

American Medical Association

Physicians dedicated to the health of America



1101 Vermont Avenue, NW 202 789-7400
Washington, DC 20005

September 7, 2000

STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION IN SUPPORT OF THE PAIN RELIEF PROMOTION ACT (PRPA)

The American Medical Association (AMA) supports H.R. 2260, the "Pain Relief Promotion Act" (PRPA), as reported from the Senate Judiciary Committee, offered by Chairman Orrin Hatch. The new bill represents significant improvements in addressing the continuing concerns of the physician community regarding the proper roles of the state and federal governments in regulating the practice of medicine.

The AMA is squarely opposed to physician-assisted suicide and believes it is antithetical to the role of physician as healer. The AMA strongly advocated against the Oregon public initiative that has legalized physician-assisted suicide in that State. In crafting an appropriate legislative response, physicians have been deeply concerned that legislation must recognize that aggressive treatment of pain carries with it the potential for increased risk of death, the so-called "double effect." The threat of criminal investigation and prosecution for fully legitimate medical decisions is unacceptable to the AMA.

As reported from the Senate Judiciary Committee, the legislation would recognize the "double effect" as a potential consequence of the legitimate and necessary use of controlled substances in pain management, and explicitly include this as a "safe harbor" provision for physicians in the Controlled Substances Act. This is a vital element in creating a legal environment in which physicians may administer appropriate pain care for patients without fear of prosecution.

The provisions of the Chairman's Substitute to H.R. 2260, reported by the Senate Judiciary Committee on April 27, 2000, represents substantial success in achieving the AMA's policy goals. The AMA is pleased to endorse H.R. 2260, which now contains significant improvements explained below.

- **Preserves state's role in regulating physician practice**

The PRPA preserves deference to state licensing boards and professional disciplinary authority as currently exists under the Controlled Substances Act (CSA). This bill would also maintain the current balance of authority between state and federal government, in which the DEA and state medical licensing boards have overlapping authority when it comes to physicians prescribing controlled substances.

- **The PRPA does not create new federal authority to regulate physicians**

The bill contains specific rules of construction preserving the roles of the states and federal government in regulating the practice of medicine. Furthermore the Attorney General is explicitly prohibited from creating new federal standards for pain management or palliative care; existing and developing standards in the private sector and research community will continue to be the gold standard.

- **Prohibits federal guidelines or standards of care**

The PRPA does not give the DEA new powers to regulate physicians or to evaluate whether a prescribing decision is “legitimate.” The DEA is already authorized to evaluate whether a physician’s prescribing decision is for a “legitimate medical purpose.” This amendment also negates the possibility that law enforcement might create its own standards on pain care and clarifies that the training and education programs would not interfere with the traditional role of the state in regulating the practice of medicine.

- **The PRPA will continue to foster professionally developed standards**

This bill will improve pain management and palliative care for patients by encouraging and supporting the vital research necessary for advancing the science and art of pain management and palliative care. While it authorizes grants and educational activity, the Agency for Health Research and Quality is also prohibited from creating its own standards for pain management or palliative care.

- **Expands scope of bill to cover pain management, as well as palliative care**

H.R. 2260 expands the scope of the bill to include all pain management, rather than an exclusive focus on end-of-life pain.

Again, the AMA supports the language contained in the bill reported from the Judiciary Committee which includes essential clarifications of the original bill, specifically expressing the sponsors’ intention to honor the existing authority of the states to regulate legitimate medical practice, while exercising the concurrent federal authority to regulate the prescribing and administration of controlled substances. The language of H.R. 2260 has been carefully crafted to reflect this proper balance. We urge the full Senate to pass the “Pain Relief Promotion Act,” as soon as possible.

"PAIN RELIEF PROMOTION ACT OF 2000" (H.R. 2260)

Purpose:

- (1) to amend the Controlled Substances Act to encourage physicians to use federally regulated drugs (controlled substances) such as morphine to relieve pain and discomfort;
- (2) to reaffirm that intentionally prescribing such drugs to cause patients' deaths is not authorized, and that a State law permitting assisted suicide or euthanasia does not change this federal policy;
- (3) to help educate and train health professionals on medically accepted means for alleviating pain and other symptoms for seriously ill patients, including the legitimate use of controlled substances, and to help educate law enforcement personnel to better accommodate such use.

IMPORTANT QUESTIONS:

Why is this bill needed? Pain management for seriously ill patients is underdeveloped and needs government support. Also, Congress must correct a June 1998 ruling by Attorney General Janet Reno that federally controlled drugs can be used to assist suicides wherever a state allows this.

Does the Act overturn Oregon's law allowing physician-assisted suicide? No, it tells Oregon physicians they cannot use drugs under federal control (e.g., barbiturates) for such suicides.

Does the Act expand federal authority over medical practice? No. It limits such authority, by creating an explicit "safe harbor" for doctors using controlled substances for pain control.

Does it require new scrutiny of physicians' "intent" in prescribing drugs? No. Intentionally assisting suicide violates professional ethics nationwide and the laws of most states. The bill's only new effect in 49 states is to protect pain control, even where it unintentionally risks death.

Could this law have a "chilling effect" on use of these drugs for pain control? No. When Iowa, Rhode Island and other states enacted laws to ban assisted suicide, while allowing pain control that may unintentionally hasten death, they saw dramatic increases in use of pain killing drugs like morphine. Demanding respect for patients' lives promotes care for their real needs.

Who supports the bill? American Medical Association, Catholic Health Association, American Society of Anesthesiologists, American Academy of Pain Management, National Conference of Catholic Bishops, National Hospice and Palliative Care Organization, National Right to Life Committee, Not Dead Yet...a wide array of pro-life, disability rights and medical organizations.

STATUS: Passed by House of Representatives in October 1999, 271-to-156. Now pending in Senate, with 41 sponsors (5 Democrats), led by Don Nickles (R-OK) and Joe Lieberman (D-CT).

Background: AMA Reference Committee on Legislation responds to concerns about Pain Relief Promotion Act

At the American Medical Association's semi-annual House of Delegates meeting in San Diego, a Reference Committee addressing legislative issues heard testimony December 5 on whether to change the AMA's stance supporting the Pain Relief Promotion Act (H.R. 2260, S. 1272). The Reference Committee was chaired by Cathy O. Blight, M.D., past president of the Michigan State Medical Society. Excerpts from the committee's final report follow.

Despite differing opinions about the bill's content, there appeared to be near consensus among the speakers at the Reference Committee that physician-assisted suicide is not an acceptable medical practice and that every effort should be made through proactive legislation or other means to encourage the rendering of effective and compassionate palliative and end-of-life care to all patients in need of such...

Turning to the actual bill and existing law, the majority of testimony centered on several major issues including the scope of DEA authority, the need to oppose the criminalization of medical practice, and promoting, while not hindering, state palliative and end-of-life care guidelines...

In the spirit of moving forward in a positive manner and with the recognition that the substantial weight of testimony argued in favor of continued support for the "Pain Relief Promotion Act of 1999," your Reference Committee urges the adoption of the substitute resolution based on the facts presented at the hearing, including:

First, your Reference Committee agrees with the bill's sponsors that the "Pain Relief Promotion Act of 1999" would for the first time establish in federal law substantial new protections for physicians prescribing controlled substances in the ordinary course of patient treatment. This position is substantiated by a Department of Justice letter dated October 19, 1999, wherein it is affirmatively stated that "*H.R. 2260 would eliminate any ambiguity about the legality of using controlled substances to alleviate the pain and suffering of the terminally ill by reducing any perceived threat of administrative and criminal sanctions in this context. The Department accordingly supports those portions of H.R. 2260 addressing palliative care.*"

Second, because the bill would amend existing statutory law in the Controlled Substances Act, in existence for decades, the suggestion that the bill would extend DEA authority or create new penalties, although passionately stated, is without legal merit. The bill would do neither of these things by a "plain meaning" reading of its language. Instead, it would legislatively acknowledge the legitimate medical purpose of prescribing controlled substances, even if one effect were ultimately to cause death, the so-called "double effect." This intent has been confirmed by debate on the House floor relating to the bill, as well as in a comprehensive Congressional Record statement by Senator Nickles. As it currently stands, physicians are potentially susceptible to DEA scrutiny any time they prescribe controlled substances. This new bill would truncate this authority, but retain DEA authority to investigate instances where controlled substances are used to effectuate a physician-assisted suicide.

Finally, your Reference Committee finds without legal merit allegations that state palliative care guidelines would be overridden by [the Act], or that the DEA would have any new authority to promulgate federal guidelines under this bill.

Americans for Integrity in Palliative Care

"To care, always...to kill, never"

July 12, 2000

John Seffrin, Ph.D.
Chief Executive Officer, ACS
American Cancer Society

Dear Dr. Seffrin:

We write to you as professionals dedicated to pain management and the treatment and cure of cancer to express our concern regarding the American Cancer Society's opposition to the Pain Relief Promotion Act (H.R. 2260).

Attached is an analysis of the legislation, produced by Americans for Integrity in Palliative Care, responding to the ACS's objections. We fully endorse this analysis and we hope you will take the opportunity to review it. We respectfully ask that the American Cancer Society reconsider its position opposing this much needed legislation. The Pain Relief Promotion Act has already been endorsed by the American Medical Association, The American Academy of Pain Management, the American Pain Society, and the National Hospice and Palliative Care Organization, among others. We believe that the American Cancer Society should also join in support of this legislation.

Thank you for your attention to this matter. We would be happy to meet with you to further discuss this issue. (You may contact Gene Tarne, communications director for AIPC, at (703) 684-8352). Passage of the Pain Relief Promotion Act can only benefit those suffering the pain of cancer, and those who treat them.

Sincerely,

Eric Chevlen, M.D.
Diplomate, American Board of Medical Oncology
Diplomate, American Board of Hospice and Palliative Medicine
Diplomate, American Board of Pain Medicine
Medical Director of Palliative Care
St. Elizabeth Hospital
Youngstown, OH

William M. Petty, M.D.
Clinical Associate Professor, Oregon Health Sciences University
Gynecological Oncology

C. Christopher Hook, M.D.
Consultant in Hematology
Chair, Myeloproliferative Disorders Disease-Oriented Group
Member, Palliative Care Task Force Mayo Clinic, Rochester, MN

**200 Daingerfield Road
Suite 100
Alexandria, VA 22314
(703) 684-8352
fax (703) 684-5813**

Communications Counsel

**Eugene Tarne
Michelle Powers**

Founding Members

C. Everett Koop, M.D.

Herbert Hendin, M.D.

Eric Chevlen, M.D.

Walter R. Hunter, M.D.

Wesley J. Smith, Esq.

Edmund Pellegrino, M.D.

Ralph Miech, M.D., Ph.D.

Carlos F. Gomez, M.D., Ph.D.

William Toffler, M.D.

N. Gregory Hamilton, M.D.

James Towey, Esq.

John G. Niedzwicki, M.D., Ph.D.
Hawthorn Cancer Center, North Dartmouth, MA
Member, American Society of Clinical Oncology
Adjunct Asst. Professor, Dept. Of Molecular
Pharmacology, Brown University

Diane Savarese, M.D.
Oncology and Pain Management
Associate Professor
Department of Medicine
University of Massachusetts Medical School

Kevin FitzGerald, S.J. Ph.D.
Assistant Professor of Medicine
Division of Hematology/Oncology
Loyola University Medical Center, IL

Carlos Gomez, M.D.
Medical Director, Palliative Care Service
University of Virginia Health System

Ralph P. Miech, M.D., Ph.D.
Associate Professor Emeritus
Dept of Molecular Pharmacology, Physiology &
Biotechnology
Brown University School of Medicine

N. Gregory Hamilton, M.D.
Associate Clinical Professor of Psychiatry
Oregon Health Sciences University

Gary Lee, M.D.
Medical Oncologist
Medical Director
Hospice of Sacred Heart Medical Center
Eugene, OR

Kenneth R. Stevens, Jr. M.D.
Professor and Chairman,
Dept. Of Radiation Oncology
Oregon Health Sciences University

Nancy Valko, R.N.
Oncology/Hospice

Karen Bell, R.N.
Director, Providence Hospice
Portland, OR

Edmund D. Pellegrino, M.D.
John Carroll Professor of Medicine and Medical Ethics
Center for Clinical Bioethics
Georgetown University Medical Center

William Toffler, M.D.
Professor of Family Medicine
Oregon Health Sciences University

cc:

Harmon Eyre, M.D.
Chief Medical Officer, ACS

Daniel Smith
National Vice President
Federal and State Government Relations

Americans for Integrity in Palliative Care

"To care, always...to kill, never"

**200 Daingerfield Road
Suite 100
Alexandria, VA 22314
(703) 684-8352
fax (703) 684-5813**

Communications Counsel

**Eugene Tarne
Michelle Powers**

Founding Members

C. Everett Koop, M.D.

Herbert Hendin, M.D.

Eric Chevlen, M.D.

Walter R. Hunter, M.D.

Wesley J. Smith, Esq.

Edmund Pellegrino, M.D.

Ralph Miech, M.D., Ph.D.

Carlos F. Gomez, M.D., Ph.D.

William Toffler, M.D.

N. Gregory Hamilton, M.D.

James Towey, Esq.

IMPROVING PALLIATIVE CARE FOR PATIENTS AND PROVIDERS

A Response to the American Cancer Society's Position Paper on The Pain Relief Promotion Act

As an ad hoc alliance of medical experts and others dedicated to optimum palliative care for terminally ill patients, Americans for Integrity in Palliative Care strongly supports the Pain Relief Promotion Act ("PRPA," H.R. 2260, S. 1272). We are therefore concerned with assertions made by the American Cancer Society in a position paper criticizing the Act, criticisms we believe are without merit.

We readily endorse everything the ACS statement says about the current crisis in pain management, and the priority which must be given to improving the quality of life for patients with cancer and their families. Many of our board members have dedicated their professional lives to these causes. If we believed that PRPA had the adverse effects that the ACS's advisors imagine, we would not support it either. But the ACS's stated concerns are based on a misreading of PRPA and of the Controlled Substances Act (CSA) which it amends.

Below we comment on the mistaken claims in the ACS statement which ground its negative conclusion about PRPA. Our hope is that the ACS leadership will revisit these claims and arrive at a less prejudicial judgment on PRPA.

Claim: "The Pain Relief Promotion Act... would ban the use of federally-controlled substances for physician-assisted suicide."

Actually the existing Controlled Substances Act already does this, as even attorney general Janet Reno conceded in June 1998 when she exempted Oregon from this otherwise universal standard. In the other 49 states, it is contrary to state criminal law and/or medical licensing standards to assist a suicide; thus it is automatically contrary to the CSA to use federally controlled substances for such activity. See 21 USC 824 (a)(2) and 824(a)(3). Since 1984, the CSA has also said that (quite aside from what state law may say) it is contrary to federal law to use these substances in ways that endanger "public health and safety." 21 USC 824 (a)(4), referencing 823 (f)(5). Chiefly under this latter provision, practitioners have had their DEA prescribing licenses suspended or revoked for their role in facilitating suicides. See, e.g., case of Dr. Hugh Schade, 60 FR 56354 (Nov. 8, 1995); case of Dr. Murray Walker, 55 FR 5306 (Feb. 14, 1990). This is why the relevant section of PRPA is headed: "Reinforcing *Existing* Standard for Legitimate Use of Controlled Substances." Such reaffirmation is necessary only because of attorney general Reno's flawed ruling of 1998.

Claim: “In an effort to ban the use of federally controlled substances for physician-assisted suicide, the Pain Relief Promotion Act amends the federal Controlled Substances Act (CSA), placing responsibility of determining legitimate medical practice with the Drug Enforcement Agency (DEA).”

It is the *current* federal standard that demands a controlled substance “must be issued for a legitimate medical purpose.” 21 CFR 1306.04. The CSA further indicates that “ethical medical practice” is “determined by the Secretary of Health and Human Services on the basis of a consensus of the views of the American medical and scientific community.” 21 USC 801a (3). That is exactly what DEA administrator Thomas Constantine did in November 1997, in determining that physician-assisted suicide is not recognized by HHS or by any national medical group as a legitimate medical practice. PRPA simply reinstates Mr. Constantine’s reasonable judgment on this point, which was set aside by attorney general Reno in 1998 with the unprecedented argument that state legislators and voters can unilaterally redefine “medical practice” within the meaning of federal law. It was Oregon that ignored the consensus of the medical profession, by labeling assisted suicide a legitimate medical practice. Congress is under no obligation to follow Oregon’s lead by authorizing use of federally controlled drugs for such killing.

Claim: “Unfortunately, ‘intent’ cannot be easily determined, particularly in the area of medicine where effective dosage levels for patients may deviate significantly from the norm.”

Yes, intent is difficult to prove. So by requiring the government to prove “intent” to kill before it can penalize a physician who claims to be practicing pain management, PRPA provides new protection for such a physician. Under current law, a physician can lose his or her DEA license for “negligent” or unintentional involvement in a patient’s death. See, e.g., case of Dr. Pompeyo Braga Bonado, 55 FR 37579 (Sept. 12, 1990); case of Dr. John Copeland, 59 FR 46063 (Sept. 6, 1994). Incidentally, the “intent” standard criticized here is an integral part of almost every existing state law (and The Assisted Suicide Funding Restriction Act, the only current federal law) against assisted suicide – laws which the American Cancer Society says it supports and defends. The explicit distinction between “intentional” killing, and the unintentional hastening of death that may rarely occur during aggressive pain management, was incorporated into these laws at the insistence of medical and hospice groups. Enactment of such laws has generally been followed by dramatic increases in use of morphine for pain control.

Claim: “The question of deciding intent should remain in the hands of those properly trained to make such decisions – the medical community and state medical boards.”

We agree. Therefore PRPA explicitly reaffirms that the usual division of labor between state and federal authorities must be maintained – so that in all 50 states, state medical boards will remain the first line of defense against misuse of controlled substances. See H.R. 2260 as amended, Sec. 201 (a)(3), Sec. 202. The only exception is the rare case in which a physician assists the suicide of a patient with cancer or another terminal illness under the new Oregon law – and in such a case, it is the physician who formally announces his or her intent to assist the patient’s suicide. PRPA authorizes no increased scrutiny of physicians’ intent by the DEA. Nor can it be used to authorize new national standards or requirements for pain management. *Id.*, Sec. 201 (a)(4)(B).

Claim: “The DEA would now explicitly be charged with overseeing the medical use of controlled substances, resulting in a negative impact on cancer pain treatment.”

Just the opposite is true. The DEA scrutinizes the use of controlled substances for pain control now, sometimes in ways that can instill fear in medical practitioners. Specifically it investigates palliative care physicians who prescribe unusually large doses of morphine for pain control, to check whether they may be guilty of “overprescribing.” PRPA provides new protection against such scrutiny. It declares that efforts to control pain in the usual course of professional practice fall into the realm of “legitimate medical purpose,” and thus are *outside* the authority of the DEA. The DEA only has authority to investigate *diversion* of controlled substances *away* from “legitimate medical purposes.”

Claim: “The current CSA maintains a suitable balance between the interest of government to regulate and monitor the diversion and misuse of controlled substances with the needs of patients. Amending the CSA as in the PRPA would disturb this delicate balance.”

With all due respect, currently that balance is tilted toward “effective” law enforcement, sometimes to the detriment of effective pain management. Even the continuing education program which the CSA authorizes for DEA officials and other law enforcement personnel is completely dedicated to “effective” prevention of misuse, not to ensuring that legitimate use for pain control is accommodated – an imbalance that PRPA corrects. See: 21 USC 872(a); PRPA, Sec. 202. Physicians now fear legal liability in cases where their efforts to control pain may unintentionally hasten death or may be suspected of doing so. The shift in this balance created by PRPA is to the benefit of the doctor and patient.

Claim: “The original intent and historical interpretation of the CSA revolve around control of the trafficking, diversion and misuse of controlled substances, not determining legitimate medical practice.”

This is a puzzling claim. Under the existing CSA, it is precisely diversion *from* a “legitimate medical purpose” that triggers federal enforcement. That is how one determines whether controlled substances are being misused. PRPA does not change this – it only clarifies that sincere efforts to control patients’ pain should be left as much as possible to the individual medical judgment of the physician, even where the large doses needed to control pain may unintentionally hasten death.

Claim: “It is also important to note that by amending the CSA, PRPA does not prohibit all physician-assisted suicide, but only those events using federally controlled substances.”

Keeping in mind that PRPA does not create a new “prohibition” on anything (see above), this statement is basically correct. The Act does not reach out to create a federal ban on assisted suicide, but prevents the misuse of federal authority and federal prescribing licenses to facilitate assisted suicide. The debate on a federal ban on assisted suicide – its pros and cons, and its constitutionality – must wait for another day. The immediate task is to discontinue the federal government’s current practice of actively assisting the suicides of cancer patients’ lives in Oregon. Clearly, as indicated by the ACS statement, that urgently needed and overdue task is politically difficult enough.

Claim: “The Pain Relief Promotion Act will send a clear message to the DEA and state and local law enforcement agencies that Congress now intends for the CSA to apply to the area of pain management – an area where the CSA has not historically played a role.”

Again, the opposite is true. By declaring, for the first time in a federal statute, that pain management is a “legitimate medical purpose” for use of controlled substances, PRPA places this field *outside* the enforcement authority of the DEA. In practice, current DEA scrutiny of such legitimate medical decision making is all too apparent to palliative care physicians in the field.

Claim: “The Pain Relief Promotion Act would ban the use of federally controlled substances for physician-assisted suicide at the expense of controlling pain and advancing symptom management.”

There is no basis for such a claim. Ten pages of this 11-page bill are completely devoted to promoting pain management, funding better training of doctors and nurses in palliative care, and requiring education of law enforcement officials in how to better accommodate health professionals’ use of controlled substances for pain relief. The only passage of this bill that could conceivably provide the basis for the above claim is the following, from Sec. 201 (a):

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

Clearly, even this passage is *primarily* devoted to protecting and promoting aggressive pain management. *One sentence* of the 11-page PRPA reaffirms that this protection does not extend to *authorizing* the intentional and deliberate use of federally controlled drugs to kill patients. No organization that supports pain management and opposes assisted suicide should object to this reaffirmation of longstanding federal policy. To demand deletion of that final sentence is to demand that Congress authorize the prescribing of pain control drugs even when they will certainly kill the patient and are clearly and deliberately intended to do just that.

We hope the American Cancer Society will review PRPA in light of the above information and analysis, and decide that it has nothing to fear from this well-crafted and important legislation.

Life at Risk

A Chronicle of Euthanasia Trends in America

Vol. 10, No. 5 July 2000

NCCB Secretariat for Pro-Life Activities

Maine, Congress Prepare for Suicide Votes

As the U.S. Senate awaits the end of its month-long August recess and an expected September vote on the Pain Relief Promotion Act, the issue of assisted suicide is about to become uppermost – literally – in the minds of many voters in Maine.

An initiative to legalize physician-assisted suicide, repeatedly rejected by Maine's legislature, will top the state ballot as "Question 1" on November 7, its position determined by a random drawing by the Secretary of State on May 25. Supporters of the "Death with Dignity Act" also have the advantage of ballot language designed to reassure – some say, to mislead – voters: "Should a terminally ill adult who is of sound mind be allowed to ask for and receive a doctor's help to die?"

The Act itself, modeled after Oregon's law, speaks of a patient's "request for medication for the purpose of ending that patient's life," but that language will not appear on the ballot. The proposed law does not change what patients would be "allowed" to request, but what physicians would be allowed to do that is now forbidden as the crime of "aiding or soliciting suicide."

Announcing formation of Maine Citizens Against the Dangers of Physician-Assisted Suicide on May 17, disability rights advocate Steven Tremblay said the Act is moving forward because Maine has been chosen as a target state by the national assisted suicide movement. "It has nothing to do with compassionate care," he said. "It has everything to do with a national political campaign marching into our state and forcing their agenda on Maine people" [Maine Citizens web site, www.noassistedsuicide.com/news/051700.htm].

Supporting his charge are the records of campaign contributions filed with the state through June 1. They show that the PAC promoting the

initiative, Mainers for Death with Dignity, raised \$606,018, about 95% of which came from out-of-state contributors. Four PACs opposing the initiative raised \$629,337; but three of them listed no out-of-state contributions, while the fourth, Coalition for the Compassionate Care of the Dying, received more than 99% of its funds from within the state.

"We're getting a national battle fought out in the state of Maine," says political scientist Douglas Hodgkin of Bates College in Lewiston. He warns that Mainers "should be aware of the possibility that somebody could be hijacking the process from outside" [*Portland Press Herald*, 7/12/00]. In fact, supporters have emphasized their need for "generous support from all over the country to ensure a successful campaign" [Mainers for Death with Dignity web site, www.mdwd.org].

Out-of-state donors to the Maine effort include the political arm of the Hemlock Society, members of other Hemlock affiliates, and Oregon Death with Dignity. But these groups will soon have to dust off their "states' rights" rhetoric for the coming vote in Congress, where Senators Ron Wyden (D-OR) and Don Nickles (R-OK) have reached an agreement allowing the Pain Relief Promotion Act to reach the Senate floor in September. Senator Wyden says that he will filibuster the legislation -- but if supporters win 60 votes on an initial motion to limit debate and proceed to a vote, he "won't be unreasonable" in continuing to block consideration [*The Oregonian*, 7/28]. He says he may have to rely on a veto from President Clinton, who he personally briefed on the measure on June 19 aboard Air Force One [*Id.*, 7/29].

The federal bill would not overturn the Oregon law or the Maine proposal, but forbid use of federally controlled drugs for assisted suicides performed under such laws while expanding federal protection for use of these drugs for pain control.



News Briefs

Dutch to Modify Child Euthanasia Bill

The Dutch government has resubmitted its proposal for formally legalizing assisted suicide and euthanasia, while modifying its controversial provision allowing euthanasia for children.

When first proposed to Parliament over a year ago, the bill allowed for cases where children from 12 to 16 years old could request and receive euthanasia "against the wishes of their parents." The modified proposal still allows child euthanasia in this age group, but not over parents' objections [*New York Times*, 7/14/00].

Still unclear is the fate of another controversial feature of the original bill, allowing adults to sign advance directives requesting euthanasia in the event of future mental incompetency. This would allow legal euthanasia for patients with dementia or Alzheimer's disease for the first time [*Id.*, 6/20].

Dutch euthanasia practice has long included lethal injections for children, including newborn infants, with parental consent.

ABC Suing to Interview Kevorkian

Barred from conducting an on-camera interview with Jack Kevorkian in prison, ABC News is waging a court battle against the Michigan Department of Corrections.

Corrections Director Bill Martin has refused a request from the ABC program "20/20" to let Barbara Walters interview Kevorkian and two fellow inmates. Martin invoked a state prisons policy that took effect last March, barring TV crews except for stock footage and scenes of inmates taking part in prison activities. A county circuit judge found in favor of ABC on July 13, saying the prison policy infringes on First Amendment rights [AP, 7/13]. However, this ruling was blocked two weeks later by a state appellate court [*Washington Times*, 7/30]. Kevorkian is serving a 10-to-25-year

sentence for second-degree murder, for giving a lethal injection to Thomas Youk last September.

Euthanasia Cases in the News

- In **New York**, federal officials have brought murder charges against Michael J. Swango for giving lethal injections to three patients. Each patient died under his care at a Veterans Affairs hospital in Northport, New York while he was a medical resident with the Stony Brook Health Sciences Center in 1993. Prosecutors say Swango is a serial killer who obtains medical posts through "lies and deception" and has been killing and endangering patients since medical school. The indictment was issued as he finished serving three and a half years in a federal prison in Colorado for fraudulently obtaining the Northport post. He won that job by lying about an earlier incident in Illinois, in which he made five co-workers ill by lacing their coffee and doughnuts with an arsenic-based ant killer [*New York Times*, 7/12].

- In **New Mexico**, a hiker who stabbed his friend to death in what he claimed was a "mercy killing" was sentenced on May 10 to serve two years in prison and five years of probation. Raffi Kodikian, 26, said he killed David Coughlin, 26, at his request after the two had been lost for days in the desert without water [AP, 5/11].

- In **Utah**, a jury has convicted psychiatrist Robert Allen Weitzel on two counts of manslaughter and three counts of negligent homicide for his role in the death of five patients. Prosecutors had sought a murder conviction, claiming that Weitzel intentionally killed the patients by weakening them with large doses of sedating drugs and then administering lethal doses of morphine; his defense attorney claimed he acted in good faith to provide comfort care. Accepting neither claim, the jury found that Weitzel acted recklessly and with criminal negligence. The patients, who died in a period of 16 days under Weitzel's care, had been receiving treatment for loud and combative behavior stemming from senile dementia [*Salt Lake Tribune*, 7/11].

VERBATIM: ACADEMIC EXPERTS ON THE PAIN RELIEF PROMOTION ACT

On April 24, a group of 47 bioethicists wrote to the Senate Judiciary Committee opposing the Pain Relief Promotion Act, now poised for a Senate vote in September. The signers said they have "differing views about the moral issues arising in end-of-life situations," but agree that the Act is "a dangerous bill" that "will undercut the effective delivery of pain relief." Drafting the letter was University of Pittsburgh law professor Alan Meisel; he and 15 other signers submitted amicus briefs in 1997 unsuccessfully urging the Supreme Court to create a constitutional right to assisted suicide.

On July 28 a response was sent to all Senators by the Act's chief sponsors, Don Nickles (R-OK) and Joe Lieberman (D-CT). The new letter, signed by 104 experts in law, medicine and ethics, was prepared by Americans for Integrity in Palliative Care, an ad hoc alliance of palliative care experts and others who support the Act. Signers include former surgeon general C. Everett Koop, Harvard law professor Mary Ann Glendon, palliative care expert Eric Chevlen, and Dr. C. Christopher Hook, director of ethics education for the Mayo Clinic. Excerpts follow:

The Act promotes pain management and palliative care for the terminally and chronically ill in several ways. First, it calls on the Department of Health and Human Services to collect and disseminate available protocols and guidelines on palliative care to make these more widely known among medical professionals, health care entities and the general public. Second, it provides \$5 million a year for training grants to help medical professionals learn the latest techniques for pain management and palliative care. Third, it provides a new explicit "safe harbor" in the federal Controlled Substances Act (CSA) for medical professionals' use of federally controlled drugs to relieve pain, even in those rare cases where death may unintentionally be hastened. Fourth, it provides for continuing education for Drug Enforcement Administration (DEA) agents and other law enforcement personnel, so they will understand this safe harbor and the legitimate

need for large palliative doses of painkilling medications. Fifth, it clarifies the law so the CSA is not construed to authorize use of these federally controlled drugs for assisted suicide and euthanasia.

This last-named feature is itself an important contribution to palliative care. If our society is to commit itself to addressing the real needs of dying patients for pain control and compassionate care, our government must say clearly to these patients that it will not support the "quick fix" of deliberately seeking the death of seriously ill citizens. To condone physician-assisted suicide would erode trust between patients and their physicians, and undermine society's commitment to the more difficult but infinitely more rewarding task of meeting patients' real needs.

In an April 24 letter, some bioethicists express a different view. They suggest that the Act's explicit rejection of assisted suicide and euthanasia is an imposition on physicians, a needless assault on medical decision making that will undermine optimum palliative care.

With due respect to these colleagues, their argument is seriously flawed. Specifically they do not recognize or understand key provisions of the Act or the legal context in which they are offered.

Below we answer the key questions raised by the April 24 letter.

1. Does the Act's "intent standard" force physicians to become more cautious in treating pain?

On the contrary: Currently the DEA has authority to act whenever controlled substances are used contrary to the "public interest," including any case where they are used to endanger "public health and safety" (21 USC 823, 824(a)(4)). Under these broad standards, federal authority to revoke a physician's DEA registration for *unintentional*

(continued page 4)

104 Experts on the Pain Relief Promotion Act (continued)

(continued from page 3)

involvement in suicides or other overdoses has no clear statutory limit. By requiring proof of *intent* to cause death in cases where physicians sought to relieve pain, the Act provides new protection compared with current law. As approved by the Senate Judiciary Committee the Act adds still greater protection for physicians, by requiring that such intent be proved by "clear and convincing evidence" rather than the usual "preponderance of evidence" now used in all DEA administrative proceedings...

2. Will a more explicit policy against use of these drugs for assisted suicide have a "chilling effect" on their use for pain control?

The April 24 letter says it will, and adds that "the evidence for this claim is legion." In fact, the evidence *against* that claim is overwhelming. In recent years a number of states have enacted laws similar to the federal Act – laws which forbid assisted suicide while explicitly allowing pain control that may unintentionally hasten death. These states have seen dramatic *increases* in use of controlled substances like morphine for pain control. After Iowa and Rhode Island passed such laws in 1996, per capita use of morphine *doubled* in those states (see April 25 testimony of Dr. Eric Chevlen before the Senate Judiciary Committee). South Dakota saw a similar increase in 1997, after it imposed civil penalties for aiding a suicide while

enacting a disclaimer on the legitimacy of pain control. Veterans Administration hospitals showed dramatic improvements in palliative care after a similar policy was applied to them by the Assisted Suicide Funding Restriction Act of 1997.

Physicians may well be "chilled" in doing pain control when the law increases scrutiny of their use of drugs *for pain control*. But the Pain Relief Promotion Act reduces such scrutiny, by stating: "For purposes of this Act and any regulations to implement this Act, alleviating pain or discomfort in the usual course of professional practice is a legitimate medical purpose for the dispensing, distributing, or administering of a controlled substance that is consistent with public health and safety, even if the use of such a substance may increase the risk of death." To call any practice a "legitimate medical purpose" in the CSA is to place it beyond DEA scrutiny, because the agency has authority only to scrutinize the diversion of these drugs toward "nonmedical" use....

Many signers of the April 24 letter are more closely associated with campaigns for assisted suicide than with the drive for better palliative care; 16 of them have signed amicus curiae briefs to the Supreme Court favoring a constitutional "right" to assisted suicide. That fact does not, by itself, nullify their arguments. It does indicate that some attacks on the proposed Act may be motivated by factors other than concern for palliative care.

Return Service Requested

Washington, D.C. 20017-1194

3211 4th Street NE

NCCB Secretariat for Pro-Life Activities

Life at Risk

**COMMON SENSE REASONS TO SUPPORT H.R. 2260
THE PAIN RELIEF PROMOTION ACT (PRPA)**

-- AS PASSED BY THE SENATE JUDICIARY COMMITTEE --

**THE PRPA CREATES A NEW "SAFE HARBOR" FOR PHYSICIANS WHO
PRESCRIBE AGGRESSIVELY TO HELP THEIR PATIENTS IN PAIN**

The Act would explicitly recognize that increased risk of death may sometimes be a potential consequence of the legitimate and necessary prescribing of controlled substances for pain management. It establishes – for the first time in federal statute – a legal "safe harbor" so that physicians may aggressively and appropriately treat their patients who are in pain without the threat of criminal investigation and prosecution for fully legitimate medical decisions.

**THE PRPA PRESERVES DEFERENCE TO STATE LICENSING BOARDS AND
PROFESSIONAL DISCIPLINARY AUTHORITY, AS CURRENTLY EXISTS UNDER
THE CONTROLLED SUBSTANCES ACT (CSA)**

The Legislative History underlying current law explicitly states that evaluations of whether a DEA registration are in the public interest (the statutory standard) should be based on a series of factors, the first of which is "*the recommendation of the appropriate State licensing board or professional disciplinary body.*" (P.L. 98-473, p. 266) It further states that the Attorney General's authority to deny a physician's registration "*would continue to give deference to the opinions of State licensing authorities, since their recommendations are the first factors to be considered with respect to practitioner applications.*" (P.L. 98-473, p. 267) The PRPA does nothing to change this balance of authority.

**THE PRPA DOES NOT CREATE NEW FEDERAL AUTHORITY TO REGULATE
PHYSICIANS**

The DEA and state medical licensing boards currently have overlapping authority when it comes to physicians prescribing controlled substances. The bill contains specific rules of construction preserving the roles of the states and federal government in regulating the practice of medicine. Furthermore, the Attorney General is explicitly prohibited from creating new federal standards for pain management or palliative care; existing and developing standards in the private sector and research community will continue to be the "gold standard."

**THE PRPA DOES NOT GIVE THE DEA NEW POWERS TO EVALUATE WHETHER A
PRESCRIBING DECISION IS "LEGITIMATE"**

Under current regulation, a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his [or her] professional practice." (21 CFR 1306.04) The DEA *already* has the power to evaluate whether a physician's prescribing decision is for a "legitimate medical purpose." Therefore, the DEA is *already* authorized to evaluate physician intent. The PRPA actually *protects* physicians who are prescribing aggressively for pain by explicitly carving out a "safe harbor."

**THE PRPA WILL CONTINUE TO FOSTER PROFESSIONALLY DEVELOPED
STANDARDS TO IMPROVE PAIN MANAGEMENT AND PALLIATIVE CARE FOR
PATIENTS**

The PRPA encourages and supports the vital research necessary to advance the science and art of pain management and palliative care. While it authorizes grants and educational activity, it explicitly prohibits the Attorney General or the Agency for Health Research and Quality (AHRQ) from creating their own standards for pain management or palliative care that would then be used by law enforcement to prosecute physicians or other practitioners.

Assisted Suicide File

10-19-99

1999 OCT 18 4:51 PM

Reed
Jennings
Padesta

THE WHITE HOUSE
WASHINGTON

October 18, 1999

ACTION MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed
Chris Jennings

SUBJECT: Assisted Suicide Legislation

Call for letter to send letter
but I'm basically OK
on that Ban - if pain
relief not affected
+ no offensive burden
to keep on life support when

Wojcik
BC

On Wednesday, the House is tentatively scheduled to vote on H.R. 2260, the Pain Relief Promotion Act of 1999. As you will recall, this legislation, sponsored by Congressman Hyde, modifies the Controlled Substances Act (CSA) to create criminal penalties for the use of a controlled substance in physician assisted suicides. It also takes new steps to protect the appropriate provision of palliative care, a significant modification to the previous version of this legislation.

While the Department of Justice strongly supports the palliative care provisions of the bill, it has strong concerns about the federalism issues it raises and the penalty structure it creates. They would like to forward the attached letter of opposition to the House Judiciary Committee outlining these concerns. This letter does not include a veto threat. We recommend that the letter be sent, but that the White House refrain from public comment on the legislation.

BACKGROUND

Representative Hyde introduced the H.R. 2260 this summer. It is the second generation of the legislation known as the Lethal Drug Abuse Prevention Act of 1998 (LDAP). As you will recall, you and virtually every respected consumer and health care provider group, including the AMA, opposed LDAP because of the fear that the legislation would inhibit pain relief for the terminally ill. The provisions of most concern to provider and consumer groups included the establishment of broad prosecutorial authority for law enforcement officials, allowing the investigation of health care providers that were suspected of planning to use or of having used a controlled substance to assist in a suicide, and the absence of a proactive statement protecting the provision of appropriate palliative care.

H.R. 2260 would make physician-assisted suicide using controlled substances subject to administrative, civil, and criminal sanctions, and effectively ban the practice in all 50 states. However, Representative Hyde has modified the old version of this legislation to incorporate an explicit statement that using a controlled substance to alleviate pain and discomfort is a legitimate medical purpose, even if the use of the controlled substance increases the likelihood of death. It also narrows prosecutorial authority to suspected cases of the use of a controlled substance in an assisted suicide, and requires local, state, and Federal law enforcement personnel to receive information on palliative care in continuing education programs. Because

THE PRESIDENT HAS SEEN
5-20-98

THE WHITE HOUSE

WASHINGTON

May 18, 1998

MEMORANDUM FOR THE PRESIDENT

FROM: PHIL CAPLAN *Phil*

SUBJECT: Assisted Suicide Legislation

*cannot
oppose outright
given my
position*

*copied
Reed
Ruff
COS
Kagan*

In response to an inquiry from Sen. Hatch and Rep. Hyde, the Justice Department has determined internally that the DEA has no authority under the Controlled Substances Act (CSA) to take adverse action against physicians who assist patients in ending their lives legally under Oregon law. The attached memo from Bruce Reed and Chuck Ruff seeks a decision from you on how the Administration should roll out Justice's conclusion, and in particular respond to likely legislation sponsored by Hatch and Hyde. The Hatch/Hyde approach would authorize the DEA to pursue criminal actions against physicians prescribing medications for assisted suicides.

Agency Views. Justice believes the Administration should not support Hatch/Hyde for several reasons: (i) federalism principles call for the federal government to defer to the states as the primary regulators of the medical profession; (ii) DEA's approach to narcotics issues is inconsistent with the sensitivity required in pursuing doctors who are assisting the terminally ill; (iii) resource drain on the DEA; (iv) new mission would damage DEA's relationship with the medical profession, which is a frequent DEA partner in narcotics cases. HHS/FDA concurs with Justice, stressing the historic deference given to states on regulating doctors.

Your views on assisted suicide. Bruce/Chuck feel your longstanding opposition to assisted suicide is not necessarily inconsistent with the agencies' position. Both the federalism rationale and the notion that assisted suicide is not an appropriate issue to be handled by federal narcotics agents are reasonable and consistent arguments in light of your opposition to assisted suicide.

Options. Four are presented; Option #3 is the recommended option. **Option 1:** Endorse Hatch/Hyde -- no support. **Option 2:** Oppose Hatch/Hyde but suggest openness to alternatives; welcome the intent of the bill but raise concerns; attempt to find compromise with the GOP, although it will be very difficult to do so -- no support. **Option 3:** "Kick the Can" Strategy -- similar to Option 2 but rather than search out compromise, we would attempt to forestall legislative action this year. Delay would allow medical groups, states and others to weigh in that federal approaches in this area are ill advised. *Chuck* and *Bruce* support this option believing federal drug agents should not regulate doctors, assisted suicide is not an area for federal legislation and "kicking the can" is the best way to prevent a bill. *Larry Stein* concurs but notes that your views in this area should be made clear. *DOJ/HHS* prefer this option over Option 2, but really support Option 4. **Option 4:** Oppose Hatch/Hyde outright. Risks a confrontation with Congress, which will likely pass a bill over your objection, and may appear inconsistent with your opposition to assisted suicide.

Option 1 Option 2 Option 3 (recommended) Discuss

Assisted Suicide File

DATE: June 5, 2000
MEMORANDUM TO: KAREN TRAMONTANO
CHRIS JENNINGS
FROM: BARBARA WOOLLEY
RE: PAIN MANAGEMENT MEETING

Date of event: Tuesday June 6, 2000

Time of event: 11:00am - noon

Place of event: Rm. 100, OEOB

Purpose: The purpose of the meeting is for the coalition of groups to share their position on H.R. 2260; the "Pain Management Act of 1999." As you know, the intent of the bill would be to prevent federally controlled substances from being used in assisted suicides. This coalition is opposed to the bill because "it may put physicians who are appropriately prescribing pain narcotics at risk for both civil and criminal liability." **They requested the meeting to send the message that they oppose the bill, should it pass the Senate and reach the President's desk they would urge the President to veto the legislation.**

Attendees: Susan Emmer, American Geriatrics Society
James Guest, American Pain Foundation
Jeffrey Human, American Academy of Family Physicians
Stephanie Williams Reed, American Nurses Association
Bill Zavarello, Bass & Howes
[Cathy Bonk cannot attend the meeting due to a conflict in New York]

The Revised "Pain Relief Promotion Act" (H.R. 2260) Remains Bad Medicine for Patients

"If the bill becomes law, it will almost certainly discourage doctors from prescribing or administering adequate doses of drugs to relieve the symptoms of dying patients."
- *New England Journal of Medicine Editorial (12/16/99)*

Summary: Almost 40 major organizations of doctors, nurses, hospices, pharmacists, pain experts and patients, along with hundreds of nationally prominent experts in palliative care, law and bioethics, publicly oppose the misnamed "Pain Relief Promotion Act." Chief among their concerns:

- It would inhibit aggressive use of controlled substances to fight pain.
- It would expand the DEA's role from fighting illegal drug trafficking to regulating the practice of medicine – a responsibility presently handled by state authorities that should remain with the states and for which the DEA is unqualified and inappropriate anyway.
- It fails to promote real and meaningful solutions for improving pain relief.
- It would not even achieve the bill's underlying goal of reducing assisted suicide.

Empowering the DEA to investigate and punish the medical judgments of doctors, nurses and pharmacists will deter many of them from aggressively treating pain and cause patients to suffer needlessly.

The proposed Pain Relief Promotion Act would expand the DEA's role from fighting illegal drug trafficking to regulating the practice of medicine. It would give DEA agents explicit authority to question and investigate the *intent* of any physician or other healthcare worker who provides a controlled substance to a patient in pain who subsequently dies. "The result," writes a former attorney with the DEA's Office of General Counsel, "will necessarily be an increase in the DEA scrutiny of physicians treating patients for severe pain where death has occurred." If convicted under provisions of the Pain Relief Promotion Act, a healthcare professional would face a minimum mandatory 20-year sentence.

Numerous studies have shown that physicians in the U.S. are grossly undertreating pain and that fear of investigation is a leading cause of their reluctance to aggressively manage pain. If this bill passes, many doctors, pharmacists and other healthcare professionals will be more hesitant than they already are to dispense powerful pain-relieving drugs. They will fear losing their livelihood if their intentions are misinterpreted, and they will fear the time, cost and negative publicity of having to mount a defense to a DEA allegation in the first place.

DEA agents are unqualified to assume the new role of judging between legitimate medical use of controlled substances and intentionally causing death.

Palliative care experts note that the line between increasing the risk of death while treating pain (allowable under the bill) and intentionally causing death (a crime) can be hard to distinguish. The DEA acknowledged in a recent letter to Congress that it "lacks the resources or the expertise" to investigate patient deaths. The DEA testified in the last Congress that it would compensate by consulting medical textbooks for help – hardly a substitute for years of medical

education. In fact, even if DEA agents were given limited medical training, they would still be poorly equipped to second-guess doctors, nurses, and pharmacists with years of education and experience.

Pain relief therapy should be managed and monitored by healthcare professionals – physicians, nurses, and pharmacists – not by federal law enforcement officers whose job is to fight illegal trafficking in drugs. Oversight of the practice of medicine should remain with the expert medical authorities in each state without DEA duplication or interference.

Why increase the federal bureaucracy when state medical and pharmacy boards already fully regulate the unauthorized medical use of controlled substances?

All 50 states license physicians and pharmacists and have boards of medical experts to review and discipline practitioners who violate medical practice standards, including the medical misuse of controlled substances. Forty-nine states prohibit physician-assisted suicide. It makes no sense to add a redundant, unnecessary, and potentially contradictory layer of federal bureaucracy to the practice of medicine in those states in order to achieve the bill's underlying purpose – nullifying Oregon's law.

The "double effect" factor in prescribing pain medication is already protected.

The bill's proponents argue that one of its main values is that it protects physicians who prescribe a drug for pain relief that also has the potential "double effect" of increasing the risk of death. But this protection for "double effect" is already long-standing DEA policy and does not need to be codified into law – especially when it would be at the price of expanding the DEA's role into medical oversight and investigation of physicians' intent. What is needed is not a new law, but rather better implementation and communication of the DEA's existing policy.

By adding even more changes to the Controlled Substances Act than the original bill, the reported version creates additional confusion.

The legislation as reported adds language designed to be reassuring by saying that the bill should not be construed to alter the roles of the federal and state governments in regulating the practice of medicine. But at the same time the bill enhances the DEA's authority to regulate the dispensing and administering of controlled substances – a major medical practice. Another section limits certain federal actions but then undoes the limit by adding "except that the Attorney General may take such other actions as may be necessary to enforce this Act." These and other new ambiguities will leave the medical community guessing as to the actual extent of the new federal powers. Meanwhile, the provision that will have the most chilling effect on pain management – the clause explicitly authorizing the DEA to investigate a healthcare practitioner's "intent" – remains unchanged.

Former Harvard Law School Dean James Vorenberg and other experts summarized the changes as follows: "Senator's Hatch's substitute bill doubles the size of the original H.R. 2260 by adding to it some hastily put together jurisdictional and procedural provisions that exacerbate the bill's potential for frightening physicians into undertreating pain."

The privacy of the patient's family will likely be invaded during a DEA investigation, even if no wrongdoing has occurred.

To build a case that meets the bill's "clear and convincing evidence" standard, the DEA would likely have to interview grieving family members, nurses, doctors and health aides to determine what the patient and doctor said and what they intended. This may force the disclosure of communications classified as "privileged" under state law and the release of medical records protected under state medical privacy laws. A subsequent conclusion by the DEA that there is no evidence to justify prosecution will not undo the harm that the investigation caused the family and healthcare providers.

The bill will not stop assisted suicide, but rather will likely have the perverse effect of increasing suicides among desperately ill patients in pain.

Rabbi J. David Bleich, who testified before the Senate Judiciary Committee in support of the bill, acknowledged that the bill "will not have the effect of reducing the incidence of physician-assisted suicide." He added, "I doubt very much... that the passage of the bill will prevent as much as a single suicide." Medical experts have noted that a physician could circumvent this law by prescribing a non-controlled substance or an over-the-counter drug, or by using a chemical like carbon monoxide.

Rather than achieving its main goal of reducing physician-assisted, the bill will likely have the unintended effect of increasing suicides among desperately ill patients by deterring some physicians from dispensing large but necessary quantities of the strongest pain-relieving drugs available to the seriously ill.

The use of state morphine statistics to justify PRPA is a red herring.

Proponents of this legislation argue that it will not have a chilling effect on pain management because in some states that have passed similar laws against assisted suicide the use of morphine went up. But that argument is a fallacy. Proponents ignore the fact that some top-ranked states for per capita morphine use – including three of the top five states – have no comparable statutes to PRPA. They fail to recognize that the national average for morphine use increased during the periods they cite and that morphine use increased in most states during this period, not just in a few states with PRPA-type laws.

Indeed, some states that passed laws similar to PRPA experienced a decrease in morphine use or an increase less than the national average. Also, most morphine is prescribed for acute and chronic pain – not end-of-life care – so the morphine statistics don't really tell us about the chilling effect on the use of pain medication at the end of life.

Finally, state laws against intentionally using controlled substances for assisted suicide are implemented by state medical and regulatory authorities; that's entirely different from the chilling impact of having federal crime-fighters responsible for combating illegal drug traffic taking on this new function.

PRPA would not address the needs of terminally ill Americans or those suffering from chronic pain.

Fifty million Americans suffer from chronic pain, 2.4 million Americans die each year, and 25 million Americans each year experience acute pain from surgery or injury. Chronic pain alone costs an estimated \$100 billion annually in medical expenses, lost income, and lost workdays. This bill's narrow provisions for education, training and research and the minimal authorization of only \$5 million will have no real impact. It fails to address in a meaningful way the real needs to improve pain management and palliative care such as:

- Increasing basic and applied research and developing new protocols and practices
- Improving pain management education among all healthcare professions
- Reducing regulatory burdens on dispensers of controlled substances
- Increasing access to and reimbursement for pain medications
- Increasing public awareness about the need and availability of strong pain treatment.

Congress should develop a genuine, comprehensive, and well-funded bill that truly promotes improved pain management and palliative care and is worthy of the title "Pain Relief Promotion Act."

If Congress wants to prohibit physician-assisted suicide, it should enact a narrowly-tailored criminal statute to ban it.

The medical community is just now starting to make small gains in reversing the gross undertreatment of pain. It makes no sense to tamper with the Controlled Substances Act and risk undoing this delicate balance. Congress can pass a separate law addressing assisted suicide. It should not turn the "War on Drugs" into a "War on Patients."

Many clinicians in the trenches strongly oppose PRPA because of its chilling effect on pain management...and even organizations supporting PRPA are deeply divided.

Several major organizations that have expressed support for the Pain Relief Promotion Act have done so with deep divisions and differences of opinion among their memberships. Meanwhile, almost 40 major organizations of doctors, nurses, hospices, pharmacists, pain experts and patients, along with hundreds of nationally prominent experts in palliative care, law and bioethics, publicly oppose the bill.

Virtually every major nursing organization concerned about pain management and palliative care is opposed – including the American Nurses Association, Hospice and Palliative Nurses Association, Oncology Nursing Society, American Society of Pain Management Nurses, and others. Major physicians organizations against the bill include the American Academy of Family Physicians, American Geriatrics Society, American Academy of Hospice and Palliative Medicine, several state medical societies, and others. A long list of hospice and pharmacy groups, pain patient organizations, individual pain management specialists, bioethicists and legal scholars are also opposed.

The bottom line is that respected and experienced members of the medical community, as well as other professionals and patient advocates, have concluded that the so-called Pain Relief Promotion Act will be harmful to patients who suffer from pain. Congress should not pass this well-intended but harmful legislation.

Organizations and Individuals Who Have Publicly Opposed The Misnamed "Pain Relief Promotion Act" (H.R. 2260) (Selected List)

Physicians

American Academy of Family Physicians
 American Academy of Hospice and Palliative Medicine
 American Academy of Pharmaceutical Physicians
 American Geriatrics Society
 California Medical Association
 Massachusetts Medical Society
 North Carolina Medical Society
 Oregon Medical Association
 Rhode Island Medical Association
 San Francisco Medical Society
 Society of General Internal Medicine

Nurses

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

Hospices

Hospice Federation of Massachusetts
 Indiana State Hospice and Palliative Care Association
 Kansas Association of Hospices
 Maine Consortium of Palliative Care and Hospice
 Maine Hospice Council
 Missouri Hospice and Palliative Care Association
 New Hampshire State Hospice Organization
 New Jersey Hospice and Palliative Care Organization
 New York State Hospice Organization
 Oregon Hospice Association

Pharmacists

American Pharmaceutical Association
 American Society of Health-System Pharmacists

Pain Management Specialists

(Below is a partial list of over 120 physicians specializing in pain medicine who signed letters to the Senate Judiciary Committee in opposition to PRPA)
 James N. Campbell, M.D. (Johns Hopkins)
 Edward Covington, M.D. (Cleveland Clinic)
 Scott Fishman, M.D. (Univ. of California, Davis; author of The War on Pain)
 Kathleen Foley, M.D. (Memorial Sloan-Kettering)
 Joel Frader, M.D. (Pediatric Palliative and Hospice Care Program, Children's Memorial Hospital, Chicago)
 Martin Grabois, M.D. (Baylor College of Medicine)
 Eric Taler, M.D. (Washington Hospital Center)

Patient and Health Organizations

American Pain Foundation
 American Society for Action on Pain
 College on Problems of Drug Dependence
 National Foundation for the Treatment of Pain
 Triumph Over Pain Foundation

Bioethicists

(Below is a partial list of 49 bioethicists who signed a letter to the Senate Judiciary Committee or testified in opposition to PRPA)
 Margaret P. Battin, Ph.D. (Univ. of Utah)
 Arthur Caplan, Ph.D. (Director of the Center for Bioethics, Univ. of Pennsylvania)
 Joseph Fins, M.D., F.A.C.P. (Cornell)
 Kenneth Goodman, Ph.D. (Director, Bioethics Program, Univ. of Miami)
 Alan Meisel, J.D. (Director, Center for Bioethics and Health Law, Univ. of Pittsburgh)
 Bonnie Steinbock, Ph.D. (SUNY)
 Ernie Young, Ph.D. (Co-Director, Center for Biomedical Ethics, Stanford)

Law Professors and Lawyers

(Below is a partial list of attorneys who have provided legal opinions or written in opposition to PRPA)
 Charles H. Baron (Boston College)
 Norman L. Cantor (Rutgers)
 Rebecca Dresser (Washington Univ.)
 Charles Fried (Former Solicitor General under Pres. Reagan)
 John A. Gilbert, Jr. (Former attorney in DEA's Office of General Counsel)
 Maxwell J. Mchlman (Case Western Reserve)
 James Vorenberg (Former Dean, Harvard Law School)

Major Newspapers/Medical Journals

Boston Globe (Ellen Goodman column)
Los Angeles Times
New England Journal of Medicine
New York Times
St. Louis Post-Dispatch
Washington Post

Life at Risk

A Chronicle of Euthanasia Trends in America

Vol. 10, No. 4 May/June 2000

NCCB Secretariat for Pro-Life Activities

Suicide Lobby Targets Pain Relief Act

While it approved the Pain Relief Promotion Act (H.R.2260) on April 27, the Senate Judiciary Committee waited until May 23 to file its report on the measure and clear it for full Senate consideration. While supportive groups are anxious that the legislation move forward as soon as possible, Senate Majority Leader Trent Lott has yet to schedule it for a vote.

The committee report includes a minority statement riddled with factual errors, signed by only four Democrats out of the committee's 18 members. The minority statement misreports the number of patients who have used Oregon's assisted suicide law to kill themselves using federally controlled drugs. That statement also quotes Justice Department criticisms made against a different 1998 bill, mistakenly citing them as criticisms of the current bill; and it claims the Act would overturn a "states' rights" feature of the federal Controlled Substances Act that was already repealed by Congress in 1984.

Judiciary Committee changes to the bill's language have won support from groups who earlier had concerns, including the American Academy of Pain Medicine and American Pain Society and some state medical societies. While some medical groups still oppose the Act, these are generally groups that do not share the American Medical Association's position against assisted suicide.

The American Academy of Family Physicians, for example, has urged President Clinton to veto the bill because it would require training of law enforcement personnel in "how to conduct investigations and enforcement actions" involving physicians' use of controlled substances [AAFP release, 5/23/00]. Actually it is existing law that calls for such training; the new bill urges training these officials in how to "better accommodate"

physicians' use of controlled substances for pain control. In fact AAFP may have another reason for opposing the bill. In 1996 its board endorsed a resolution, supported by almost half its Congress of Delegates, to formally reject the AMA position against assisted suicide [*Physician's Weekly*, 11/1/96]; the group has declined in recent years to join medical groups' Supreme Court briefs and other statements against the practice.

A more egregious example of hidden agendas can be found on the Web site of Hemlock of Wisconsin. The site urges members to help defeat the Act because it would "invalidate the Oregon Law legalizing Physician Aid in Dying." But it encourages them to use other arguments when they contact Senators. "Identifying as a Hemlock member probably won't help," the site advises [www.hemlock.wis.org/Hyde-Nickles.html].

It now seems that Senator Ron Wyden of Oregon, the Act's chief Senate opponent, may not have been candid about his own agenda. In an October 23, 1999 opinion piece in the *New York Times*, Wyden declared that he disagrees with his home state's policy allowing assisted suicide but opposes federal intrusion in that policy. But in the May 29 issue of *The Weekly Standard*, attorney Wesley Smith reveals that Wyden's chief aide working against the pain relief bill is a well-known pro-suicide activist. James L. Werth, a congressional fellow in Wyden's office, is a former board member of the Nebraska Hemlock Society and the Death with Dignity National Center. His books justifying "rational suicide" are sold on the national Hemlock Society's Web site.

Wyden and his allies in the assisted suicide movement do not have the votes or the arguments to defeat the Act outright. But they hope to make it controversial enough that Majority Leader Lott, facing a crowded Senate calendar in this election year, will not bring it to the Senate floor. Their ploy may still succeed.



News Briefs

"No" to Patent for Human Euthanasia

The European Union's patent office has ruled that a "euthanasia cocktail" devised by Michigan State University can't be used on humans.

The university first applied for the patent in 1994 for use in "mammals." But when critics pointed out that the application did not exclude use in humans, the university refused to amend it, saying that the law may change in the future to allow such use (see December 1996 *Life at Risk*).

The patent office's ruling was sought by the German Hospice Foundation, the drug company Hoechst and others. It requires re-formulating the patent to specifically exclude use on human beings (Reuters, 5/23/00; ZENIT News Agency, 5/26).

Assisted Suicide in State Courts

In **Colorado**, the state Court of Appeals has rejected a claim by an 81-year-old man that the state's ban on assisted suicide violates his federal constitutional right to "free exercise of religion."

Robert Sanderson, a former district judge, had made various constitutional claims in favor of a right to assisted suicide in 1996, but these were dismissed by a state district judge in 1998. He had appealed only his "freedom of religion" claim to the Court of Appeals, arguing that he "believes that God, or nature, intended that the free will of man be exercised in all circumstances according to his own best judgment with due consideration for others."

Citing the U.S. Supreme Court's 1990 ruling in *Employment Division v. Smith*, however, a three-judge panel of the Court of Appeals unanimously ruled that "an individual's religious beliefs do not excuse the individual from compliance with an otherwise valid law prohibiting conduct that the State is free to regulate." The court said it knows of no other case in which laws against assisted suicide were challenged on religious grounds [Associated Press, 6/8; *Sanderson v. State of Colorado*, Colo. Ct. of Appeals, No. 96CV0012 (June 8, 2000)].

In **Alaska**, however, a claim on behalf of a state constitutional right to assisted suicide will be heard by the state supreme court. The case is on appeal from a September ruling by a superior court judge, who found no such right in the Alaska constitution. The American Civil Liberties Union has filed a "friend of the court" brief in favor of the constitutional claim. Filing briefs against it are the National Legal Center for the Medically Dependent and Disabled, Alaska Catholic Conference, Alaskan Doctors Against Physician Assisted Suicide, Physicians for Compassionate Care, and the Alaska chapter of the disability rights group Not Dead Yet. The case will be argued this fall, with a ruling expected next year [Catholic News Service, 5/10].

Maine Campaign Kicks Off

A proposal to legalize physician-assisted suicide will appear at the top of Maine's November ballot this year. The ballot question, crafted by supporters, will read: "Should a terminally ill adult, who is of sound mind, be allowed to ask for and receive a doctor's help to die?"

Campaign finance reports show that Mainers for Death with Dignity raised \$605,018 through June 1 (chiefly from out-of-state sources) and spent \$595,384. Two groups opposing the initiative, the Coalition for the Compassionate Care of the Dying and Maine Citizens Against the Dangers of Physician Assisted Suicide, raised \$223,988 and spent \$156,499 in the same period. This led to reports that supporters are "outspending opponents by better than 3-1" [AP, 6/8] – which is somewhat misleading, because supporters spent almost half a million dollars solely for paid signature-gatherers to get the proposal on the ballot.

Reporting on a forum on the Portland campus of the University of New England on June 9, a local newspaper described it as a "major coup" for supporters that Dr. Marcia Angell, an editor of the *New England Journal of Medicine*, came out in support of the Maine proposal. Apparently the paper was unaware that Angell has ardently supported legalization of assisted suicide for years [Portland Press Herald, 6/10].

VERBATIM: SENATOR JOSEPH BIDEN ON THE PAIN RELIEF PROMOTION ACT

Mr. Chairman, I want to say a few words about the Pain Relief Promotion Act, a bill which I am proud to support.

This bill does two important things: it makes clear that prescribing pain medication -- *even when it may increase the risk of death* -- is a "legitimate medical purpose" under the Controlled Substances Act and it makes clear that prescribing medication for the purpose of assisting suicide is not.

Now, truth in advertising here -- I am opposed to legalizing physician-assisted suicide in this country, period.

In contrast to abortion -- where some may argue about whether or not there is a life at stake -- in assisted suicide there is no question that there is a human life in being. Physician-assisted suicide is the most dangerous slippery slope, in my view, that the nation can embark upon.

But this bill does more than just rule out the use of controlled substances to kill a patient. Just as important, it also urges doctors to educate themselves about pain management and palliative care and it makes clear that prescribing adequate pain medication *is* a legitimate use of controlled substances.

Currently, too many doctors are afraid to give a patient a high dose of pain killers for fear that their actions will appear suspicious or for fear that the remedy may have the "double effect" of hastening death. It is critical that doctors feel free to adequately manage pain so that patients do not suffer needlessly.

Now, let me dispel a couple of myths and tell you what this bill will not do. It will not have a "chilling effect" on pain management. Critics have alleged that if this legislation passes, the Drug Enforcement Administration will begin to investigate doctors more vigorously. That is certainly not the intent of this bill.

And furthermore the DEA has stated that they have no intention of investigating doctors unless the doctor has admitted to using controlled substances to kill a patient or if state authorities have concluded that was the case. The DEA has written:

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

If you need proof, just look at states which have passed measures similar to the one we are debating today. There has been no "chilling effect." Iowa, Kansas, Kentucky, Louisiana, Michigan, Tennessee, Rhode Island and Virginia have enacted laws making clear that providing pain medication even to the point where death is hastened is legitimate medical practice. And in each of those states, per capita use of morphine has increased as doctors feel more comfortable giving their patients the medication they need. I fully expect that passing the bill before us today will increase proper pain management nationwide.

This bill has the support of the medical community -- the American Medical Association, American Academy of Pain Management, National Hospice Organization, American Pain Society, American Academy of Pain Management, and the Catholic Medical Association. These groups would not lend their names to a piece of legislation which is not in the best interest of patients. I hope that my colleagues will join me in supporting this bill today.

- Statement in Senate Committee on the Judiciary, April 27, 2000

Life at Risk is published ten times annually by the Secretariat for Pro-Life Activities, National Conference of Catholic Bishops, 3211 4th Street NE, Washington D.C. 20017-1194. Editor: Richard M. Doerflinger. Phone: (202) 541-3070. Fax: (202) 541-3054. No charge for subscription; annual donation requested.
VISIT OUR WEB SITE: <http://www.nccbuscc.org/prolife/publicat/index.htm>

Background: Poll on Assisted Suicide and Federal Drugs

As the U.S. Senate prepares to consider the Pain Relief Promotion Act, a new national poll indicates strong support for the Act's policy – and remarkably high interest in assisted suicide as an election-year issue.

The Wirthlin Worldwide poll surveyed 1001 adults by phone May 19-23. It found 66% opposing use of federally controlled drugs for assisted suicide and euthanasia. Asked how important a candidate's position on assisted suicide and euthanasia would be in their vote, 31% said it would be "very important" in how they vote on election day – and 81% of that group would be more likely to support a candidate who opposes assisted suicide and euthanasia.

The survey, commissioned by the National Right to Life Committee, had a margin of error of $\pm 3\%$ for answers from the total sample. Questions were as follows:

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

Yes - 29%

No - 66%

Don't know/refused - 5%

"Generally speaking, how important will a candidate's position on the issues of assisted suicide and euthanasia be in determining whether or not you will vote for that candidate?"

Important - 64% (very important - 31%)

Not so important - 36% (not important at all - 18%)

Don't know/refused - 1%

Asked of the 638 respondents answering "very important" or "somewhat important":

"And, would you be more likely to vote for a candidate who [ROTATE] favors assisted suicide and euthanasia, or a candidate who opposes assisted suicide and euthanasia?"

Favor candidate opposing assisted suicide - 65%

Favor candidate supporting it - 32%

Depends on the candidate - 2%

Don't know/refused - 2%

Same question asked of the 311 respondents viewing the issue as "very important":

Favor candidate opposing assisted suicide - 81%

Favor candidate supporting it - 18%

Depends on the candidate - 1%

Don't know/refused - 1%

[Source: Release by National Right to Life Committee and Wirthlin Worldwide, 5/30/00]

Return Service Requested

Washington, D.C. 20017-1194

3211 4th Street NE

NCCB Secretariat for Pro-Life Activities

Life at Risk

Americans for Integrity in Palliative Care

"To care, always...to kill, never"

**200 Daingerfield Road
Suite 100
Alexandria, VA 22314
(703) 684-8352
fax (703) 684-5813**

Communications Counsel

**Eugene Tarne
Michelle Powers**

Founding Members

C. Everett Koop, M.D.

Herbert Hendin, M.D.

Eric Chevlen, M.D.

Walter R. Hunter, M.D.

Wesley J. Smith, Esq.

Edmund Pellegrino, M.D.

Ralph Miech, M.D., Ph.D.

Carlos F. Gomez, M.D., Ph.D.

William Toffler, M.D.

N. Gregory Hamilton, M.D.

James Towey, Esq.

FOR IMMEDIATE RELEASE
April 6, 2000

CONTACT: Gene Tarne/Michelle Powers
(703) 684-8352

AMERICANS FOR INTEGRITY IN PALLIATIVE CARE URGES SENATE APPROVAL FOR PAIN RELIEF PROMOTION ACT

*Palliative care providers and their patients deserve
protections and improved care that bill promotes*

Americans for Integrity in Palliative Care urges the Senate Judiciary Committee to approve the Pain Relief Promotion Act (S. 1272), which the committee will consider today. The Pain Relief Promotion Act will give the federal government's endorsement and financial support to the urgent task of improving pain management and palliative care services for the chronically and terminally ill, without approving assisted suicide. The legislation provides new protection for doctors using controlled substances in the provision of palliative care.

The legislation Pain Relief Promotion Act has been endorsed by the nation's leading professional medical societies, including the American Medical Association, the American Academy of Pain Management, the National Hospice and Palliative Care Organization, and the American Society of Anesthesiologists, among others.

This legislation has already passed the House with an overwhelming bipartisan majority, 271 to 156.

Americans for Integrity in Palliative Care urges the Senate to quickly pass the Pain Relief Promotion Act. Doctors and their patients deserve no less.

-###-

Americans for Integrity in Palliative Care

"To care, always...to kill, never"

April 3, 2000

Dear Judiciary Committee Member:

**200 Daingerfield Road
Suite 100
Alexandria, VA 22314
(703) 684-8352
fax (703) 684-5813**

Communications Counsel

**Eugene Tarne
Michelle Powers**

Founding Members

C. Everett Koop, M.D.

Herbert Hendin, M.D.

Eric Chevlen, M.D.

Walter R. Hunter, M.D.

Wesley J. Smith, Esq.

Edmund Pellegrino, M.D.

Ralph Miech, M.D., Ph.D.

Carlos F. Gomez, M.D., Ph.D.

William Toffler, M.D.

N. Gregory Hamilton, M.D.

James Towey, Esq.

Some medical groups have criticized the proposed federal Pain Relief Promotion Act which your committee will soon consider. We believe, however, that such criticism is based on an incomplete understanding of this important legislation's meaning and effect. Specifically, some groups have expressed a fear that legislation of this kind may expand federal authority over pain control, intrude into medical practice, or overturn state guidelines on pain management.

Americans for Integrity in Palliative Care supports this legislation. Having studied the bill, we agree with the conclusions reached by the American Medical Association's Reference Committee on Legislation in December (following): Objectively, such charges are without merit. In fact, this bill does just the opposite. But to understand why, it is necessary to be clear on certain key terms in federal law.

The Pain Relief Promotion Act writes the following two sentences into the federal Controlled Substances Act:

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

To understand what this provision achieves for physicians practicing pain management, one must be clear on the meaning of the key phrases "usual course of professional practice" and "legitimate medical purpose." Both are terms of art with definite legal meanings.

By saying that a physician must be practicing within "the usual course of professional practice," the Act defers to professional societies and state licensing authorities as to how one defines the scope of medical practice. As one legal expert has written, "when a physician prescribes a controlled substance in the course of professional practice, he or she is outside the DEA's [Drug Enforcement Administration's] enforcement authority. The responsibility for policing prescriptions of these drugs in the course of professional practice rests with state regulatory authorities, such as state medical boards" (Charles Wilson, "Establishing a Right to Palliative Care at the End of Life" (www.bazelon.org/pall8ari.html)).

By saying that a physician who so practices shall be seen by the federal government as serving a "legitimate medical purpose," the Act is not creating new federal authority or establishing a new federal definition of medicine. On the contrary: It is establishing that the entire practice of pain control (as defined by professional societies and states), up to and including pain control that may increase the risk of death, is to be left alone

by the DEA. This is because the DEA has no authority to regulate medicine as such -- it only has authority to prevent "diversion" to "non-medical" purposes which endanger health and safety. As the Justice Department stated in a letter to House Judiciary Committee chairman Henry Hyde last October: "Because a physician who acts with a 'legitimate medical purpose' is acting in compliance with the Act, H.R. 2260 creates a 'safe harbor' against administrative and criminal sanctions when controlled substances are used for palliative care."

So a translation into ordinary English of the proposed Act might read as follows: "If you're practicing pain control in accord with the medical standards set by your profession and/or your state licensing authorities, the DEA now has orders from Congress to leave you alone to do your job. In particular, the DEA must recognize that the side-effect of increasing the risk of death, when this is demanded by the needs of aggressive pain control, is ethically accepted throughout the profession and should not be confused with illicit activity." This new protection, of course, does not extend to cases where a doctor intentionally gives out drugs for the purpose of causing people's deaths -- but then, that is a felony in almost every state already, and has never been accepted by the profession or by the federal government as part of ethical medical practice.

This does not mean that states have absolute and unreviewable authority to define the scope of federal law -- that has never been true under the Supremacy Clause of the Constitution. But federal law will prevail over state law (and even then, only for purposes of implementing the federal law) in cases of direct conflict. And the only time a state law could conflict with this federal law is when (a) it tries to authorize deliberate killing of patients or (b) it tries to condemn doctors who do pain control that may unintentionally hasten death. The first case is of interest only to Oregon; the second has been more than a theoretical threat in some states, and doctors should welcome another authority to cite in their defense. Some state prosecutors have actually tried to indict doctors for homicide when their hospice patients die with large doses of morphine in their bodies. Now doctors in these situations will be able to point to the acceptance of the principle of double effect in federal law.

Even the existence of this clear federal standard does not force the states to change their state laws: for example, a state may still allow doctors who assist suicides to keep their state medical licenses. But the fact that federal law explicitly accepts the principle of double effect can certainly be used in state proceedings to show how broadly the principle is accepted.

The charge that it is inappropriate for government to judge "intent to kill" in such cases is simply thirty years late. The federal Controlled Substances Act has always authorized the DEA to revoke the federal registrations of doctors who use those registrations to violate state laws. The vast majority of state laws already make it a crime to "intentionally" assist a suicide; and the DEA has the authority already to make its own determination as to whether each element of the crime was proved. The new bill doesn't change any of this: its only new legal effect is to provide new protection for pain control that may unintentionally hasten death. If the government thereby finds it more difficult to pursue doctors because it has to prove "intent," that is a difficulty that protects the physician, giving him or her every benefit of doubt.

State medical societies are understandably concerned that the law should give as much deference as possible to local professional standards and to individual physicians practicing aggressive pain control. It is tragic that when a law finally comes along that does just that, it is opposed because key legal terms are being misunderstood.

More details on the relationship between federal law and state guidelines on pain control are set forth in the following fact sheet by AIPC. I hope this information is helpful in your consideration of this important legislation, which we believe deserves your support.

Sincerely,


Gene Tarnie

Communications Counsel
Americans for Integrity in Palliative Care

Americans for Integrity in Palliative Care

"To care, always...to kill, never"

200 Daingerfield Road
Suite 100
Alexandria, VA 22314
(703) 684-8352
fax (703) 684-5813

Communications Counsel

**Eugene Tarne
Michelle Powers**

Founding Members

C. Everett Koop, M.D.

Herbert Hendin, M.D.

Eric Chevlen, M.D.

Walter R. Hunter, M.D.

Wesley J. Smith, Esq.

Edmund Pellegrino, M.D.

Ralph Miech, M.D., Ph.D.

Carlos F. Gomez, M.D., Ph.D.

William Toffler, M.D.

N. Gregory Hamilton, M.D.

James Towey, Esq.

The Pain Relief Promotion Act and State Guidelines on Palliative Care: Compatibility, Not Conflict

A question has been raised whether the Pain Relief Promotion Act (PRPA) of 1999 will somehow override or preempt helpful regulations on palliative care that have been enacted by the states. Americans for Integrity in Palliative Care believes any concern on this point is misplaced, for the following reasons:

- While states sometimes have reason to be wary of federal intrusions into their practices, such misgivings do not apply to the Pain Relief Promotion Act. This is clear from the language of the bill itself and from the bill's intent, as made explicit by one of its sponsors, Tom Coburn, a practicing physician and Representative from Oklahoma:

"Is it the intent of this bill to undermine States' ability to help patients access appropriate palliative care? No, it is not the intent whatsoever. Is it the intent of this bill to create a fear on the part of physicians so they will not do the proper thing when it comes to caring for end-of-life, pain-enduring patients? No, that is not the intent. And that is not the consequence... What we actually do is define better so that we do not put physicians at risk and give them a safe harbor."

"Are we trying to go around guidelines for end-of-life issues in the State? No, we are not trying to do that at all. What we are trying to say is have whatever guidelines they want, but as far as the use of narcotics, we do not think that those narcotics ought to be used to intentionally take a life."

— Rep. Tom Coburn, Congressional Record, 10/27/99, page H10880

- No state law on palliative care will be superseded by the Pain Relief Promotion Act. The legislation merely clarifies that it is no violation of the federal Controlled Substances Act (CSA) to dispense, distribute or administer a controlled substance to alleviate pain or discomfort. This provision has the effect of bringing federal law into conformity with similar provisions already enacted by the states. When state guidelines allow a pain management practice — up to and including one that may involve unintentionally hastening death — health professionals will now have explicit assurances that they need not fear federal liability for following such guidance.
- States will remain free, as they always have been, to enact their own legislation on palliative care. Any additional standards that the states may set to ensure that pain management is practiced in the most responsible and effective manner remain completely within their authority. Section 201 of H.R. 2260 actually instructs the Department of Health and Human Services to "collect and disseminate" such existing protocols and make them more widely available so physicians in other states can learn about available resources in this field. Obviously this provision would make no sense if the legislation

were designed to preempt such protocols. American Medical Association President Thomas Reardon, M.D. correctly notes that the PRPA "does not pre-empt state initiatives that encourage pain management."

- **Strictly speaking, even the Oregon law is not preempted or overturned by the federal bill.** Only when state and federal laws directly conflict with each other, as when one law *requires* what another *forbids*, does federal preemption arise in this field of law [Cf. Aspen Health Law Center, *Pharmacy Law Answer Book* (Aspen Publications: Gaithersburg, MD 1996), p. 9; R. Abood and D. Brushwood, *Pharmacy Practice and the Law* (Aspen Publications: Gaithersburg, MD 1997), p.23]. Oregon state law allows assisted suicide in certain cases, while the federal law adds that if such assisted suicides are done there are certain federally controlled drugs that cannot be used for the purpose. Both laws continue to stand, since the Oregon law does not require that suicides be assisted using federally regulated drugs. In the other 49 states, there is no conflict at all between the federal law and state laws providing for the use of controlled substances to manage pain.

In Oregon, doctors will simply have to use drugs that do not implicate the federal government in actively facilitating and supporting assisted suicide. As AIPC founding member Dr. Walter Hunter notes: "Under this law, Oregon physicians and patients will remain free to pursue assisted suicide. They just cannot use the medications covered by the Controlled Substances Act (CSA). And that should not create undue hardship since, to my knowledge, no double blinded controlled clinical studies have been conducted anywhere to determine the precise lethal dose of these medications. In other words, Oregon physicians can use any medication not covered by the CSA to cause death. And they can use it as they have been doing with controlled substances: guessing at the dose necessary to cause death 100% of the time for those patients they wish to see dead."

-###-



Washington, D.C. 20537

APR 05 2000

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

Dear Chairman Hatch:

This is in response to your request for the position of the Drug Enforcement Administration (DEA) on a proposed amendment to the Pain Relief Promotion Act of 1999, H.R. 2260. This amendment would raise the burden of proof in administrative hearings involving physician-assisted suicide from the preponderance-of-the-evidence standard to a clear-and-convincing evidence standard. DEA opposes this amendment.

The imposition of the clear-and-convincing evidence standard would be an abrupt departure from the standard of proof that has always been applied in administrative cases under the Controlled Substances Act (CSA). Starting with the enactment of the CSA in 1970, and continuing to the present, Congress has mandated that proceedings to deny, revoke, or suspend registration be conducted in accordance with the Administrative Procedure Act (APA). Under the APA, the preponderance-of-the-evidence standard is to be applied in administrative proceedings. *Steadman v. S.E.C.*, 450 U.S. 91 (1981). This standard, along with the other procedural safeguards contained in the APA, has been in effect for more than 50 years. DEA finds no reason to depart now from this traditional approach.

DEA does not support the concept of applying different evidentiary standards depending on the nature of the particular administrative case, which is inherent in the proposed amendment. DEA believes that the preponderance-of-the-evidence standard should continue to be applied uniformly in all administrative cases. See 21 U.S.C. §§ 823(f), 824(a) (listing factors to be considered for denial or revocation of registration).

Even in Oregon (the only state that expressly authorizes physician-assisted suicide), the preponderance-of-the-evidence standard applies in state medical licensing proceedings. See *Gallant v. Board of Medical Examiners*, 159 Or.App. 175 (1999) This illustrates how the APA standards properly remain the model for administrative proceedings throughout the nation.

H.R. 2260 does not alter the long-standing federal requirement that controlled substances be dispensed only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The bill simply makes clear that, in determining whether a registration is consistent with the public interest, the Attorney General (and DEA, by designation) "shall give no force and effect to State law authorizing assisted suicide or euthanasia." Since Oregon is the only state with a law permitting assisted suicide, DEA's authority to take administrative action in every other state would not be changed by H.R. 2260.

There is no foundation to the allegation that if H.R. 2260 were enacted DEA would seize the opportunity to investigate patient deaths. It has always been state and local authorities who take primary responsibility for investigating suspicious deaths. DEA has no plans -- and lacks the resources or expertise -- to take this role from the state and local authorities.

I also wish to comment briefly on the pain treatment aspect of H.R. 2260. As indicated in the bill, the issue of pain treatment is distinct from the issue of physician-assisted suicide. I agree with and support the provision of the bill which specifies that the dispensing of a controlled substance to alleviate pain or discomfort in the usual course of professional practice is a legitimate medical purpose, even if the use of such substance may increase the risk of death.

I understand that there are some who have made the claim that this law will make practitioners reluctant to dispense controlled substances in the quantities required to properly treat pain. I want to emphasize that DEA fully supports the effective treatment of pain. This is clearly demonstrated by the fact that DEA has dramatically increased the annual quotas for pain medications over the past ten years. During this period, the morphine quota has been increased by a factor of 2.5, fentanyl by a factor of 7.75, oxycodone by a factor of 3, hydromorphone by a factor of 3.3 and hydrocodone by a factor of 3. In addition, DEA has worked actively with the Federation of State Medical Boards in its development of the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. These guidelines were adopted on May 5, 1998 and DEA fully supports them. I am concerned by statements indicating that some groups do not understand our position on pain relief. Members of my staff are available to meet with representatives of these groups to discuss this critical health care issue.

If you have any additional questions, please contact me at (202) 307-8000.

Sincerely,



Donnie R. Marshall
Acting Administrator

Facts
about the
revised
"Pain Relief
Promotion
Act":

It Remains Bad Medicine for Patients

effectively treating pain, and it should be defeated...

"The bill claims not to 'alter the roles of the federal and state governments in regulating the practice of medicine,' but then goes on to do just that, declaring that 'the attorney general shall give no force and effect to state law authorizing or permitting assisted suicide or euthanasia.'

"Hatch's bill would effectively require the federal Drug Enforcement Administration to determine whether physicians are appropriately prescribing pain medications. That is a task that, as the DEA admitted in a letter to Congress last month, it 'lacks the resources or the expertise' to do.

"There's also no evidence that doctors are over-medicating patients to hasten their deaths. On the contrary, the few studies that do exist indicate that under-medication of the terminally ill is more of a problem. For instance, a 1998 New York state task force on pain management polled 3,000 physicians and found 71% admitting that they had under-medicated patients for pain to avoid being punished by state medical boards."

The San Jose Mercury News
April 6, 2000

Compassionate death? Or painful?

"Who is best qualified to decide how much pain medication to prescribe for severely ill people in the last days of their lives: doctors or cops?..."

"The bill makes it legal for doctors to prescribe doses of morphine and other controlled drugs that may increase the risk of death, but makes it a crime punishable by 20 years in prison to prescribe drugs with the intent of causing death.

Editorials opposing the so-called "Pain Relief Promotion Act" (HR 2260)

Los Angeles Times
April 26, 2000,

Do Not Suffer This 'Pain Relief' Bill

"Sen. Orrin Hatch's Pain Relief Promotion Act is... hardly true to its name. Its broad provisions, far from improving palliative care, could in fact discourage doctors from

"As any doctor knows, the line between increasing the risk of death and intentionally causing death is fine indeed. Some patients can tolerate huge doses of medication that would kill others. Compassionate physicians routinely prescribe amounts that they know will hasten death when there is no alternative to agonizing pain.

"Threatened with DEA investigations and prison, doctors are likely to under-medicate, and the severely ill and their families will suffer..."

"Doctor or cop? Think about it. Which one would you want calling the shots if you or a loved one were facing agonizing pain and no hope of recovery?"

The Washington Post
February 16, 2000

A Bad Bill on Dying

"The House last year used a seemingly hard-to-oppose cause, pain relief for the dying, to camouflage and pass a bill that essentially overturned Oregon's controversial law legalizing assisted suicide. Now the Senate may take up the ill-conceived, misleadingly named Pain Relief Promotion Act.

"One can have serious qualms about legalizing assisted suicide, as we do, and still object to Congress's repeated efforts to reverse a state's legitimate attempt to find its own way on a contentious and troubling subject..."

"This year's bill purports to fix the problem by limiting penalties to drugs prescribed 'with the intent' to cause death. (It also allocates money for palliative care.) But the fix doesn't work. Doctors who treat the dying say the line is inevitably fuzzy between a dose that hastens death and one that merely eases it; doctors (or nurses or pharmacists) afraid of criminal sanctions would be deterred not just from the former but from the latter as well."

The New York Times
August 14, 1999

Flawed Pain-Relief Bill

"In a misguided effort to legislate against physician-assisted suicide, a bill awaiting action in the House Judiciary Committee could discourage

doctors from providing aggressive pain relief to patients with terminal illnesses...

"The new bill tries to address that concern by declaring that alleviating pain through drugs is a legitimate medical purpose, 'even if the use of such a substance may increase the risk of death.' But doctors would still have reason to worry that they could be investigated and charged with intent to cause death even when no such intent existed..."

"The bill would also undo the Oregon Death With Dignity Act, a voter-approved state statute that allows physician-assisted suicide in narrow circumstances for terminally ill patients. There is no reason for the federal government to usurp the right of Oregon or any other state to regulate medical practices according to the will of the voters..."

"The House should help desperate patients by dropping the ill-conceived restrictions on doctors, and focus instead on more federal support for palliative care."

St. Louis Post Dispatch
October 31, 1999

Legislating pain and death

"The most serious public issue standing in the way of our right to die peacefully is not the tortuous ethical question of physician-assisted suicide. It is under-treatment of pain by doctors fearful of criminal prosecution if powerful medications hasten the death of the terminally ill.

"The House passage of the Pain Relief Promotion Act of 1999 can only heighten our fears. Sponsored by pro-life activist Henry Hyde of Illinois, the bill would effectively overturn Oregon's law – twice passed by voters – allowing physicians to prescribe, but not administer, lethal drugs for a patient with less than six months to live.

"It's troublesome that the House overturned the will of Oregon's people. Equally disturbing is the House's overruling of Attorney General Janet Reno, who had said the federal government would not prosecute Oregon doctors who assisted in suicides within the parameters set down by Oregon's law. The bill is expected to pass the Senate and be signed by President Bill Clinton, even though the Justice Department criticized the

act as 'heavy-handed.' Mr. Clinton opposes physician-assisted suicide.

"Just as alarming is the chilling effect this law would have on doctors treating patients who don't want to die, but just live their final days in the absence of agony... This is a meddling bill that would make bad law."

The New England Journal of Medicine
December 16, 1999

Caring for the Dying – Congressional Mischief

"If the bill becomes law, it will almost certainly discourage doctors from prescribing or administering adequate doses of drugs to relieve the symptoms of dying patients. To be sure, the bill pays lip service to promoting adequate pain relief. It states that doctors may use controlled substances to alleviate pain or discomfort, 'even if the use of such a substance may increase the risk of death' – a prerogative doctors have always had. But in the next sentence, it forbids 'intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death.' Thus, the bill turns on discerning physicians' intentions in administering controlled substances and provides for harsh penalties if those intentions are found not to conform with a 'legitimate medical purpose.'

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



Secretariat for Pro-Life Activities

3211 Fourth Street, N.E. Washington, DC 20017-1194 (202) 541-3070 FAX (202) 541-3054

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

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

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

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

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

Was the law directed against physicians?

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

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

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

physical injury and danger, they involve more than half of the hospital entries for illegal use and overdose of drugs" (Rep. Sawyer, Cong. Record, 9/18/84, H9680).

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

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

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

Columnist: It's time to stop federally assisted suicides

By Richard M. Doerflinger

The most urgently needed pro-life legislation of this Congress now stands ready for Senate floor debate. The lives and well-being of countless vulnerable citizens hang in the balance as senators decide what action to take next.

The bill is the Pain Relief Promotion Act (H.R. 2260, S. 1272), a measure to encourage use of federally controlled drugs for pain management without allowing assisted suicide and euthanasia. It was overwhelmingly approved by the House of Representatives last fall; now it has finally been approved by the Senate Judiciary Committee and cleared for Senate floor action.



Richard Doerflinger

The act contains much that should be welcomed by doctors and patients concerned about good care for dying patients. It takes a first step toward "mainstreaming" palliative care as an integral part of good medicine: establishing an information exchange on guidelines for optimum care, and providing \$5 million a year in training grants for health professionals to improve



pain control for the chronically and terminally ill. It also provides a legal "safe harbor" for physicians working in the usual course of professional practice to alleviate intractable pain, including cases where the large doses needed for pain control may unintentionally risk hastening death.

Under current law, the federal Drug Enforcement Administration (DEA) can scrutinize all use of controlled substances like morphine, to ensure that they are used only for "legitimate medical purposes" and are not abused to endanger "public health and safety." The problem is, the law is not clear on where "legitimate medicine" ends and threat to "health and safety" begins. So a doctor who uses large doses of painkillers may be suspected of "excessive prescribing" and investigated for wrongdoing. The result: Many doctors become overly cautious in prescribing these powerful drugs — or never obtain a DEA prescribing license to use them at all.

The new act tells the DEA to defer to doctors' medical judgment in this area, freeing health professionals to use whatever dosage will effectively relieve pain. It is no surprise, then, that the act is en-

dorsed by the American Academy of Pain Medicine, American Pain Society, National Hospice and Palliative Care Organization, and American Medical Association (AMA).

So why is it taking Congress so long to pass the act? It has to do with two sentences in this 10-page bill. To clarify the outer limit of the "safe harbor" for physicians, the act reaffirms that federal law does not "authorize" intentional use of these drugs for the purpose of killing patients. It adds that this federal standard remains intact even if a state drops its own legal penalties for assisting suicides.

The most urgently needed pro-life legislation of this Congress now stands ready for Senate floor debate.

These are modest and sensible provisions, restating that the federal government does not want to get into the business of assisting suicides. But it has ignited a firestorm of protest from Oregon Senator Ron Wyden, whose state has legalized physician-assisted suicide, and from a few medical groups who don't think assisted suicide is such a bad idea.

Opponents of the bill claim to be concerned about other issues.

They say the bill will somehow actually suppress pain control instead of promoting it — a difficult claim to take seriously, when states enacting similar laws against assisted suicide have seen dramatic increases in use of morphine for pain control. They say the bill infringes on "states' rights," although it simply clarifies the scope of the "legitimate" purposes for which a federal prescribing license may be used. The bottom line is that if these opponents prevail, the federal government will keep actively assisting the killing of patients in Oregon by providing the lethal means.

Increasingly, it is clear that such groups are driven by a particular view of assisted suicide itself. A few state medical societies oppose the bill, but generally they are the same state affiliates — Oregon, Vermont, Rhode Island — that dissent from the AMA's position against assisted suicide. The American Pharmaceutical Association opposes the bill, but has a policy opposing any law that forbids pharmacist-assisted suicide. The California Medical Association is urging the AMA to reverse course and oppose the bill, but its chief argument is that the federal bill would counter Oregon's "important and overdue effort" to legalize assisted suicide!

Finally, as revealed in an article by Wesley Smith in the May 29

issue of the *Weekly Standard*, Senator Wyden himself is working hand-in-glove with the assisted suicide movement. His top advisor on the bill, psychologist James L. Werth, has served on the board of the Nebraska Hemlock Society and written books justifying "rational suicide."

These findings should strengthen the resolve of Congress to pass what may be the only pending pro-life bill with a good chance of being signed by President Clinton. The only reason now for the Senate not to move this bill is that it simply can't work up sufficient concern about the federal government's current role in helping to kill terminally ill patients in Oregon.

The fact is this: Each of the 43 patients committing state-approved suicides thus far in Oregon received their lethal doses by federal authorization, using federal prescribing licenses. If that doesn't send a chill up the spines of lawmakers concerned about abuse of government power, nothing will.

Once you find an abuse this egregious, you put a stop to it. The Senate's Republican leadership should not delay, but bring up the Pain Relief Promotion Act now.

Mr. Doerflinger is Associate Director for Policy Development at the Secretariat for Pro-Life Activities, National Conference of Catholic Bishops.

Secretariat for Pro-Life Activities

3211 Fourth Street, N.E. Washington, DC 20017-1194 (202) 541-3070 FAX (202) 541-3054

Past Cases Show DEA Authority to Act Against Assisted Suicide

Currently, practitioners run afoul of the federal Controlled Substances Act if their actions cause or contribute to the use of federally regulated drugs for fatal or near-fatal overdoses. In one recent case, a doctor was denied a DEA registration because he gave potentially lethal drugs to a depressed patient who *he should have known* might well use them for suicide. The following list of cases from the *Federal Register* is far from exhaustive:

- 1. 60 FR 56354 (Nov. 8, 1995): Case of Dr. Hugh Schade:** The doctor was negligent because he gave potentially lethal amounts of Darvocet to a depressed patient who used them to commit suicide. Giving these drugs to a patient in this mental state, said one expert witness, was "like handing him a loaded gun." While Dr. Schade was also convicted of negligent homicide under state law because of this case, his DEA application was denied not on the basis that he had violated a state law [21 USC § 823(f)(3)], but on the separate basis that his conduct objectively threatened "public health and safety" [21 USC § 823(f)(5)].
- 2. 62 FR 16189 (April 4, 1997): Case of Dr. Jose R. Castro:** Here a patient died of a drug overdose using controlled substances which the doctor prescribed "for no legitimate medical reason." The doctor had lost his state license to prescribe controlled substances on this basis, so it was automatic that he lost his federal registration as well; there was no need to apply the "public health and safety" standard independently.
- 3. 49 FR 6577 (February 22, 1984): Case of Dr. Samuel Fertig:** A physician was denied a DEA registration because he had prescribed massive quantities of controlled substances to several young people who used them in lethal overdoses. Acknowledging that the physician had been restored to full medical licensure in his state, the DEA Administrator nonetheless ruled that the physician "was responsible, directly or indirectly, for the deaths of several young people" (49 FR at 6579) and hence that the application must be denied to protect "public health and safety."
- 4. 63 FR 8477 (February 19, 1998): Case of Townwood Pharmacy:** A woman reported to the DEA that her daughter, who had a drug problem, had overdosed several times using drugs from this pharmacy. From the notice it is clear that if this was proved, it would have counted against the pharmacy under the "public health and safety" standard; but there was no clear evidence that the woman obtained the drugs from this pharmacy. The pharmacy's registration was revoked on other grounds.
- 5. 55 FR 5306 (Feb. 14, 1990): Case of Dr. Murray J. Walker, Jr.:** This physician prescribed Percodan for non-medical purposes to several people; one woman died of a drug overdose. Her boyfriend then cooperated with investigators because he believed the physician "was responsible for the woman's death" (55 FR at 5306). In revoking the physician's registration the DEA noted: "Substances are controlled because they are potentially dangerous and therefore should be handled with extreme care. Respondent has failed to exercise such care and, as a result, has ignored his duties as a health care professional to protect the public health and safety from the illicit use of these drugs" (Id. at 5307).

6. **55 FR 4250 (February 7, 1990): Case of Dr. Rodrigo I. Ramirez:** While conducting an unauthorized treatment program for drug addicts, this physician issued a prescription for large quantities of Dolophine and Xanax to a patient who died the next day from an overdose. The Oklahoma Medical Board suspended his state registration to prescribe certain controlled substances, but later reinstated him under supervision. The DEA concluded that he had “prescribed controlled substances without medical need and in excess of the amount considered good medical practice” (55 FR at 4252). Despite the physician’s argument that he had been sufficiently punished under state law, the DEA revoked his federal registration, saying: “The Administrator cannot and will not in all cases rely on state authorities to monitor and regulate a registrant holding a DEA controlled substances registration where there is evidence that the registrant has violated Federal law and has demonstrated conduct which may further threaten the public health and safety” (Id. at 4252).

7. **45 FR 61047 (September 15, 1980): Case of Dr. Joyce E. Millette:** This physician supplied controlled substances to many drug addicts, including one man who used the drugs in a lethal overdose and a young man who was rendered unconscious by an overdose. The second young man’s father, a dentist, testified that the physician “had prescribed drugs without adequate knowledge of the condition or medical background of the patient, in strengths and amounts which could have brought about dependency and possible death” (45 FR at 61048). At least two other potentially fatal drug overdoses were attributable to drugs the physician had prescribed. The DEA noted: “A DEA registration carries with it enormous potential for harm. Controlled substances, properly administered or prescribed, may be very useful in the course of medical treatment. Improperly used, they have the potential for dependency, addiction and even death” (Id. at 61048). Revoking the physician’s registration, the DEA noted that “several overdose incidents and at least one death were attributable to the controlled substances she prescribed. The Administrator finds it hard to conceive of a more compelling case for revoking a registration or denying an application” (Id. at 61049). The Administrator also expressed regret that the law at that time did not allow for effective DEA action prior to a physician’s “prosecution and conviction” under state law, noting: “In a case such as this, such a procedure might conceivably have saved lives” (Id. at 61049). [Four years later the DEA received such authority from Congress to revoke registrations independently of whether state law had been violated.]

8. **51 FR 5422 (February 13, 1986): Case of Dr. Rex A. Pittenger:** This physician “prescribed numerous controlled substances for no apparent legitimate medical reason.” After one patient died of a drug overdose, he was convicted of involuntary manslaughter and other felonies in one state and lost his medical license in another; on these grounds both his DEA registrations were revoked.

9. **48 FR 49937 (October 28, 1983); 54 FR 53382 (December 28, 1989); 59 FR 6297 (February 10, 1994): Case of Dr. David W. Bradway:** This physician’s registration was revoked after he was convicted under state law on various counts, most notably “one count of manslaughter by unlawfully distributing controlled substances in such a grossly negligent [and] reckless manner as to cause the death of an individual” (48 FR at 49937). Years later, after allegedly rehabilitating and resuming medical practice, the physician applied for a new DEA registration; citing the fact that “a death was directly attributable to Respondent’s misuse of his DEA Certificate of Registration,” the DEA denied the application, stating: “It is the position of

the DEA that a Certificate of Registration to handle controlled substances is a privilege, not a right, and it should only be granted to doctors who have demonstrated high standards of ethical conduct and who are completely trustworthy in handling dangerous controlled substances which, as can be seen in this case, can have a devastating impact on individuals who abuse them" (54 FR at 53384). In 1992, again applying for a DEA registration, the physician "testified with great sincerity and obvious pain concerning the remorse and regret that he felt about the events leading to the individual's death" and submitted a psychiatric report and further evidence of rehabilitation (59 FR at 6298). However, due to "the egregious nature of Respondent's past conduct," the DEA ruled in 1994 (15 years after the patient's death) that "the registration of the Respondent is still not in the public interest" (Id. at 6299).

10. **55 FR 37579 (September 12, 1990): Case of Dr. Pompeyo Q. Braga Bonado:** The DEA found that granting a registration to this physician would be "clearly contrary to the public interest." 55 FR at 37580. The physician had prescribed controlled substances to several individuals "for no legitimate medical purpose," including one man addicted to Percocet who was hospitalized after a suicide attempt. "As a health care professional and DEA registrant," the DEA noted, "Respondent bears a heavy responsibility to ensure that the controlled substances he prescribes are not abused." Id. at 37580.

11. **59 FR 46063 (September 6, 1994): Case of Dr. John W. Copeland:** This physician's registration was revoked because he had prescribed Ritalin and other drugs to many addicted persons without a legitimate medical need. One patient obtained anabolic steroids from the physician after revealing that he had taken them in the past, was depressed and had attempted suicide ten months earlier; a medical expert testified that it is "medically dangerous" to give anabolic steroids to a patient with prior depression. The DEA found that the physician's continued registration was contrary to the public interest, in part because his actions endangered public health and safety.

Several of these cases illustrate two points. First, in judging whether continuing a registration will serve the "public interest," the DEA may assess whether the registrant's practice threatens "public health or safety" independently of whether he or she can be shown to have violated state law. Second, while the *absence* of a state license automatically means that the federal government will issue no license, the converse is not true -- that is, "state licensure is a necessary *but not sufficient* condition for DEA registration" (63 FR at 8479 [Feb. 19, 1998]). Under current law, DEA registration requirements do not depend solely upon the policies of individual states.

October 18, 1999

ACTION MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed
Chris Jennings

SUBJECT: Assisted Suicide Legislation

On Wednesday, the House is tentatively scheduled to vote on H.R. 2260, the Pain Relief Promotion Act of 1999. As you will recall, this legislation, sponsored by Congressman Hyde, modifies the Controlled Substances Act (CSA) to create criminal penalties for the use of a controlled substance in physician assisted suicides. It also takes new steps to protect the appropriate provision of palliative care, a significant modification to the previous version of this legislation.

While the Department of Justice strongly supports the palliative care provisions of the bill, it has strong concerns about the federalism issues it raises and the penalty structure it creates. They would like to forward the attached letter of opposition to the House Judiciary Committee outlining these concerns. This letter does not include a veto threat. We recommend that the letter be sent, but that the White House refrain from public comment on the legislation.

BACKGROUND

Representative Hyde introduced the H.R. 2260 this summer. It is the second generation of the legislation known as the Lethal Drug Abuse Prevention Act of 1998 (LDAP). As you will recall, you and virtually every respected consumer and health care provider group, including the AMA, opposed LDAP because of the fear that the legislation would inhibit pain relief for the terminally ill. The provisions of most concern to provider and consumer groups included the establishment of broad prosecutorial authority for law enforcement officials, allowing the investigation of health care providers that were suspected of planning to use or of having used a controlled substance to assist in a suicide, and the absence of a proactive statement protecting the provision of appropriate palliative care.

H.R. 2260 would make physician-assisted suicide using controlled substances subject to administrative, civil, and criminal sanctions, and effectively ban the practice in all 50 states. However, Representative Hyde has modified the old version of this legislation to incorporate an explicit statement that using a controlled substance to alleviate pain and discomfort is a legitimate medical purpose, even if the use of the controlled substance increases the likelihood of death. It also narrows prosecutorial authority to suspected cases of the use of a controlled substance in an assisted suicide, and requires local, state, and Federal law enforcement personnel to receive information on palliative care in continuing education programs. Because

of these modifications, the bill is now supported by many of the groups who previously opposed it, including the AMA, the National Hospice Association, and the National Academy of Pain Management.

Notwithstanding the modifications to the bill, a number of provider organizations, including the American Nurses Association and the American Academy of Family Physicians, still oppose this legislation because they feel that H.R. 2260 will place the Department of Justice in the position of regulating the practice of medicine, which is traditionally the purview of the states. In addition, since this legislation would effectively nullify the Oregon Death With Dignity Act, Governor Kitzhaber and Senator Wyden view this legislation as an unnecessary intrusion into state policy making and oppose its passage.

The Justice Department is very supportive of the new provisions protecting appropriate palliative care. However, because H.R. 2260 effectively blocks all state policy-making on the issue of physician assisted suicide, the Attorney General shares the federalism concerns of the Oregon delegation. In addition, she believes that the legislation establishes criminal and administrative sanctions that will be burdensome and difficult to implement and enforce.

RECOMMENDATION

The Department of Justice wants to ensure that their concerns are not construed as opposition to the legislation's intent. The Attorney General, like you, strongly opposes physician assisted suicide, but believes the legislation's approach can be improved. Although she has no interest in engaging in a protracted dispute with Senator Nickles (who has introduced a similar bill in the Senate) and Congressman Hyde, she feels strongly that her Department should formally voice their concerns to the Congress, with the hope of an opportunity to address some of them, particularly the criminal and administrative penalty provisions, in conference.

We would recommend that the Department of Justice be permitted to forward this letter. Having said this, and given the cross-currents of opinion on this issue and on this bill, we believe that there should not be a strong White House public statement on the legislation until and unless it has been submitted to you for signature.



Assisted Suicide File

U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

October 19, 1999

The Honorable John Conyers, Jr.
Ranking Minority Member
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

passed out of House
271 to 156 -
not veto proof majority
(only 62%)

Dear Congressman Conyers:

NO SAP - just this letter

This letter presents the views of the Department of Justice on H.R. 2260, the "Pain Relief Promotion Act of 1999."

H.R. 2260 makes two changes to federal drug law as it relates to the use of controlled substances by terminally ill patients. First, the bill clarifies that controlled substances may be used to alleviate pain in the course of providing palliative care to terminally ill patients. The bill also funds research and education on the appropriate use of controlled substances for this purpose. The Department strongly supports these provisions of H.R. 2260.

Second, H.R. 2260 states that the use of controlled substances to assist a terminally ill person in committing suicide is not authorized by federal law. The Department opposes physician-assisted suicide, but is concerned about the propriety of a federal law that would unquestionably make physician-assisted suicide a federal crime with harsh mandatory penalties. Imposing such penalties would also effectively block State policy making on this issue at a time when, as the Supreme Court recently noted in Washington v. Glucksberg, 117 S. Ct. 2258, 2275 (1997), the States are still "engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide."

Palliative Care

Section 101 of H.R. 2260 amends section 303 of the Controlled Substances Act ("CSA"), 21 U.S.C. § 823, to specify that the use of controlled substances to "alleviat[e]

pain or discomfort in the usual course of professional practice" is a "legitimate medical purpose" under the CSA, 21 U.S.C. § 841, "even if the use of such a substance may increase the risk of death." Because a physician who acts with a "legitimate medical purpose" is acting in compliance with the Act,¹ H.R. 2260 creates a "safe harbor" against administrative and criminal sanctions when controlled substances are used for palliative care. Sections 102, 201 and 202 amend the CSA and the Public Health Service Act (42 U.S.C. § 299) to authorize the Attorney General, the Administrator of the Agency for Health Care Policy and Research, and the Secretary of the Health and Human Services Department to conduct research on palliative care, to collect and distribute guidelines for the administration of palliative care, and to award grants, cooperative agreements, and contracts to health schools and other institutions to provide education and training on palliative care.

The Department fully supports these measures. H.R. 2260 would eliminate any ambiguity about the legality of using controlled substances to alleviate the pain and suffering of the terminally ill by reducing any perceived threat of administrative and criminal sanctions in this context. The Department accordingly supports those portions of H.R. 2260 addressing palliative care.

Physician Assisted Suicide

H.R. 2260 would amend section 303 (21 U.S.C. § 823) of the CSA to provide that "[n]othing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death." By denying authorization under the CSA, H.R. 2260 would make it a federal crime for a physician to dispense a controlled substance to aid a suicide.² A physician who prescribes the controlled substances most commonly used to aid a suicide would, because he or she necessarily intends death to result, face a 20-year mandatory minimum sentence in federal prison (as well as civil and administrative sanctions under the Act).³

¹ See, e.g., 21 C.F.R. § 1306.04(a) (authorizing prescriptions only for "legitimate medical purposes").

² The criminal provisions of the CSA are triggered by the absence of proper authorization. See 21 U.S.C. § 841(a) ("Except as authorized by this subchapter, it shall be unlawful . . .") (emphasis added).

³ See 21 U.S.C. § 841(b)(1)(C) (setting 20 year mandatory minimum sentence when death results from the distribution of a Schedule II substance); 21 C.F.R. § 1308.12(a)-(c) (defining Schedule II substances). Schedule III drugs, which are sometimes used, do not carry

The Administration strongly opposes the practice of physician-assisted suicide and would not support the practice as a matter of federal policy. H.R. 2260 side-steps the federal policy question, however, and operates instead by blocking State policy making on an issue that many, including the Supreme Court, think is appropriately left to the States to decide as each chooses.⁴

Moreover, H.R. 2260 would affirmatively interfere with State policy making in a particularly heavy handed way by using 20-year mandatory prison sentences (as well as civil and administrative sanctions) to effectively preclude States from adopting any policy that would authorize physician-assisted suicide, even if that authorization contains carefully drafted provisions designed to protect the terminally ill.

For these reasons, H.R. 2260 is particularly intrusive to State policy making, and the Department accordingly opposes this portion of the bill.⁵ The Department would, however, be willing to work with you in formulating a legislative or regulatory solution that obviates the concerns identified in this letter.⁶

any mandatory minimum sentence. See 21 U.S.C. § 841(b)(1)(D).

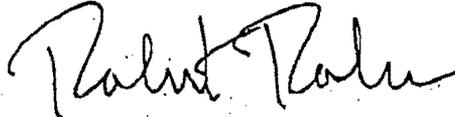
⁴ Glucksburg, 117 S. Ct. 2258, 2274 (noting that debate over physician-assisted suicide is underway in the States, "as it should in a democratic society"); id. at 2303 (O'Connor, J., concurring) (endorsing majority's result, which left "the . . . challenging task of drafting appropriate procedures for safeguarding . . . liberty interests . . . to the 'laboratory' of the States"); id. at 2293 (Souter, J., concurring) (emphasizing that, in light of current state experimentation, "[t]he Court should stay its hand to allow reasonable legislative consideration [of this difficult issue]").

⁵ This approach to physician-assisted suicide is consistent with the Department's approach to "medical marijuana." The legality of the latter turns on factual, not ethical, questions. That is, the scheduling of controlled substances is based on scientific testing to determine, among other things, whether they have any "currently accepted medical use for treatment in the United States," a "high potential for abuse," and "a lack of accepted safety for use . . . under medical supervision." 21 U.S.C. § 812(b)(1) and Schedule I(c)(10). As a result, the CSA appropriately creates a uniform national system of drug scheduling. Where an issue turns solely on ethics, not science, it is reasonable to allow individual states to reach their own conclusions, rather than impose a uniform national standard through implied preemption of state medical standards.

⁶ Any solution should also be careful not to make state-authorized assisted suicides more painful, as H.R. 2260 appears to do. H.R. 2260's prohibitions would only reach controlled substances, which are most often used as sedatives and not as the actual agents of death. As a result, H.R. 2260 might well result in physician-assisted suicides that do not use sedatives and

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

Sincerely,



Robert Raben
Assistant Attorney General

pain-controlling substances that are accordingly more painful.

Summary

The current system of state medical licensure has worked well in assuring that the public health is protected. The evaluation of a medical practitioner is best performed at a level of government that allows regulators to take advantage of professional and personal relationships with individuals whose judgment they trust. Since being established in the late nineteenth century in response to a number of incidents in which patients were harmed, State medical licensure boards have evolved into sophisticated regulatory agencies dedicated to ensuring that the public is protected from unacceptable practitioners. The four central goals of all state medical licensure boards are:

1. To ensure that physicians have attained an adequate level of clinical competence prior to offering their services to the public;
2. To ensure that physicians who seek a license are fit in areas beyond clinical competency, such as psychological balance;
3. To promote the highest professional standards for the practice of medicine, in many cases by requiring the completion of medical education on a regular basis; and,
4. To ensure that physicians whose capability to practice has been impaired are properly disciplined and monitored.

The third and fourth goals have become more important in recent years as it has become increasingly important to ensure that physicians who were qualified at the time of initial licensure continue to be qualified as the body of knowledge a practitioner should know changes and as the physician gets older.

Historical Overview of Medical Licensure

The organization of state medical boards began in the mid-seventeenth century with the passage of a law in Massachusetts which allowed only those considered the most learned in the field to engage in the practice of medicine. Since that time, the role of states in regulating the medical profession has continually evolved with each state having enacted into law, its own medical practice act.

During the last century each state has enacted and amended its own version of a medical practice act. While the specifics of each medical practice act differ, each prescribes through statute and implementing regulation the process by which the initial granting of a license and the monitoring of the privilege to practice medicine shall be accomplished.

Today, there are 54 allopathic and 16 osteopathic state medical boards which have the authority to license physicians, to regulate the practice of medicine within the state, and to discipline those

who violate the relevant medical practice act. In particular, state medical boards:

- Establish academic and clinical skill standards for all license applicants;
- Require periodic re-registration of medical licenses in order to review the qualifications of licensees on a regular basis; (the frequency of re-registration required varies from state to state)
- Investigate and adjudicate allegations of physician misconduct;
- Take appropriate disciplinary action against any physician who is found to have violated the state medical practice act. The action taken may involve sanctions that range from license revocation to consent agreements and fines.

These central functions of state medical boards serve to accomplish the primary purpose of medical licensure; protecting the public from substandard medical care.

As the practice of medicine has become more complex, the assessment of competence through licensing examinations has grown progressively more comprehensive and complex. Today, the United States Medical Licensing Examination (USMLE), an exhaustive three-part exam covering all aspects of both academic learning in the medical field and the application of clinical skills in simulated care settings, is required of all applicants for medical licensure in all jurisdictions in the United States.

The assessment of competence by state medical boards does not end with the initial determination at the time of first licensure, however. All physicians are subject to peer review while licensed. Hospitals, other health care organizations, and insurance companies are asked to provide licensing boards information about adverse actions they have taken against individual physicians as they occur. These reports are reviewed by boards and, if necessary, disciplinary action is taken. In addition, a majority of state boards require all licensees to continue their medical education in order to maintain licensure, by completing educational courses in order to maintain their licensure. These processes are designed to help identify those individuals who should no longer be engaged in the practice of medicine and to ensure that physicians maintain their level of medical knowledge and clinical abilities.

Determining an individual's fitness to practice medicine is more difficult than assessing academic clinical competence. Fitness includes a multitude of psychological and personality-related issues. Lack of fitness to practice could be based on a physician's criminal behavior, substance abuse, or sexual misconduct. A medical licensing board must adjudicate complaints against physicians which range from the obviously frivolous to the potentially criminal. The medical boards' attention to these matters is evidenced by a steady increase in the number of disciplinary actions boards have taken over the past several years. Growing public awareness of the role of state medical boards in ensuring the delivery of high-quality medical care has been accomplished by the boards' actively and continuously educating both physicians and the public about the professional standards expected of those who practice medicine.

THE FEDERATION OF STATE MEDICAL BOARDS OF THE UNITED STATES, INC.

MODEL GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

(Adopted May 2, 1998)

Section I: Preamble

The (*name of board*) recognizes that principles of quality medical practice dictate that the people of the State of (*name of state*) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Agency for Health Care and Research Clinical Practice Guidelines for a sound approach to the management of acute¹ and cancer-related pain.²

The medical management of pain should be based upon current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly and the quantity and frequency of doses should

¹ Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.

² Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research, U.S. Department of Health and Human Resources, Public Health Service. March 1994.

be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The (*state medical board*) is obligated under the laws of the State of (*name of state*) to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and

intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities including (1) urine/serum medication levels screening when requested (2) number and frequency of all prescription refills and (3) reasons for which drug therapy may be discontinued (i.e. violation of agreement).

4. Periodic Review

At reasonable intervals based upon the individual circumstance of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, such as ability to work, need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should re-evaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose

living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

6. Medical Records

The physician should keep accurate and complete records to include (1) the medical history and physical examination (2) diagnostic, therapeutic and laboratory results (3) evaluations and consultations (4) treatment objectives (5) discussion of risks and benefits (6) treatments (7) medications [including date, type, dosage, and quantity prescribed] (8) instructions and agreements and (9) periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance with Controlled Substances Laws and Regulations

To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state, and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (*any relevant documents issued by the state medical board*) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute pain: Acute pain is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time limited and is responsive to opioid therapy, among other therapies.

Addiction: Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic Tolerance: Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain: A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

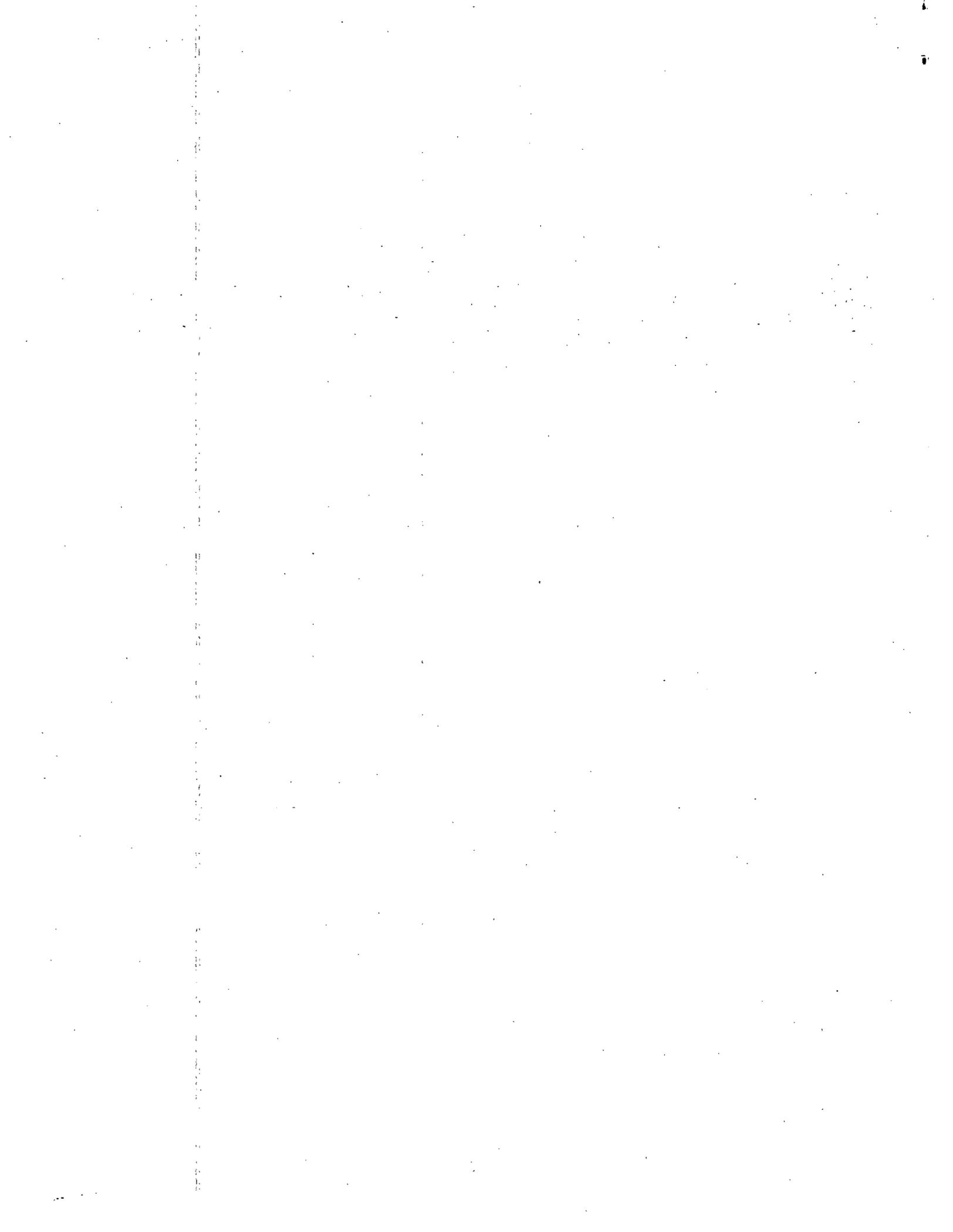
Pain: an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence: Physical dependence on a controlled substance is a physiologic state of neuroadaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction: Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse: Substance abuse is the use of any substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

Tolerance: Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.



Fast Moving Federal Legislation Will Hurt Seriously-Ill Patients Suffering Severe Pain

The *Lethal Drug Abuse Prevention Act* (H.R. 4006/S. 2151), introduced by Congressman Hyde and Senator Nickles, seeks to prohibit physician-assisted suicide by prosecuting doctors and pharmacists who dispense federally controlled substances for such a purpose. The bill, however, will inflict real (though unintended) harm on seriously ill Americans suffering severe pain and should be defeated.

Under the bill, a physician alleged by a patient's family, friend, or anyone else to have prescribed a controlled drug such as morphine with the "intent" of assisting a suicide will be investigated by the Drug Enforcement Administration (DEA). The DEA could then revoke the doctor's DEA registration, impose large fines, and put him or her in jail. The medical community's fear of the DEA's power is so strong that such a law will cause many physicians to "err on the side of caution" and underprescribe these strong pain drugs or use less effective non-controlled substitutes. Patients will suffer.

A Broad Range of Medical and Health Groups Oppose H.R. 4006/S. 2151

The following organizations oppose H.R. 4006/S.2151 because it will hurt patients in severe pain and do nothing to address the underlying reasons why some seriously ill patients seek physician-assisted suicide in the first place. The underlying problems with the bill cannot be corrected by amendment, and the bill must be defeated.

Academy of Managed Care Pharmacy

AIDS Action Council

American Academy of Hospice & Palliative Medicine

American Alliance of Cancer Pain Initiatives

American Association of Colleges of Pharmacy

American Association for Geriatric Psychiatry

American College of Clinical Pharmacy

✓ American College of Physicians - American Society of Internal Medicine

✓ American Geriatrics Society

✓ American Medical Association

✓ American Nurses Association

American Pain Foundation

American Pharmaceutical Association

American Society of Clinical Oncology

American Society of Consultant Pharmacists

American Society of Health System Pharmacists

American Society of Pain Management Nurses

Americans for Better Care of the Dying

Cancer Care, Inc.

Federation of State Medical Boards

✓ Hospice and Palliative Nurses Association

Leukemia Society of America, Inc.

National Alliance of Breast Cancer Organizations

National Coalition for Cancer Survivorship

National Health Council

National Hospice Organization

Oncology Nursing Society

Oregon Hospice Association

Susan G. Komen Breast Cancer Foundation

Pain Care Coalition

US-TOO International, Inc.

Y-ME National Breast Cancer Organization

Assisted Suicide -- Priority of Senator Nickles and Congressman Hyde

The Republican Leadership has indicated that it may push for a version of the Nickles' assisted suicide legislation (S. 2151, the Lethal Drug Abuse Prevention Act), which would direct the Drug Enforcement Agency (DEA) to use the Controlled Substances Act (CSA) to apply penalties to physicians who used pain killer medications to assist in a suicide. This legislation was drafted to, in effect, preempt an Oregon state law that permits assisted suicide. Although (like the President), Senator Wyden opposes assisted suicide, he **STRONGLY** opposes any use of Federal law to preempt a law supported via referendum by the citizens of Oregon.

Because of the serious concerns medical groups like the AMA (who also oppose assisted suicide) have about the likely intimidating impact S. 2151 could have on physicians prescribing pain management medications for terminally ill patients, the AMA, the American Nurses Association, the American College of Physicians and numerous other national health care organizations strongly oppose the Nickles/Hatch/Hyde bill. They believe such legislation would exacerbate a long-documented problem of physicians under prescribing pain medications for the appropriate management of terminally ill patients. While we have repeatedly underscored the President's longstanding position against assisted suicide and our willingness to work on this legislation in the future (see attached letter to Judiciary Chairman Hatch), we have advised the Committee that their current bill is flawed and premature because it does not adequately address health care professionals' legitimate concerns in this area.

Senator Nickles' may be pushing for an alternative to his original bill or his most recent amendment, which attempted to codify a DEA letter on this issue that indicated DEA had the authority to this under current law -- a position which DoJ subsequently rejected. The latest rumor is that he has an alternative that DPC, White House Counsel, and DoJ has never seen. Altering our position on this issue would be vehemently attacked by Senator Wyden, the health care interest groups we have worked with for years, and the media elite who have consistently chastised the Nickles' approach.

Suggested Talking Points:

- As you know, the President strongly opposes assisted suicide. He reiterated this position when he signed the Assisted Suicide Funding Restriction Act just last year.
- However, as the Justice Department made clear in a letter to the Senate Judiciary Committee less than a month ago, we cannot support the Nickles/Hatch/Hyde bill -- or something that resembles it -- because we believe it has great potential to exacerbate the current problem of under prescribing pain medications designed to appropriately alleviate the suffering of the terminally ill.
- Our opposition to this bill is shared by many respected national health organizations, many of which also oppose assisted suicide, including the AMA, the Nurses Association, the American College of Physicians and numerous other national health care groups.
- As we have repeatedly said, we are willing to spend the time necessary to determine if appropriate legislation or other interventions can be designed. But this is the wrong policy, on the wrong vehicle, at the wrong time.



U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

September 16, 1998

The Honorable Orrin G. Hatch
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510-6275

Dear Mr. Chairman:

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

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

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

There is broad consensus that the American medical system does a poor job of providing palliative care to terminally ill patients and, in particular, that it fails to provide effective pain management. As a result, many patients unnecessarily suffer excruciating pain and some patients -- in pain or fearing future pain -- seriously consider suicide (physician assisted or otherwise).

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

The Lethal Drug Abuse Prevention Act is designed to address physicians' fears by prohibiting sanctions as long as physicians do not dispense the controlled substance with the intent of causing death. However, the issue of intent would not necessarily be resolved simply by asking physicians about their intent. To establish intent, the DEA might also need to investigate the details of the physician's prescribing practices and of the physician's relationships with the patient and the patient's family.

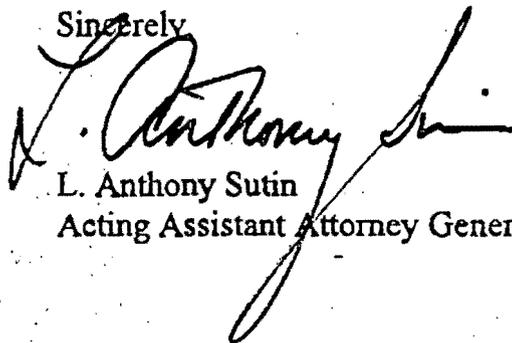
It is precisely the fear of a DEA investigation that creates the potential to inhibit physicians from providing adequate pain medication to terminally ill patients. In response, physicians may undermedicate patients, patients may suffer unnecessary pain and, as a result of increased incidence of great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

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

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

The Administration believes that working together we can develop an appropriate way to address this important issue. We look forward to working with you in the future. The Office of Management and Budget has advised that there is no objection from the standpoint of the Administration's program to the presentation of this report. If we may be of additional assistance, we trust that you will not hesitate to call upon us.

Sincerely,

A handwritten signature in black ink, appearing to read "L. Anthony Sutin". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

L. Anthony Sutin
Acting Assistant Attorney General

cc: The Honorable Patrick J. Leahy
Ranking Minority Member