supersedes our prior letter to you dated October 29, 1997. You asked for FDA views on whether delivering, distributing, dispensing, prescribing, filling a prescription, or administering a controlled substance with the deliberate intent of assisting in a suicide would violate the Federal Food, Drug, and Cosmetic (FDC) Act, applicable regulations, or other Federal law subject to FDA enforcement.

In order to market a new drug, a sponsor must demonstrate (generally through a new drug application) that the product is safe and effective for its intended uses. See, §§ 201(p), 505, FDC Act. The intended uses for which a drug has been determined to be safe and effective (approved uses) appear in the product's package insert (the approved labeling). Approved drugs may only be labeled and promoted for their approved uses.

Numerous prescription drugs approved by FDA potentially could be considered not safe and effective, or potentially could endanger human life, if these drugs are used for purposes other than the specific uses approved by FDA (off-label uses) or not used in the manner described in the approved labeling. While an argument could be made that off-label uses of prescription drugs for physician-assisted suicide would violate the FDC Act, physician off-label uses generally are regulated by individual state licensing boards and authorities. We believe that regulating drugs for physician-assisted suicide through FDC Act enforcement actions also would be inappropriate in the context of current state regulation and the national debate over this practice.

We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,

  
Diane E. Thompson  
Associate Commissioner  
for Legislative Affairs

Page 2 - The Honorable Tom Bliley

cc: The Honorable John D. Dingell  
Ranking Minority Member  
Committee on Commerce



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

OCT 29 1997

Food and Drug Administration  
Rockville MD 20857

The Honorable Thomas J. Bliley, Jr.  
Chairman, Committee on Commerce  
House of Representatives  
Washington, D.C. 20515-6115

Dear Mr. Chairman:

This is in response to your letter of September 19, 1997 requesting the Food and Drug Administration's (FDA) views on 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 Federal Food, Drug, and Cosmetic (FDC) Act, applicable regulations, or other Federal law subject to FDA enforcement.

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Associate Commissioner  
for Legislative Affairs

cc: The Honorable John D. Dingell  
Ranking Minority Member  
Committee on Commerce

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## U.S. House of Representatives

## Committee on Commerce

Room 2125, Rayburn House Office Building

Washington, DC 20515-6115

September 19, 1997

JAMES E. DERDERIAN, CHIEF OF STAFF

Michael A. Friedman, M.D.  
 Lead Deputy Commissioner  
 Food and Drug Administration  
 5600 Fishers Lane  
 Rockville, MD 20857

Dear Dr. Friedman:

As Chairman of the House Commerce Committee, I write seeking the Food and Drug 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 Federal Food, Drug, and Cosmetic Act, applicable regulations, rulings, or other federal law subject to FDA enforcement, notwithstanding the enactment of a State law such as Oregon's Measure 16 rescinding 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. This list has been derived from Derek Humphrey's *Final Exit: The Practicalities of Self-Deliverance and Assisted Suicide for the Dying* (Hemlock Society 1991), at 117-120.

Interpretations of other agencies suggest that assisted suicide is not a legitimate medical practice within the meaning of federal law. The Health Care Financing Administration, for example, has written 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.) In addition, under existing regulations of the Drug Enforcement Administration, a lawful 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. § 1306.04.

Michael A. Friedman, J.  
September 19, 1997  
Page 2 of 2

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 a healer...." [See Briefs 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, § 2:211 (App. 11a).]

In my view, the prescription and use of drugs deliberately to assist a person to commit suicide cannot be consistent with FDA standards regarding "health," "legitimate medical use," and "safe and effective use" of drugs [*e.g.*, 21 U.S.C. §§301 (U), 353 (b)(1)(B), 355; 21 C.F.R. §§312.22(a), 312.2(b)(iii)] especially when the practice of assisted suicide 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. Past FDA action as upheld by the United States Supreme Court indicated that the agency's interest in ensuring that drugs are "safe and effective" and do not endanger human life is no less compelling in the case of patients with life-endangering illnesses. [*United States v. Rutherford*, 442 U.S. 544 (1979).]

As you know, this is an area of special interest to the Congress. On March 20, the Committee that I chair, by a 45-to-2 vote, approved legislation (H.R. 1003) to prohibit 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, passed 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 serious concerns were any federal agency to construe the intentional prescribing of lethal drugs for suicide as a legitimate medical practice. Therefore, I would be grateful for your prompt response.

Sincerely,

  
Tom Bliley  
Chairman



## DEPARTMENT OF HEALTH &amp; HUMAN

MAY 1 - 1998

Mr. John Neithercut  
32 Leighton St.  
Fitchburg, MA 10420

Dear Mr. Neithercut:

Rep. John Olver has referred your letter on recent Administration and Congressional proposals to restructure the Medicare program to my office for a response. In your letter you express opposition to Medicare paying for physician assisted suicide. You also asked Mr. Olver to vote in favor of changes to Medicare that would allow Medicare beneficiaries "to add their own money to be able to get unmanaged fee for service plans under MedicarePlus". We refer to such plans as "private fee for service plans".

In regard to your first issue, in general, the Medicare statute limits Medicare coverage to items and services that "are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Physician assisted suicide, even if allowed under state law, does not meet these statutory criteria. As such, the program is prohibited from making payment for it. Further, there is no provision in the President's balanced budget proposal to change Medicare so that it would cover physician-assisted suicide, either under the fee for service program or through a contracting managed care plan.

In regard to your second concern, the President has been clear that he does not support private fee for service plans as an option for Medicare beneficiaries because such an option could hurt many beneficiaries while helping none. The rationale for the President's position is as follows:

- o Currently, the law places limits on what doctors, hospitals and others can charge either the Medicare program or Medicare beneficiaries. For instance, if the Medicare approved charge for a physician visit is \$100, the beneficiary's share of the cost is limited to somewhere between \$20 and \$35 (depending on whether or not the doctor is a Medicare "participating physician"). Physicians are prohibited from billing for more than the "limiting charge" which is 115 percent of the Medicare payment amount.
- o Similarly, when a beneficiary goes to the hospital, whether the hospital charges \$5,000 or \$10,000 for the stay, the hospital can charge the beneficiary only certain established deductible and coinsurance amounts and it must accept Medicare's payment as payment in full.