

Testimony of
Joseph Onek
Principal Deputy Associate Attorney General
United States Department of Justice
Washington, D.C.

to the United States Senate
Committee on the Judiciary

July 31, 1998

Mr. Chairman and Members of the Committee:

Thank you for the opportunity to testify on this important issue. My name is Joseph Onek and I am the Principal Deputy Associate Attorney General at the Department of Justice. My statement will focus on the legislation introduced as S. 2151, the "Lethal Drug Abuse Prevention Act of 1998." After presenting my statement, I will be pleased to answer any questions that you may have concerning the broader issue of physician assisted suicide in relation to the enforcement authority of the Department of Justice.

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

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

The new Board would afford a peer review process to any practitioner aggrieved by a show cause order under 21 U.S.C. § 824(c) proposing to take adverse action against a practitioner's registration in light of physician-assisted suicide. This provision would for the first time inject a regulatory peer review process into the quasi-judicial administrative discipline process. The Board's opinion would be "admissible" in any show cause hearing, but would it be binding in effect? If the DEA went against the Board's decision, either in favor of or against the physician, what would be the likely result on appeal? We think this Board -- undoubtedly a well-intended innovation designed to give the physician a fair hearing -- unnecessarily creates a myriad of difficult issues.

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

Mr. Chairman, that completes my prepared remarks. I would be pleased to respond to any questions that you or other Members of the Committee may have.

TO: Chris Jennings
From: Alissa Fox

WP 9/16/98

Pain Relief or Crime?

OF THE HANDFUL of states that have weighed the tough question of whether to legalize physician-assisted suicide, only one, Oregon, has actually done so. Efforts to pursue nationally a "right to die," or a right to be helped to die on request, have failed—rightly, in our view—to jump ahead of states in working through this problem. Likewise, the Supreme Court declined to find a "right to die" that would have overturned laws penalizing the practice in New York and Washington.

Nine months after Oregon reaffirmed its lone decision with a referendum, though, Congress is weighing a bill that would undo it by indirect means—means that would, in the view of many who oppose physician-assisted suicide, do wide-ranging and unrelated damage to medical practice. The bill, sponsored by Rep. Henry Hyde and slated for action today, would authorize the Drug Enforcement Administration to investigate any doctor who prescribed a dose of painkiller that might be lethal—and, if it found evidence of intent to kill, revoke that doctor's license.

Such a law would certainly render Oregon's inoperative. More important, though, it would

expose to prosecution any doctor in the country who engaged in the relatively new practice of palliative care—giving patients enough painkillers to make them comfortable in the final stages of a painful disease.

Anyone who has been a near witness to such an ordeal knows that keeping a dying patient comfortable in this way may come perilously close to hastening a death that may be only a few hours or days away. Doctors already walk a fine line; supporters of the Oregon law say it has freed doctors to do better pain relief at the end of life, meaning in turn that fewer patients feel the need to take the lethal prescriptions to which they now have a right.

It's out of concern for palliative care that the American Medical Association, which opposes assisted suicide, nonetheless is strongly against the Hyde bill and the precedent of criminalizing doctors' judgment calls. Even setting aside the doubtful wisdom of overturning a state's carefully constructed attempt to take its own path on assisted suicide, the harm done to pain relief and the dying is reason enough to reject this bill.

DOJ Position on Physician-Assisted Suicide Provisions of H.R. 2260

Here are the bare bones points DOJ wants made in any views letter on H.R. 2260 (the Pain Relief Promotion Act of 1999) concerning those provisions of the bill that are, according to the sponsors' staff, intended to and would, if implemented, certainly chill (if not effectively shut down) the use of controlled substances in physician-assisted suicide processes authorized by state law.

- H.R. 2260 is much more about inappropriate federalism than it is about physician-assisted suicide.
- H.R. 2260 expressly forbids the prescribing or administering of a controlled substance to assist a suicide and forbids the Attorney General from taking into account any state law authorizing physician-assisted suicide in determining whether a physician's registration is consistent with the public interest for purposes of the Controlled Substances Act.
- The Administration strongly opposes physician assisted suicide and would not support the practice as a matter of federal policy.
- Consistent with this view, the Administration strongly supports the ban on federal funding of physician assisted suicide.
- The prohibitions of H.R. 2260 do not, however, present a question of a federal policy choice but, in fact, operate to block state policy on an issue that the Administration (and the Supreme Court) have acknowledged is appropriately left wholly to the States to decide as each chooses. H.R. 2260 would affirmatively interfere with state policy making in a particular heavy handed way by imposing federal criminal felony liability carrying a mandatory 20-year prison sentence as well as civil and administrative sanctions.
- Accordingly, the Administration's objection to H.R. 2260 is based on federalism, and not on the merits of banning physician-assisted suicide.
- Aside from the federalism point, H.R. 2260 might well result in physician-assisted suicides that do not use sedative and pain-controlling substances because H.R. 2260's prohibitions would only reach controlled substances, which are used as sedatives and not as the actual agents of death.

I was wrong about this sorry

*Chris -
I have no comments on this except that I don't think it addresses Jane's PBDR concerns. For what it's worth, the Federalism issue is what Wyden has pushed in his statements.*

DRAFT -- NOT FOR RELEASE

September 11, 1998
(House)

*1 legislation
P. Pellicci
P. Pellicci*

H.R. 4006 - Lethal Drug Abuse Prevention Act of 1998
(Reps. Hyde (R) IL and Oberstar (D) MN)

*for
concerned
Pellicci
care
concerned*

The President is opposed to assisted suicide and any Federal support for it. The Administration, however, opposes H.R. 4006 because it represents a flawed approach to the sensitive area of Federal regulation of medicine. In particular, the Administration is concerned that the bill's insertion of the Drug Enforcement Administration (DEA) into the role of overseer of the practice of medicine in the unique circumstances of suffering, terminally ill patients would inevitably divert agency attention away from its core drug enforcement mission. In addition, the medical, scientific, ethical, and related aspects of the practice of medicine at the end of life would involve the DEA in issues in which it has no particular expertise.

Pay-As-You-Go Scoring

H.R. 4006 could affect both direct spending and receipts: therefore, it is subject to the pay-as-you-go requirement of the Omnibus Budget Reconciliation Act of 1990. OMB's preliminary scoring estimate of this bill is that it would have a net effect of less than \$500,000.

(Do Not Distribute Outside Executive Office of the President)

This Statement of Administration Policy was developed by the Legislative Reference Division (Pellicci) in consultation with .

OMB/LA Clearance: _____

The proposed position is identical to that contained in a Justice Department letter to the House Judiciary Committee on H.R. 4006 on August 3, 1998. H.R. 4006 was reported by the House Judiciary Committee on August 6th by voice vote.

Background

The legislation is a result of Attorney General Reno's recent decision that physician-assisted suicide does not fall under the purview of the Drug Enforcement Administration (DEA) under current law governing controlled substances but instead should be governed by State law. The

State of Oregon has legalized the use by physicians of lethal doses of controlled substances in suicide for terminally ill patients.

Summary of H.R. 4006

H.R. 4006 would make it a violation of the Controlled Substances Act of 1970 to intentionally distribute or dispense a controlled substance to assist in suicide or euthanasia. Persons who violate the bill's provisions could face revocation of their license to prescribe controlled substances. In addition, H.R. 4006 would require the Attorney General to create a Medical Advisory Board on Pain Relief to assist in resolving disputes over the dispensing of controlled substances in cases of assisted suicide or euthanasia.

Under current law, medical practitioners who are licensed by State medical boards must also register with the Attorney General through the DEA if they intend to dispense or prescribe controlled substances. Practitioners many now lose their Federal registration to dispense those substances if the Attorney General, after considering specific factors, determines that the registration would not be in the public interest. Intentionally dispensing or prescribing controlled substances to assist or facilitate a suicide or euthanasia is not included in that list of factors. Under H.R. 4006, however, it would be grounds for suspending or revoking a practitioner's Federal license.

Pay-As-You-Go Scoring

According to BASD (Balis), H.R. 4006 could affect both direct spending and receipts; therefore, it is subject to the pay-as-you-go requirement of the Omnibus Budget Reconciliation Act of 1990. OMB's estimates that the net effect of H.R. 4006 would be less than \$500,000. CBO concurs.

LEGISLATIVE REFERENCE DIVISION DRAFT

September 11, 1998 - 11:00 a.m.

lack of
provision

concerns
state phy.

ORRIN G. HATCH, UTAH, CHAIRMAN

Assisted Suicide File

STROM THURMOND, SOUTH CAROLINA
CHARLES E. GRASSLEY, IOWA
ARLEN SPECTER, PENNSYLVANIA
FRED THOMPSON, TENNESSEE
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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20610-6275

MANUE COONEY, Chief Counsel and Staff Director
BRUCE A. COHEN, Minority Chief Counsel

September 9, 1998

Mr. Joseph N. Onek
Principal Deputy Associate Attorney General
United States Department of Justice
Washington, D.C. 20530

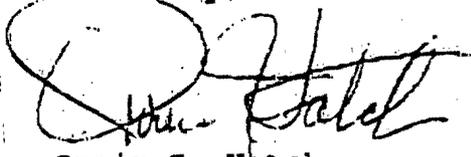
Dear Mr. Onek:

The Committee on the Judiciary is preparing for further consideration of S. 2151, the Lethal Drug Abuse Prevention Act of 1998, a bill which clarifies Federal law with respect to the use of a controlled substance in assisting a suicide.

It has come to my attention that you have not yet reported back to us with the further information you agreed to provide during your July 31 testimony before the Committee on this subject. Given the Department's opposition to S. 2151 as presently drafted, at the hearing I explored with you the Administration's views on how to implement the President's opposition to physician-assisted suicide. I urged that you work with us to effect a legislative solution to the problem, and you responded "I will certainly report back with a sense of urgency." I further noted my desire to have this resolved before the end of August, a deadline which has now passed, and you again replied that you intended to cooperate.

I am sensitive to the workload your agency faces. At the same time, with the projected congressional adjournment date only one month away, if the Committee is to have the benefit of your further views on S. 2151, I must ask that you provide us with the promised information by the end of this week, September 11, 1998. If you or your staff have any questions, please contact Patricia Knight at 224-6306.

Sincerely,



Orrin G. Hatch
Chairman

UNITED STATES DEPARTMENT OF JUSTICE

Office of Nicholas M. Gess
Associate Deputy Attorney General

950 Pennsylvania Avenue, N.W.
Room 4220
Washington, DC 20530
Telephone: (202) 514-0835



Will it stop covered
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If the dog don't bark
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When are gray's -- med
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- three issues
- time of release (AFTER markup)
 - less emphasis on CSA prob
 - Federalism section too strong.

TO: Chris Jennings

OFFICE NUMBER:

FAX NUMBER:

FROM:

DATE/TIME:

NUMBER OF PAGES INCLUDING THIS SHEET:

TELEPHONE NUMBER OF PERSON TO CONTACT UPON RECEIPT:

456-5557

Nicholas M. Gess

September 8, 1999

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202 347 7045

(hm)

5145000
ELEANOR
ACTENSON

* * * FAX NUMBER: (202) 514-9368 PHONE NUMBER 202-514-0835 * * *

REMARKS: Chris - Copy of this went over to OMB for circulation, but I wanted you to have one directly. Physician-assisted suicide issue is back, with markup today / tomorrow. Proposed letter now pared down - Pls. Call when you have a moment so we can discuss White House desires on this. Thanks.



U.S. Department of Justice

Office of Legislative Affairs

right after making

Office of the Assistant Attorney General

Washington, D.C. 20530

can't send before hearing too complicated

DRAFT 9/7/1999

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

Dear Mr. Chairman:

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.

← insert language on POTUS stance against assisted suicide.

Second, H.R. 2260 provides that the use of controlled substances to assist a terminally ill person in committing suicide is not authorized by federal law. The Administration is opposed to physician-assisted suicide as a policy matter, but we are concerned about the federalism and other policy ramifications of making physician-assisted suicide a federal crime with harsh mandatory penalties 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," and in the face of the choice of the citizens of at least one state to adopt a highly regulated and circumscribed procedure which could not be complied with without violating this bill.

At the President's 1997 directive made [unclear] [unclear] [unclear] However, [unclear] the Dept [unclear]

Palliative Care

Section 101 of H.R. 2260 amends section 303 of the 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 Controlled Substances Act, 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

Section 101 amends section 303 (21 U.S.C. 823) of the Controlled Substances Act (CSA) to add subsection (i), which provides that "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." We understand that the sponsors of this bill intend, by withdrawing authorization under the CSA, to make it a federal crime for a physician to dispense a controlled substance to aid a suicide. If the CSA were amended by H.R. 2260, a physician who prescribes the controlled substances most commonly used to aid a suicide would, because he 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).² H.R. 2260 makes no exception for states like Oregon that authorize physician-assisted suicide, even though any physician complying with Oregon's procedures would effectively prepare the federal case against himself or herself because the Oregon law requires physicians to document their patients' intent to have

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

² 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 any mandatory minimum sentence. See 21 U.S.C. § 841(b)(1)(D).

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the physicians assist with their suicides.³

Although the Administration strongly opposes physician-assisted suicide and supports the ban on federal funding of such an activity, H.R. 2260's federally imposed penalties would effectively preclude states from adopting a policy authorizing physician-assisted suicide, even when the state authorization contains narrowly drafted conditions designed to protect the terminally ill (as Oregon's Death with Dignity Act does).⁴ The Supreme Court in Washington v. Glucksburg declined to cut short the policy debate now underway in state legislatures by precluding States from banning physician-assisted suicide, and we think it may be similarly inadvisable to curtail the debate by precluding States from regulating physician-assisted suicide, such as by requiring clear documentation of actions in order to protect the patient.⁵ As many Justices noted in Glucksburg, this is the type of issue best left to the States in the first instance.⁶ We accordingly oppose federal legislation, such as H.R. 2260, that would take away from states their ability to make policy judgments about this difficult moral and ethical issue.⁵

³ See, e.g., Or. Rev. Stat. § 127.855 (specifically requiring a physician in Oregon to "document[] or file[]" evidence of compliance with the Oregon Act's specific requirements concerning the patient's request to end his or her life in the patient's medical record, and "indicat[e] that all requirements under [the Oregon law] have been met"); id. §§ 127.800-127.897 (listing requirements).

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 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. In contrast, the only "evidence" supporting a

09/18/99 WED 09:14 FAX

Moreover, we doubt whether H.R. 2260 would be entirely effective in preventing physician-assisted suicide, and it may have perverse consequences to the extent that it allows the practice. It is our understanding that in the most common "prescription" for death, controlled and non-controlled substances are used in combination; in such cases, the controlled substance is used as a sedative while the non-controlled substances is the actual cause of death. Because H.R. 2260 bans only the use of controlled substances, it is probable that at least some patients and physicians in states with authorized physician-assisted suicide procedures would forego the controlled substance sedative, resulting in more painful deaths for the patients.

Thank you for this opportunity to present our views. The Office of Management and Budget has advised us that from the standpoint of the Administration, there is no objection to the submission of this letter. Please do not hesitate to call upon us if we may be of further assistance.

Sincerely,

Jon P. Jennings
Acting Assistant Attorney General

cc: Honorable John Conyers, Jr.
Ranking Minority Member

*Does not
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federal prohibition on physician-assisted suicide under the Oregon Death with Dignity Act would be the ethical views of federal officials. 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.

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*Rm Karen Popp
483*

**THE
CATHOLIC HEALTH
ASSOCIATION
OF THE UNITED STATES**

FAX TRANSMITTAL FORM



DATE: September 1, 1998
TO : Chris Jennings
COMPANY : White House
FAX NUMBER : 456-5542

FROM : Peter M. Leibold
TITLE : General Counsel
PHONE (DIRECT): 721-6319

NUMBER OF PAGES (INCLUDING COVER SHEET):

1875 Eye St, NW #1000
Washington, DC 20008-5409

Phone 202-296-3993
Fax 202-296-3997

COMMENTS :

Chris, here are the materials related to the Lethal Drug Abuse Prevention Act. Give me a call with any questions. By the way, I am told that the Baby Doe legislation in the early 80s may have an analogy in which HHS had to make a finding prior to DOJ initiating an investigation. I have not looked at the legislation, but you may want to do that.

FACAS\H4006.COM

Oregon Rules on disclosure

[AMENDMENT IN THE NATURE OF A SUBSTITUTE]

[Reported by the Subcommittee on the Constitution on July
22, 1998]

105TH CONGRESS
2D SESSION

H. R. 4006

To clarify Federal law to prohibit the dispensing or distribution of a controlled substance for the purpose of causing, or assisting in causing, the suicide or euthanasia of any individual.

IN THE HOUSE OF REPRESENTATIVES

JUNE 5, 1998

Mr. HYDE (for himself and Mr. OBERSTAR) introduced the following bill; which was referred to the Committee on the Judiciary, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on June 5, 1998]

A BILL

To clarify Federal law to prohibit the dispensing or distribution of a controlled substance for the purpose of causing, or assisting in causing, the suicide or euthanasia of any individual.

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

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the "Lethal Drug Abuse Pre-*
5 *vention Act of 1998".*

6 **SEC. 2. LETHAL DRUG ABUSE PREVENTION.**

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

10 *“(i) DENIAL OF REGISTRATION.—The Attorney Gen-*
11 *eral shall determine that registration of an applicant under*
12 *this section is inconsistent with the public interest if—*

13 *“(1) during the 5-year period immediately pre-*
14 *ceding the date on which the application is submitted*
15 *under this section, the registration of the applicant*
16 *under this section was revoked under section*
17 *304(a)(4); or*

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

23 *(b) SUSPENSION OR REVOCATION OF REGISTRA-*
24 *TION.—*

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

4 (A) by redesignating paragraphs (4) and
5 (5) as paragraphs (5) and (6), respectively; and
6 (B) by inserting after paragraph (3) the fol-
7 lowing:

8 “(4) has intentionally dispensed or distributed a
9 controlled substance with a purpose of causing, or as-
10 sisting in causing, the suicide or euthanasia of any
11 individual, except that this paragraph does not apply
12 to the dispensing or distribution of a controlled sub-
13 stance for the purpose of alleviating pain or discom-
14 fort (even if the use of the controlled substance may
15 increase the risk of death), so long as the controlled
16 substance is not also dispensed or distributed for the
17 purpose of causing, or assisting in causing, the death
18 of an individual for any reason;”

19 (2) *CONFORMING AMENDMENT.*—Section
20 304(a)(5) of the Controlled Substances Act (21 U.S.C.
21 824(a)(5)) (as redesignated by paragraph (1) of this
22 subsection) is amended by inserting “other” after
23 “such”.

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

1 (1) by striking "(c) Before" and inserting the fol-
2 lowing:

3 "(c) PROCEDURES.—

4 " (1) ORDER TO SHOW CAUSE.—After any hear-
5 ing under paragraph (3), and before";

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

7 "(2) ASSISTED SUICIDE.—At any proceeding
8 under paragraph (1) based on subsection (a)(4), if a
9 registrant claims that the action of the registrant that
10 is a basis for a proposed revocation or suspension is
11 an appropriate means to relieve pain or discomfort
12 that does not constitute a violation of subsection
13 (a)(4), the Attorney General shall have the burden of
14 proving, by clear and convincing evidence, that a
15 purpose of the action was to cause, or assist in caus-
16 ing, the death of an individual. In meeting such bur-
17 den, it shall not be sufficient to prove that the reg-
18 istrant knew that the use of the controlled substance
19 may increase the risk of death.

20 "(3) MEDICAL ADVISORY BOARD ON PAIN RE-
21 LIEF.—

22 "(A) IN GENERAL.—The Attorney General
23 shall by regulation establish a board to be known
24 as the Medical Advisory Board on Pain Relief
25 (referred to in this subsection as the 'Board').

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“(B) MEMBERSHIP.—The Attorney General shall appoint the members of the Board—

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

*the bed of
and patients
care*

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

“(C) DUTIES OF BOARD.—

“(i) HEARING.—If an applicant or registrant claims that any action (or, in the case of a proposed denial under section 303(i)(2), any potential action) that is a basis of a proposed denial under section 303(i), or a proposed revocation or suspen-

1 sion under subsection (a)(4) of this section,
2 is an appropriate means to relieve pain
3 that does not constitute a violation of sub-
4 section (a)(4) of this section, the applicant
5 or registrant may seek a hearing before the
6 Board on that issue.

7 “(ii) BOARD ACTION.—Based on a
8 hearing under clause (i), the Board shall
9 issue an advisory opinion regarding wheth-
10 er the action at issue is an appropriate
11 means to relieve pain that does not con-
12 stitute a violation of subsection (a)(4). The
13 opinion of the Board under this clause shall
14 be admissible in any hearing pursuant to
15 an order to show cause under paragraph
16 (1).”

17 **SEC. 3. CONSTRUCTION.**

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

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

AMENDMENT NO.

Calendar No.

Purpose: To provide guidance to the health care community regarding the criteria which will be used by the Department of Justice and the Drug Enforcement Administration to initiate investigations of health care practitioners under the Lethal Drug Abuse Prevention Act of 1998.

In the Senate of the United States -- 105th Cong., 2d Sess.

To amend section 304 of the Controlled Substances Act to require the Attorney General to issue "Investigative Guidelines" related to the requirements of the Lethal Drug Abuse Prevention Act of 1998.

Ordered to lie on the table and be printed

AMENDMENT intended to be proposed by Mr. _____

Redesignate section 3 as section 4 and add the following.

Section 3. __ Investigative Guidance

Create new subsection 304(h), titled "Investigative Guidance. _____

(1) "IN GENERAL. __ Within six months of enactment of the Lethal Drug Abuse Prevention Act of 1998, the Attorney General, after consultation with the Secretary of Health and Human Services and representatives of the organizations consulted under subsection (c)(3)(B)(ii) of this section (as amended by this Act), shall issue written guidance with respect to the general criteria which will be used by the Department of Justice and the Drug Enforcement Agency to initiate and conduct investigations for suspected violations of section 304(a)(4).

(2) CONSIDERATIONS IN DEVELOPING CRITERIA. __ In developing the guidance required by this section, the Attorney General shall consider at minimum the following factors:

(A) The important federal policy of preventing registrants from using the registration pursuant to section 303 to cause, or assist in causing, the suicide, euthanasia, or mercy killing of another individual;

(B) The potential negative impact that investigations which do not uncover violations of subsection (a)(4) of this section may have on the dispensing of pain medication and the provision of palliative care by health care providers;

(C) The need to improve pain management and palliative care for people with life threatening illness;

(D) The existing resources of the Department of Justice and the Drug Enforcement Agency;

(E) The fact that assisting in suicide in almost all states is a violation of state law and that a registrants' violation of these state laws using a controlled substance would itself already constitute grounds for a denial, revocation or suspension of a registration under section 303 or this section;

(F) With respect to states in which assisting suicide or euthanasia does not violate state law under certain circumstances, if reports are filed with state authorities, the fact that subpoenaing copies of those reports from state authorities at regular intervals may be the predominant means of conducting investigations in those states;

(G) The need to meet the ultimate burden of proving a violation of subsection (a)(4) of this section by clear and convincing evidence in any proceeding under subsection (c)(2) of this section;

(H) The fact that increased dosages of pain medication are often medically required for patients living with life threatening illness, do not indicate any intent regarding the purposeful taking of life, and must be considered carefully before being used as the sole or primary impetus for initiating investigations, revocation or suspension proceedings; and

(I) Any other considerations the Attorney General believes are relevant and material.

(3) CONTENTS OF THE GUIDANCE. __ The guidance should include in general terms

(A) The methods used to investigate alleged violations of section (a)(4);

(B) Whether and how the Department will provide the applicant or registrant the opportunity to discuss the allegation or accusation prior to the serving of an order to show cause under subsection (c) of this section;

(C) Whether and how the Department will consider the impact on pain management in the initiation and performance of investigations;

(D) Whether and how the Department will use levels of pain dosages alone in making determinations related to initiating investigations or revocation or suspension proceedings;

(E) How the department proposes to continue the practice of delegating investigative responsibilities to state authorities in states where assisting in suicide with a controlled substance is a felony under state law or a violation of a state controlled substances act; and

(F) Any other issues which the Attorney General believes are relevant and material.

(4) REPORT TO CONGRESS. __ The Attorney General shall provide a copy of its "Investigative

Guidance" to the Chairman and the Ranking Member of the Committee on the Judiciary and the Committee on Commerce in the House of Representatives and the Committee on the Judiciary in the Senate of the United States not more than six months after the date of enactment of the Lethal Drug Abuse Prevention Act of 1998.

AMENDMENT NO.

Calendar No.

Purpose: To provide grants to train physicians and other health care professionals in 1) the appropriate use of controlled substances to relieve pain; and 2) the legal requirements related to the use of controlled substances for alleviating pain.

In the Senate of the United States -- 105th Cong., 2d Sess.

To amend Title VII, Part E of the Public Health Service Act to provide a grant program for educating health care professionals in pain

Ordered to lie on the table and be printed

AMENDMENT intended to be proposed by Mr. _____

Redesignate Section 3 as Section 4 and add the following:

"Section 3. Promoting Physician Understanding of Pain Management and the Requirements of Federal Law

(a) Purpose.--The purpose of this section is to provide grants to eligible entities to train practicing physicians and other health care professionals in the appropriate use of controlled substances for the purpose of alleviating pain or discomfort and in the legal requirements related to the use of controlled substances for alleviating pain or discomfort.

(b) Pain Management.-- Title VII, Part E of the Public Health Service Act is amended by adding a new section 779:

"Section 779. Pain Management.--

(a) GRANTS. -- The Secretary, in consultation with the Attorney General, may make grants to, or enter into contracts with, any eligible applicant to help such applicant fund authorized activities under an application approved under subsection (d).

(b) USE OF AMOUNTS:--

(1) In General.-- Amounts provided under subsection (a) shall be used by the recipients to fund training projects designed to--

(A) Educate practicing physicians and other health care professionals in the appropriate use of controlled substances for the purpose of alleviating pain; and

(B) Educate practicing physicians in the requirements of federal

drug laws, including the Controlled Substances Act, the Assisted Suicide Funding Restriction Act of 1997, the Lethal Drug Abuse Prevention Act of 1998, and the Federal Intractable Pain Regulation, such that those laws should not be construed as impediments to efforts to alleviate pain or discomfort (even if such efforts may unintentionally increase the risk of death) and should not be misunderstood as discouraging the use of appropriate amounts of controlled substances to control pain for those for whom it is medically indicated.

(2) **Methods.**-- A recipient of funds under subsection (a) may use various methods for carrying out the projects described in paragraph (1).

(3) **Preferences in Making Awards.**-- In making awards under this section, the Secretary shall give preference to:

(A) any qualified applicant that incorporates the use of appropriate law enforcement personnel or material into their project methodology; and

(B) applicants that will be deemed as having credibility by practicing physicians and health care professionals in the delivery of effective and appropriate pain management.

(c) **ELIGIBLE APPLICANTS.**-- Applicants eligible to obtain funds under subsection (a) shall include public or nonprofit educational institutions, nonprofit organizations related to the delivery or provision of health care, nonprofit organizations with specific expertise in palliative care, and associations of health care professionals and providers. Applicants eligible to obtain funds under subsection (a) shall not include for-profit entities, either directly or through a subcontract or grant.

(d) **APPLICATIONS.**--

(1) **Submission.**-- In order to receive a grant under subsection (a) an entity shall submit an application to the Secretary.

(2) **Forms.**-- An application submitted under this subsection shall be in such form, be submitted by such date, and contain such information as the Secretary shall require.

(c) **AUTHORIZATION OF APPROPRIATIONS.**-- For the purpose of carrying out this section, there is authorized to be appropriated \$5,000,000 for each of the fiscal years 2000 through 2005.

THE
CATHOLIC HEALTH
ASSOCIATION
OF THE UNITED STATES

July 23, 1998

The Honorable Susan Collins
SR-172 Russell Senate Office Building
Washington, DC 20510

Dear Senator Collins,

I thoroughly enjoyed our dinner at Senator Rockefeller's house on July 20th. As you know, I share your concern about the quality of palliative care in our nation. For that reason, I am enclosing some material and a tape that has been produced by a coalition in which the Catholic Health Association participates: Supportive Care of the Dying: A Coalition for Compassionate Care. If you have time, I urge you to look at the tape. It is a moving and emotional learning experience.

The coalition is dedicated to promoting cultural change that will encourage society to provide supportive care, compassionate relief of suffering, and pain and symptom management for people with life threatening illness. Of course, part of that cultural change is the support of legislative initiatives designed to spur imaginative approaches to providing improved palliative care.

After our conversation, I looked again at Section 7 of your and Senator Rockefeller's bill, the Advance Planning and Compassionate Care Act. I believe that it would be an excellent addition to the Lethal Drug Abuse Prevention Act of 1998 (LDAPA). CHA supports the latter bill, but has expressed concerns to the sponsors that it not have the unintended effect of chilling physicians' appropriate dispensing of pain medication.

Although Section 7 amends the Social Security Act, which may as you know create certain jurisdictional dilemmas, its promotion of demonstration projects in palliative care will help to ameliorate certain concerns about the LDAPA among many health care providers dedicated to improving palliative care. I would certainly endorse its attachment to the LDAPA.

Once again, I enjoyed our conversation. If there is anything you need from CHA, do not hesitate to give me a call, or you can have your staff call Peter Leibold in our Washington office at 202-296-3993.

Sincerely,

Reverend Michael D. Place, STD
President and Chief Executive Officer



WASHINGTON OFFICE
1875 Eye Street, NW
Suite 1000
Washington, DC 20006-5409
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Ronald A. Carson

Drugs and Pain

When a dying patient complains of unbearable pain, the doctor needs to be able to provide relief without fear of being sanctioned. People at the end of life have a right to treatment of moderate pain as well, since persistent discomfort erodes the quality of those last weeks and months.

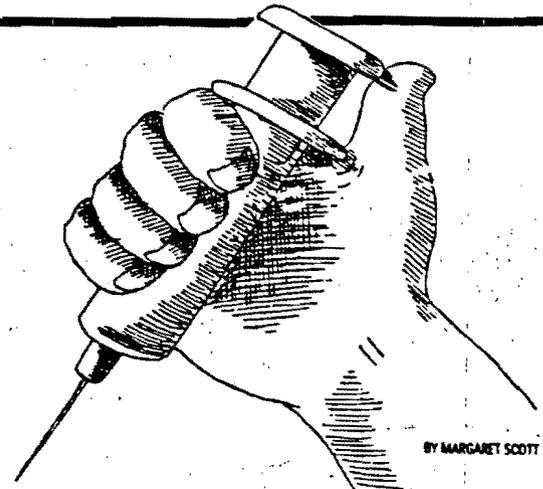
Gradually, care for the dying has been improving. Public interest in hospice and other alternatives to high-tech hospital death has been on the rise. Barriers to effective pain treatment were beginning to come down. Then last month Congress got into the act with a proposal to require the Drug Enforcement Administration to revoke the license of any physician who intentionally causes a patient to die.

If it becomes law, the Lethal Drug Abuse Prevention Act of 1998, introduced by Rep. Henry Hyde (R-Ill.) and Sen. Don Nickles (R-Okla.), will put a damper on progress now being made in providing pain relief to dying patients.

If the politicians who crafted this legislation truly want to prevent physician-assisted suicide, they're taking the wrong approach. Fear of unrelieved pain ranks among the main reasons people give for requesting help ending their lives. Intimidating doctors into being stingy with painkillers is not the solution. Granted, the proposed bill allows physicians free rein in prescribing drugs to alleviate pain, but the amount of morphine, for example, required to relieve the severe pain of bone cancer may also repress respiration to a point that may be lethal. Physicians in fear of losing their licenses are likely to err on the side of caution and under-prescribe. And the message that this bill sends to patients and their families is that pain control is dangerous, that expecting to be comfortable near the end is unrealistic and maybe even immoral—that it's better for the dying to tough it out.

Last year the Supreme Court ruled that physician-assisted suicide was a matter for the states to decide. Since then, legislatures around the country have taken up that issue. Regardless where one stands on the question of whether physicians should be permitted to help dying patients voluntarily end their lives, a consensus is growing that your doctor should be able to ease your passage. What worries people most is the prospect of dying in misery. With good family support, good nursing care and adequate pain control, dying in misery is not necessary.

Adequate pain control has been an option since 1989, when Texas became the first of several states to pass an



BY MARGARET SCOTT

Intractable Pain Act that authorizes physicians licensed by the Board of Medical Examiners to prescribe or administer dangerous drugs to treat intractable pain. Not that passing a law necessarily solves problems, but it can pave the way to a solution.

Despite recent advances, the reluctance of physicians generally to relieve dying patients' pain is widely documented. Doctors need to be informed about what the law says and to be confident that they will not be punished for practicing state-of-the-art end-of-life care. State medical boards, which are responsible for disciplining physicians who abuse prescribing privileges, are bringing their members' knowledge of this issue up to date.

Our health care system still has trouble treating patients once treatment comes down to comfort, rather than cure. The art and science of palliative care—the comprehensive management of the physical, psychological, social, spiritual and existential needs of patients—finally are being introduced into medical and nursing school curricula and continuing education programs.

Public awareness of the need for end-of-life planning is growing. Choosing the right course when the choice is between prolonging life and maintaining life's quality happens one patient, one family member, one doctor at a time. More people are realizing how important it is to talk with those closest to them, and with their doctors, about how they want to be treated when the end is near. The ham-fisted proposal before Congress would stymie this hard-won progress.

When dying patients say the pain is unbearable, doctors must be free to provide comfort. These very personal decisions should remain in the hands of those who have the biggest stake in their outcome—patients and their families, and the doctors and nurses entrusted with their care.

The writer is director of the Institute for the Medical Humanities, the University of Texas Medical Branch at Galveston.

**Statement on S.2151/H.R.4006 by Skip Baker,
President of ASAP (American Society for Action on Pain)
August 20, 1998**

I suffer from Ankylosing Spondylitis of the sacrum, which is like having the base of your spine in a steel vice at all times. It produces truly "suicidal pain levels" if not treated with adequate narcotic pain medicine, which is nearly impossible for victims to get. It took me 13 years of battle to have my medication approved at 500mg per day, and even now each month when it comes time for my next month's supply I have to ask myself: "Is THIS the month they come after my doctor and I look into the abyss? Is this the month I die? Will he be able to write my prescription?"

I speak with pain patients all over the country who have this same fear each month, wondering if they will live to see the end of the year. We all go home with our prescription bottles each month, thinking to ourselves: "Another month of life assured." The pain is so bad for many that they know they could not avoid suicide without the medicine.

Ankylosing Spondylitis causes the joints and vertebra to try to fuse together. This puts pressure on the nerves and causes excruciating vice-like pain. It won't show up on film for 14 years, on average, after the pain starts and many doctors are afraid to treat the pain because of this lack of proof on film – but the HLA-B27 antigen blood test should be proof enough. However some patients don't get diagnosed because doctors don't want to be "stuck with" another Chronic Pain Patient. The devastation is total: Loss of job, loss of car, loss of wife and home, and finally the patient faces the unending pain unless he or she can get diagnosed and treated.

Mornings are the worst time for a victim of Ankylosing Spondylitis. The vice-like, burning pain affects the entire body. It takes me two hours each morning to get enough pain medicine into my blood to control the pain. If this bill passes, it will become difficult for me and millions of others to get adequate pain medication. For some, it will become impossible.

Many doctors have turned me down for pain medication. Since my very life depended on getting the medicine, I had to spend a great deal of my time "doctor shopping" to get enough medicine to function. That cost jobs and income. At times I had to go for more than a year without adequate pain medicine, trying to function on other types of medication that didn't work to control the pain, because of doctors' fears of the regulators.

Many times when I was able to get prescriptions, I'd have problems getting druggists to fill the prescriptions. I now get messages almost daily from other pain patients who also have problems with their pharmacists, unwilling to

fill their prescriptions over their fear of the DEA. So the patient is caught between the doctors, the pharmacists and the DEA in a life and death struggle. Pure panic soon sets in and the patient faces that for years. It's like bending a coat hanger back and forth until it snaps.

What happens if a severe pain sufferer can't get the medication they need. They commit suicide, or die of heart attacks and strokes, or suffer inhuman, unbearable pain that you can't even imagine unless you've been there. I got a note from one woman wanting to give me the right to file suit if her untreated pain kills her. Another woman I spoke with a month or so ago couldn't get a doctor to prescribe pain medicine for her and a week later she took her own life. Because I help pain patients find doctors, I read some of the most desperate notes one can imagine. They often start with words like, "I'm at the end of my rope here, and suicide is on my mind constantly."

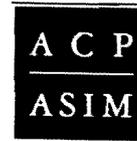
The suicide rate has shot upwards, according to the Centers for Disease Control, for the first decade since the 1940s, and I feel it's due to the problems in getting pain medicine since the mid-1980s. That's when it started to get very hard for me to get pain medication because of the DEA's war on drugs which, for pain sufferers, has become a war on patients. Before that doctors treated my pain. But with an overly zealous DEA looking over their doctor's shoulder, many patients tell me they are given only one or two four-hour pain pills per day for their suffering. Some can get only 30 pills per month. That would be just 4 hours of pain relief a day, if the pill is even strong enough to control the pain, which it often is not. You need to keep putting the pills into the system every four hours to have the pain control.

In a study published in the Journal of Pain and Symptom Management, only 19 of 22,000 patients taking opioid medications for the treatment of pain became addicted to the opioids. That shows us that less than one tenth of one percent are at risk for addiction. Yet the drug war would lead us to believe it's the other way around.

By expanding the DEA's powers, increasing its control over the practice of medicine, and further scaring physicians and pharmacists from prescribing and supplying adequate amounts of pain medication, the proposed "Lethal Drug Abuse Prevention Act" would twist this bad situation even more out of shape. It will be a disaster for those of us who suffer from chronic, intractable pain and I have no doubt it will drive many pain sufferers to suicide. For God's sake, don't do this to us.

Skip Baker, President, ASAP, American Society for Action on Pain
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Statement
of the
American College of Physicians–American Society of Internal Medicine



American College
of Physicians
American Society
of Internal Medicine

Robert B. Copeland, MD, MACP
Chair, Board of Regents
August 20, 1998

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The American College of Physicians–American Society of Internal Medicine (ACP-ASIM), the nation's largest medical specialty society, strongly opposes the Lethal Drug Abuse Prevention Act (H.R. 4006/S. 2151). The underlying tenet of the medical profession is: First, do no harm. Ironically, this bill could bring undue suffering to hundreds of thousands of terminally-ill patients across the country. On behalf of the College's more than 100,000 physician and medical student members, we urge Congress to reject this legislation and commission a thorough analysis of the complex issues surrounding end-of-life care.

Internists, physicians who specialize in adult medicine, treat dying patients almost daily. We fear this bill could have the unintended consequence of increasing the already too-large numbers of patients dying in severe, constant pain.

The goal of this legislation is to prevent physician-assisted suicide. It attempts to do this by revoking a physician's license to prescribe narcotics for *any* purpose if a government investigation finds that the physician prescribed narcotics to hasten death at a patient's request. However, this issue is not a black or white. How would the government be able to decide which physicians to investigate, especially since a patient who is terminally ill could have died at anytime?

ACP-ASIM opposes the Lethal Drug Abuse Prevention Act because it would:

Adversely affect the care of terminally-ill patients. Pain is the symptom most dreaded by dying patients. In order to control pain effectively, physicians who are skilled in the care of dying patients often prescribe large doses of narcotics. Multiple studies have shown that government regulation is a barrier to prescribing adequate pain control. For example, a New York study found administrative hassles to decrease the likelihood physicians will prescribe needed painkillers, so the state recently enacted legislation to eliminate many of those hassles. (See attached.) If administrative hassles are a deterrent to appropriate end-of-life care, imagine the effect of a national law that threatens to revoke a physician's license to prescribe narcotics.

Jeopardize patients' privacy. In order to defend themselves, physicians under investigation would have to disclose to government investigators the details of patient care that should be held in confidence.

Intrude on family members' privacy. Investigators would have to question grieving family members about the most private of family matters in order to determine the circumstances surrounding their loved one's death.

Damage a physician's professional standing. A mere accusation of violating the Controlled Substances Act is a very serious matter and would damage a physician's reputation even if he or she is ultimately exonerated. There is also the danger that physicians who hear about such investigations will decide that the safest course of action would be to reduce their use of narcotics—even though narcotics provide the best form of pain relief.

The medical profession has just begun to make great strides in the area of pain management. One example is ACP-ASIM's multi-faceted project that educates internists and their patients about appropriate end-of-life care and effective pain relief for dying patients.

The care of dying patients is complex and controversial. Instead of enacting legislation that attempts to draw a line where no line can be drawn, Congress should authorize a meaningful study on the myriad end-of-life care issues.

Progress Against Pain

New York's Governor George Pataki signed a bill last week eliminating much of the red tape doctors encounter as they prescribe painkillers for severely ill patients. The medical system's inadequate treatment of patient pain has recently been receiving increasing attention in the medical journals. "Not to relieve pain optimally is tantamount to moral and legal malpractice," says Dr. Edmund D. Pellegrino in the May 20 Journal of the American Medical Association. So New York's action is a significant step forward.

First, doctors will no longer have to use a triplicate form to prescribe controlled substances like narcotics, barbiturates and amphetamines. Instead, a single form will relay the dose information to a pharmacist who will electronically relay that information to the state.

And to overcome a huge legal hurdle, the relevant terminology has been changed so that doctors can prescribe higher doses of medications. An "addict" was previously defined as anyone who habitually used a narcotic drug. Now, it's a person who *unlawfully* uses a controlled substance. And a "habitual user" is redefined to be someone who repeat-

edly and unlawfully uses a controlled substance. Though slight, these definitions will ease the anxiety of many physicians.

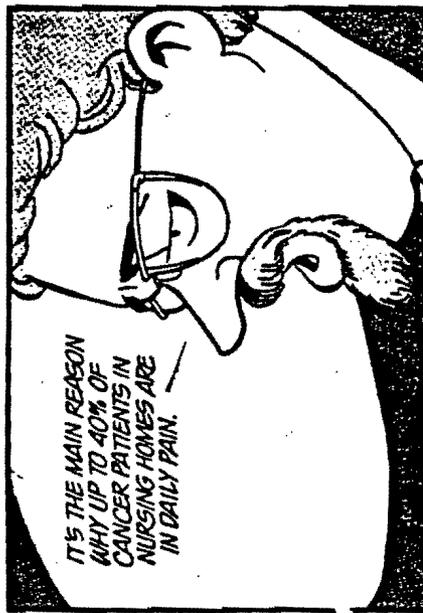
Many doctors are afraid to prescribe morphine and other drugs that are well tolerated in many suffering patients out of fear they'll be labeled "pushers." Since the triplicate form monitoring system was established in 1977, many physicians have pulled back from helping some of their most anguished patients.

Tales of pharmacists refusing to fill prescriptions have been common, with some doctors sneaking their patients contraband pills. Still, despite New York's lead, this will be a slow process as doctors overcome their longtime fear. "The boards of health have terrified us," says Dr. Philip Alper, internist and professor at the University of California San Francisco. "I avoid prescribing pain medication because it will cause problems."

As with the landmark critique of assisted suicide that was produced during the Cuomo administration, New York is showing that it is indeed possible for the political system to respond to matters as complex as the treatment of intractable pain.

DOONESBURY

By Garry Trudeau



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AMERICAN PAIN FOUNDATIONSM

**STATEMENT TO MEMBERS OF THE U.S. SENATE
AND HOUSE OF REPRESENTATIVES
ON S. 2151/H.R. 4006
“THE LETHAL DRUG ABUSE PREVENTION ACT OF 1998”**

**James A. Guest
Executive Director
American Pain Foundation**

The American Pain Foundation is a nonprofit education, information and advocacy organization dedicated to the cause of effective pain management and representing the interests of pain sufferers. Our mission is to prevent and relieve unnecessary pain and improve the quality of life and daily function of persons who suffer from pain. We speak on S. 2151/H.R. 4006 on behalf of pain patients.

The American Pain Foundation does not support physician assisted suicide. What we do support is effective pain management for those who suffer from intractable, chronic pain. We oppose S. 2151/H.R. 4006 because it would deter rather than promote effective treatment. Indeed, because of the deterrent effect, S. 2151/H.R. 4006 is actually more likely to increase rather than decrease the incidence of suicide, assisted and otherwise, by those who can no longer tolerate the agony of pain.

I want to underscore how serious and pervasive the problem of disabling chronic pain is in America and how disastrous it would be to inadvertently inhibit good pain management:

- **Disabling pain is epidemic.** 16% of households in America have someone who suffers from severe chronic pain and over 50 million people today have disabling chronic pain.
- **Pain is devastating to individuals and families.** When pain persists it permeates the patient's entire life, making it difficult to concentrate and to perform even routine tasks. Lost workdays and medical costs can be financially ruinous. One of the most common reasons people cite for supporting Dr. Jack Kevorkian's controversial views on physician-assisted suicide is fear of intractable pain.

- **Pain is costly to society.** The annual cost of chronic pain (including medical expenses, lost income and lost productivity) is an estimated \$100 billion. Lost workdays resulting from pain add up to over 50 million a year.
- **Most pain is treatable.** According to the Agency for Health Care Policy and Research, 90% of cancer pain can be relieved through relatively simple means. For most types of pain, there is a safe, effective treatment available that can alleviate if not eliminate the pain.
- **Most pain is undertreated.** Over 70% of cancer patients, for example, experience moderate to severe pain during their illness, yet fewer than half of these receive adequate treatment for their pain.
- **Most pain sufferers are undermedicated.** In a large survey of oncologists, 86% of respondents felt that the majority of patients with pain were undermedicated. The same is true for most other types of pain. Many physicians are reluctant to prescribe opioids because they mistakenly think their patients will become addicted to the drug or because they fear investigation and sanctions by regulatory bodies.
- **Opioids are not addictive when taken for pain.** Too many people – patients, health care providers, policymakers – have the misimpression that opioids and other medications taken for pain are addicting. That is simply not true – studies have shown that less than 1/10 of 1% of patients taking opioids for pain become addicted – but the myth about addiction drives many tragic decisions that result in the undertreatment of pain and the needless suffering that follows.

It is crucial that Congress avoid taking action that would exacerbate rather than alleviate the widespread problem of pain and the serious undertreatment of pain. We applaud the intent of S. 2151/H.R. 4006 when it states that one of the purposes is “to encourage physicians to prescribe controlled substances as medically appropriate in order to relieve pain and discomfort, by reducing unwarranted concerns that their registration to prescribe controlled substances will thereby be put at risk, if there is no intent to cause a patient’s death.”

The reality, though, is that the effect of S. 2151/H.R. 4006 will be to discourage, not encourage, medically appropriate use of opioids and other controlled substances to alleviate pain. The Judiciary Committees have received ample testimony from the medical community spelling out this undeniable reality. Experience as well as common sense as well as the overwhelming view of health care professionals tells you that giving the Drug Enforcement Administration increased powers and more bureaucracy to monitor and make judgments about the practice of medicine will deter health care professionals from good pain management at a time when pain is already vastly undertreated.

There are two big, highly complex issues involved in S. 2151/H.R. 4006: (1) physician-assisted suicide, and (2) the need for better pain management. Each issue raises important unanswered questions and deserves full and proper consideration in its own right. Assisted suicide goes far beyond the use of controlled substances. And relieving pain goes far beyond the DEA.

We urge you to undertake full and thoughtful hearings and careful deliberation on each of these two issues – not linking them together by the pressure for hasty action, but considering them separately on their own merits. Meanwhile, potentially serious and far-reaching changes in the treatment of pain should not occur simply as the by-product of a bill on assisted suicide.

The War on Drugs has already become a War on Patients by deterring doctors from prescribing adequate amounts of opioids and other controlled substances for pain. Now, before deciding whether or not to give the DEA an expanded role in the practice of pain management – before running the risk of making it harder for pain sufferers to get relief – listen to the actual words of pain sufferers as shared on the Internet through the American Society for Action on Pain:

- *Going into my 12th year of not a pain free day. Just because we're not "terminal" doesn't mean we have to suffer; worse yet, many die from suicide; know so, and I was a smidgen away from being one of the statistics, and if my pain meds are pulled, by the DEA dictating to my pain specialist what I am allowed to have to control agony they cannot begin to imagine, a statistic I shall become.*
- *After 5 years and one suicide attempt (Nov. 1994) I was started on Methadone 5mg a day titrated up to 40 mg a day, finally some relief, I actually was able to get out of bed and do a little living. During the next 5 months, I was titrated up to 70 mg a day and was told it was as high as he could go with it, a month later I was back to my old self, with the headache growing worse and my doctor saying, he was sorry, but there was no more he could do, although when I hurt so bad I just screamed and cried, he would send me to the ER for some pain control....I do not want to live anymore, I am a 30 yr old man who is crying as I type this letter, because I can just no longer stand the pain and the impact it has made on my life, as well as my family's....I don't want to die, I want to live and be productive and see my little girl grow up, but I really feel I have been sentenced to death and my crime was I was in the wrong place at the wrong time and I am forever going to have these headaches.*
- *One of my dearest friends...was planning suicide after 11 years of living with the unbearable pain of arachnoiditis.. (She had "gotten permission" from her family to take her own life over her suffering. It's one more proof*

that the DEA must be stopped. Americans should not have to commit suicide over untreated pain.

- *I was unable to care for my three children, most of my day was spent in bed in terrible pain. I had no quality of life. I was seriously considering taking my own life, as the pain was absolutely unbearable and I was unable to get any relief. I was suicidal, even though taking one's own life is totally against my beliefs and my religion. I point this out to you to emphasize the desperation to which patients of intractable pain can fall.*
- *I like many others have thought of committing suicide due to my pain. The feeling that I can not take the pain any more is all too real for me. I pray to God almost on a daily basis for him to please take me and save me from this horrible life of pain. I am made to feel guilty because I seek pain meds to treat my pain by close minded doctors. My whole life revolves around pain and thoughts of suicide.*
- *My doctor said...that most fibro patients end up killing themselves. Well maybe if we got the meds we needed we wouldn't kill ourselves. ...Why can't they see that.*

And listen to a physician talk about the chilling effect that regulatory sanctions – and the threat of regulatory sanctions – can have on the availability of good pain management:

My license to practice medicine has been placed in probationary status by [the state medical board] for over prescribing narcotic analgesics to 4 patients with chronic, non-malignant pain. Three of the four patients are deceased, two by suicide when their narcotic analgesics were discontinued and one by congestive heart failure. This action was taken, not as the result of patient complaint, but from a complaint registered by an anonymous pharmacist. As a result of the limitations placed on my license, I have been terminated by three insurance plans, comprising 35% of my practice, lost my eligibility for Family Practice recertification, and lost a part-time position as medical director.

I have never been named in a malpractice suit, never been previously censure by any professional organization, and have the continued support of my patients formerly treated for chronic pain with narcotic analgesics.

My livelihood is being taken away because of compassionate, well-documented care of patients with FDA approved medications which were not diverted but used for the relief of intractable and verifiable chronic pain. This is not due to a lack of education regarding the proper use of narcotic analgesics. Regulation has destroyed my career and put fear into

my colleagues who are wisely, if not humanely, terminating their narcotic-prescribing practices for other than acute or terminal pain.

We implore you not to cause unnecessary pain and suffering by making it harder for physicians to provide effective pain relief, as will be the case under S. 2151/H.R. 4006. Don't let the impetus to fashion a response to the Oregon law turn back the clock on achieving better pain management. Don't make the victims of intractable pain victims a second time as innocent bystanders in the debate on physician assisted suicide.

Let me say again, the American Pain Foundation is not in favor of physician assisted suicide. But the Controlled Substances Act is the wrong vehicle to deal effectively with the issue because of the impact on the legitimate practice of medicine and effective pain management. S. 2151/H.R. 4006 is likely to result in excruciating and avoidable pain for hundreds of thousands of Americans – probably millions of Americans – who suffer from severe chronic pain.

Finally, people in pain have a hard time being taken seriously. Doctors, friends, even family members accuse them of making it up or overreacting. The message from society often seems to be tough it out, don't complain, don't be a whiner, don't bother me. Pain is stigmatized by society.

Well, we are deadly serious about the dangers of S. 2151/H.R. 4006. We hope that you, our Senators and Congressmen, will take pain sufferers and their concerns seriously – deciding that Congress should devote the time needed for full, thorough and separate attention to both physician assisted suicide and effective pain management, and deciding against passage of S. 2151/H.R. 4006.

August 19, 1998

August 13, 1998

The Honorable Ron Wyden
717 Hart Senate Office Bldg.
Washington, D.C. 20510

Dear Senator Wyden:

The undersigned organizations represent people with cancer, their families and their caregivers. We are writing to express our concerns about S. 2151, the Lethal Drug Abuse Prevention Act of 1998, which we believe will hinder the ability of individuals with cancer to receive proper management of their pain.

Patients with cancer often suffer serious pain as a result of their illness, and the likelihood that they will have severe pain increases to over 70 percent in the terminal stages of the disease. We know that the quality of life for individuals with cancer and other life-threatening illnesses can be measurably improved if their pain is properly controlled. There is no reason cancer patients should suffer uncontrolled pain, if they receive aggressive treatment for it.

Unfortunately, many cancer patients still suffer unnecessarily for many reasons, including physicians' fear regarding the scrutiny of government regulators and law enforcement officials if they prescribe pain medications in sufficient quantities and doses to control pain. By expanding the authority of the federal government to regulate the dispensing of pain medication under the Controlled Substances Act and establishing a Medical Review Board on Pain Relief, the Lethal Drug Abuse Prevention Act will add a layer of government regulation and oversight that will further discourage the proper treatment of pain.

Individuals with cancer start the fight for their lives when they receive their diagnosis. They aggressively seek those therapies that offer the best chance of extending and improving their lives, including proper pain control. We urge you to refrain from a legislative approach that will make the lives of individuals with cancer more difficult.

National Coalition for Cancer Survivorship
Cancer Care, Inc.
Susan G. Komen Breast Cancer Foundation
National Alliance of Breast Cancer Organizations
US-TOO International, Inc.
Y-ME National Breast Cancer Organization

Leukemia Society of America, Inc.
American Society of Clinical Oncology
Oncology Nursing Society

August 12, 1998

POSITION STATEMENT ON HR 4006/S 2151

Americans for Better Care of the Dying (ABCD) is a grassroots membership organization dedicated to improving the lives of seriously ill patients and their families. To that end, ABCD has been working to educate caregivers, consumer advocates, the public and the media -- about both the proven paths to better care for those facing the end of life and also the pitfalls and barriers. This bill could be a calamity for all of us who want reliably good care for dying persons and their families.

ABCD is formally opposed to legalization of physician-assisted suicide and firmly believes that a vote against this bill is a vote against physician-assisted suicide. This well-intentioned legislation will likely reverse the recent trend toward better support and pain relief at the end of life. Making dying worse and making care less reliable will increase the demand for physician-assisted suicide.

Proponents of this bill speak as if it will offer a clean and simple vote on the propriety of legalizing assisted suicide in this country. *Ironically, this bill would not succeed at stopping the practice of legal physician-assisted suicides in the state of Oregon (the only state in the US where it is presently legal). There are too many ways to assist in suicide that do not involve a physician prescribing a controlled substance. Kevorkian has used carbon monoxide, which is not even a drug!*

This bill envisions having the Drug Enforcement Administration investigate allegations of wrongdoing, which are to be judged by the quite ambiguous and unworkable standard of the "intent" of the physicians involved. *Physicians will want to avoid the uncertainty, fear, exposure of patient privacy, and loss of reputation such proceedings entail. Many will find it more acceptable to provide less vigorous relief of pain and other symptoms rather than to risk these harms.*

As the attached hypothetical cases illustrate, severe and pervasive harms will come from just the investigations of alleged wrongdoing—even if the alleged perpetrators are eventually completely exonerated. The "advisory board" comes at the end of the investigation, so it can't dilute the problems created by making a police authority, the DEA, into the arbiter of the standards of good end-of-life care. Even the standard of "intent" used in the bill, which is workable enough as a guideline for medical ethics, is completely impractical as a component of criminal law.

Presently inadequate care of those nearing the end of life should be an outrage and a shame for a society which could readily do so much better. Americans are afraid of what awaits them in that last phase of life. But this bill only worsens the situation. There does need to be a federal agenda—and that requires addressing standards and financing, having thoughtful discussion, gathering data, and trying out innovations. We should commit to engaging in those challenges. Only real reform will allow Americans to be confident of comfort and choice at the end of life.

Case #1

Alpha Nursing Home has long prided itself on being responsive to community needs and striving to be a thoroughly caring institution. Over the past decade, they had gradually developed the expertise to keep almost all of their severely ill patients on-site, rather than transferring them to the hospital for every problem. Families were pleased with the continuity and confidence, and with the thought that "Mother won't be sent away to die."

Then, an unfortunate misunderstanding arose. Mrs. Smith, a 94 year-old lady with severe life-long schizophrenia developed colon cancer. Her family and caregivers decided to keep her comfortable where she lived and to try not to hospitalize her or to restrain her. Her illness was quite painful and she could not understand much of what was going on. To keep her comfortable required high doses of opioid drugs, as well as enemas, assiduous skin care, and her favorite music playing on the radio. As a result, she spent her time either asleep or moving about anxiously, seeming to be diffusely uncomfortable and not eating or attending to what people would say or do around her. Her sister, 82 years old, took the physician aside during rounds, saying: "Doctor, I hope this won't go on much longer. It is no good for her, or for me." The Doctor responded: "I understand. It is very hard to wait for the end." The sister replied: "I hope you will do all that she needs to keep her from more suffering." Later that day, the doctor ordered that her pain medications be increased, aiming to keep her in a twilight sleep all or most of the time until the end. Within hours, she was found dead.

An agency nurse, hired just to cover a temporary absence of a regular staff nurse, was distressed by this and called the physician saying, "Don't you think that your medicines killed her? Weren't you really just treating the family and cutting her life short?" The physician did not take much time in explaining, just saying that the nurse misunderstood. Whereupon, she filed a complaint in her agency and it ended up being forwarded to the DEA. Of course, by the time that the agent arrived to investigate a few days later, recollections of many were uncertain. He seized all records and started developing a description of what happened. Just having this burly man in a suit who carried a gun and was sitting on the nursing unit reviewing records caused a "top to bottom" change in the environment. Everyone became guarded. Some became angry. Others said that the doctor was getting what he deserved and that the nursing home should never aim to take care of patients "that sick." Overall, the questioning was paralyzing to normal business. Tensions arose especially when the agent found that the medical record included a note that said "We can only hope for a gentle passage - and soon!" No one was more stricken in being questioned than the sister, who quickly understood that the agent was trying to see whether she had set out to have her sister killed.

Although the investigation was eventually called off, the institution was not the same. When the next patient needed aggressive pain management near death, everyone was on "pins and needles" about what they said, what they "let" families say, and how things were documented in the chart. The entire experience was distressing for all involved, and the nursing home staff realized that they were no longer sure that they could be proud of good care and could effectively reassure families. When the nursing home administration later reviewed its budget, they noted that end-of-life care was obtainable at the hospital and that the nursing home would be in a much better financial position if that were done. They tried not to note that transfers to strange environments are often disastrous for old and frail nursing home residents. The physician had come to feel more safe there too. Within a few months, an excellent care system that served a community well was dismantled. None of the new patients or families even knew that they were now getting second rate care.

Case #2

Mr. Smith, a 72 year-old man with prostate cancer, was dying rather miserably. He could not walk and had to have a catheter. His bones were riddled with cancer and he had a great deal of pain. He was already taking 120mg of morphine in a sustained release form every six hours, and still said that the pain is "11 on a scale of 0 to 10." He could not move in bed. Baths were excruciating. Enemas caused so much pain that he became nauseous and dizzy. He had lost 40 pounds. His home care nurse called his doctor seeking more pain medication. The doctor had not seen him at home ever and had not seen him at all since he was last in the hospital for radiation, three months ago. The doctor had never had a patient on this much morphine. No one had suggested hospice care. The doctor said to try hot water bottles and to move him less.

The nurse was distraught and convinced his wife to call another doctor who might come see him at home. The second doctor was uncomfortable with the situation and tried to just offer to talk with Doctor #1 about options in pain management – but Doctor #1 was not interested. All this had taken four days, before Doctor #2 came to see him. The patient was immobile and withdrawn. Any movement caused unbearable tension in muscles and resulted in expletives, along with "Get away from me. You are no good." Mrs. Smith was in tears. Doctor #2 offered to try injections of morphine until Mr. Smith was at least more comfortable. After four injections of 60 mg every 15 minutes, Mr. Smith was resting quietly. Doctor #2 agreed to take over care from this time to death but decided not to suggest hospice support because it would mean losing the trusted home care nurse. He set up a schedule which more than doubles the morphine dose.

The pharmacy resisted delivering this much of an opioid drug, but finally agreed. However, the sudden jump in opioid use through this pharmacy occasioned a call from the DEA. In error, the agent ends up calling Doctor#1 who said that Doctor #2 was using narcotics irresponsibly. Mr. Smith had died before the agent called Doctor #2, who contended that everything was done correctly. The agent called the wife and nurse. They readily admitted that they wanted Mr. Smith to die and would have been grateful if Doctor #2 had just given him enough morphine to see that he died: "He was suffering so much." However, they are not sure whether Doctor #2 really did that or not. Doctor #2 claimed that he had no such intent, but he acknowledged that he increased the doses in the last few days on the basis of reports from the wife and nurse, since he did not see the patient alive again after that first visit. The agent is quite perplexed as to what the "intent" was here, and whether there is anything to be troubled by. Doctor #2, on the other hand, was much less perplexed. He has lost reputation and income for trying to help out in a tough situation. It will be a long time before he does that again.

Open Letter to Mr. Richard Doerflinger, Associate Director,
Secretariat for Pro-Life Activities, NCCM, USCC. [U.S. Catholic Conference]

Subject: HR 4006

From: Rev. Mr. John D. Kelly, Pastoral Care Coordinator,
Palliative Care Service, Providence Hospital, Washington, D.C.

Dear Mr. Doerflinger,

In the Catholic Standard of July 30, 1998 (and, I presume, in other newspapers in the nation) there was your article "Protecting the Care of Patients." In this article you argued in favor of the Lethal Drug Abuse Prevention Act of 1998 (HR 4006). You stated that the Bill is "simple" and "straight forward." It is neither.

On August 6, 1998, in response to Dr. Joanne Lynn's "e-mail alerts" you sent your own e-mail to the same addresses offering a "friendly rebuttal." In this message you stated that your list of experts "have done something that the vast majority of those who claim to oppose the bill have not done: they have actually read the bill." Not a nice way to speak of those who oppose this bill when, in the matter of Physician Assisted Suicide (PAS) the "vast majority" IS ONE YOUR SIDE!

In my nearly twenty years as a Pastoral Care person in the field of Hospice and Palliative Care, a field in which the primary focus has been on pain control and symptom management, it has been demonstrated that the most difficult part of this work is not convincing patients or families to accept Hospice or Palliative care. The most difficult part has been the acceptance by physicians of good pain control and symptom management methods as well as all the other issues involved in end-of-life care. The literature in this field is replete with examples of physicians resistance to these issues. (See SUPPORT Study JAMA, 274/20, '95 in which Dr. Lynn was a principal investigator).

Another study done by a coalition of Catholic health care providers indicated "serious lack of professional education in skills, behavior and value of comprehensive supportive care for patients with life threatening illness." (Report by Supportive Care of the Dying: A Coalition of Compassionate Care, SCD: CCC, June, 1997). In a separate article by Alicia Super, R.N., and Lawrence Plutko, two principals in SCD: CCC one "danger sign" pointing to causes and consequences of inadequate care of the dying is "physicians fear of litigation as the rationale for transferring dying patients to intensive care units (Health Progress, March-April, 1996).

On a personal note, I have been present when doctors have ignored Advanced Directives and/or Living Wills and have continued active, acute care treatment of patients when a family member threatens litigation unless "everything is done". It is not a pleasant sight watching a patient die under these circumstances

The consequences of this proposed legislation are surely predictable, and they will come from not only those physicians who have been resistant to accepting good end-of-life care for patients, but also from those physicians who use their skills in palliative and other good caring measures. While the protection clause appears reasonable, the very possibility of having a charge levied against them will be an implicit deterrent to the practice of effective pain-control measures. The promise of a "Medical Advisory Board on Pain Relief" while it sounds good means only that it will be necessary for the legitimate physician who uses the controlled substance to alleviate pain to expend time, energy and effort to defend himself or herself in an investigation when charged by anyone who chose to bring the charge.

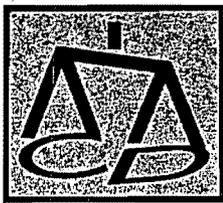
You can add to that the fact that such an investigation can subject him or her to injurious publicity. This is the predictable "simple" and "straight forward" consequence of this Bill. One might wish that denial of physician assisted suicides would be equally predictable but with the ready availability of non-controlled substances for this purpose, this result is highly unlikely, even in Oregon. The possibility, however remote, to file a complaint with the DEA will be enough to deter a physician from acting appropriately – EVEN WHEN HE/SHE KNOWS THE ACT IS JUSTIFIED! The total cost of defending himself AND the consequent publicity will not be worth the effort. How many of us in any walk of life would risk facing this challenge?

Sweetening this bill by being more protective of Palliative Care or by adding money to educate in end-of-life care is of little or no benefit if the threat of investigation and review are still there. As Dr. Ira Byock suggested to Senator Nickel this bill should be scrapped and better legislation providing funding for education should be enacted.

This is a mischievous bill. It does not warrant acceptance by those who are properly opposed to assisted suicide or euthanasia in any form. It should not be supported by organizations or bodies of any Christian church simply because the harm it will do to patients far outweighs the questionable good it will do in the prevention of assisted suicide. To put this within the phraseology of "Issues In the Care of Dying" (pg. 5, Ethical and Religious Directives for Catholic Health Care Services, NCCB, 1995) the "excessive burden" imposed on patient, physician and family (including "excessive expense" on physicians) far outweighs the "reasonable hope of benefit" in deterring assisted suicide. (Quoted phrases are from Dir 56, NCCB, 1995).

Rev. Mr. John D. Kelly
Pastoral Care Coordinator
Palliative Care Service
Providence Hospital, Washington, D.C.

CHOICE IN DYING



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fax 202-338-0242

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fax 212-870-2040

MEMORANDUM

To: Sue Hoechstetter

From: Carol E. Sieger, Esq.
Choice In Dying, Inc.

Date: August 6, 1998

Re: *State of Kansas v. Naramore*
No. 77,069
Date of Decision: June 26, 1998
Court of Appeals of the State of Kansas

The following is a brief summation of a recent Kansas Court of Appeals opinion involving the criminal prosecution of a physician who had been convicted of attempted murder in the context of controlling the pain of a terminally ill patient.

Legal History:

Jury Trial/ January 1996: The jury returned verdicts of attempted murder on Count I (see facts below) and second-degree murder on count II (facts not repeated for purposes of this memo.) Dr. Naramore was sentenced to concurrent terms of 5 to 20 years. He was free on parole at the time of the Court of Appeals decision.

Court of Appeals decision: The court ordered acquittal of the physician because there was insufficient evidence to establish criminal guilt. The Court believed that based on the medical testimony a reasonable jury would have to find reasonable doubt as to the physician's guilt and as such should have reached a non-guilty verdict.

As of August 5th the Court of Appeals decision had not been appealed to the Kansas Supreme Court.

Facts of Case:

78 year old woman with a history of cancer which at the time of her admission to the hospital in May 1992 had spread widely and she was considered terminal. The patient at that time was experiencing increasing pain. Dr. N., after examining her, spoke with the family re: increasing the pain medication. They discussed her living will and that the increased use of pain medication could possibly hasten her death. The family agreed to increase the medication. Dr. N. gave the patient two different types of pain medication, however, the family only gave consent to small amounts of morphine due to fears of respiratory failure. Dr. N. removed himself from the case because of

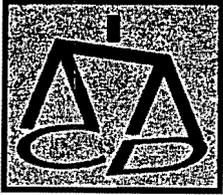
conflicts with the family regarding the amount of pain medication that was appropriate. She was transported to another hospital where she died several days later.

Implications:

The Court of Appeals decision is a victory and may lift some of the uncertainty regarding criminal liability. However, there is concern that a criminal prosecution such as this one, even though ultimately in the physician's favor, will still have a chilling effect on the prescribing of sufficient narcotics to control pain in the terminally ill.

Although today's technology can alleviate most severe pain, studies show that many terminally ill people still die in pain. It is clear from the literature that doctors undertreat pain. There are several barriers to the treatment of pain, not the least being physicians' fear of disciplinary actions and criminal prosecution. While criminal prosecutions such as this one are relatively few, even the possibility of an investigation can significantly inhibit a physician's willingness to provide the quantities of strong narcotics necessary to relieve some severe pain. The ramification of cases such as this could be enormous.

CHOICE IN DYING



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August 5, 1998

The Honorable Orrin Hatch
Chairman of Senate Judiciary Committee
SD-224 Dirksen Senate Office Building
Washington, DC 20510-6875

Dear Chairman Hatch:

As Executive Director of Choice In Dying, I appreciate the opportunity to submit this letter for the record for the July 31st Senate Judiciary Committee hearing about physician assisted suicide. I am writing about S.2151, "The Lethal Drug Abuse Prevention Act." Choice In Dying, which pioneered living wills, is a 56 year-old not-for-profit organization dedicated to improving the way people die in this country by improving communication between patients, families and their doctors and by educating everyone about alternatives to physician assisted suicide. In December and earlier this month we conducted briefings at the Capitol for legislators, their staff, and the health care community about such alternatives.

We urge you, on behalf of our 140,000 supporters from all around the country, to oppose or radically amend, S.2151. Our constituents are terminally ill patients, members of their families and their health care providers. They are concerned that the proposed legislation, if enacted, **will not facilitate much needed improvement in care for the dying** (and thus dramatically decrease interest in physician assisted suicide), but rather would result in serious backsteps in such care, particularly related to pain management.

According to a 1997 Institute of Medicine study, physicians already are wary of treating pain effectively because of existing drug prescribing laws and regulations. S.2151 will increase hesitancy to adequately prescribe by raising the specter of career-damaging Drug Enforcement Agency (DEA) investigations of prescribing decisions. Who would want to tell a person, dying in horrendous pain, that sufficient pain medication cannot be prescribed because the intent of such a prescription might be misinterpreted?

Instead of moving legislation that would result in punishment for those in pain, I strongly encourage you to debate and pass laws that will improve access to humane, compassionate, high-quality end-of-life care. Such laws, for example, might include requirements that physicians demonstrate competence in pain management before being granted license to prescribe controlled substances. Or such laws might include much more robust and far-reaching education for the public about options to physician assisted suicide like hospice and other palliative care programs.

Chairman Orrin Hatch
August 5, 1998
Page 2

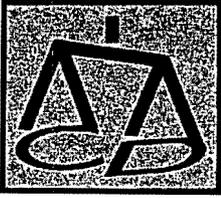
One excellent bill that would do this is the bipartisan Advance Planning and Compassionate Care Act of 1997, S.1345. We urge you to discuss this proposed law with Senator Susan Collins (R-ME) and Senator Jay Rockefeller (D-WV), its primary sponsors, and to support this effort.

We stand ready to work with you to create policy and other proposals that will help improve care for the dying and their families and provide truly better options to physician assisted suicide.

Sincerely yours,

Karen Orloff Kaplan, MPH, ScD
Executive Director

CHOICE IN DYING



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August 5, 1998

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

Dear Chairman Hyde:

As Executive Director of Choice In Dying, I am writing to express our opposition to HR.4006, "The Lethal Drug Abuse Prevention Act." Choice In Dying, which pioneered living wills, is a 56 year-old not-for-profit organization dedicated to improving the way people die in this country by improving communication between patients, families and their doctors and by educating everyone about alternatives to physician assisted suicide. In December and earlier this month we conducted briefings at the Capitol for legislators, their staff, and the health care community about such alternatives.

We urge you, on behalf of our 140,000 supporters from all around the country, to oppose or radically amend, HR.4006. Our constituents are terminally ill patients, members of their families and their health care providers. They are concerned that the proposed legislation, if enacted, **will not facilitate much needed improvement in care for the dying** (and thus dramatically decrease interest in physician assisted suicide), but rather would result in serious backsteps in such care, particularly related to pain management.

According to a 1997 Institute of Medicine study, physicians already are wary of treating pain effectively because of existing drug prescribing laws and regulations. HR.4006 will increase hesitancy to adequately prescribe by raising the specter of career-damaging Drug Enforcement Agency (DEA) investigations of prescribing decisions. Who would want to tell a person, dying in horrendous pain, that sufficient pain medication cannot be prescribed because the intent of such a prescription might be misinterpreted?

Instead of moving legislation that would result in punishment for those in pain, I strongly encourage you to debate and pass laws that will improve access to humane, compassionate, high-quality end-of-life care. Such laws, for example, might include requirements that physicians demonstrate competence in pain management before being granted license to prescribe controlled substances. Or such laws might include much more robust and far-reaching education for the public about options to physician assisted suicide like hospice and other palliative care programs.

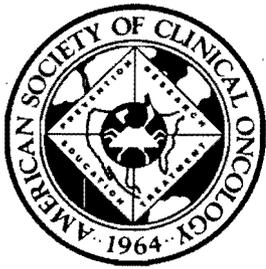
Chairman Henry J. Hyde
August 5, 1998
Page 2

One excellent bill that would do this is the bipartisan Advance Planning and Compassionate Care Act of 1997, HR.2999/S.1345. We urge you to discuss this proposed law with Representative Sander Levin (D-MI), Senator Susan Collins (R-ME) and Senator Jay Rockefeller (D-WV), its primary sponsors, and to support this effort.

We stand ready to work with you to create policy and other proposals that will help improve care for the dying and their families and provide truly better options to physician assisted suicide.

Sincerely yours,

Karen Orloff Kaplan, MPH, ScD
Executive Director



American Society of Clinical Oncology

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John R. Durant, MD

August 3, 1998

The Honorable Henry J. Hyde
U.S. House of Representatives
2110 Rayburn House Office Building
Washington DC 20515-1306

Dear Congressman Hyde:

The American Society of Clinical Oncology (ASCO) is the medical professional society that represents physicians and other health professionals that treat people with cancer. ASCO's more than 12,000 members are trained to provide the best available care, including pain management, to the millions of Americans with a diagnosis of cancer. We are writing to express our concern about the unintended consequences of legislation recently introduced in the House and referred to the Committee on the Judiciary.

The "Lethal Drug Abuse Prevention Act of 1998," H.R. 4006, would greatly expand the authority of the federal government to regulate the dispensing of pain medication under the Controlled Substances Act. While the legislation purports to be limited to cases in which physicians "intentionally" prescribe controlled substances for the purpose of assisting suicide, the question of intent may be a difficult one to resolve. The risk of losing the ability to prescribe such essential medications will undoubtedly deter some physicians from aggressive treatment of pain in patients with cancer and other life-threatening diseases.

The failure adequately to address pain is a major issue in the treatment of cancer, and the problem is particularly acute among the elderly and minorities, as recently reported in a study published in the June 17, 1998, *Journal of the American Medical Association (JAMA)*. 1998;279:1877-1882). One reason for this inadequacy is identified in an accompanying editorial--i.e., physician fears of regulatory scrutiny under the Controlled Substance Act if they aggressively treat cancer pain. Thus, under existing legal requirements, physicians are already reluctant to prescribe pain medications in sufficient quantities to control pain. We fear that an additional layer of regulatory uncertainty generated by the proposed legislation would make an already bad situation even worse.

1998

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1999

ANNUAL MEETING

MAY 15-18

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Patients in the last days of life as a result of cancer have a right to aggressive treatment of their pain. Quantities of controlled substances required to address this intense pain may approach levels that could be misinterpreted as reflective of an intent to assist in suicide, even though there may be no such intent. No physician that prescribes pain medications will fail to take account of the possibility that prescribing decisions may be second-guessed by the new bureaucracy that would be established under the legislation.

There is no question that this new regulatory regime will exert a chilling effect on the prescribing decisions of physicians confronted with uncontrolled cancer pain in their patients. This is a shame because states generally have demonstrated their competency to regulate the difficult issues related to pain management and potential assisted suicide. We have serious reservations about the necessity for creation of a new federal bureaucracy in the form of the Medical Review Board on Pain Relief.

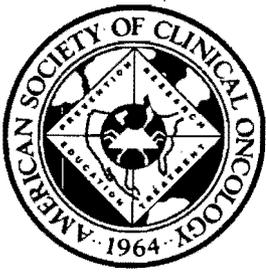
People with cancer rightly expect their physicians to prescribe the necessary medications to treat their pain. They do not want their physicians to be deterred from adequately treating their cancer pain by the threat of oversight from a panel of federal regulators. We urge the sponsors of this legislation to reconsider its advisability and request that members of the Committee withhold their support.

For your information, ASCO's policy statement on "Cancer Care at the End of Life," which addresses regulation of pain management and the difficult question of assisted suicide, is available on the Society's web page at www.asco.org/prof/pp/html/f-pl.htm. Please feel free to contact Deborah Kamin, ASCO's Director of Public Policy, at 703-299-1050, if you have any questions or require further information.

Sincerely,

A handwritten signature in cursive script that reads "Allen Lichter".

Allen Lichter, M.D.
President



American Society of Clinical Oncology

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August 6, 1998

The Honorable Orrin G. Hatch
United States Senate
131 Russell Senate Office Building
Washington, DC 20510-4402

Dear Senator Hatch:

The American Society of Clinical Oncology (ASCO) is the medical professional society that represents physicians and other health professionals that treat people with cancer. ASCO's more than 12,000 members are trained to provide the best available care, including pain management, to the millions of Americans with a diagnosis of cancer. We are writing to express our concern about the unintended consequences of legislation recently introduced in the House and referred to the Committee on the Judiciary.

The "Lethal Drug Abuse Prevention Act of 1998," S. 2151, would greatly expand the authority of the federal government to regulate the dispensing of pain medication under the Controlled Substances Act. While the legislation purports to be limited to cases in which physicians "intentionally" prescribe controlled substances for the purpose of assisting suicide, the question of intent may be a difficult one to resolve. The risk of losing the ability to prescribe such essential medications will undoubtedly deter some physicians from aggressive treatment of pain in patients with cancer and other life-threatening diseases.

The failure adequately to address pain is a major issue in the treatment of cancer, and the problem is particularly acute among the elderly and minorities, as recently reported in a study published in the June 17, 1998, *Journal of the American Medical Association* (JAMA.1998;279:1877-1882). One reason for this inadequacy is identified in an accompanying editorial (JAMA.1998;279:1914-1915) --i.e., physician fears of regulatory scrutiny under the Controlled Substance Act if they aggressively treat cancer pain. Thus, under existing legal requirements, physicians are already reluctant to prescribe pain medications in sufficient quantities to control pain. We fear that an additional layer of regulatory uncertainty generated by the proposed legislation would make an already bad situation even worse.

1998

FALL EDUCATION

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NOVEMBER 13-15

CHICAGO, IL

1999

ANNUAL MEETING

MAY 15-18

ATLANTA, GA

FOR INFORMATION
ABOUT

ASCO MEETINGS

PHONE: 703-631-6200

FAX: 703-818-6425

Patients in the last days of life as a result of cancer have a right to aggressive treatment of their pain. Quantities of controlled substances required to address this intense pain may approach levels that could be misinterpreted as reflective of an intent to assist in suicide, even though there may be no such intent. No physician that prescribes pain medications will fail to take account of the possibility that prescribing decisions may be second-guessed by the new bureaucracy that would be established under the legislation.

There is no question that this new regulatory regime will exert a chilling effect on the prescribing decisions of physicians confronted with uncontrolled cancer pain in their patients. This is a shame because states generally have demonstrated their competency to regulate the difficult issues related to pain management and potential assisted suicide. We have serious reservations about the necessity for creation of a new federal bureaucracy in the form of the Medical Review Board on Pain Relief.

People with cancer rightly expect their physicians to prescribe the necessary medications to treat their pain. They do not want their physicians to be deterred from adequately treating their cancer pain by the threat of oversight from a panel of federal regulators. We urge the sponsors of this legislation to reconsider its advisability and request that members of the Committee withhold their support.

For your information, ASCO's policy statement on "Cancer Care at the End of Life," which addresses regulation of pain management and the difficult question of assisted suicide, is available on the Society's web page at <http://www.asco.org/prof/pp/html/f-pl.htm>. Please feel free to contact Deborah Kamin, ASCO's Director of Public Policy, at 703-299-1050, if you have any questions or require further information.

Sincerely,



Allen Lichter, M.D.
President

Assisted
Suicide

Karen Popp

Dear Mr. Chairman:

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

Janet Reno

cc: Ranking Minority Member

TALKING POINTS FOR CALL TO SENATOR WYDEN

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

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

MEMORANDUM

TO: Jonathan Schwartz

June 4, 1998

FR: Chris Jennings

RE: Outstanding Qs & As vis a vis assisted suicide

cc: Gregory King, Gary Grindler, and Joe Graupensterger

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

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

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

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

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

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

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

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

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

OREGON ASSISTED SUICIDE Q&As

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

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

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

Q. Does the DEA agree with this decision?

A. Yes.

Q. Did the White House review this decision?

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

Q. Is that unusual?

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

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

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

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

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

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

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

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

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

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

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

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

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