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LEGALIZED PHYSICIAN-ASSISTED SUICIDE IN OREGON — THE FIRST YEAR'S EXPERIENCE

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ABSTRACT

Background and Methods On October 27, 1997, Oregon legalized physician-assisted suicide. We collected data on all terminally ill Oregon residents who received prescriptions for lethal medications under the Oregon Death with Dignity Act and who died in 1998. The data were obtained from physicians' reports, death certificates, and interviews with physicians. We compared persons who took lethal medications prescribed under the act with those who died from similar illnesses but did not receive prescriptions for lethal medications.

Results Information on 23 persons who received prescriptions for lethal medications was reported to the Oregon Health Division; 15 died after taking the lethal medications, 6 died from underlying illnesses, and 2 were alive as of January 1, 1999. The median age of the 15 patients who died after taking lethal medications was 69 years; 8 were male, and all 15 were white. Thirteen of the 15 patients had cancer. The case patients and controls were similar with regard to sex, race, urban or rural residence, level of education, health insurance coverage, and hospice enrollment. No case patients or control patients expressed concern about the financial impact of their illness. One case patient and 15 control patients expressed concern about inadequate control of pain ($P=0.10$). The case patients were more likely than the control patients to have never married ($P=0.04$) and were more likely to be concerned about loss of autonomy due to illness ($P=0.01$) and loss of control of bodily functions ($P=0.02$). At death, 21 percent of the case patients and 84 percent of the control patients were completely disabled ($P<0.001$).

Conclusions During the first year of legalized physician-assisted suicide in Oregon, the decision to request and use a prescription for lethal medication was associated with concern about loss of autonomy or control of bodily functions, not with fear of intractable pain or concern about financial loss. In addition, we found that the choice of physician-assisted suicide was not associated with level of education or health insurance coverage. (N Engl J Med 1999;340:577-83.)

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On October 27, 1997, Oregon legalized physician-assisted suicide.¹ Although there have been many studies of physician-assisted suicide, there are no data on the experiences of patients and physicians when the practice is legal.²⁻⁸ Physician-assisted suicide is practiced in the Netherlands but is subject to criminal prosecution, even though such prosecutions are rare. We report on the first year of experience with legalized physician-assisted suicide in Oregon.

The Oregon Death with Dignity Act allows terminally ill state residents to receive prescriptions for self-administered lethal medications from their physicians.¹ It does not permit euthanasia, in which a physician or other person directly administers a medication to a patient in order to end his or her life. To obtain a prescription for a lethal medication, the law requires that the patient be an adult resident of Oregon who is "capable" (able to make and communicate decisions about his or her health care) and who has an illness that is expected to lead to death within six months. The patient must make one written and two oral requests to his or her physician. The two oral requests must be separated by at least 15 days. The patient's primary physician and a consultant are required to confirm the diagnosis of a terminal condition and the prognosis, determine that the patient is capable, and refer the patient for counseling, if either believes that the patient's judgment is impaired by depression or some other psychiatric or psychological disorder. The primary physician must also inform the patient of all feasible alternatives, such as comfort care, hospice care, and pain-control options. To comply with the law, physicians must report all prescriptions that they write for lethal medications to the Oregon Health Division.⁹ Reporting is not required if patients begin the process of requesting a prescription but do not actually receive it. Physicians and patients who adhere to the requirements of the act are protected from criminal prosecution.¹

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METHODS

Although the Oregon Death with Dignity Act states that actions taken in accordance with the law do not constitute suicide, we use the term "physician-assisted suicide" rather than "death with dignity" to describe the provisions of this law. Physician-assisted suicide is the term used by the public and in the medical literature to describe the voluntary self-administration of lethal medications prescribed by a physician expressly for the purpose of ending one's life.

Data Collection

Physicians who write prescriptions for lethal medications are required by law to report specific information to the Oregon Health Division.¹⁹ We matched the death certificates for all patients who requested and received prescriptions for lethal medications with the physicians' reports on the prescriptions and abstracted data on the dates of the requests, consultations, and demographic characteristics of the patients. The physicians were contacted to obtain any missing data or clarify discrepancies.

We contacted each physician who had prescribed lethal medications and determined whether the patient used them. We then asked the physician a series of questions about the patient's illness, insurance status, end-of-life care, prescribed medications, and medical and functional status at the time of death. Functional status was coded with the use of the scale developed by the Eastern Cooperative Oncology Group.¹⁰ The physician was asked, both specifically and in an open-ended fashion, whether the patient had expressed concern about end-of-life issues. If the patient took the lethal medications, we collected data on the rapidity of their effect and on unexpected adverse reactions. We also collected data on each physician's age, sex, number of years in practice, and medical specialty. We did not interview the patients, their families, or other physicians who provided care at the end of life. Reporting forms and the questionnaire used to interview the physicians are available on the World Wide Web (at www.ohd.hr.state.or.us/cdpe/chs/pas/pas.htm) or from the National Auxiliary Publications Service.*

Cohort and Case-Control Analyses

We compared the patients and physicians who participated in physician-assisted suicide with those who did not. For this analysis, a case patient was defined as a person who had died between January 1, 1998, and December 31, 1998, after ingesting a lethal dose of medication prescribed under the Death with Dignity Act. (No prescriptions for lethal medications were written under the act in 1997.)

We calculated mortality rates using death-certificate data for 1996 from the Oregon Health Division (1996 was the most recent year for which final mortality data were available). We compared the demographic characteristics of the case patients with those of the cohort of Oregon residents who had died in 1996 from similar underlying illnesses (e.g., lung cancer, breast cancer, and chronic obstructive pulmonary disease).

We also performed a matched case-control study comparing the case patients with control patients who died from similar underlying illnesses but who did not receive prescriptions for lethal medications. Using Oregon death certificates issued in 1998, we matched up to three control patients to each case patient according to the underlying illness, age (within 10 years of the case patient's age), and date of death (within 30 days of the case patient's death).

We collected data on the demographic characteristics and end-of-life care and concerns of the control patients, as well as the characteristics of their physicians, from death certificates and interviews with the physicians, using the same methods as those described for case patients. The physician who signed the death certificate was interviewed, unless he or she specifically referred us to another

physician. Control patients were considered ineligible for the study if their physicians refused to be interviewed, could not be contacted after three attempts, or were unavailable for an interview within seven days after the first attempted contact or if we were unable to identify a physician responsible for the patient's end-of-life care. Only control patients who would have met the requirements of the Death and Dignity Act were included in the analysis.

The institutional review board of the Oregon Health Division and the Human Subjects Research Office at the Centers for Disease Control and Prevention both determined that the reporting system and study design were part of the routine surveillance and evaluation required by the Oregon Death with Dignity Act and, as such, were not subject to formal review by the institutional review board of either institution.

Statistical Analysis

Univariate analyses were performed with use of the Mantel-Haenszel chi-square test and Fisher's exact test. The results of matched analyses are expressed as Mantel-Haenszel odds ratios and summary chi-squares. The Mann-Whitney U test was used to compare continuous variables. Two-tailed P values that were less than or equal to 0.05 were considered to indicate statistical significance. Statistical calculations were performed with Epi Info, version 6.04b.¹¹

RESULTS

Patients Who Received Lethal Prescriptions

Information on 23 persons who received prescriptions for lethal medications in 1998 under the Death with Dignity Act was reported to the Oregon Health Division. Of the 23, 15 died after taking their lethal medications, 6 died from their underlying illnesses, and 2 were alive as of January 1, 1999. The characteristics of the 21 prescription recipients who died in 1998 are shown in Table 1. Their age ranged from the 3rd to the 10th decade of life. Twenty of the patients had been residents of Oregon for longer than six months when they received their prescriptions. One patient had moved to Oregon four months before her death so that her family could care for her, not because physician-assisted suicide was legal in the state. All the reports submitted by the physicians who prescribed lethal medications were in full compliance with the law. Eighteen of the 21 prescription recipients had cancer; 12 of the 18 had lung, ovarian, or breast cancer.

Twenty of the 21 patients received prescriptions for 9 g of secobarbital or pentobarbital; 1 received a prescription for 1 g of secobarbital to be used in conjunction with an oral narcotic. The patients also received prescriptions for a number of nonlethal medications to be used concurrently with the lethal medication (Table 1).

The Process of Physician-Assisted Suicide

Among the 15 case patients who died after ingesting the prescribed lethal medication, the median time from ingestion to unconsciousness (available for 11 patients) was 5 minutes (range, 3 to 20 minutes), and the median time from ingestion to death (available for 14 patients) was 26 minutes (range, 15 min-

*See NAPS document no. 05504 for 17 pages of supplementary material. Order from NAPS, c/o Microfiche Publications, 248 Hempstead Tpke., West Hempstead, NY 11552.

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TABLE 1. CHARACTERISTICS OF PATIENTS WHO RECEIVED PRESCRIPTIONS FOR LETHAL MEDICATIONS AND TIMING OF EVENTS.

CHARACTERISTIC	PATIENTS WHO DIED AFTER INGESTING LETHAL MEDICATION (N=15)	PATIENTS WHO DIED FROM TERMINAL ILLNESS (N=6)	TOTAL (N=21)
Demographic characteristics			
Median age (yr)	69	47	69
White (no. of patients)	15	6	21
Male sex (no. of patients)	8	3	11
Oregon resident for more than 6 mo (no. of patients)	15	5	20
Resident of Portland area (no. of patients)	7	4	11
Legal requirements (no. of patients)			
Psychiatric or psychological consultation obtained	4	0	4
Physician's report in full compliance with law	15	6	21
Underlying illness (no. of patients)			
Cancer (all types)	13	5	18
Lung, ovarian, or breast cancer	9	3	12
Acquired immunodeficiency syndrome	0	1	1
Congestive heart failure	1	0	1
Chronic obstructive pulmonary disease	1	0	1
Medications prescribed (no. of patients)			
Secobarbital (9 g)	13	6	19
Pentobarbital (9 g)	1	0	1
Secobarbital (1 g) and morphine (1 g)	1	0	1
Antiemetic agent	14	5	19
Agent that promotes gastric motility	6	5	11
Chlorpromazine	1	0	1
Beta-blocker	3	3	6
Timing of events (days)			
Interval between first and second oral requests			
Median	18	30	20
Range	15-68	16-83	15-83
Interval between first oral request and death			
Median	20	93	26
Range	15-75	26-101	15-101
Interval between receipt of prescription and death			
Median	1	28	4
Range	0-22	8-66	0-66

ures to 11.5 hours). No complications, such as vomiting or seizures, were reported.

Mortality Data

The 15 physician-assisted suicides accounted for 5 of every 10,000 deaths in Oregon in 1998, with the 28,900 deaths that occurred in 1996 (the most recent year for which final data were available) used as the denominator.¹² The rate of physician-assisted suicide among persons who died from cancer was 19 per 10,000 (13 of 6784 deaths). In the cohort of case patients and the 5604 Oregon residents who died from similar underlying illnesses in 1996, age, race, sex, level of education, and rural or urban residence were not associated with the likelihood of physician-assisted suicide (Table 2). As compared with persons who were married, those who were divorced or had never married were more likely to choose physician-assisted suicide (risk ratio for divorced persons, 6.8; 95 percent confidence interval,

1.3 to 37.2; $P=0.03$; risk ratio for persons who had never married, 23.7; 95 percent confidence interval, 4.4 to 128.9; $P<0.001$).

Case-Control Study

We were unable to obtain information for 17 of 81 potential control patients (21 percent): we could not contact the physicians who cared for 12 patients, and it was not clear who provided care at the end of life for 5. Of the 64 potential control patients for whom physician-interview data were available, 21 (33 percent) would not have been eligible for a prescription under the Death with Dignity Act: 10 were not capable of making decisions about their health care, 2 were not Oregon residents, 2 could not take oral medications, and for 7 patients, the time between the physician's determination that the patient had less than 6 months to live and death was less than the required 15-day waiting period. We successfully collected data on 3 matched control pa-

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TABLE 2. CHARACTERISTICS OF CASE PATIENTS AND OREGON RESIDENTS WHO DIED FROM SIMILAR ILLNESSES IN 1996.

CHARACTERISTIC*	OREGON RESIDENTS WHO DIED IN 1996 (N=5604)	CASE PATIENTS (N=15)	RATE OF PHYSICIAN-ASSISTED SUICIDE (PER 10,000 DEATHS)	RISK RATIO (95% CI)†	P VALUE
Median age (yr)	74	69	—	—	0.40
Race (no.)					
Nonwhite	116	0	0.0	1.0‡	
White	5450	15	27.4	Undetermined	1.00
Sex (no.)					
Female	3026	7	23.1	1.0‡	
Male	2578	8	30.9	1.3 (0.5-3.7)	0.57
Residence (no.)					
Rural	3582	8	22.3	1.0‡	
Urban (Portland area)	2022	7	34.5	1.6 (0.6-4.3)	0.39
Education (no.)					
Did not graduate from high school	1540	3	19.4	1.0‡	
High-school graduate§	3901	12	30.7	1.6 (0.5-5.6)	0.58
College graduate	614	4	64.7	3.3 (0.8-14.8)	0.11
Marital status at death (no.)					
Married	2703	2	7.4	1.0‡	
Widowed	1868	5	26.7	3.6 (0.7-18.6)	0.13
Divorced	789	4	50.4	6.8 (1.3-37.2)	0.03
Never married	224	4	175.4	23.7 (4.4-128.9)	<0.001

*Data on race were available for 5566 Oregon residents who died in 1996 from illnesses that were similar to the case patients' underlying illnesses, data on education were available for 5441, and data on marital status were available for 5584.

†CI denotes confidence interval.

‡This was the reference category.

§This category includes college graduates.

tients for each of 14 case patients, with a single control patient matched for 1 case patient.

As in the analysis of mortality data for Oregon in 1996, the case patients and control patients did not differ statistically according to race, sex, rural or urban residence, or educational level (Table 3). The case patients were more likely than the control patients to have never married ($P=0.04$).

End-of-Life Issues

None of the case patients or control patients expressed concern to their physicians about the financial impact of their illness. We found no significant differences between case patients and control patients with respect to insurance coverage at the time of death. One of the case patients (7 percent) and 15 of the control patients (35 percent) expressed concern about pain at the end of life ($P=0.10$). Similar proportions of case patients and control patients were receiving hospice care at the time of death, had advance medical directives, and died at home. The proportions of patients who expressed concern about being a burden to family members, friends, or other care givers or about the inability to participate in activities that made life enjoyable did not differ significantly between the two groups. However, the case patients were more likely than the control patients to

express concern about loss of autonomy (odds ratio, 7.3; 95 percent confidence interval, 1.5 to 35.9) or loss of control of bodily functions (e.g., incontinence or vomiting) as a result of their illness (odds ratio, 9.0; 95 percent confidence interval, 1.6 to 51.4). At the time of death, the case patients had a higher functional status than the control patients; 21 percent of the case patients, as compared with 84 percent of the control patients, had a score of 4, indicating that they were completely disabled ($P<0.001$).

Characteristics of the Physicians

Fourteen physicians wrote prescriptions for lethal medications for the 15 case patients. Forty physicians provided care at the end of life for the 43 control patients. The physicians for the case patients were similar to the physicians for the control patients with regard to sex, specialty, age, and number of years in practice, although there was a trend for the case patients' physicians to be older and in practice longer (Table 4).

Six case patients requested lethal medications from one or two physicians before finding a physician who would begin the prescription process. Five of these six case patients were specifically referred for discussion of physician-assisted suicide to the physicians who eventually wrote their prescriptions.

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TABLE 3. CHARACTERISTICS OF CASE PATIENTS AND MATCHED CONTROL PATIENTS.

CHARACTERISTIC*	CASE PATIENTS (N=15)	CONTROL PATIENTS (N=43)	MATCHED ODDS RATIO (95% CI)†	P VALUE
Demographic characteristic				
Median age — yr	69	74	—	0.70
White race — no. of patients (%)	15 (100)	43 (100)	1.0	1.00
Male sex — no. of patients (%)	8 (53)	15 (35)	4.5 (0.6–32.1)	0.30
Oregon resident for more than 6 mo — no. of patients (%)	15 (100)	43 (100)		
Resident of Portland area — no. of patients (%)	7 (47)	16 (37)	1.4 (0.4–4.9)	0.87
Education — no. of patients (%)				
Did not graduate from high school	3 (20)	11 (27)	1.0‡	
High-school graduate§	12 (80)	30 (73)	1.4 (0.3–9.7)	0.90
College graduate	4 (27)	7 (17)	Undetermined	1.00
Marital status — no. of patients (%)				
Married	2 (13)	20 (47)	1.0‡	
Widowed	5 (33)	14 (33)	1.7 (0.1–24.7)	0.93
Divorced	4 (27)	7 (16)	7.5 (0.7–354.5)	0.12
Never married	4 (27)	2 (5)	Undetermined	0.04
Insurance coverage — no. of patients (%)				
Private insurance	8 (53)	28 (65)	1.0‡	
Medicare only	4 (27)	7 (16)	6.0 (0.3–288.4)	0.41
Oregon Medicaid	2 (13)	7 (16)	0.8 (0.1–7.7)	0.81
No insurance	1 (7)	0	Undetermined	0.56
Unknown	0 (0)	1 (2)	Undetermined	0.56
Functional-status score of 4 — no. of patients (%)	3 (21)	32 (84)	0.1 (0.0–0.4)	<0.001
Hospice care or advance directives — no. of patients				
Enrolled in hospice program	10 (71)	32 (74)	0.8 (0.2–4.2)	1.00
Written advance directives	11 (79)	37 (92)	0.4 (0.1–3.3)	0.55
Died at home — no. of patients (%)	12 (80)	29 (67)	3.5 (0.4–29.7)	0.55
Concern about end-of-life issues — no. of patients (%)				
Cost of treating illness or prolonging life	0	0	—	
Burden on family, friends, or other care givers	2 (13)	15 (35)	0.2 (0.0–1.5)	0.21
Inability to participate in activities	10 (67)	26 (60)	1.2 (0.3–4.3)	1.00
Inadequate pain control	1 (7)	15 (35)	0.2 (0.0–1.4)	0.10
Loss of autonomy due to illness	12 (80)	17 (40)	7.3 (1.5–35.9)	0.01
Loss of control of bodily functions	8 (53)	8 (19)	9.0 (1.6–51.4)	0.02
Duration of patient-physician relationship — days				
Median	69	720	—	0.03
Range	15–3780	35–7284		

*Data on education were available for 15 case patients and 41 control patients, functional-status scores were available for 14 case patients and 38 control patients, hospice data were available for 14 case patients and 43 control patients, and data on advance directives were available for 14 case patients and 40 control patients.

†CI denotes confidence interval.

‡This was the reference category.

§This category includes college graduates.

¶A score of 4 indicated complete disability.

||Percentages do not sum to 100 because some patients expressed concern about more than one issue.

Physicians for 29 of the 43 control patients (67 percent) would have refused to write a prescription for lethal medication had the patient requested it; physicians for 9 control patients (21 percent) would have provided prescriptions, and physicians for 5 control patients (12 percent) were unsure how they would have responded to such a request. Six control patients (14 percent) had discussed physician-assist-

ed suicide with their physicians, but none had begun the formal request process. In one instance, the patient discussed physician-assisted suicide with her physician in early 1998 but did not want to be a "test case." In another instance, the patient's primary physician was an employee of a health care system that did not allow its physicians to participate in assisted suicide.

TABLE 4. CHARACTERISTICS OF PHYSICIANS WHO PRESCRIBED LETHAL MEDICATIONS AND PHYSICIANS WHO PROVIDED CARE AT THE END OF LIFE FOR CONTROL PATIENTS.

CHARACTERISTIC	PHYSICIANS OF CASE PATIENTS (N=14)	PHYSICIANS OF CONTROL PATIENTS (N=40)	ODDS RATIO (95% CI)*	P VALUE
Male sex — no. (%)	11 (79)	35 (88)	0.5 (0.1–3.4)	0.41
Primary care specialty — no. (%)†	9 (64)	22 (55)	1.5 (0.4–6.6)	0.55
Age — yr				0.07
Median	51	44	—	
Range	37–69	30–62	—	
Years in practice				0.11
Median	18	12	—	
Range	1–45	1–36	—	

*CI denotes confidence interval.

†Primary care specialties included family practice, internal medicine, obstetrics, and gynecology.

DISCUSSION

Many people feared that if physician-assisted suicide was legalized, it would be disproportionately chosen by or forced on terminally ill patients who were poor, uneducated, uninsured, or fearful of the financial consequences of their illness.^{13–16} In our study of physician-assisted suicides in Oregon in 1998, we found no evidence to support these fears. The case patients and the larger cohort of patients with similar terminal illnesses did not differ statistically with respect to age or education. In addition, the case patients did not differ from the matched control patients with respect to insurance status, and neither the case patients nor the control patients expressed concern about the financial impact of their illness. Our conclusion, however, is based on a relatively small number of patients. Ongoing surveillance is needed.

Considerable debate over physician-assisted suicide has focused on the lack of data on the lethal medications prescribed and on the rapidity of their effect and adverse reactions.^{17–20} We found that the lethal medications prescribed to the case patients were similar, perhaps as a result of information available through advocacy groups. With one exception, all prescriptions were for 9 g of a fast-acting barbiturate and an antiemetic agent. The time to unconsciousness was fairly uniform. The majority of the patients for whom data were available were unconscious within 5 minutes after taking the lethal medication, and all were unconscious within 20 minutes. Although the majority of the patients died within 1 hour, four patients died more than 3 hours after taking the prescribed medications, and one died 11.5 hours afterward. This last patient was reported to have taken all 9 g of the prescribed barbiturate and to

have been unconscious within five minutes. Thus, the time to death is not always rapid or predictable.

Do patients request lethal prescriptions because of inadequate care at the end of life? Our data do not support this hypothesis. The proportions of case patients and control patients with advance medical directives were similar, and similar proportions of case patients and control patients (71 percent and 74 percent, respectively) were enrolled in a hospice program. Oregon ranks third nationally in the rate of hospice admissions.¹⁶ Three case patients who were not receiving hospice care had repeatedly declined offers of such care. Only one case patient expressed concern to her physician about inadequate control of pain at the end of life. The fact that 14 of the 15 patients did not express concern about pain control at the end of life may reflect advances in palliative care in Oregon, which ranks among the top five states in per capita use of morphine for medical purposes.²¹

We found that the case patients were significantly more likely than the control patients to have expressed concern to their physicians about loss of autonomy and loss of control of bodily functions. Seventy-nine percent of the case patients were not completely disabled when they took their lethal medications. This suggests that controlling the time of death was important to them. Many physicians reported that their patients had been decisive and independent throughout their lives or that the decision to request a lethal prescription was consistent with a long-standing belief about the importance of controlling the manner in which they died. Thus, the decision to request and use a prescription for lethal medications during the first year of legalized physician-assisted suicide in Oregon was associated with views on autonomy and control, not with fear of intractable pain or concern about financial loss.

In 1998, many physicians and some hospital systems in Oregon did not participate in physician-assisted suicide. Forty percent of the case patients were unable to initiate the prescription process with the first physician they approached and had to request a prescription from a second or third physician. This is probably an important reason why the case patients had shorter relationships with their physicians than the control patients did with their physicians. Fewer than one quarter of the control patients' physicians would have written a prescription for a lethal medication if it had been requested. In an anonymous survey of Oregon physicians in 1995, fewer than 50 percent stated that they would provide a lethal prescription if physician-assisted suicide were legal.³ Several hospital systems in Oregon (e.g., the Veterans Affairs hospitals, the Indian Health Service, and at least one Catholic hospital system) specifically prohibit participation in physician-assisted suicide by patients or staff in their facilities.²² The absence of participation in physician-assisted suicide

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on the part of some physicians and hospital systems may have influenced our findings with respect to the characteristics of the case patients.

The Oregon Health Division is charged with collecting information under the Death with Dignity Act but is also obligated to report any cases of noncompliance with the law to the Oregon Board of Medical Examiners.^{23,24} Our responsibility to report noncompliance makes it difficult, if not impossible, to detect accurately and comment on underreporting. Furthermore, the reporting requirements can only ensure that the process for obtaining lethal medications complies with the law. We cannot determine whether physician-assisted suicide is being practiced outside the framework of the Death with Dignity Act.

The 14 physicians who wrote prescriptions for lethal medications represented a variety of specialties and a wide range of ages and years in practice. For some of these physicians, the process of participating in physician-assisted suicide exacted a large emotional toll, as reflected by such comments as, "It was an excruciating thing to do . . . it made me rethink life's priorities," "This was really hard on me, especially being there when he took the pills," and "This had a tremendous emotional impact." Physicians also reported that their participation led to feelings of isolation. Several physicians expressed frustration that they were unable to share their experiences with others because they feared ostracism by patients and colleagues if they were known to have participated in physician-assisted suicide. The legitimacy of these fears and their influence on the willingness of physicians to participate in physician-assisted suicide under the Oregon Death with Dignity Act are likely to affect the ability of otherwise eligible patients to choose physician-assisted suicide.

This study was conducted as part of the required surveillance and public health activities of the Oregon Health Division and was supported by division funds.

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HEALTH CARE FINANCING ADMINISTRATION

**ADDRESSEE:**

Devorah

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C+4

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GENERAL SERVICES ADMINISTRATION			

Congressman attacks suicide law

Rep. Tom Bliley of Virginia accuses administrators of illegally using federal funds to pay for assisted-suicide services in Oregon

Thursday March 25, 1999

By Jim Barnett and Erin Hoover Barnett of The Oregonian staff

A congressman who opposes Oregon's doctor-assisted suicide law is pursuing a new strategy to limit the law's effectiveness.

Rep. Tom Bliley, R-Va., chairman of the House Commerce Committee, on Wednesday accused the Health Care Financing Administration of paying for assisted-suicide services in Oregon in violation of a law banning federal funds for such services.

Bliley released a letter his committee received March 5 from HCFA administrator Nancy-Ann Min Deparle, who acknowledged there was a "remote possibility" that a doctor might have mistakenly submitted an assisted-suicide claim to the Oregon Health Plan before Dec. 1, 1998.

On Dec. 1, the Oregon Health Plan launched its system for covering assisted suicides, using state money. The same system is used to pay for abortions, for which federal funding is also banned.

Deparle's letter said the Oregon Health Plan had taken sufficient steps to comply with a 1997 law banning federal funding of assisted suicides. Claims for these services are sent to a separate post office box, and staff time spent processing these claims is paid only with state dollars.

Although Medicaid might have reimbursed an assisted-suicide claim, such a mistake was "highly unlikely," Deparle said.

The window of time that a claim might have been erroneously processed was after the state decided in February 1998 that assisted suicide would be covered by the Oregon Health Plan but before the plan's administrators had devised a separate billing system.

Claims for services, such as office visits for dying patients pursuing assisted suicide or for the lethal prescription itself, could have been submitted before the plan was able to flag and separate those claims, an Oregon Health Plan official said.

The Oregon Health Division reported in February that of the 15 people who used assisted suicide to die in 1998, two were on the Oregon Health Plan.

Bliley seized on Deparle's acknowledgment that a mistake was possible. Payment of an assisted-suicide claim "would be a clear violation of the law," Bliley said, adding that the Commerce Committee would investigate whether the law had been broken.

Bliley's committee passed up a chance to weigh in on the issue last year. But he might be taking up the mantle of another powerful Republican, Rep. Henry Hyde of Illinois, who led a charge against the Oregon law last summer and fall.

Hyde, chairman of the House Judiciary Committee, pushed through a bill to prohibit doctors from prescribing lethal doses of drugs, but the measure stalled in the waning days of the 105th Congress.

Public funding of assisted suicide has been a contentious issue, both nationally and locally. Opponents contend that using public dollars sanctions the practice of assisted suicide or opens up the possibility that poor people covered by the Oregon Health Plan could be steered toward it as a cheap end-of-life option. Proponents of public funding say not covering assisted suicide discriminates against the poor.

Health Care Financing Administration officials visited Oregon and asked Oregon Health Plan officials to take several steps to address Bliley's concerns, said Lynn Read, assistant director of the state Office of Medical Assistance Programs,

which administers the health plan.

Oregon officials will report to HCFA by April 1. If billing mistakes are found, adjustments will be made to reimburse with state dollars any federal money spent, Read said.

Read's office is developing special billing codes for services related to assisted suicide, so that if a claim is submitted to the wrong place, the computer will reject it.

You can reach Jim Barnett at 202-383-7819 or by e-mail at jim.barnett@newhouse.com. You can reach Erin Hoover Barnett at 503-294-5011 or by e-mail at ehbarnett@news.oregonian.com



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Committee on Commerce News Release



Bliley Releases HCFA Response on Physician Assisted Suicide: HCFA Admits Federal Funds Were Possibly Used in Oregon & Calls for Enactment of Safeguards

March 24, 1999

Contact: Christina Gungoll, Eric Wohlschlegel
(202) 225-5735

WASHINGTON (March 24) – The Health Care Financing Administration said that "there is a remote possibility a physician may have erroneously submitted claims to Oregon fee-for-service Medicaid for services related to physician-assisted suicide," in a letter released today by House Commerce Committee Chairman U.S. Representative Tom Bliley (R-VA).

In April 1997, Congress passed the Assisted Suicide Funding Restriction Act. This law, which received almost unanimous support in Congress, prohibits the use of Federal funds for purposes related to assisted suicide, including the Medicaid program.

The letter Chairman Bliley released today from HCFA was in response to a February 15, 1999 request for information from Bliley and other members of the House Commerce Committee to the Department of Health and Human Services. The members asked for written documentation showing that federal law was being followed by the State of Oregon in the administration of its assisted suicide program.

"HCFA's letter revealed that federal tax dollars may have been used to pay for services related to physician assisted suicide in Oregon, which would be a clear violation of the law," Bliley said. "The Commerce Committee will continue its oversight effort to determine whether the law was broken."

In its response, HCFA said it has "already initiated discussions with Oregon Medicaid to develop a process for recouping any federal funds" that may have been used unlawfully. HCFA also said it has asked the State of Oregon to implement additional safeguards to ensure that no Federal funds are used in the administration or implementation of its assisted suicide program in compliance with the law.

The State of Oregon will complete its analysis to determine whether any federal funds were used to pay for physician assisted suicide services on April 1, 1999. Following the completion of the analysis, the Commerce Committee has requested a full briefing from HCFA on the results.

####

This page was last modified on 03/24/99 10:06:59 AM EST

UNITED STATES DEPARTMENT OF JUSTICE

Office of Nicholas M. Gess
Associate Deputy Attorney General

950 Pennsylvania Avenue, N.W.
Room 4210
Washington, DC 20530
Telephone: (202) 514-0835



TO: Chris Jennings, DPC

OFFICE NUMBER:

FAX NUMBER: 456-5557

FROM: Nicholas M. Gess

DATE/TIME: June 15, 1999

NUMBER OF PAGES INCLUDING THIS SHEET:

TELEPHONE NUMBER OF PERSON TO CONTACT UPON RECEIPT:

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

REMARKS: FYI

A handwritten signature, likely of Nicholas M. Gess, is written in dark ink. The signature is stylized, with a large 'N' and 'G' and a long, sweeping underline.

106TH CONGRESS
1ST SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. NICKLES introduced the following bill; which was read twice and referred
to the Committee on _____

A BILL

To amend the Controlled Substances Act to promote pain management and palliative care without permitting assisted suicide and euthanasia, and for other purposes.

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 "Pain Relief Promotion
5 Act of 1999".

1 **TITLE I—USE OF CONTROLLED**
2 **SUBSTANCES CONSISTENT**
3 **WITH THE CONTROLLED SUB-**
4 **STANCES ACT**

5 **SEC. 101. REINFORCING EXISTING STANDARD FOR LEGITI-**
6 **MATE USE OF CONTROLLED SUBSTANCES.**

7 Section 303 of the Controlled Substances Act (21
8 U.S.C. 823) is amended by adding at the end the follow-
9 ing:

10 “(i)(1) For purposes of this Act and any regulations
11 to implement this Act, alleviating pain or discomfort in
12 the usual course of professional practice is a legitimate
13 medical purpose for the dispensing, distributing, or admin-
14 istering of a controlled substance that is consistent with
15 public health and safety, even if the use of such a sub-
16 stance may increase the risk of death. Nothing in this sec-
17 tion authorizes intentionally dispensing, distributing, or
18 administering a controlled substance for the purpose of
19 causing death or assisting another person in causing
20 death.

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

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

3 **SEC. 102. EDUCATION AND TRAINING PROGRAMS.**

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

6 (1) by striking “and” at the end of paragraph
7 (5);

8 (2) by striking the period at the end of para-
9 graph (6) and inserting “; and”; and

10 (3) by adding at the end the following:

11 “(7) educational and training programs for
12 local, State, and Federal personnel, incorporating
13 recommendations by the Secretary of Health and
14 Human Services, on the necessary and legitimate
15 use of controlled substances in pain management
16 and palliative care, and means by which investiga-
17 tion and enforcement actions by law enforcement
18 personnel may accommodate such use.”.

19 **TITLE II—PROMOTING**
20 **PALLIATIVE CARE**

21 **SEC. 201. ACTIVITIES OF AGENCY FOR HEALTH CARE POL-**
22 **ICY AND RESEARCH.**

23 Part A of title IX of the Public Health Service Act
24 (42 U.S.C. 299 et seq.) is amended by adding at the end
25 the following:

1 **"SEC. 906. PROGRAM FOR PALLIATIVE CARE RESEARCH**
2 **AND QUALITY.**

3 **"(a) IN GENERAL.**—The Administrator shall carry
4 out a program to accomplish the following:

5 **"(1)** Develop and advance scientific understand-
6 ing of palliative care.

7 **"(2)** Collect and disseminate protocols and evi-
8 dence-based practices regarding palliative care, with
9 priority given to pain management for terminally ill
10 patients, and make such information available to
11 public and private health care programs and provid-
12 ers, health professions schools, and hospices, and to
13 the general public.

14 **"(b) DEFINITION.**—For purposes of this section, the
15 term 'palliative care' means the active total care of pa-
16 tients whose prognosis is limited due to progressive, far-
17 advanced disease. The purpose of such care is to alleviate
18 pain and other distressing symptoms and to enhance the
19 quality of life, not to hasten or postpone death."

20 **SEC. 202. ACTIVITIES OF HEALTH RESOURCES AND SERV-**
21 **ICES ADMINISTRATION.**

22 **(a) IN GENERAL.**—Part D of title VII of the Public
23 Health Service Act (42 U.S.C. 294 et seq.), as amended
24 by section 103 of Public Law 105-392 (112 Stat. 3541),
25 is amended—

1 (1) by redesignating sections 754 through 757
2 as sections 755 through 758, respectively; and

3 (2) by inserting after section 753 the following
4 section:

5 **"SEC. 754. PROGRAM FOR EDUCATION AND TRAINING IN**
6 **PALLIATIVE CARE.**

7 "(a) IN GENERAL.—The Secretary, in consultation
8 with the Administrator for Health Care Policy and Re-
9 search, may make awards of grants, cooperative agree-
10 ments, and contracts to health professions schools, hos-
11 pices, and other public and private entities for the develop-
12 ment and implementation of programs to provide edu-
13 cation and training to health care professionals in pallia-
14 tive care.

15 "(b) PRIORITIES.—In making awards under sub-
16 section (a), the Secretary shall give priority to awards for
17 the implementation of programs under such subsection.

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

22 "(1) means for alleviating pain and discomfort
23 of patients, especially terminally ill patients, includ-
24 ing the medically appropriate use of controlled sub-
25 stances;

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

7 “(3) recent findings, developments, and im-
8 provements in the provision of palliative care.

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

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

21 “(f) PEER REVIEW GROUPS.—In carrying out section
22 799(f) with respect to this section, the Secretary shall en-
23 sure that the membership of each peer review group in-
24 volved includes one or more individuals with expertise and
25 experience in palliative care.

1 “(g) DEFINITION.—For purposes of this section, the
2 term ‘palliative care’ means the active total care of pa-
3 tients whose prognosis is limited due to progressive, far-
4 advanced disease. The purpose of such care is to alleviate
5 pain and other distressing symptoms and to enhance the
6 quality of life, not to hasten or postpone death.”.

7 (b) AUTHORIZATION OF APPROPRIATIONS; ALLOCA-
8 TION.—

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

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

19 **SEC. 203. EFFECTIVE DATE.**

20 The amendments made by this title take effect Octo-
21 ber 1, 1999, or on the date of the enactment of this Act,
22 whichever occurs later.



U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

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 policy as it relates to the use of controlled substances by terminally ill patients. First, the bill provides 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 supports these provisions of H.R. 2260.

Second, H.R. 2260 states that the use of controlled substances to assist a terminally ill person in committing suicide is not authorized by federal law. Although the Administration is opposed to physician-assisted suicide as a policy matter, the Department is concerned about this bill in two respects -- its possible impact on the Attorney General's discretion in regulating controlled substances and its use of the Controlled Substances Act (CSA) to reflect a federal policy concerning physician-assisted suicide.

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 et seq., "even if

Draft

July 30, 1999 (5:29PM)

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 et seq.) 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, 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. Ambiguity about the legality of using controlled substances to alleviate the pain and suffering of the terminally ill can inhibit physicians from prescribing adequate pain medication for these patients. H.R. 2260 would eliminate this ambiguity and remove the threat of administrative and criminal sanctions in this context. This will allow physicians to act according to their professional judgment in caring for the terminally ill, who are often in the most extreme pain.

We understand that the American Medical Association is advocating an amendment to section 102 of the bill that would curtail the Department's discretion in enforcing the CSA by subjecting the enforcement authority of the Drug Enforcement Administration (DEA) to any guidelines that the Health and Human Services (HHS) Department promulgates on the proper use of controlled substances for palliative care purposes. We do not think it is good policy to constrain the discretion and judgment of the DEA, the agency with expertise in enforcing the nation's drug laws, with guidelines promulgated an agency whose considerable expertise lies elsewhere. Nor is such a provision necessary to ensure HHS input since DEA agents would already be required by H.R. 2260 to take HHS guidelines into account in deciding whether to proceed. Accordingly, we would oppose such an amendment to section 102.

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

As currently written, however, the portions of H.R. 2260 addressing palliative care have the Department's support.

Physician Assisted Suicide

Section 101 amends section 303 (21 U.S.C. 823) of the CSA to add subsection (i), providing that "[n]othing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death."

This language may be construed to curtail the Attorney General's authority under the CSA. Because the amendment modifies all of section 303,² which is the section that authorizes the Attorney General to register individuals to manufacture and dispense controlled substances under certain circumstances, H.R. 2260 could, if read as a prohibition, restrict the scope of all registrations granted by the Attorney General. Under this reading, no registration could allow a physician to dispense controlled substances for the purpose of assisting in a suicide. The newly proposed subsection (i)(2) narrows the scope of registration of physicians practicing in States, like Oregon, that authorize physician assisted suicide under certain circumstances.³

If the non-authorization is interpreted as a ban, failure to adhere to the narrower restrictions mandated by H.R. 2260 would subject physicians to criminal and administrative sanctions in the event they prescribe controlled substances to assist a suicide. Because a physician's registration under 21 U.S.C. § 824 may be revoked based on an applicant's failure to comply

² The proposed amendment refers to "this section" - and not only to the newly added subsection (i). The amendment would therefore apply more broadly to all of section 303.

³ The new subsection (i)(2) would provide that "in determining whether a registration is consistent with the public interest under this Act, the Attorney General shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia." Because the "public interest" is a touchstone inquiry in a registration revocation proceeding under 21 U.S.C. § 824(a), this new subsection would grant the Attorney General authorization to revoke a registration for administration of controlled substances to assist a suicide.

"with applicable State, Federal, or local laws relating to controlled substances," the Attorney General would have the power to revoke or suspend registrations of physicians who have violated the terms of their registrations by prescribing controlled substances for the purpose of assisting in suicides. H.R. 2260 might also authorize criminal prosecution because the CSA makes it a crime "for any person knowingly or intentionally" to dispense a controlled substances "[e]xcept as authorized by this subchapter."⁴ If H.R. 2260 is construed to mean that a physician's registration did not permit dispensing for the purpose of assisting a suicide, then such dispensing would not be "authorized by this subchapter."⁵

More fundamentally, we are not convinced that a federal law prohibiting physician-assisted suicide would be wise policy at this time. Although the President strongly opposes the practice of physician-assisted suicide and supports legislation banning federal funding of such activity,⁶ a direct federal ban on

⁴ 21 U.S.C. § 841(a); see also 21 U.S.C. § 822(b) ("Persons registered by the Attorney General under this subchapter . . . are authorized to . . . dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter.") (emphasis added).

⁵ The net effect of this amendment may be essentially to checkmate state laws, such as Oregon's Death with Dignity Act, that authorize physician-assisted suicide, because physicians who comply with mandated state procedures may nevertheless lose their DEA registrations or be subject to federal criminal prosecution. Physicians under an Oregon-like scheme cannot prescribe controlled substances to assist suicide under the guise of alleviating pain because the state law requires a paper trail documenting the intent to assist in the requested suicide. See, e.g., O.R.S. § 127.855 (specifically requiring a physician in Oregon to "document[] or file[]" evidence of compliance with the Oregon Act's notice and waiting period requirements in the patient's medical record, and "indicat[e] that all requirements under [the Oregon law] have been met"). A physician who does not leave such a trail risks criminal prosecution by the State. See, e.g., id. § 127.885 (exempting physicians from criminal prosecution only if they comply with the Act).

⁶ See Assisted Suicide Funding Restriction Act (1997).

physician-assisted suicide would do more than simply prohibit federal funding. A direct prohibition would, for example, clearly overturn the judgment of Oregon voters that physician-assisted suicide is appropriate under certain conditions and after certain procedures have been followed.

The moral and ethical issues surrounding the propriety of physician-assisted suicide are difficult and are currently being debated in State legislatures all across the nation. The Supreme Court in Washington v. Glucksburg declined to cut short this debate by precluding States from banning physician-assisted suicide, and we think it may be similarly advisable not to curtail the debate by precluding States from authorizing physician-assisted suicide. As many Justices noted in Glucksburg, this is the type of issue best left to the laboratory of the States in the first instance.⁷ For these reasons, we think the time is not yet ripe for federal intervention.

Additionally, the Department does not believe that the Controlled Substances Act is an effective or appropriate vehicle for establishing a federal policy on physician-assisted suicide. In practical terms, the CSA is an ineffective tool for banning physician-assisted suicide. 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.

More broadly, the CSA is a complex regulatory system,

⁷ 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]").

supported by criminal, civil and administrative penalties, designed to keep legally available controlled substances within lawful channels of distribution and use, and to prevent their diversion to illicit channels. See S. Rep. No. 91-613, at 3 (1969). The particular drug abuse that Congress intended to prevent in the Act was the abuse deriving from stimulant, depressant, or hallucinogenic effect on the central nervous system of controlled substances. The Controlled Substances Act is therefore ill-suited to be the platform for the articulation of national policy on physician-assisted suicide because physician-assisted suicide does not involve either the issue of diversion of drugs to illicit channels or the issue of drug abuse for psychoactive effects. Nor does it make sense to charge the DEA with interpreting federal policy regarding the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide,"⁸ simply because such suicide may involve the use of controlled substances. Furthermore, addressing an issue as charged as physician-assisted suicide in this way obfuscates the importance of discussion and debate about the wisdom of such a policy, and may hinder Congressional accountability for the policy, which is a valued aspect of our system of government.

Thank you for this opportunity to present our views. The Office of Management and Budget has advised use that from the standpoint of the Administration's program, there is no objection to 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

⁸ Washington v. Glucksburg, 117 S. Ct. 2258, 2275 (1997).

O:\BAI\BAI00.458

S.L.C.

AMENDMENT NO. _____

Calendar No. _____

Purpose: To provide for a complete substitute.

IN THE SENATE OF THE UNITED STATES—106th Cong., 2d Sess.

H.R. 2260

To amend the Controlled Substances Act to promote pain management and palliative care without permitting assisted suicide and euthanasia, and for other purposes.

Referred to the Committee on _____
and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended
to be proposed by Mr. HATCH

Viz:

1 Strike all after the enacting clause and insert the fol-

2 lowing:

3 SECTION 1. SHORT TITLE.

4 This Act may be cited as the "Pain Relief Promotion

5 Act of 2000".

6 SEC. 2. FINDINGS.

7 Congress finds that—

8 (1) in the first decade of the new millennium

9 there should be a new emphasis on pain manage-

10 ment and palliative care;

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S.L.C.

2

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

4 (3) the dispensing and distribution of certain
5 controlled substances by properly registered practi-
6 tioners for legitimate medical purposes are permitted
7 under the Controlled Substances Act and imple-
8 menting regulations;

9 (4) the dispensing or distribution of certain
10 controlled substances for the purpose of relieving
11 pain and discomfort even if it increases the risk of
12 death are legitimate medical purposes and are per-
13 missible under the Controlled Substances Act;

14 (5) inadequate treatment of pain, especially for
15 chronic diseases and conditions, irreversible diseases
16 such as cancer, and end-of-life care, is a serious pub-
17 lic health problem affecting hundreds of thousands
18 of patients every year; physicians should not hesitate
19 to dispense or distribute controlled substances when
20 medically indicated for these conditions; and

21 (6) for the reasons set forth in section 101 of
22 the Controlled Substances Act (21 U.S.C. 801), the
23 dispensing and distribution of controlled substances
24 for any purpose affect interstate commerce.

O:\BAI\BAI00.458

S.L.C.

3

1 **TITLE I—PROMOTING PAIN MAN-**
2 **AGEMENT AND PALLIATIVE**
3 **CARE**

4 **SEC. 101. ACTIVITIES OF AGENCY FOR HEALTHCARE RE-**
5 **SEARCH AND QUALITY.**

6 Part A of title IX of the Public Health Service Act
7 (42 U.S.C. 299 et seq.) is amended by adding at the end
8 the following:

9 **"SEC. 903. PROGRAM FOR PAIN MANAGEMENT AND PALLIA-**
10 **TIVE CARE RESEARCH AND QUALITY.**

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

14 **"(1)** Promote and advance scientific under-
15 standing of pain management and palliative care.

16 **"(2)** Collect and disseminate protocols and evi-
17 dence-based practices regarding pain management
18 and palliative care, with priority given to pain man-
19 agement for terminally ill patients, and make such
20 information available to public and private health
21 care programs and providers, health professions
22 schools, and hospices, and to the general public.

23 **"(b) DEFINITION.**—In this section, the term 'pain
24 management and palliative care' means—

O:\BAI\BAI00.458

S.L.G.

4

1 “(1) the active, total care of patients whose dis-
2 ease or medical condition is not responsive to cura-
3 tive treatment or whose prognosis is limited due to
4 progressive, far-advanced disease; and

5 “(2) the evaluation, diagnosis, treatment, and
6 management of primary and secondary pain, wheth-
7 er acute, chronic, persistent, intractable, or associ-
8 ated with the end of life;

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

12 **SEC. 102. ACTIVITIES OF HEALTH RESOURCES AND SERV-**
13 **ICES ADMINISTRATION.**

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

16 (1) by redesignating sections 754 through 757
17 as sections 755 through 758, respectively; and

18 (2) by inserting after section 753 the following:

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

21 “(a) **IN GENERAL.**—The Secretary, in consultation
22 with the Director of the Agency for Healthcare Research
23 and Quality, may award grants, cooperative agreements,
24 and contracts to health professions schools, hospices, and
25 other public and private entities for the development and

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1 implementation of programs to provide education and
2 training to health care professionals in pain management
3 and palliative care.

4 “(b) PRIORITY.—In making awards under subsection
5 (a), the Secretary shall give priority to awards for the im-
6 plementation of programs under such subsection.

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

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

15 “(2) applicable laws on controlled substances,
16 including laws permitting health care professionals
17 to dispense or administer controlled substances as
18 needed to relieve pain even in cases where such ef-
19 forts may unintentionally increase the risk of death;
20 and

21 “(3) recent findings, developments, and im-
22 provements in the provision of pain management
23 and palliative care.

24 “(d) PROGRAM SITES.—Education and training
25 under subsection (a) may be provided at or through health

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1 professions schools, residency training programs and other
2 graduate programs in the health professions, entities that
3 provide continuing medical education, hospices, and such
4 other programs or sites as the Secretary determines to be
5 appropriate.

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

12 “(f) PEER REVIEW GROUPS.—In carrying out section
13 799(f) with respect to this section, the Secretary shall en-
14 sure that the membership of each peer review group in-
15 volved includes individuals with expertise and experience
16 in pain management and palliative care for the population
17 of patients whose needs are to be served by the program.

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

20 “(1) the active, total care of patients whose dis-
21 ease or medical condition is not responsive to cura-
22 tive treatment, or whose prognosis is limited due to
23 progressive, far-advanced disease; and

24 “(2) the evaluation, diagnosis, treatment, and
25 management of primary and secondary pain, wheth-

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1 TITLE II—USE OF CONTROLLED
2 SUBSTANCES CONSISTENT
3 WITH THE CONTROLLED SUB-
4 STANCES ACT

5 SEC. 201. REINFORCING EXISTING STANDARD FOR LEGITI-
6 MATE USE OF CONTROLLED SUBSTANCES.

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

10 “(i)(1) For purposes of this Act and any regulations
11 to implement this Act, alleviating pain or discomfort in
12 the usual course of professional practice is a legitimate
13 medical purpose for the dispensing, distributing, or admin-
14 istering of a controlled substance that is consistent with
15 public health and safety, even if the use of such a sub-
16 stance may increase the risk of death. Nothing in this sec-
17 tion authorizes intentionally dispensing, distributing, or
18 administering a controlled substance for the purpose of
19 causing death or assisting another person in causing
20 death.

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

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

3 “(3) Nothing in this subsection shall be construed to
4 alter the roles of the Federal and State governments in
5 regulating the practice of medicine. Regardless of whether
6 the Attorney General determines pursuant to this section
7 that the registration of a practitioner is inconsistent with
8 the public interest, it remains solely within the discretion
9 of State authorities to determine whether action should
10 be taken with respect to the State professional license of
11 the practitioner or the privileges of the practitioner to pre-
12 scribe controlled substances in the State.

13 “(4) Nothing in the Pain Relief Promotion Act of
14 2000 (including the amendments made by such Act) shall
15 be construed—

16 “(A) to modify the Federal requirements that a
17 controlled substance be dispensed only for a legiti-
18 mate medical purpose by a practitioner acting in the
19 usual course of professional practice; or

20 “(B) to provide the Attorney General with the
21 authority to issue national standards for pain man-
22 agement and palliative care clinical practice, re-
23 search, or quality;
24 except that the Attorney General may take such other ac-
25 tions as may be necessary to enforce this Act.”.

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

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

5 “(c) PROCEDURES.—

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

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

8 “(2) BURDEN OF PROOF.—At any proceeding
9 under paragraph (1), where the order to show cause
10 is based on the alleged intentions of the applicant or
11 registrant to cause or assist in causing death, the
12 Attorney General shall have the burden of proving,
13 by clear and convincing evidence, that the practi-
14 tioner’s intent was to dispense or distribute a con-
15 trolled substance with a purpose of causing, or as-
16 sisting in causing, the suicide or euthanasia of any
17 individual. In meeting such burden, it shall not be
18 sufficient to prove that the applicant or registrant
19 knew that the use of controlled substance may in-
20 crease the risk of death.”.

21 SEC. 202. EDUCATION AND TRAINING PROGRAMS.

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

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

25 (5);

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1 (2) by striking the period at the end of para-
2 graph (6) and inserting “; and”; and

3 (3) by adding at the end the following:

4 “(7) educational and training programs for
5 Federal, State, and local personnel, incorporating
6 recommendations, subject to the provisions of sub-
7 sections (e) and (f) of section 902 of the Public
8 Health Service Act, by the Secretary of Health and
9 Human Services, on the means by which investiga-
10 tion and enforcement actions by law enforcement
11 personnel may better accommodate the necessary
12 and legitimate use of controlled substances in pain
13 management and palliative care.

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

17 **SEC. 203. DIVERSION CONTROL FEE ACCOUNT.**

18 Notwithstanding any other provision of law, for pur-
19 poses of section 111(b) of the Departments of Commerce,
20 Justice, and State, the Judiciary, and Related Agencies
21 Appropriations Act, 1993 (21 U.S.C. 886a), the operation
22 of the diversion control program of the Drug Enforcement
23 Administration shall be construed to include carrying out
24 section 308(i) of the Controlled Substances Act (21 U.S.C.
25 823(i)), as added by this Act, and subsections (a)(4) and

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1 (c)(2) of section 304 of the Controlled Substances Act (21
2 U.S.C. 824), as amended by this Act.

3 SEC. 204. EFFECTIVE DATE.

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

Criminal Exposure of Physicians under H. R. 2260

The basic criminal drug trafficking prohibition in the Controlled Substances Act, 21 U.S.C. § 801 et seq. (the CSA), provides, at 21 U.S.C. § 841(a): "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally -- to dispense . . . a controlled substance." The penalties for unlawful drug trafficking are set forth in subsection (b). Apart from the specified mandatory minimum penalties for certain drugs (e.g., heroin, cocaine, and methamphetamine), the penalties are generally governed by the controlled substance schedule (I through V) on which the substance is listed. In order to effect a physician-assisted suicide, it is most common to use a combination of drugs, some of which are controlled substances (e.g., opiates or barbiturates) and some of which are not (e.g., neuromuscular blocking agents or cardioplegics). All of the opiates and some of the barbiturates used are controlled in Schedule II. See 21 C.F.R. § 1308.12(a)-(c). Distribution of substances in Schedule II, "except as authorized by this subchapter," is generally subject to a penalty of 0-20 years. However, "if death or serious bodily injury results from the use of such substance," the violator "shall be sentenced to a term of imprisonment of not less than 20 years or more than life," a fine under Title 18, or both. 21 U.S.C. § 841(b)(1) (C) (emphasis added). Obviously, in a physician-assisted suicide, death is the intended result, so the 20-year minimum, with a maximum of life, would apply. If the controlled substance used is a barbiturate -- some of which are on Schedule III -- or other drug not found in Schedule II, no mandatory penalty is triggered by death or serious bodily injury. See § 841(b)(1)(D).

Intertwined with this penalty scheme, the CSA creates a regulatory system for physicians, pharmacists, and other health care practitioners ("practitioner" being defined as "a physician . . . or other person licensed [by any state or the United States] to dispense a controlled substance in the course of professional practice" (emphasis added)) that circumscribes what is "authorized by this subchapter." The overall goal of this regulatory system is to prevent the diversion of licitly manufactured controlled substances and listed chemicals to illicit channels. The section which governs prescriptions, 21 U.S.C. § 829, provides that except when dispensed directly by a practitioner, no controlled substance in Schedule II, III, or IV may be dispensed without a prescription. Although the requirement of a "medical purpose" is only mentioned with respect to dispensing of Schedule V controlled substances, see § 829(c), pursuant to its regulatory authority, see §§ 821 and 871(b), the DEA has promulgated a regulation that makes the "medical purpose" limitation explicit, as the Supreme Court noted in United States v. Moore, 423 U.S. 122, 138 n.13. The applicable DEA regulation provides:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. . . . An order purporting to be a prescription issued not in the course of professional treatment or in legitimate and authorize research is

not a prescription within the meaning and intent of [§ 829] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a) (emphasis added). Thus, the legal "hook" for the practitioner in § 829 is the very requirement of a "prescription" as that term is informed by the regulation. When a prescription is written other than in "the usual course of professional treatment" or for other than a "legitimate medical purpose," it is not a prescription at all for purposes of the CSA, and the prescriber enjoys no protection from penalties applicable to non-practitioners.

H.R. 2260, the "Pain Relief Promotion Act of 1999" (the "Act"), creates a substantial risk of criminal exposure for any physician who prescribes one or more controlled substances as part of a lethal dose to effectuate a patient's wish to end his life, even -- indeed, especially -- in a state like Oregon where doctors are permitted to do so within narrowly prescribed parameters. The Act strongly implies that physician-assisted suicide is neither part of the "usual course of professional practice" nor "a legitimate medical purpose" nor "consistent with public health and safety" -- the latter being a factor considered by the DEA in registering practitioners at 21 U.S.C. § 823(f) and a basis for revoking a registration at § 824(a). This implication is created by the wording of Sec.101 of the Act, which would amend § 823 to provide a new subsection (i). Paragraph (1) of that subsection would begin by saying that "alleviating pain or discomfort in the usual course of professional practice is a legitimate medical purpose . . . even if the use of such a substance may increase the risk of death." However, the very next sentence provides: "Nothing in this section authorizes intentionally dispensing . . . a controlled substance for the purpose of causing death or assisting another person in causing death." In this context, the statement that "[n]othing in this section authorizes" participation in an assisted suicide carries the strong implication that such conduct is in fact not authorized under the CSA. Recalling that the basic delineation of the crime of drug trafficking in the CSA is to knowingly distribute or dispense controlled substances "except as authorized by this subchapter" (i.e., Subchapter 1 of Chapter 13 of Title 21, which generally encompasses the domestic provisions of the CSA), the legal risk of prosecution is clear.

Paragraph (2) of Sec.101 exacerbates the criminal exposure created by paragraph (1). It says that "in determining whether a registration is consistent with the public interest under this Act, the Attorney General shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia." Although the drafting is limited by its terms to registration vel non of practitioners, its terms will unavoidably resonate in the realm of criminal exposure. First, it reinforces the argument that paragraph (1) is a federal ban on the use of controlled substances to facilitate physician-assisted suicide under the CSA. Second, it instructs the Attorney General to ignore state-law provisions

in this regard -- a directive with potential repercussions for interpretation of paragraph (1) as well.

Paragraph (3) adds further uncertainty to the application of this section by stating that paragraph (2) applies prospectively only. What does this mean for paragraph (1)? Are we to infer that the implicit declaration that physician-assisted suicide is not a legitimate medical purpose is intended for retroactive application? If so, this law could expose physicians who scrupulously adhered to every guideline in the Oregon Death with Dignity Act (O.R.S. §§ 127.800-127.995) to federal prosecution -- with a mandatory 20-year penalty if Schedule II substances were used -- for assisted suicides in which they participated.

The danger of prosecution of Oregon physicians is more than hypothetical. Unlike most instances of physician-assisted suicide nationwide each year that occur behind a tacitly agreed veil of secrecy, in Oregon the legal process is undertaken openly and carefully documented. These features would vastly simplify the collection of evidence for prosecution. The participating physician's identity and intention would be transparent. For practical purposes, then, if H.R. 2260 passes in its current form, Oregon physicians who comply with the Death with Dignity Act would be by far the easiest targets for federal prosecution. The irony of this outcome speaks for itself.



U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

October 19, 1999

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

Dear Congressman Conyers:

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

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

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

Palliative Care

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

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

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

Physician Assisted Suicide

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

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

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

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

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

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

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

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

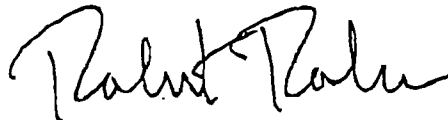
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⁵ This approach to physician-assisted suicide is consistent with the Department's approach to "medical marijuana." The legality of the latter turns on factual, not ethical, questions. That is, the scheduling of controlled substances is based on scientific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

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

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

Sincerely,



Robert Raben
Assistant Attorney General

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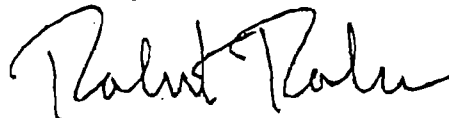
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Sincerely,



Robert Raben
Assistant Attorney General

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U. S. HOUSE OF REPRESENTATIVES

Committee on the Judiciary
Democratic Staff Office
B-351-C Rayburn House Office Building
Washington, D.C. 20515

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106TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
1st Session } 106-

PAIN RELIEF PROMOTION ACT OF 1999

OCTOBER , 1999.—Ordered to be printed

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

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 2260]

[Including cost estimate of the Congressional Budget Office]

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

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PURPOSE AND SUMMARY

H.R. 2260, the Pain Relief Promotion Act of 1999, was introduced on June 17, 1999, by a bipartisan group of 68 cosponsors and enjoys the support of the American Medical Association and the National Hospice Organization, among many other medical organizations.¹ H.R. 2260 promotes pain management and palliative care through the appropriate use of controlled substances, even if such use unintentionally hastens death, while reinforcing the uniform application of the existing standard that intentionally bringing about the death of any person is not a legitimate use of controlled substances and is not consistent with public health and safety. H.R. 2260 also authorizes the Attorney General to carry out educational training programs for law enforcement personnel and to promote greater understanding of health professionals' legitimate use of controlled substances for pain management, while authorizing the Agency for Health Care Policy and Research in the Department of Health and Human Services to collect and disseminate protocols for palliative care. Finally, H.R. 2260 authorizes a \$5,000,000 program under which the Secretary of Health and Human Services may award grants to health professions schools, hospices and other sites to develop and implement palliative care education and training. On June 24, 1999, the subcommittee conducted a hearing on H.R. 2260. On July 20, 1999, the subcommittee passed the bill without amendment by a voice vote. On September 14, 1999, the committee reported the bill favorably without amendment.

BACKGROUND AND NEED FOR THE LEGISLATION

The Controlled Substances Act and the Role of the Drug Enforcement Administration

The Controlled Substances Act of 1970 (CSA) provides a uniform national standard for the control of potentially dangerous drugs, and a system of enforcement and penalties that is, in important respects, independent of State law. The CSA prohibits any distribution of controlled substances unless the distribution is authorized pursuant to a statutory exception.² One such exception is distribution pursuant to registration by the Attorney General under 21 U.S.C. § 823. Physicians and pharmacists may apply to the Drug Enforcement Administration (DEA) for a Federal license to prescribe and administer controlled substances. The primary role of

¹ The bill has the express support of some of the leading medical groups in the country such as: American Medical Association, National Hospice Organization, Hospice Association of America, American Academy of Pain Management, American Society of Anesthesiologists, Physicians for Compassionate Care, Christian Medical and Dental Society, Catholic Health Association, Hope Hospice and Palliative Care (Florida), Americans for Integrity in Palliative Care, American College of Osteopathic Family Physicians, Coalition of Concerned Medical Professionals and the Oklahoma State Medical Association. The bill has also been endorsed by the State of Oregon's largest newspaper, the *Oregonian*.

² According to 21 U.S.C. § 841, it is "unlawful for any person [to] knowingly or intentionally . . . distribute, or dispense . . . a controlled substance" . . . "[e]xcept as authorized by this subchapter [Control and Enforcement, §§ 801-904]."

DEA with respect to pharmaceutical controlled substances is to prevent, detect, and investigate their diversion from legitimate uses while ensuring their availability for legitimate medical use.³ While physicians receive their licenses to practice medicine from State medical boards, they receive this separate registration to prescribe controlled substances from the DEA.⁴ Prescriptions for these potentially dangerous drugs must be written using DEA registrations on DEA prescription forms.

The CSA was amended in 1984 to strengthen the DEA's ability to prevent diversion of federally regulated prescription drugs for illicit purposes.⁵ The chief concern cited as justification for the 1984 amendments was the potential of controlled substances to cause physical harm and death when used for something other than a legitimate medical purpose. According to Representative Hughes, the chief House sponsor of the measure, "The bill gives to DEA greater latitude to suspend or revoke the registration of a practitioner who dispenses drugs in a manner that threatens the public health and safety."⁶ The 1984 amendments were designed to give the DEA more independent authority to revoke a physician's registration in cases where a State was unable or unwilling to intervene.⁷ The amendments authorized the DEA to revoke a physician's registration where the registration is deemed "inconsistent with the public interest"—in cases where, for example, controlled substances have been misused to endanger "public health and safety."⁸

³ All DEA policies, procedures, and investigative programs with respect to this issue are guided by the underlying principle stated in the Code of Federal Regulations which links the validity of any prescription for a controlled substance to the requirement that it be "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04.

⁴ As Congress declared in 1984 when it last revised this part of the CSA.

Registration of a physician under the Controlled Substances Act is a matter entirely separate from a physician's State license to practice medicine. Therefore, revocation of registration only precludes a physician from dispensing substances controlled under the Controlled Substances Act and does not preclude his dispensing other prescription drugs or his continued practice of medicine.

S. Rep. No. 98-225, at 267 (1983), reprinted in 1984 U.S.C.A.N. 3182, 3449 n. 40.

⁵ The amendments were approved by the U.S. Senate 91-to-1 on February 2, 1984 as part of a Comprehensive Crime Control Act (S. 1762). Almost identical language was approved by the House 392-to-1 on September 18, 1984. The House and Senate versions were reconciled and ultimately approved as part of H.J. Res. 648, a continuing resolution which became law on October 12, 1984 (Pub. L. No. 98-473, 98 Stat. 1987).

⁶ 130 Cong. Rec. 25,849 (1984). Representative Hughes also cited a government study indicating that "prescription drugs are responsible for close to 70 percent of the deaths and injuries due to drug abuse." *Id.* at 25,848.

⁷ Representative Hamilton Fish, another sponsor of the amendments, said giving such flexibility to the Federal Government was necessary because States often did not respond adequately to these abuses: "State policing of these activities, as well as peer review within the profession, have not been adequate control measures. State laws regarding the dispensing of controlled substances are also inadequate." *Id.* at 25,849.

At a hearing before the House Commerce Subcommittee on Health and the Environment, the DEA called the expanded Federal authority to revoke practitioner registration "one of the most important sections of the bill," not only because States were often ill-equipped to enforce their own drug laws but also because "many controlled drug violations involving prescription drugs are not felonies under State law and therefore cannot be used in a DEA revocation action" under then-existing law. *Dangerous Drug Diversion Control Act of 1984: Hearing on H.R. 5656 Before the Subcomm. On Health and the Env't of the House Comm. On Energy and Commerce*, 98th Cong. 404 (1984) (statement of Gene R. Haislip, Deputy Assistant Administrator, Drug Enforcement Administration).

⁸ As Representative Charles Rangel said in support of the amendments:

Under current law, the DEA must register physicians, pharmacies, or other practitioners if they are authorized to dispense drugs by the law of the State in which they practice. The public interest standard added by H.R. 5656 will provide greater flexibility to deny or revoke registrations in the most egregious cases.

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21 U.S.C. § 823 of the CSA sets forth registration requirements for controlled substances licenses and § 824 sets forth grounds for revocation. Physicians who abuse their registrations and prescribe controlled substances for non-medical purposes are subject to license revocation under § 824 and to potential criminal prosecution under § 841.⁹ Section 823 provides that the Attorney General may deny an application for registration "if such registration would be inconsistent with the public interest" as determined by consideration of several factors.¹⁰

Two of the factors listed under § 823 that are relevant to assisted suicide are: compliance with State law relating to controlled substances (21 U.S.C. § 823 (f)(4)), and the public health and safety (21 U.S.C. § 823 (f)(5)). Most States specifically prohibit assisted suicide; no State has authorized assisted suicide except Oregon.¹¹ Public health and safety has been invoked as separate grounds for revoking the registrations of physicians who prescribe drugs used in lethal overdoses.¹² In some cases, the physicians were found to

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

⁹In practice, a criminal proceeding is almost never initiated. Instead, an administrative penalty is applied (simply revoking or suspending the physician's special Federal privilege to handle controlled substances), and this effectively prevents further illicit use. Typically, the DEA does not initiate action at all until after the State has acted against a registrant.

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

¹¹Currently, 44 States prohibit assisted suicide, either through statutes or common law. Thirty-eight States prohibit assisted suicide through statutes. Alaska (Act 97-187, 1997 Session Laws), Arizona (Ariz. Rev. Stat. Ann. § 13-1103(A)(3) (West Supp. 1996-1997)), Arkansas (Ark. Code Ann., § 5-10-104(a)(2) (1993)), California (Cal. Penal Code, § 401 (West 1988)), Colorado (Colo. Rev. Stat. § 18-3-104(1)(6) (Supp. 1996)), Connecticut (Conn. Gen. Stat. § 53a-56(a)(2) (1997)), Delaware (Del. Code Ann., tit. 11, § 645 (1995)), Florida (Fla. Stat. § 782.08 (West 1992)), Georgia (Ga. Code Ann., § 16-5-5(b) (1996)), Hawaii (Haw. Rev. Stat. § 707-702(1)(6) (1993)), Illinois (Ill. Comp. Stat., ch. 720, § 5/12-31(a)(2) (Smith-Hurd Supp. 1996)), Indiana (Ind. Stat. Ann., §§ 35-42-1-2 to 35-42-1-2.5 (1994 and Supp. 1996)), Iowa (Iowa Code Ann. §§ 707A.2, 707A.3 (Supp. 1997)), Kansas (Kan. Stat. Ann., § 21-3406 (1995)), Kentucky (Ky. Rev. Stat. Ann., § 216.302 (Michie 1994)), Louisiana (La. Rev. Stat. Ann., § 14:32.12 (West Supp. 1997)), Maine (Me. Rev. Stat. Ann., tit. 17-A, § 204 (West 1983)), Maryland (1999 Md. Laws 700), Michigan (Mich. Comp. Laws Ann. § 752.1027 (West Supp. 1997-1998)), Minnesota (Minn. Stat. Ann., § 609.215 (West 1987 and Supp. 1996)), Mississippi (Miss. Code Ann., § 97-3-49 (1994)), Missouri (Mo. Ann. Stat., § 565.023(1)(2) (West Supp. 1996)), Montana (Mont. Code Ann., § 45-5-105 (1995)), Nebraska (Neb. Rev. Stat. Ann., § 28-307 (Michie 1995)), New Hampshire (N.H. Rev. Stat. Ann., § 630.4 (1996)), New Jersey (N.J. Stat. Ann., § 2C:11-6 (West 1995)), New Mexico (N.M. Stat. Ann., § 30-2-4 (Michie 1994)), New York (N.Y. Penal Law, §§ 120.30, 125.15(3) (McKenney, 1987)), North Dakota (N.D. Cent. Code, § 12.1-16-04 (Supp. 1995)), Oklahoma (Okla. Stat. Ann., tit. 21, §§ 813, 814, 815 (West 1983)), Pennsylvania (Pa. Cons. Stat. Ann., tit. 18, § 2505(b) (West 1983)), Rhode Island (R.I. Gen. Laws §§ 11-60-1 through 11-60-8 (Supp. 1996)), South Carolina (S.C. Code Ann., § 16-3-1090 (1998)), South Dakota (S.D. Certified Laws Ann., § 22-16-37 (Michie 1988)), Tennessee (Tenn. Code Ann., § 39-13-216 (Supp. 1995)), Texas (Tex. Penal Code Ann., § 22.08 (West 1994)), Virginia (Va. Code Ann., § 8.01-622.1 (Michie 1999)), Washington (Wash. Rev. Code Ann., § 9A.36.060 (West 1988)), Wisconsin (Wis. Stat. Ann., § 940.12 (West 1996)). Six States criminalize assisted suicide through common law. Alabama, Idaho, Massachusetts, Nevada, Vermont, and West Virginia. Issue Brief, Health Policy Tracking Service, National Conference of State Legislatures, (Sept. 17, 1999) (Maria Rothoner and Elizabeth Kaiser).

¹²See, e.g., Denial of Registration of Dr. Samuel Fertig, 49 Fed. Reg. 6577 (Feb. 22, 1984) (denied a registration for prescribing massive quantities of controlled substances to several young people who used them in lethal overdoses, despite fact that state license had been restored, on grounds that he "was responsible, directly or indirectly, for the deaths of several young people"); Revocation of Registration of Dr. Murray Walker, 55 Fed. Reg. 5306 (Feb. 14, 1990) (registration revoked for prescribing Percodan for non-medical purposes to several people, one of whom died of an overdose, the DEA stating, "Substances are controlled because they are potentially dangerous and therefore should be handled with extreme care. Respondent has failed to exercise such care and, as a result, has ignored his duties as a health care professional to protect the public health and safety from the illicit use of these drugs.") See 21 U.S.C. § 824(c) for the procedure for such a suspension or revocation, and 21 U.S.C. § 824(d) for the authority to "suspend any registration simultaneously with the institution of proceedings under this section, in cases where (the Attorney General) finds that there is an imminent danger to the public health or safety."

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have been negligently involved in suicides or attempted suicides.¹³ Each of these cases was theoretically a candidate for criminal prosecution under §841, but, apparently, no federal criminal prosecution followed. Even where physicians were previously convicted of manslaughter under State law for negligent and reckless involvement in a suicide or other lethal overdose, the separate Federal standard of "public health and safety" was the basis upon which the registration was revoked and, in one case, reinstatement repeatedly denied.¹⁴

Chronology of Events Preceding H.R. 2260

On November 8, 1994, Oregon voters approved Ballot Measure 16, legalizing physician-assisted suicide, by a margin of 51% to 49%.¹⁵ On November 27, 1994, however, a lawsuit was filed against the Death with Dignity Act on equal protection and due process grounds.¹⁶ On August 3, 1995, the law was held unconstitutional as a violation of the Equal Protection Clause. The State appealed the decision, and on February 27, 1997, the Ninth Circuit overturned the ruling on the basis of the plaintiffs' lack of standing.¹⁷ On October 27, 1997, the Ninth Circuit lifted the injunction against the Act. On November 4, 1997, Oregon voters rejected a referendum asking for the repeal of the Act¹⁸ and the measure was implemented at that time.

During the litigation over Oregon's assisted suicide law, Congress debated the issue of Federal funding for assisted suicide. On April 30, 1997, after a vote of 398-16 in the House and a unani-

¹³ See, e.g., Denial of Registration of Dr. Pompeyo Q. Braga Bonado, 55 Fed. Reg. 37579 (Sept. 12, 1990). Here, the DEA found that granting a registration to this physician would be "clearly contrary to the public interest." *Id.* at 37580. The physician had prescribed controlled substances to several individuals "for no legitimate medical purpose," including to one man addicted to Percocet who was hospitalized after a suicide attempt. "As a health care professional and DEA registrant," the DEA stated, "Respondent bears a heavy responsibility to ensure that the controlled substances he prescribes are not abused." *Id.* at 37580.

¹⁴ In the case of Revocation of Registration of Hugh Schade, M.D., 60 Fed. Reg. 56354 (Nov. 8, 1995). Dr. Schade gave potentially lethal amounts of Darvocet to a depressed patient who used them to commit suicide. Giving these drugs to a patient in this mental state, said one expert witness, was "like handing him a loaded gun." While Dr. Schade was also convicted of negligent homicide under state law because of this case, his DEA application was denied not on the basis that he had violated a state law, but on the separate basis that his conduct objectively threatened "public health and safety".

In the case of Revocation of Registration of David W. Bradway, M.D., 48 Fed. Reg. 49937 (Oct. 28, 1983), the physician's registration was revoked after conviction under state law on various counts, most notably "one count of manslaughter by unlawfully distributing controlled substances in such a grossly negligent [and] reckless manner as to cause the death of an individual" *Id.* at 49937. Years later, after allegedly rehabilitating and resuming medical practice, the physician applied for a new DEA registration; citing the fact that "a death was directly attributable to Respondent's misuse of his DEA Certificate of Registration," the DEA denied the application, stating: "It is the position of the DEA that a Certificate of Registration to handle controlled substances is a privilege, not a right, and it should only be granted to doctors who have demonstrated high standards of ethical conduct and who are completely trustworthy in handling dangerous controlled substances which, as can be seen in this case, can have a devastating impact on individuals who abuse them." 54 Fed. Reg. at 53384. In 1992 he again applied for a DEA registration, but due to "the egregious nature of Respondent's past conduct," the DEA ruled in 1994 (15 years after the patient's death) that "the registration of the Respondent is still not in the public interest". *Id.* at 6299.

¹⁵ See Spencer Heinz, *Assisted Suicide: Advocates Weigh In*, Oregonian, Dec. 9, 1994, at A1.

¹⁶ See *Lee v. Oregon*, 891 F. Supp. 1429, 1431 (D. Or. 1995). Federal District Court Judge Michael Hogan agreed with the opponents and issued a temporary restraining order against implementation of the Act on the day before it was to go into effect, pending a full hearing of their claims. On December 27, 1994, Judge Hogan replaced his temporary restraining order with a preliminary injunction, further delaying implementation of the Act.

¹⁷ On May 16, 1997, a petition for writ of certiorari was filed with the United States Supreme Court, and the Court denied the petition on October 14, 1997.

¹⁸ The referendum failed by a vote of 60% to 40%.

mous vote in the Senate, the President signed the Assisted Suicide Funding Restriction Act of 1997,¹⁹ which prohibits the use of Federal funds to cause a patient's death. The Act effectively prohibits the practice of assisted suicide in Federal health facilities, removes it from the scope of "treatments" on which patients must be informed under the Federal Patient Self-Determination Act, and forbids Federal subsidies to health programs or benefit packages which include assisted suicide. President Clinton lauded the bill, saying it "will allow the Federal Government to speak with a clear voice in opposing these practices," and warning that "to endorse assisted suicide would set us on a disturbing and perhaps dangerous path."²⁰

Also in 1997, the Supreme Court reviewed two Circuit Court of Appeal rulings regarding the assisted suicide laws of New York and Washington, and concluded that laws prohibiting assisted suicide do not violate the U.S. Constitution. The Solicitor General of the United States filed briefs as *amicus curiae* opposing the overturning of the State laws in each case.²¹ In his brief in the *Glucksberg* case, the Solicitor General asserted that there is a clear ethical and legal distinction between pain control that unintention-

¹⁹ 42 U.S.C. § 14401.

²⁰ Statement by President William Jefferson Clinton Upon Signing H.R. 1003, 33 Weekly Comp. Pres. Doc. 617 (May 5, 1997).

²¹ Brief for the United States as Amicus Curiae Supporting Petitioners at 17-18, *Washington v. Glucksberg*, 521 U.S. 702 (1997) (No. 96-110). Relevant portions of the *Glucksberg* brief are as follows: Health facilities controlled by the Federal Government "do not permit physicians to assist patients in committing suicide by providing lethal dosages of medication." *Id.* at 1; "Overriding State interests justify the State's decision to ban physicians from prescribing lethal medication." *Id.* at 9; "There is an important and common-sense distinction between withdrawing artificial supports so that a disease will progress to its inevitable end, and providing chemicals to be used to kill someone." *Id.* "Once a State decides to create an exception to its prohibition against assisted suicide, there is no obvious stopping point." *Id.* at 10; "One special source of concern is that terminally ill persons who contemplate suicide often suffer from undiagnosed depression and inadequately treated pain . . . In most cases, once appropriate treatment is provided, the desire for suicide abates." *Id.* at 19; "Any exception to the ban on assisted suicide therefore runs a very significant risk that persons with treatable depression and pain will be allowed to commit suicide. A State has an overriding interest in avoiding that risk and in protecting persons who would want to remain alive if provided with the appropriate treatment." *Id.* at 20; "Another area of concern is that terminally ill patients are often extremely vulnerable and susceptible to influence by physicians, family members, and others on whom they depend for support. . . The point is not that physicians or family members will attempt to coerce persons into committing suicide, although there may be some cases of that. The real dangers are much more subtle and extremely difficult to monitor and address." *Id.*; "Another difficulty with permitting doctors to prescribe lethal drugs for terminally ill patients is that illnesses can be misdiagnosed as terminal . . . If the State were to create an exception to its ban on assisted suicide for terminally ill adults, such a misdiagnosis could have tragic consequences . . . The State has an overwhelmingly strong interest in preventing such tragedies from occurring." *Id.* at 22; In the Netherlands, which allowed assisted suicide with safeguards, "a recent study shows that those procedural safeguards have not worked." *Id.* at 23; "[T]here is a very significant distinction between removing artificial supports—and thereby allowing the underlying disease to progress to its inevitable end—and providing chemicals to kill someone. In one case, the cause of death can reasonably be viewed as the underlying disease; in the other, the cause of death can only be viewed as the lethal medication." *Id.* at 24; "Once a legislature abandons a categorical prohibition against physician assisted suicide, there is no obvious stopping point." *Id.* at 26.

Similarly, after reviewing various Federal policies that forbid physician assisted suicide (as defined above) in VA hospitals, military hospitals, NIH, and Indian Health Service, the Solicitor General's *amicus* brief in *Vacco v. Quill* stated: "No Federal law authorizes or encourages physician assisted suicide." Brief for the United States as Amicus Curiae Supporting Petitioners at 2, *Vacco v. Quill*, 521 U.S. 793 (1997) (No. 95-1858); "To let a patient die is to acknowledge the futility of further medical treatment and to let nature run its course. Physician prescribed lethal medication, in contrast, provides its own fatal pathology." *Id.* at 10; "The medical profession recognizes ethical distinctions between discontinuing unwanted, futile treatments and using the tools of medicine to cause a patient's death." *Id.* at 11 (citing the AMA); "With the provision of lethal medication, the physician provides the cause of the patient's death." *Id.* at 12.

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ally hastens death and the prescribing of lethal drugs with the intent to cause death:

[T]he ethical standards of the medical community have long permitted physicians to prescribe medication in sufficient doses to relieve pain, even when the necessary dose will hasten death . . . So long as the physician's intent is to relieve pain, and not to cause death, such treatment does not violate the ethical standards of the medical community.²²

Importantly, the Solicitor General also asserted that "no Federal law . . . either authorizes or accommodates physician assisted suicide."²³

After Oregon's law was enacted, Judiciary Committee Chairman Henry J. Hyde inquired of the Administrator of the DEA, Thomas K. Constantine, whether Oregon's new law would have any impact on the administration of the CSA. Administrator Constantine replied on November 5, 1997, declaring physician assisted suicide with the use of federally controlled substances to be inconsistent with the CSA.²⁴ Under the DEA ruling, doctors given a Federal license under the CSA to prescribe federally controlled substances could not prescribe them for the purpose of assisting in a suicide. Constantine agreed with the sentiment of many members of Congress that administering a drug to deliberately cause someone to die is not a "legitimate medical purpose" within the meaning of the Controlled Substances Act.²⁵

On June 5, 1998, however, the Attorney General of the United States ruled that administering controlled substances for the purpose of causing death is to be considered part of the ordinary practice of medicine in Oregon and, therefore, exempt from CSA and DEA jurisdiction. Under the Attorney General's ruling, the CSA is enforceable against the use of controlled substances for assisted suicide in Oregon only to the extent that physicians do not comply with the provisions of Oregon's law.²⁶ Under Attorney General Reno's ruling, a DEA registration cannot be denied, revoked, or suspended in the case of "a physician who has assisted in a suicide in compliance with Oregon law."²⁷ "Adverse action against a physician who has assisted in a suicide in full compliance with the Or-

²² *Glucksberg*, 521 U.S. at 17

²³ Solicitor General's Amicus Brief at 2, *Glucksberg* (No. 96-110)

²⁴ Letter from The Honorable Thomas K. Constantine, Administrator of the Drug Enforcement Administration of the United States, to Chairman Henry J. Hyde, Committee on the Judiciary, U.S. House of Representatives (Nov. 5, 1997)

²⁵ Administrator Constantine concluded in his letter to Chairman Hyde that, "delivering, dispensing, or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a legitimate medical purpose." *Id.*

²⁶ In her letter to Chairman Hyde, however, Attorney General Janet Reno failed to mention the existing regulatory requirement that practitioners prescribe federally controlled substances only for a "legitimate medical purpose".

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).

Letter from The Honorable Janet Reno, Attorney General of the United States, to Chairman Henry J. Hyde, Committee on the Judiciary, U.S. House of Representatives (June 5, 1998).

²⁷ *Id.*

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egon Act would not be authorized by the CSA."²⁸ DEA investigation would therefore focus not on whether controlled substances have been used to take human life, but on whether human life has been destroyed in conformance with Oregon law. The Attorney General's ruling commits the DEA to a role to which it has never been assigned under the CSA—that of regulating assisted suicide as a "legitimate medical practice." This is a sharp departure from the intended purposes of the Controlled Substances Act, and from the policy required in all other Federal programs under the Assisted Suicide Funding Restriction Act.

Congressmen Henry Hyde and James Oberstar introduced a bill on June 5, 1998, in the 105th Congress, to address the problems created by the Attorney General's ruling. That bill, H.R. 4006, was reported out of committee but no further action was taken. H.R. 2260 was introduced in the 106th Congress on June 17, 1999 by Congressmen Henry Hyde and Bart Stupak.

Oregon's Assisted Suicide Law

On February 17, 1999, the Oregon Health Division released a report detailing the first full year under Oregon's physician-assisted suicide law. Twenty-three individuals received lethal substances in 1998 pursuant to the Act, while fifteen actually used the substances to cause their deaths.³⁰ Thirteen had cancer, one had a chronic lung condition and one had congestive heart failure. Only fourteen had lived in Oregon for at least six months.

The report is lacking in several respects. It does not provide objective information about the extent to which physicians have complied with the law, but, instead, relies heavily on physician self-reporting. This deficiency in objective reporting is exacerbated by the fact that the law itself is governed by a "good faith" standard that protects physicians from civil, professional, and criminal liability so long as they believe "in good faith" that they have complied with the guidelines.³¹ The report makes no serious effort to uncover the extent of covert assisted-suicide,³² and the law's confidentiality requirements³³ and its provision barring notification of family mem-

²⁸ *Id.*

³⁰ Of these fifteen, eight were men and seven were women. Of the eight who did not use the medication, six died from their own illnesses before taking the drugs and two were alive as of January 1, 1999.

³¹ Or. Rev. Stat. § 127.885 (1997). The governor of Oregon has testified that he knows of no State penalties for violating the State guidelines. *Lethal Drug Abuse Prevention Act Hearing on H.R. 4006 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 105th Cong. (July 14, 1998) (oral statement of Gov. John Kitzhaber). An Oregon physician generally acknowledged to have performed active euthanasia without his patient's consent (still a homicide under Oregon law) was declared "unprosecutable" by State officials because of the climate created by the Oregon law permitting assisted suicide. See *Doctor won't be prosecuted*, The Bulletin (Bend, OR), Dec. 11, 1997, at 7.

³² Upon releasing the report, the Oregon Health Division distributed a memorandum to State employees stating that any employee who reveals that a physician-assisted death has occurred in his or her county "will immediately be terminated." Death with Dignity Memorandum from Sharon Rice, Manager Registration Unit, Center for Health Statistics of the Oregon Health Division, to County Vital Records Registrars and Deputies (Dec. 12, 1997) reprinted in Confidentiality of Death Certificates, 14 Issues in Law & Med 333, 334 (1998). This memorandum indicates that the real purpose of this report might have been something other than the discovery and disclosure of all relevant information.

³³ Or. Rev. Stat. § 127.865 (1997).

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bers without a patient's express consent³⁴ make it very unlikely that abuses will be discovered.³⁵

Significantly, the report fails to provide any meaningful information on the mental state of the patients. Under the Oregon law, physicians are to assist suicides only in cases where a patient is expected to die in six months,³⁶ yet physicians generally concede, and the professional literature confirms, that such predictions of life expectancy are unreliable.³⁷ In addition, physicians are to assist suicides only in cases where a patient is *not* suffering from "a psychiatric or psychological disorder, or depression causing impaired judgment."³⁸ Most physicians are ill-equipped to detect depression in their patients at all, much less to determine what level of clinical depression is sufficient to cause "impaired judgment."³⁹

Specific omissions highlight the untrustworthiness of the report. The report fails to mention that the first publicly-reported case of assisted suicide in the State involved an out-of-State woman who was found to be depressed by one doctor she consulted. Within three weeks of contacting Compassion in Dying and moving to Oregon, she was dead by lethal overdose. Significantly, while two doctors had rendered opinions against the assisted suicide, including a physician who believed the woman was suffering from clinical depression, these opinions were not included in the report.⁴⁰

The Pain Relief Promotion Act of 1999

Palliative Care is a Legitimate Medical Purpose for Controlled Substances

In Title I, The Pain Relief Promotion Act amends the CSA to expressly permit and encourage the use of controlled substances for pain management and palliative care, even where such use might

³⁴Or. Rev. Stat. § 127.835 (1997).

³⁵Another factor worthy of note is that, during the first year of the assisted suicide law's operation, the Oregon Health Plan placed barriers to the funding of antidepressants (Jeanette Hamby, *The Enemy Within: State Bureaucratic Rules Threaten the Spirit of Oregon Health Plan's Founding Principles*, Oregonian, Jan. 21, 1998), restricted the availability of mental health services (Joe Rojas-Burke, *Survey Gives Oregon Health Plan High Marks*, Oregonian, Feb. 3, 1999, at B15), and restricted pain medication for poor and disabled patients (Diane Gianelli, *Suicide Opponents Rip Oregon Medicaid Pain Control Policy*, American Medical News, Sept. 28, 1998). By contrast, Oregon fully funds assisted suicide. See *Pain Relief Promotion Act of 1999, Hearing on H.R. 2260 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 106th Cong. (June 24, 1999) (statement of N. Gregory Hamilton, M.D., President of Physicians for Compassionate Care) <<http://www.house.gov/judiciary/hami0624.htm>> [hereinafter cited as Hamilton Testimony]. Some private Health Maintenance Organizations have begun to place caps on in-home palliative care while fully funding assisted suicide. *Id.*

³⁶Or. Rev. Stat. § 127.800, 127.805 (1997).

³⁷Joanne Lynn et al., *Defining the "Terminally Ill": Insights from SUPPORT*, 35 Duquesne Law Review 311 (1996); Eric Chevlen, *The Limits of Prognostication*, 35 Duquesne Law Review 337 (1996); R.A. Pearlman, *Inaccurate Predictions of Life Expectancy*, 148 Archives of Internal Medicine 2537 (1988).

³⁸Or. Rev. Stat. § 127.825 (1997).

³⁹*Lethal Drug Abuse Prevention Act: Hearing on H.R. 4006 before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 105th Cong., 2d Sess. (July 14, 1998) (oral statement of Dr. Herbert Hendin). See also, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context*, New York State Task Force on Life and the Law (May 1994), 126-8. The chief author of the Oregon law has written somewhat chillingly that "depression in itself does not rule out the physician's assistance" under the Act. See Cheryl K. Smith, *Safeguards for Physician-Assisted Suicide: The Oregon Death with Dignity Act*, in *Death, Dying and the Law* 75 (S. McLean ed., 1996).

⁴⁰See Herbert Hendin et al., *Physician-Assisted Suicide: Reflections on Oregon's First Case*, 14 Issues in Law & Med. 243 (1998).

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unintentionally hasten death.⁴¹ H.R. 2260 would include in the CSA for the first time an endorsement of pain control as a "legitimate medical purpose" for the use of controlled substances. Until now, such affirmations have been relegated to documents, such as physicians' manuals, which do not have the force of law.

Section 303(i)(1) of the CSA as amended by H.R. 2260 would read:

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

This text makes clear that practitioners may legally dispense controlled substances to alleviate pain and discomfort. By defining the alleviation of pain or discomfort as a legitimate medical purpose, H.R. 2260 protects practitioners from undue scrutiny or suspicion when they exercise their professional judgment in determining how most effectively to relieve pain. H.R. 2260 further reaffirms that the CSA does not authorize the use of controlled substances for assisting suicide. Section 303(i)(1) of the CSA as amended would read: "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."

H.R. 2260 thus codifies what is sometimes called the "principle of double effect" with regard to the use of federally controlled substances.⁴² The distinction between intended and unintended has-

⁴¹ Because the language of H.R. 2260 applies only to *dispensing, distributing, or administering* controlled substances, it can only apply to schedule II, III, IV, or V drugs. Schedule I drugs, such as marijuana (21 C.F.R. section 1308.11(d)(19)), may not be dispensed for any reason but may be used only for approved research. 21 U.S.C. section 823(f) provides, "The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered: . . . (5) such other factors as may be relevant to and consistent with the public health and safety." By contrast, the only provision authorizing registration of practitioners with respect to schedule I controlled substances is for research: "Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine qualifications and competency of each practitioner requesting registration." *Id.* Thus, a physician's or pharmacist's registration to dispense controlled substances under 21 U.S.C. section 823 does not apply to or authorize dispensing marijuana since it is a schedule I controlled substance.

⁴² The subcommittee heard testimony from a doctor specializing in hospice care who described actions intended to cause death and contrasted them with the way in which controlled substances were used to attempt to ease the pain of an AIDS patient where death was unintended. Causing a patient's death requires a sudden massive overdose of potentially dangerous drugs. Pain control involves carefully adjusting dosage until it achieves relief of pain with a minimum of side-effects. This gradual adjustment of dosage is exactly what must be avoided if one's intent is to kill—because patients quickly build up a resistance to side-effects such as the suppression of breathing. See *Pain Relief Promotion Act of 1999: Hearing on H.R. 2260 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 106th Cong. 2 (June 24, 1999) (statement of Walter R. Hunter, M.D., VistaCare Hospice) <<<http://www.house.gov/judiciary/hunt0624.htm>>> [hereinafter cited as Hunter Testimony].

According to Dr. Walter Hunter:

On a Monday morning the hospice for whom I worked received a phone call from his family that he was having difficulty breathing. His nurse and I made a house call. When we entered the room we could hear his laborious and moist respirations across the room. His respiratory rate was 44 and he was unconscious. We immediately set to

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tening of death enjoys broad support in codes of medical ethics as well as in the Assisted Suicide Funding Restriction Act of 1997.⁴³ Many States have passed laws banning assisted suicide, including provisions specifically emphasizing the distinction between assisted suicide and unintentional hastening of death in the course of pain control. In upholding New York's law against assisted suicide, the U.S. Supreme Court noted:

[w]hen a doctor provides aggressive palliative care . . . painkilling drugs may hasten a patient's death, but the physician's purpose and intent is, or may be, only to ease his patient's pain. A doctor who assists a suicide, however, "must, necessarily and indubitably, intend primarily that the patient be made dead." [Assisted Suicide in the United States, Hearing before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong., 2d Sess., 367 (1996) (testimony of Dr. Leon R. Kass)].⁴⁴

Title I, Section 303(i)(2) of the CSA as amended by H.R. 2260 would ensure the uniform application of the CSA in every jurisdiction: "Notwithstanding any other provision of this Act, in determining whether a registration is consistent with the public interest under this Act, the Attorney General shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia." If H.R. 2260 were to be enacted, using controlled substances to cause death will be regarded as inconsistent with public health and safety in all 50 States, as it had been prior to the Attorney General's 1998 ruling.⁴⁵

Enforcement of Title I Provisions

H.R. 2260 distinguishes between the use of controlled substances with the intent to manage pain and the use of controlled substances with the intent to cause death. This distinction does not

work. I gave him 40 mg of Lasix (furosemide) intravenously. There was no effect. I then gave him 10 mg of morphine intravenously. There was no effect after several minutes. I repeated the dose of 10 mg of morphine and waited several minutes. Again, there was no effect. I gave 5 mg of morphine. There was still no effect. I then gave 5 mg of Valium (diazepam) in an attempt to sedate him and ease the work of breathing. There was no effect. I repeated the Valium dose and there was still no effect. I gave 5 mg of morphine, waited, saw no effect and gave another 10 mg of morphine. After a few minutes, his respirations decreased to about 20. This was a reasonable goal. However, instead of stabilizing at 20, they continued to diminish and he stopped breathing several minutes later.

Id. Dr. Hunter also testified repeatedly that H.R. 2260 would not change the way he practices palliative care. Hunter Testimony

⁴³ 42 U.S.C. § 14402(b)(4). In distinguishing palliative care from euthanasia, the subcommittee heard testimony that:

[t]he medical profession has long recognized that efforts to control pain using powerful drugs may sometimes have side-effects. The physician's intent in these cases, however, is to use the minimum dosage needed to control the pain; any risk of hastening death is not intended, but is foreseen as the unavoidable side-effect of a legitimate medical action.

See *Pain Relief Promotion Act of 1999: Hearing on H.R. 2260 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 106th Cong. 3-4 (June 24, 1999) (statement of Richard M. Doerflinger, National Conference of Catholic Bishops) <<<http://www.house.gov/judiciary/doer0624.htm>>> [hereinafter cited as *Doerflinger Testimony*]. "The important factor here is the agent's intent. . . . The goal of pain control is a patient who is relieved of pain. The goal of assisted suicide is a world that is relieved of one more patient." *Id.* at 4.

⁴⁴ *Vacca v. Quill*, 117 S.Ct. 2293, 2298-9, 2302 (1997).

⁴⁵ Importantly, H.R. 2260 does not preempt Oregon's law legalizing assisted suicide in specified circumstances. Its only legal effect is to forbid the use of those drugs which are federally controlled for this purpose.

U. S. HOUSE OF REPRESENTATIVES

Committee on the Judiciary
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create a new requirement that law enforcement officials question doctors' intent in using controlled substances for pain control. The Federal Assisted Suicide Funding Restriction Act, which governs all Federal health programs and health facilities, uses this same distinction between pain control that may unintentionally hasten death and the intentional use of drugs to assist suicides. In addition, the overwhelming majority of State laws prohibiting assisted suicide use the *scienter* requirement of "intent" to determine whether a physician has violated the criminal law by providing potentially lethal drugs to a patient.⁴⁶ Moreover, since § 823(f)(4) of the CSA regards noncompliance with State law as one factor for consideration in the denial or revocation of a controlled substances registration, the concept of intentional assistance in suicide was routinely contemplated in the enforcement of the CSA prior to H.R. 2260.

It is the committee's view that, while the States are the first line of defense against misuse of prescription drugs, the Federal Government should enforce its own standard as to what constitutes such misuses when a State cannot or will not do so. In Oregon, reports and records required by the assisted suicide law will demonstrate whether federally controlled substances have been intentionally dispensed to assist suicide. Under section 127.865(b) of the Oregon Revised Statutes, "The [Oregon Health] Division shall require any health care provider upon dispensing medication pursuant to ORS 127.800 to 127.897 to file a copy of the dispensing

⁴⁶ *E.g.*, Louisiana (La. Rev. Stat. Ann. § 32.12 (West 1998)) in 1995; Rhode Island (R.I. Gen. Laws. § 11-60-3 (1998)) and Iowa (Iowa Code Ann. § 707A.2 (West 1998)) in 1996; Virginia (Va. Code Ann. § 8.01-622.1 (Michie 1999)) in 1998, and Maryland (1999 Md. Laws 700) in 1999.

Various State laws use the following phrases: "intentionally causes or aids another person to commit suicide" N.Y. Penal Law § 125.15 (McKinney 1999); Conn. Gen. Stat. Ann. § 53a-56 (West 1999); and Or. Rev. Stat. § 163.125 (1998); "purposely aids another to commit suicide", N.J. Stat. Ann. § 2C.11-6 (West 1999); "purposely causes or aids another person to commit suicide" Ark. Code Ann. § 5-10-104 (Michie 1997); "intentionally aids or solicits another to commit suicide" 18 Pa. Cons. Stat. Ann. § 2505 (West 1998); "purposely aids or solicits another to commit suicide" N.H. Rev. Stat. Ann. § 630.4 (1998); "intentionally in any manner advises, encourages, abets or assists another in taking his own life" S.D. Codified Laws § 22-16-37 (Michie 1999); "willfully furnishes another person with any deadly weapon or poisonous drug, knowing that such person intends to use such weapon or drug in taking his own life . . . if such person thereafter employs such instrument or drug in taking his own life" Okla. Stat. Ann. tit. 21, § 814 (West 1998); "deliberately aiding another in the taking of his own life" N.M. Stat. Ann. § 30-2-4 (Michie 1999); "intentionally aids another person to commit suicide" Alaska Stat. § 11.41.120 (Michie 1998); Del. Code Ann. tit. 11, § 632 (1998); "deliberately aids, or advises, or encourages another to commit suicide" Cal. Penal Code § 401 (West 1998); "intentionally or knowingly aids, abets, facilitates, solicits, or incites another person to commit suicide," or "provides to, delivers to, procures for, or prescribes for another person any drug or instrument with knowledge that the other person intends to commit suicide with the drug or instrument" N.D. Cent. Code § 12.1-16-04 (1999); "with the purpose of assisting another person to commit or to attempt to commit suicide, knowingly and intentionally either: (1) provides the physical means by which another person commits or attempts to commit suicide, or (2) participates in a physical act by which another person commits or attempts to commit suicide" Ky. Rev. Stat. Ann. § 216.302 (Michie 1998).

Some States have explicit disclaimers about pain control; for example: "This section does not apply to the following: (1) A licensed health care provider who administers, prescribes, or dispenses medications or procedures to relieve a person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, unless such medications or procedures are intended to cause death." Ind. Code Ann. § 35-42-1-2.5 (1999); "health care professional," and "unless the medications or procedures are knowingly and intentionally administered, prescribed, or dispensed to cause death." Ky. Rev. Stat. Ann. § 216.304 (1998); "[assisted suicide prohibitions] do not preclude the use of medications or procedures necessary to relieve a person's pain or discomfort if the use of the medications or procedures is not intentionally or knowingly prescribed or administered to cause the death of that person." N.D. Cent. Code § 12.1-16-06 (1999).

Even Oregon's criminal law continues to punish actions in which a person intentionally causes or aids another person in committing suicide except for a certain class of terminally ill people Or. Stat. § 163.125 (1999).

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record with the division." Thus, in order to escape criminal liability that would otherwise exist under Oregon law for assisting a suicide, a physician must file a form listing the precise drugs used to assist a suicide with State authorities. Therefore, the DEA may identify all cases in which federally controlled substances have been used to assist suicide in Oregon in compliance with Oregon law simply by obtaining reports from the Oregon Health Division without ever having to review patient medical records or otherwise investigate doctors.⁴⁷ Doctors in Oregon who prescribe controlled substances for pain relief only will have no reason to fear investigation of their use of controlled substances for pain, and should not, therefore, be deterred in any way from prescribing pain relief.

Promoting Palliative Care Through Education and Training

According to the American Medical Association, "the prohibition on physician-assisted suicide provides health care professionals with a tremendous incentive to improve and expand the availability of palliative care."⁴⁸ This judgment has been confirmed time and time again, as new State and Federal restrictions on assisted suicide have been followed by significant progress in palliative care and increases in the use of controlled substances for pain control.⁴⁹ The American Medical Association has previously testified before this subcommittee, however, that the failure of most States to expressly permit pain management that may unintentionally hasten death has "generated reluctance among physicians to prescribe adequate pain medication."⁵⁰ In short, people may be suffering needlessly because of a lack of understanding about the appropriate use of pain medicine in palliative care. H.R. 2260 will do much to correct this grave and unnecessary problem by encourag-

⁴⁷The DEA has authority to subpoena dispensing records from State authorities. Under 21 U.S.C. § 876 of the CSA, "[i]n any investigation . . . with respect to controlled substances, the Attorney General may . . . require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Attorney General finds relevant or material to the investigation."

⁴⁸Brief of the American Medical Association, *et al.*, as Amicus Curiae in Support of Petitioners at 22, *Vacco v. Quill*, 521 U.S. 793 (1997) (No. 95-1858).

⁴⁹See Doerflinger Testimony (citing advances in palliative care in Veterans Administration hospitals after enactment of the Assisted Suicide Funding Restriction Act as well as increased morphine use after enactment of state bans on assisted suicide). The DEA has released its figures on per capita morphine use for the period of January to June 1999. Drug Enforcement Admin., U.S. Dep't of Justice, Statistics on Individual State Consumption of Morphine (on file with Subcomm. on the Constitution of the House Comm. on the Judiciary). Kansas experienced a significant increase in morphine use following the addition of civil penalties to its existing criminal ban on assisted suicide in 1998; previously ranked 35th among states in morphine use, Kansas is now ranked second with 2287 grams per 100.00 population. *Id.* Louisiana was ranked 41st in morphine use in 1994, the year before enactment of its assisted suicide ban, it is now 9th among states in morphine use. *Id.* Tennessee was ranked 16th in morphine use in 1992, the year before it enacted a ban on assisted suicide, and has risen to 8th place among states. *Id.* Empirical evidence, therefore, supports the AMA's claim that clear laws against assisted suicide promote aggressive pain management. Thus, the two purposes of H.R. 2260—to clarify the federal policy against assisted suicide and in favor of pain management—are mutually supportive.

The DEA figures show Oregon with the highest per capita consumption of morphine, at 2332 grams per 100,000 population. *Id.* Two comments are in order with regard to Oregon. First, the DEA figures do not indicate for what the morphine is used. Some assisted suicides may use large doses of morphine (as did one of the 15 cases reported in the Oregon Health Division report), and it is unknown how many unreported cases of assisted suicide occur now that the state has officially sanctioned assisted suicide. Second, the current per capita consumption (2332) is slightly less than per capita consumption during the first half of 1998 (2385)—the period before the Attorney General "decriminalized" assisted suicide under the CSA.

⁵⁰Hearing on Assisted Suicide in the United States Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong. (April 29, 1996) (statement of Lonnie R. Bristow, M.D., President, American Medical Association).

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ing doctors to use controlled substances to relieve pain and suffering and by educating health care professionals and law enforcement personnel about palliative care. One medical expert who testified before the subcommittee stated that, "pain management without this bill is abysmal in the United States . . . [H.R. 2260] provides a much needed service to the dying while protecting vulnerable persons from the real and dangerous effects of the acceptance and practice of assisted suicide/euthanasia as public policy."⁵¹

In Title I, H.R. 2260 authorizes the Attorney General to carry out educational programs for law enforcement personnel, based on recommendations by the Secretary of Health and Human Services, on the necessary and legitimate use of controlled substances in pain management and palliative care. This provision is designed to encourage law enforcement personnel to defer to medical judgments by health professionals practicing aggressive pain management. In Title II, the bill amends the Public Health Services Act⁵² to authorize programs within the Department of Health and Human Services to develop and advance the scientific understanding of palliative care and for education and training in palliative care. Title II provides for the awarding of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities to develop and implement palliative care education and training programs for health care professionals in palliative care. The decision to award these programs will be made by peer review groups, each of which must include one or more individuals with expertise and experience in palliative care.

HEARINGS

The committee's Subcommittee on the Constitution held a hearing on H.R. 2260 on June 24, 1999. Testimony was received from the following witnesses: Samira Beckwith, President and CEO, Hope Hospice, Past Chairperson for the National Hospice Organization; Ann Jackson, Executive Director and CEO, Oregon Hospice Association; N. Gregory Hamilton, M.D., Physicians for Compassionate Care; David E. Joranson, M.S.S.W., Senior Scientist and Director of The Pain and Policy Studies Group, Comprehensive Cancer Center, The University of Wisconsin Medical Group; Richard Doerflinger, Associate Director for Policy Development, Secretariat for Pro-Life Activities, National Conference of Catholic Bishops; Walter R. Hunter, M.D., Associate National Medical Director, VistaCare Hospice; David Orentlicher, M.D.; J.D., Professor, Indiana University School of Law-Indianapolis Center for Law and Health; and Thomas Marzen, General Counsel, The National Legal Center for the Medically Dependent & Disabled, Inc.

COMMITTEE CONSIDERATION

On July 20, 1999, the Subcommittee on the Constitution met in open session and ordered favorably reported the bill H.R. 2260, without amendment, by voice vote, a quorum being present. On September 14, 1999, the committee met in open session and or-

⁵¹ Hunter Testimony

⁵² 42 U.S.C. § 294 et seq.

dered favorably reported the bill H.R. 2260 without amendment by a recorded vote of 16 to 8, a quorum being present.

VOTE OF THE COMMITTEE

1. An amendment was offered by Mr. Watt to insert language that would authorize the dispensing of a controlled substance for the purpose of causing death or assisting in causing death when in compliance with applicable State, Federal or local laws and to strike language requiring the Attorney General to give no force and effect to State law authorizing or permitting assisted suicide or euthanasia. Mr. Scott requested a division of the question. Section 1 of the amendment was offered by Mr. Watt to insert language establishing exceptions for applicable State, Federal and local laws. The amendment was defeated by a 13-15 rollcall vote.

ROLLCALL NO. 1.

	Ayes	Nays	Present
Mr. Sensenbrenner		X	
Mr. McCollum			
Mr. Gekas		X	
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot		X	
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease		X	
Mr. Cannon			
Mr. Rogan			
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough			
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank	X		
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler			
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan	X		
Mr. Delahunt			
Mr. Wexler	X		
Mr. Rothman	X		
Ms. Baldwin	X		
Mr. Weiner	X		
Mr. Hyde, Chairman		X	
Total	13	15	

2. An amendment was offered by Mr. Watt to strike language to give no force or effect to State law authorizing or permitting assisted suicide or euthanasia. The amendment was defeated by a 12-15 rollcall vote.

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ROLLCALL NO. 2

	Ayes	Nays	Present
Mr. Sensenbrenner		X	
Mr. McCollum			
Mr. Gekas		X	
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot		X	
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease		X	
Mr. Cannon			
Mr. Rogan			
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough			
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank	X		
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler			
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan	X		
Mr. Delahunt			
Mr. Waxler	X		
Mr. Rothman	X		
Ms. Baldwin	X		
Mr. Weiner			
Mr. Hyde, Chairman		X	
Total	12	15	

3. An amendment was offered by Mr. Scott to strike Section 101 of Title I of the bill regarding reinforcing the existing standard for legitimate use of controlled substances. The amendment was defeated by a 12-16 rollcall vote.

ROLLCALL NO. 3

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum		X	
Mr. Gekas		X	
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot		X	
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease		X	

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ROLLCALL NO. 3—Continued

	Ayes	Nays	Present
Mr. Cannon		X	
Mr. Rogan			
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough			
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank	X		
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler			
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan	X		
Mr. Delahunt			
Mr. Wexler	X		
Mr. Rothman	X		
Ms. Baldwin	X		
Mr. Weiner			
Mr. Hyde, Chairman		X	
Total	12	16	

4. An amendment was offered by Mr. Conyers requiring that the government prove beyond a reasonable doubt in a criminal proceeding and by clear and convincing evidence in a civil proceeding that the doctor distributed controlled substances with the intent to cause death. The amendment was defeated by a 9-15 rollcall vote.

ROLLCALL NO. 4

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum			
Mr. Gekas		X	
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte			
Mr. Chabot		X	
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease		X	
Mr. Cannon			
Mr. Rogan		X	
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough		X	
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank	X		
Mr. Berman			
Mr. Boucher			
Mr. Nadler			

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ROLLCALL NO. 4—Continued

	Ayes	Nays	Present
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters			
Mr. Meehan			
Mr. Delahunt			
Mr. Wexler	X		
Mr. Rothman	X		
Ms. Baldwin	X		
Mr. Weiner			
Mr. Hyde, Chairman		X	
Total	9	15	

5. An amendment was offered by Mr. Conyers allowing a doctor to assert an affirmative defense that he did not intend to cause death with controlled substances when his intent to cause death had already been proven by the government. The amendment was defeated by a 10-16 rollcall vote.

ROLLCALL NO. 5

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum			
Mr. Gekas			
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot		X	
Mr. Barr		X	
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease			
Mr. Cannon		X	
Mr. Rogan		X	
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough		X	
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank			
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler	X		
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan			
Mr. Delahunt			
Mr. Wexler			
Mr. Rothman			
Ms. Baldwin	X		
Mr. Weiner	X		
Mr. Hyde, Chairman		X	

ROLLCALL NO. 5—Continued

	Ayes	Nays	Present
Total	10	16	

6. An amendment was offered by Ms. Jackson Lee to exempt pre-existing State law from the provisions of the bill. The amendment was defeated by a 9-14 rollcall vote.

ROLLCALL NO. 6

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum			
Mr. Gekas			
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot			
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease			
Mr. Cannon		X	
Mr. Rogan		X	
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough		X	
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank			
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler			
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan			
Mr. Delahunt			
Mr. Wexler			
Mr. Rothman			
Ms. Baldwin	X		
Mr. Weiner	X		
Mr. Hyde, Chairman		X	
Total	9	14	

7. An amendment was offered by Mr. Berman providing that violation of title I shall not result in criminal liability. On unanimous consent Mr. Berman modified his amendment to read at the end of page 2, line 24, add the following: Nothing in this section shall constitute any criminal liability other than that already existing. The amendment was defeated by a 9-16 rollcall vote.

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ROLLCALL NO. 7

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum			
Mr. Gekas		X	
Mr. Coble		X	
Mr. Smith (TX)		X	
Mr. Gallegly		X	
Mr. Canady		X	
Mr. Goodlatte		X	
Mr. Chabot		X	
Mr. Barr			
Mr. Jenkins		X	
Mr. Hutchinson		X	
Mr. Pease			
Mr. Cannon		X	
Mr. Rogan		X	
Mr. Graham		X	
Ms. Bono		X	
Mr. Bachus			
Mr. Scarborough		X	
Mr. Vitter		X	
Mr. Conyers	X		
Mr. Frank	X		
Mr. Berman	X		
Mr. Boucher			
Mr. Nadler			
Mr. Scott	X		
Mr. Watt	X		
Ms. Lofgren	X		
Ms. Jackson Lee	X		
Ms. Waters	X		
Mr. Meehan			
Mr. Delahunt			
Mr. Waxler			
Mr. Rothman			
Ms. Baldwin	X		
Mr. Weiner			
Mr. Hyde, Chairman		X	
Total	9	16	

8. Final Passage. The motion to report the bill, H.R. 2260, favorably without amendment to the whole House. The motion was agreed to by a rollcall vote of 16-8.

ROLLCALL NO 8

	Ayes	Nays	Present
Mr. Sensenbrenner			
Mr. McCollum			
Mr. Gekas	X		
Mr. Coble	X		
Mr. Smith (TX)	X		
Mr. Gallegly	X		
Mr. Canady	X		
Mr. Goodlatte	X		
Mr. Chabot	X		
Mr. Barr			
Mr. Jenkins	X		
Mr. Hutchinson	X		
Mr. Pease			
Mr. Cannon	X		
Mr. Rogan	X		

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ROLLCALL NO. 8—Continued

	Ayes	Nays	Present
Mr. Graham	X		
Ms. Bono	X		
Mr. Bachus			
Mr. Scarborough	X		
Mr. Vitter	X		
Mr. Conyers		X	
Mr. Frank		X	
Mr. Berman			
Mr. Boucher			
Mr. Nadler			
Mr. Scott		X	
Mr. Watt		X	
Ms. Lofgren		X	
Ms. Jackson Lee		X	
Ms. Waters		X	
Mr. Meehan			
Mr. Delahunt			
Mr. Wexler			
Mr. Rothman			
Ms. Baldwin		X	
Mr. Weiner			
Mr. Hyde, Chairman	X		
Total	15	8	

COMMITTEE OVERSIGHT FINDINGS

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the committee reports that the findings and recommendations of the committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

COMMITTEE ON GOVERNMENT REFORM FINDINGS

No findings or recommendations of the Committee on Government Reform were received as referred to in clause 3(c)(4) of rule XIII of the Rules of the House of Representatives.

NEW BUDGET AUTHORITY AND TAX EXPENDITURES

Clause 3(c)(2) of House Rule XIII is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the committee sets forth, with respect to the bill, H.R. 2260, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

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U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 24, 1999.

Hon. HENRY J. HYDE, *Chairman,*
Committee on the Judiciary,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2260, the Pain Relief Promotion Act of 1999.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Mark Grabowicz (for effects on spending by the Department of Justice), who can be reached at 226-2860; Cyndi Dudzinski (for costs to the Health Resources and Services Administration), who can be reached at 226-9010; Jeanne De Sa (for costs to the Agency for Health Care Policy and Research), who can be reached at 226-9010; Lisa Cash Driskill (for the state and local impact), who can be reached at 225-3220; and John Harris (for the private-sector impact), who can be reached at 226-2618.

Sincerely,

DAN L. CRIPPEN, *Director.*

H.R. 2260—Pain Relief Promotion Act of 1999.

SUMMARY

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

Assuming appropriation of the necessary amounts, CBO estimates that implementing H.R. 2260 would result in additional discretionary spending of about \$24 million over the 2000-2004 period. Enacting this legislation could affect direct spending and receipts, so pay-as-you-go procedures would apply; however, CBO estimates that the amounts involved would be less than \$500,000 a year.

H.R. 2260 contains both an intergovernmental and a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the bill would result in no costs to state, local, or tribal governments, so the threshold established in UMRA (\$50 million in 1996, adjusted annually for inflation) would not be exceeded. CBO also estimates that the costs of the private-sector mandate would fall below the threshold established in UMRA (\$100 million in 1996, adjusted for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

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

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By fiscal year, in millions of dollars

	2000	2001	2002	2003	2004
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Estimated Authorization Level	7	7	7	2	2
Estimated Outlays	3	6	7	5	3

BASIS OF ESTIMATE

For the purposes of this estimate, CBO assumes that the bill will be enacted by or near the beginning of fiscal year 2000, that the necessary amounts will be provided for each year, and that outlays will follow historical spending rates for these activities.

Spending Subject to Appropriation

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

The existing HRSA grant program received an appropriation of \$21 million for fiscal year 1999. This program is part of a larger HRSA activity which has a current authorization of such sums as necessary through fiscal year 2002. H.R. 2260 would increase the existing target level of \$23 million a year (within that "such sums" authorization) by \$5 million. The agency would use the additional funds to award grants to public and private entities to develop, implement, and evaluate education and training programs in palliative care.

H.R. 2260 would direct AHCPR to develop a research program to improve palliative care, mainly through the collection and dissemination of guidelines for providing such care. CBO estimates that implementing this provision would cost about \$1 million in fiscal year 2000 and \$2 million annually thereafter, assuming the appropriation of the necessary amounts. (The agency received an appropriation of \$100 million for 1999.)

Direct Spending and Revenues

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

Violators of the bill's provisions also could be subject to criminal fines, so the federal government might collect additional fines if the bill is enacted. Collections of such fines are recorded in the budget as governmental receipts (revenues), which are deposited in the

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Crime Victims Fund and spent in subsequent years. CBO expects that any additional receipts and direct spending would be negligible.

PAY-AS-YOU-GO CONSIDERATIONS

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

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 2260 contains an intergovernmental mandate as defined in UMRA, but CBO estimates that complying with the mandate would impose no costs on state, local, or tribal governments, and thus would not exceed the threshold established in that act (\$50 million in 1996, adjusted annually for inflation).

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

ESTIMATED IMPACT ON THE PRIVATE SECTOR

H.R. 2260 would create a new private-sector mandate for physicians registered to prescribe or administer federally controlled substances by prohibiting the use of such substances in physician-assisted suicides. The bill would require the Drug Enforcement Administration to treat the use of controlled substances for physician-assisted suicide as a violation of the Controlled Substances Act in all states, including those where the practice is permitted by law. Doctors who violate the prohibition would lose their registration, would have to give up their stocks of controlled substances, and could face criminal prosecution. Currently, Oregon is the only state that allows physician-assisted suicide. The number of doctors affected and the costs associated with the mandate would be small.

ESTIMATE PREPARED BY:

Federal Costs: DOJ—Mark Grabowicz (226-2860); HRSA—Cyndi Dudzinski (226-9010); AHCPR—Jeanne De Sa (226-9010)
Impact on State, Local, and Tribal Governments: Lisa Cash Driskill (225-3220)

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Impact on the Private Sector: John Harris (226-2618)

ESTIMATE APPROVED BY:

Peter H. Fontaine
Deputy Assistant Director for Budget Analysis

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the committee finds the authority for this legislation in Article 1, section 8, clauses 1, 3 and 18 of the Constitution.

SECTION-BY-SECTION ANALYSIS AND DISCUSSION

Section 101: Reinforcing Existing Standard for Legitimate Use of Controlled Substances:

This section amends the Controlled Substances Act to clarify that doctors and other licensed health care professionals are authorized to dispense, distribute, or administer controlled substances for the legitimate medical purpose of alleviating a patient's pain or discomfort even if the use of these drugs may increase the risk of death. This section also reinforces the current law that the administration, dispensing, or distribution of a controlled substance for the purpose of assisting a suicide is not authorized by the Controlled Substances Act.

This section provides that the Attorney General in implementing the Controlled Substances Act shall not give force or effect to any State law permitting assisted suicide or euthanasia.

This section provides that the provisions of the bill are effective upon enactment with no retroactive effect.

Section 102: Education and Training Programs

This section authorizes the Attorney General to incorporate the recommendations of the Secretary of Health and Human Services to carry out educational and research training programs for law enforcement personnel on the necessary and legitimate use of controlled substances in pain management and palliative care.

TITLE II

Section 201. Activities of Agency for Health Care Policy and Research

This section amends the Public Health Services Act by authorizing a program responsibility for the Agency for Health Care Policy and Research in the Department of Health and Human Services to develop and advance the scientific understanding of palliative care. The Agency is directed to collect and disseminate protocols and evidence-based practices for palliative care with priority for terminally ill patients. This section has a definition of palliative care which is based on the World Health Organization's definition.

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Section 202. Activities of Health Resources and Services Administration

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

This section requires the applicant for the award to include three educational and informational components in the program 1) the program must have a component that addresses a means for alleviating pain and discomfort, especially in terminally ill patients, including the use of controlled substances; 2) the program must provide information and education on the applicable law on controlled substances, and 3) the information and education must provide recent findings and developments in the improvement of palliative care. Health professional schools, residency training programs, continuing education, graduate programs in the health professions, hospices, and other sites as determined by the Secretary will be used as program sites.

This section requires the Secretary to evaluate the grant, cooperative agreement or contracted programs.

This section mandates that the Secretary shall include one or more individuals with expertise and experience in palliative care in each peer review group involved in the selection of the palliative care awards.

This section defines palliative care.

This section authorizes an additional \$5,000,000 annually for the palliative care award program and authorizes the grant cycle to begin with the fiscal year 2000.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT**TITLE II—CONTROL AND ENFORCEMENT**

* * * * *

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

* * * * *

U. S. HOUSE OF REPRESENTATIVES

Committee on the Judiciary
Democratic Staff Office
B-351-C Rayburn House Office Building
Washington, D.C. 20515

FACSIMILE COVER LETTER

TO:

Chris Jennings

FAX NO:

PAGES: 39 ^{in 3 batches} (including this page)

FROM:

 PERRY APELBAUM ANTHONY FOXX STEPHANIE PETERS TED KALO X CAROLYN DONNELLY KEENAN KELLER SAMPAK GARG CORI FLAM

COMMENTS:

~~Batch 1 - 12 pages~~
~~Batch 2 - 16 pages~~
Batch 3 -

If parts of this transmission are unclear or transmission
was faulted, please call: (202) 225-6906.

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REGISTRATION REQUIREMENTS

SEC. 303. (a) * * *

* * * * *

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

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

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

* * * * *

PART E—ADMINISTRATIVE AND ENFORCEMENT PROVISIONS

* * * * *

EDUCATION AND RESEARCH PROGRAMS OF THE ATTORNEY GENERAL

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

(1) * * *

* * * * *

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

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

(7) *educational and training programs for local, State, and Federal personnel, incorporating recommendations by the Secretary of Health and Human Services, on the necessary and legitimate use of controlled substances in pain management and palliative care, and means by which investigation and enforcement actions by law enforcement personnel may accommodate such use.*

* * * * *

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PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE VII—HEALTH PROFESSIONS
EDUCATION

* * * * *

PART D—INTERDISCIPLINARY, COMMUNITY-
BASED LINKAGES

* * * * *

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

(a) *IN GENERAL.*—The Secretary, in consultation with the Administrator for Health Care Policy and Research, may make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in palliative care.

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

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

(1) means for alleviating pain and discomfort of patients, especially terminally ill patients, including the medically appropriate use of controlled substances;

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

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

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

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

(f) *PEER REVIEW GROUPS.*—In carrying out section 799(f) with respect to this section, the Secretary shall ensure that the membership of each peer review group involved includes one or more individuals with expertise and experience in palliative care.

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(g) *DEFINITION.*—For purposes of this section, the term “palliative care” means the active total care of patients whose prognosis is limited due to progressive, far-advanced disease. The purpose of such care is to alleviate pain and other distressing symptoms and to enhance the quality of life, not to hasten or postpone death.

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

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

* * * * *

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

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

* * * * *

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

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

* * * * *

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

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

(b) *ALLOCATION.*—

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

(A) * * *

* * * * *

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

* * * * *

TITLE IX—AGENCY FOR HEALTH CARE POLICY AND RESEARCH

PART A—ESTABLISHMENT AND GENERAL DUTIES

* * * * *

SEC. 906. PROGRAM FOR PALLIATIVE CARE RESEARCH AND QUALITY.

(a) *IN GENERAL.*—The Administrator shall carry out a program to accomplish the following:

(1) *Develop and advance scientific understanding of palliative care.*

(2) *Collect and disseminate protocols and evidence-based practices regarding palliative care, with priority given to pain*

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management for terminally ill patients, and make such information available to public and private health care programs and providers, health professions schools, and hospices, and to the general public.

(b) DEFINITION.—For purposes of this section, the term “palliative care” means the active total care of patients whose prognosis is limited due to progressive, far-advanced disease. The purpose of such care is to alleviate pain and other distressing symptoms and to enhance the quality of life, not to hasten or postpone death.

* * * * *

DISSENTING VIEWS

We strongly oppose H.R. 2260, the "Pain Relief Promotion Act of 1999." This legislation represents an unnecessary intrusion into the sensitive relationship between terminally-ill patients and their physicians and would empower Federal law enforcement agents to second-guess the considered medical judgment of physicians, pharmacists, and patients. Moreover, by threatening medical professionals with long prison sentences and strict liability, this bill would inhibit physicians from aggressively treating pain, limit patient access to palliative care, and make death more painful.

The bill amends the Controlled Substances Act¹ ("CSA"), which sets forth a system of enforcement and penalties for the manufacture and distribution of controlled substances.² The bill has the effect of prohibiting physicians and pharmacists from prescribing controlled substances that cause death and subjects them to criminal penalties (i.e., imprisonment and fines) and civil penalties (i.e., revocation of their license to distribute controlled substances) under the Controlled Substances Act.³ The bill also requires the Attorney General to ignore any State law that permits assisted suicide.⁴

The provision of the bill requiring the Attorney General to ignore State laws permitting assisted suicide would overturn directly the State of Oregon's Death with Dignity Act, which permits physician-assisted suicide under controlled circumstances.⁵ In doing so, however, the bill ignores the safeguards in the Oregon law and violates basic principles of federalism.⁶ Moreover, H.R. 2260 runs counter to unanimous Supreme Court decisions authorizing and encourag-

¹ 21 U.S.C. §§ 801-852.

² *Id.* Among other things, the Controlled Substances Act ("CSA") first lists the compounds that are regulated as controlled substances, meaning that persons must have permission from the Attorney General to manufacture and distribute them. Physicians and pharmacists seeking to prescribe controlled substances to alleviate pain must apply to the Drug Enforcement Administration ("DEA") for a license to administer them for "legitimate medical purposes."

³ See *id.* §§ 824, 841.

⁴ H.R. 2260 § 101. Other portions of the bill permit the Attorney General to hold educational and training programs for law enforcement personnel on the appropriate use of controlled substances for palliative care. *Id.* § 102. Title 11 of the bill amends the Public Health Service Act to develop palliative care research programs. *Id.* §§ 201-02.

⁵ Oregon's law permits a competent adult, who is a resident of Oregon and has been determined by two physicians to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die, to make a written request for medication for the purpose of ending his or her life. Numerous procedural safeguards have been built into the Oregon law to ensure that patients cannot end their lives clandestinely with the help of their doctors. For example, two doctors must diagnose the patient as having a terminal disease and as being of sound mind. The patient's request must be in writing and be witnessed by two disinterested people. In addition, only terminally-ill patients are eligible, so people suffering from depression which causes impaired judgment or other mental and physical illnesses will not be able to end their lives with a physician's assistance. Furthermore, Oregon's law creates severe penalties for abuses under the Act.

⁶ *Id.* § 101 ("Notwithstanding any other provision of this Act, in determining whether a registration is consistent with the public interest under this Act, the Attorney General shall give no force and effect to State law authorizing or permitting assisted suicide or euthanasia.")

ing the States to engage in meaningful debate and experimentation on the issue of physician-assisted suicide.⁷

It is for these reasons that several groups concerned about pain relief and the quality of medical care either formally oppose or have significant concerns with title I of H.R. 2260. Among them are the Oregon Medical Association;⁸ American Alliance of Cancer Pain Initiatives; the American Pain Foundation; the American Pharmaceutical Association; the American Society of Health-System Pharmacists; the American Society of Pain Management Nurses;⁹ the American Academy of Family Physicians;¹⁰ the Oregon Hospice Association;¹¹ the San Francisco Medical Society;¹² the Rhode Island Medical Society;¹³ and the Hospice Federation of Massachusetts.¹⁴ Moreover, the U.S. Department of Justice opposed predecessor legislation in the last Congress.¹⁵

I. H.R. 2260 VIOLATES BASIC PRINCIPLES OF FEDERALISM

Our opposition to this bill is not tantamount to support for physician-assisted suicide; instead, title I of this bill raises serious federalism concerns because it inserts the Federal Government into what traditionally has been a local medical oversight process, the regulation of medical practices. The federalism issue arises because a significant motive of H.R. 2260's sponsors is to nullify an Oregon referendum that permits physician-assisted suicide.¹⁶

One of the fundamental tenets of federalism is that the States are free to act as independent laboratories of democracy. In this case, after considerable debate, the people of the State of Oregon decided that terminally-ill people should have the ability to control the time and manner of their death, and the nation can now look

⁷ *Vacco v. Quill*, 521 U.S. 793 (1997), *Washington v. Glucksberg*, 521 U.S. 702 (1997).

⁸ Letter from Richard G. Kincade, President, Oregon Medical Ass'n, to the Honorable Ron Wyden (D-OR), U.S. Senator (July 19, 1999) [hereinafter OMA Letter].

⁹ Letter from the American Alliance of Cancer Pain Initiatives, the American Pain Foundation, the American Pharmaceutical Ass'n, the American Soc'y of Health-System Pharmacists, and the American Soc'y of Pain Management Nurses to the Honorable Henry J. Hyde, Chair, House Comm. on the Judiciary (July 19, 1999).

¹⁰ Letter from Neil H. Brooks, MD, Chair, Amer. Academy of Family Physicians, to the Honorable Henry J. Hyde, Chair, House Comm. on the Judiciary (Aug. 12, 1999) [hereinafter AAFP Letter].

¹¹ *Hearing on H.R. 2260, the "Pain Relief Promotion Act of 1999," Before the Subcomm. on the Const. of the House Comm. on the Judiciary*, 106th Cong., 1st Sess. (June 24, 1999) (written statement of Ann Jackson, Executive Director, Oregon Hospice Ass'n) [hereinafter *June 24, 1999 Subcomm. Hearing*].

¹² Letter from William H. Goodson, III, MD, President, San Francisco Medical Soc'y, to the Honorable Nancy Pelosi (D-CA), U.S. Representative (Aug. 20, 1999).

¹³ Letter from Steve DeToy, Rhode Island Medical Society, to Member of Congress (Aug. 3, 1999).

¹⁴ Letter from D. Rigney Cunningham, Exec. Dir., Hospice Found. of Mass., to the Honorable Ron Wyden (D-OR), U.S. Senator (Aug. 3, 1999).

¹⁵ Letter from L. Anthony Sutin, Acting Asst. Attorney General, Office of Legislative Aff., U.S. Dept. of Justice, to the Honorable Henry J. Hyde (R-IL), Chair, House Comm. on the Judiciary 1 (Aug. 3, 1998) (letter concerning H.R. 4006, 105th Cong., 2d Sess. (1998)).

¹⁶ *Judiciary Committee to Markup "Pain Relief Promotion Act of 1999" Tuesday*, Press Release of the Honorable Henry J. Hyde, Chair, House Comm. on the Judiciary (Sept. 8, 1999). Most surprising is the majority's wavering stance on the importance of State referenda. The majority appears to believe that State referenda are worthwhile when they do things such as eliminate affirmative action in California and has even introduced legislation to promote the use of referenda, such as H.R. 1252, the "Judiciary Reform Act of 1998." Chairman Hyde said that H.R. 1252 "recognizes that State referenda reflect, more than any other process, the one-person/one-vote system, and seeks to protect a fundamental part of our national foundation." 144 Cong. Rec. H2246 (daily ed. April 23, 1998) (statement of Rep. Hyde). The current legislation seems to constitute a complete about-face from that position.

to Oregon to see how well such a law functions.¹⁷ The Death with Dignity Act has overwhelming support among Oregonians: 65% of Oregon voters and 66% of Oregon physicians are in favor of it.¹⁸

Ruling in 1997 on the constitutionality of a State of Washington statute that prohibited physician-assisted suicide, the U.S. Supreme Court observed that "[t]hroughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society."¹⁹ While some of the States engaged in the debate have decided to prohibit physician-assisted suicide,²⁰ Oregon has not. In a blow to federalism, H.R. 2260 would nullify the democratic will of the people of Oregon as expressed through two ballot referenda. This debate should continue in the States, where it belongs. Dr. David Orentlicher, of the Indiana University Center on Law and Health, stated in his testimony before the Constitution Subcommittee:

Congress and the courts have long recognized the importance of the laboratory of State experimentation on complicated matters of social policy. Because the optimal approach is often not clear, our Federal system encourages States to try different approaches. With local variations, the country can discover the best course of action. . . . In a bold departure from the Supreme Court's guidance, this Act would bring an abrupt end of State experimentation and the accompanying efforts to protect dignity and independence at the end of life.²¹

A side effect of this contravention of federalism is the politicization of medical standards, which currently are decided on a State-by-State basis. In effect, the Federal Government, through the Justice Department and the Drug Enforcement Administration, would come closer to establishing itself as a "national medical board." As the Oregon Medical Association stated:

If the Department of Justice is authorized to rule whether prescription of pain medications is a "legitimate medical purpose" we can only conclude that it must adopt Federal regulations to determine the standard of medical care, which may directly conflict with State responsibility for standards of practice for end of life care.²²

¹⁷ Physicians with the Oregon Health Department have stated that, by 1998, after the law's first full year in effect, only 23 people had requested lethal prescriptions and only 15 of them had used them. Alissa J. Rubin, *Oregon Assisted-Suicide Law at Risk*, L.A. TIMES, Sept. 14, 1999.

¹⁸ See Oregon Death With Dignity Legal Defense and Education Center, *The Oregon Death With Dignity Act and The Drug Enforcement Administration*.

¹⁹ *Washington*, 521 U.S. at 735.

²⁰ See *Vacco*, 521 U.S. at 805-06 (listing State laws that prohibit physician-assisted suicide).

²¹ *June 24, 1999 Subcomm. Hearing* (written statement of David Orentlicher, MD, Director, Center of Law and Health, Indiana Univ. School of Law, at 5).

²² OMA Letter. Concerns about a "national medical board" are not limited to Oregon—physicians all across the country "remain[] concerned that a law enforcement agency determination of when pain management practices crosses over into assisted suicide would require the Federal Government to begin to define what is appropriate medical practice." AAFP Letter.

II. H.R. 2260 INCLUDES CRIMINAL PENALTIES THAT WOULD DISCOURAGE PHYSICIANS AND PHARMACISTS FROM AGGRESSIVELY TREATING PAIN

We are also concerned that the bill would discourage physicians and pharmacists from aggressively treating pain by subjecting them to criminal penalties.²³ Although the bill does not explicitly reference any criminal provisions, it amends the CSA in a manner that clearly will result in the application of criminal law provisions to physicians and pharmacists for dispensing controlled substances that cause death.

This is because the CSA—the regime that H.R. 2260 amends—operates as a criminal law, and nothing in the bill alters that operation. Current law, in the form of § 841 of the CSA, states, “[e]xcept as authorized by this subchapter, *it shall be unlawful* for any person knowingly or intentionally—(1) to manufacture, distribute, or dispense . . . a controlled substance.”²⁴ The penalties for violation of § 841 include up to life in prison as well as a \$1 million fine.²⁵

H.R. 2260 amends the CSA to prohibit the dispensing of drugs that result in death by amending § 823 of the CSA to state “[n]othing in this section authorizes intentionally dispensing, distributing, or administering a controlled substance for the purpose of causing death or assisting another person in causing death.”²⁶ Because no provision in H.R. 2260 provides any authority negating the criminal law provisions provided in current law under § 841 of the CSA, it is clear that the same criminal law penalties will apply to persons who dispense drugs which result in death.²⁷

Although the majority disputes this point, attorneys and physicians agree that H.R. 2260 would subject professionals to criminal penalties.²⁸ For instance, the respected law firm of Heller Ehrman White & McAuliffe noted in a legal opinion that “it is glaringly apparent and deeply troubling [that the bill] will subject physicians to *criminal prosecution* with respect to the medically and ethically difficult decision-making process that they must engage in when providing care during the often painful end of life period.”²⁹ Furthermore, Dr. David Orentlicher, of the Center of Law and Health at Indiana University’s School of Law, testified that H.R. 2260 is worse than last Congress’s bill because, “with this Act, physicians are at risk not merely for revocation of their license to prescribe

²³ See 21 U.S.C. § 841. While the majority contends that title I of the bill will enable physicians to treat patients experiencing great pain, we believe that this bill will still have a chilling effect on such practices because physicians could be accused of causing death even when they intended only to reduce pain. See discussion *infra* part II.

²⁴ 21 U.S.C. § 841(a)(1).

²⁵ *Id.* § 841.

²⁶ H.R. 2260 § 101.

²⁷ The Supreme Court has held affirmatively that the Government can use § 841 to criminally prosecute physicians registered under the CSA for misuse of controlled substances. *United States v. Moore*, 423 U.S. 122, 124 (1975).

²⁸ In opposing the bill, the *New York Times* has observed that under H.R. 2260, “doctors would still have reason to worry that they could be investigated and charged with intent to cause death even when no such intent existed.” *Flawed Pain Relief Bill*, N.Y. TIMES, Aug. 14, 1999, at A12 (op-ed). “Critics [of the bill] are particularly concerned about the bill’s provision of criminal penalties for physicians found to have intentionally dispensed a narcotic to assist in a suicide. Law enforcement officers, they say, could easily misinterpret large doses of morphine meant to relieve the pain of pervasive cancer.” Alissa J. Rubin, *Oregon Assisted-Suicide Law at Risk*, L.A. TIMES, Sept. 14, 1999.

²⁹ Letter from Nicholas W. van Aelstyn, Heller Ehrman White & McAuliffe, to the Honorable Ron Wyden (D-OR), U.S. Senator (July 21, 1999) (emphasis added).

controlled substances—as called for in last year's Lethal Drug Abuse Prevention Act—they are also subject to jail time."³⁰

Criminal penalties will discourage physicians and pharmacists from aggressively treating pain because they will fear prosecution.³¹ Richard G. Kincade, the President of the Oregon Medical Association, stated that "[the bill] is an unprecedented expansion of Government power and is subject to significant and varying interpretations, which will place physicians in the position of defending their practice in pain management if a patient dies."³² This is particularly harmful because physicians already under-medicate patients for fear of being sanctioned under the *current* law.³³ In its June 24, 1999 testimony before the Constitution Subcommittee, the Oregon Hospice Association pointed out that "the climate that already exists in end-of-life care encourages levels of caution which too frequently result in increased pain and suffering for sick and dying people. This proposed bill would only worsen those conditions."³⁴ The San Francisco Medical Society also noted:

In an era when a concerted and long-overdue effort is being made to lessen physicians' fears of prescribing appropriate amounts of medications for pain, we do not need to send a frightening and mixed message of increased investigation, criminalization, and politicization of what should be a private matter between patients and their physicians.³⁵

Of course, if the majority really wanted to make it clear that H.R. 2260 would not lead to criminal liability, they would have specified as such in the text of the bill. They failed to do so. Moreover, when Rep. Berman (D-CA) offered an amendment at the full Committee markup to specifically provide that the bill's provisions would impose no criminal penalties,³⁶ the proposal was rejected on a party-line vote.

³⁰ June 24, 1999 Subcomm. Hearing (written statement of David Orentlicher, MD, Director, Center of Law and Health, Indiana Univ. School of Law, at 2).

³¹ We are also concerned that the bill will dissuade physicians from sharing information with pharmacists about the patient's therapy. Pharmacists will not know the reason the drug is being prescribed and will not be subject to liability. H.R. 2260 will thus lessen the communication among health care providers at the very instant when the pharmacist could provide valuable insight on advancements in areas such as pain management therapy.

³² OMA Letter.

³³ "Even without a Federal criminal statute, studies of therapy for cancer-related pain found that more than half of patients were under-medicated. In a 1986 study of nearly 900 physicians, 86% said most cancer patients were under-treated. Many physicians acknowledged that they feared raising the suspicions of local medical boards or running afoul of State laws." Alissa J. Rubin, *Oregon Assisted-Suicide Law at Risk*, L.A. TIMES, Sept. 14, 1999.

³⁴ June 24, 1999 Subcomm. Hearing (written statement of Ann Jackson, Executive Director, Oregon Hospice Ass'n, at 2).

³⁵ Letter from William H. Goodson, III, MD, President, San Francisco Medical Soc'y, to the Honorable Nancy Pelosi (D-CA), U.S. Representative (Aug. 20, 1999). See also June 24, 1999 Subcomm. Hearing (written statement of David E. Joranson, Pain & Policy Studies Group, Univ. of Wisconsin Comprehensive Cancer Center, at 6-7); *id.* (written statement of David Orentlicher, MD, Director, Center Law and Health, Indiana Univ. School of Law, at 3) ("As several major studies indicate, the reality is that legal concerns already make physicians overly cautious about prescribing the medications necessary to relieve the pain of their patients. Given the seriously disruptive and traumatic nature of criminal prosecutions, this Act will make physicians err even more on the side of caution.").

³⁶ The amendment stated in relevant part: "Sec. 103 CRIMINAL LIABILITY.—No violation of the provisions of this title shall result in criminal liability."

III. H.R. 2260 APPEARS TO SUBJECT PHYSICIANS AND PHARMACISTS TO STRICT LIABILITY FOR EFFECTIVELY TREATING PAIN

We also object to the strict liability provisions that appear to be created by the bill, which threaten to penalize physicians and pharmacists whose patients died from an intentional dispensation of controlled substances *even if* the death was *not* intended.

The bill would subject physicians to this type of strict liability because of the purpose and operation of the CSA. Under current law, if a person or entity distributes illegal controlled substances, they are subject to automatic sanctions. There is no need for the law to countenance unintentional distributions of illegal drugs such as heroin because professionals should have the knowledge and discretion to avoid any such distribution.

Thus, for good reason the CSA is currently written as a strict liability law for both criminal and civil purposes and contains no intent requirement. For example, with regard to criminal liability, § 841 of the CSA States, "[i]n the case of a violation of subsection (a) of this section involving [a specific quantity of a specific controlled substance], such person shall be sentenced to a term of imprisonment which may not be less than [a specific number of years] and if death . . . results from the use of such substances, shall not be less than [term of imprisonment], a fine not to exceed [specific amount], or both."³⁷ And with regard to the civil liability, § 824 of the CSA provides that the Attorney General can revoke the controlled substance license of any physician who "has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section."³⁸

The problem arises in that H.R. 2260 introduces an offense—distribution of controlled substances that leads to death³⁹—that is inherently intent based, yet the bill contains no provision that allows the physician or pharmacist to avoid strict or automatic legal responsibility by establishing that they merely intended to relieve pain, even where death inadvertently results, as is often the case in terminal illness situations.

The bill's proponents argue that its introductory language, which States that controlled substances can be used to relieve pain even if the risk of death is increased,⁴⁰ would protect doctors whose patients *unintentionally* die from controlled substances. The introductory language is, however, *not* written in an operative manner; it merely states that it is the bill's *purpose* that controlled substances be used to relieve pain even if such substances increase the risk of death. There is no assurance that courts or prosecutors would

³⁷ 21 U.S.C. § 841(b).

³⁸ *Id.* § 824(a)(4). In determining what conduct is in the public interest for controlled substances, the Attorney General must consider, among other things, (1) a registrant's compliance with Federal, State, and local laws, and (2) the public health and safety. See *id.* § 823. The statute does not specifically state that using a controlled substance outside of a legitimate medical purpose is inconsistent with the public interest, but courts have upheld Drug Enforcement Administration orders to registrants implying that non-legitimate medical uses of controlled substances would not be within the public interest. See *Harline v. DEA*, 148 F.3d 1199 (10th Cir. 1998).

³⁹ Again, this offense is introduced by virtue of § 101 of H.R. 2260 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."

⁴⁰ H.R. 2260 § 101.

refer to that language in determining whether to prosecute and/or incarcerate physicians or pharmacists who might dispense controlled substances that *unintentionally* led to death.

The weight of legal authority supports the view that the bill may result in strict liability for physicians and pharmacists. The law firm of Heller Ehrman has stated that the legislation would leave physicians exposed to penalties "even if their subjective intent was to provide palliative care."⁴¹ In addition, the Supreme Court has reaffirmed the view that the CSA operates to provide strict liability.⁴²

Although the majority refuses to acknowledge the strict liability implications of the bill, their actions and the bill's legislative history suggest otherwise. Again, if the majority wanted to require that intent be established for a doctor or pharmacist to violate the CSA, they could have done so by stating as much in the text of the bill, but they failed to do so. Moreover, the majority tellingly rejected two amendments offered by Ranking Member Conyers (D-MI) that would have (1) required the Government to prove the *intent of the physician or pharmacist to cause death*,⁴³ and (2) permitted physicians and pharmacists an affirmative defense to establish that they did not intend to cause death through the distribution of a controlled substance.⁴⁴

IV. H.R. 2260 CONTRAVENES THE PURPOSE OF THE CONTROLLED SUBSTANCES ACT AND IMPOSES ADMINISTRATIVE DIFFICULTIES

This bill is misguided also in the manner in which it attempts to ban physician-assisted suicide and in its creation of administrative difficulties. As discussed earlier, the bill amends the CSA in a specific attempt to regulate medical practice and prohibit the use of controlled substances to cause death. The CSA, however, was *not* intended to regulate medical decision making; it clearly states that it is, instead, a law that addresses drug diversion and trafficking.⁴⁵ In opposing predecessor legislation last Congress, the Justice Department recognized this and noted these types of bill "would inevitably divert [DEA] attention away from the core mission of strictly controlling Schedule I drugs and preventing the abuse, diversion of

⁴¹ Letter from Nicholas W. van Aelstyn, Heller Ehrman White & McAuliffe, to the Honorable Ron Wyden (D-OR), U.S. Senator (July 21, 1999).

⁴² *United States v. Johnson*, 71 F.3d 539, 542 (6th Cir. 1995) (holding that, to obtain a conviction under the CSA, the Government must prove that (1) the defendant distributed a controlled substance, (2) the defendant acted intentionally or knowingly, and (3) the defendant acted without a legitimate medical purpose and outside the course of professional practice) (citing *United States v. Varma*, 691 F.2d 460, 462 (10th Cir. 1982)).

⁴³ The amendment stated: "(4) In any proceeding governed by the rule set forth in this subsection, the party asserting conduct that is not consistent with public health and safety or not consistent with the public interest must prove beyond a reasonable doubt (in a criminal case) or by clear and convincing evidence (in a civil proceeding) the intent to dispense, distribute, or administer a controlled substance for the purpose of causing death or assisting another person in causing death."

⁴⁴ The amendment stated: "(4) AFFIRMATIVE DEFENSE.—It shall be an affirmative defense to a civil or criminal proceeding under this title that a person charged with a violation under this subsection was intending to alleviate pain or discomfort in the usual course of professional practice, including dispensing, distributing, or administering a controlled substance, even if the use of such a substance may have increased the risk of death. Such affirmative defense may be established by a preponderance of the evidence."

⁴⁵ 21 U.S.C. §§ 801–801a.

and trafficking in all scheduled drugs."⁴⁶ David E. Joranson of the University of Wisconsin's Comprehensive Cancer Center pointed out that, to the extent medical and scientific decisions are made on the Federal level, they should be within the province of the U.S. Department of Health of Human Services, not the U.S. Department of Justice.⁴⁷

Not only does the bill contort the purpose of the CSA, it also would lead to the establishment of a new and burdensome oversight mechanism whereby the DEA would be expected to police every prescription that every healthcare worker, distributor, and manufacturer in the country dispenses. Moreover, the DEA could monitor such activities only by imposing vast new paperwork requirements on all regulated parties or through a network of healthcare workers reporting on each other, the likes of which would be unprecedented and fundamentally destructive to the proper functioning of the practice of medicine. All of this would occur even though the DEA has no expertise whatsoever in medical care.⁴⁸

CONCLUSION

Although some of us do not support the practice of physician-assisted suicide, none of us can support this legislation. This bill overrides Oregon law, which legalized physician-assisted suicide in that State. While there have been instances in our Nation's history where it was appropriate for Federal law to supercede State law in order to fulfill constitutional imperatives, such as the realm of civil rights, this is not one of those occasions. States historically have regulated the medical profession, and the Federal Government has no constitutional authority or imperative to do so now.

Furthermore, we are concerned about the effect this legislation would have on the treatment of pain. If this legislation is enacted, physicians will fear writing prescriptions that could trigger a Federal enforcement process that would ruin their careers and throw them in jail. Consequently, they will be reluctant to prescribe the large doses of narcotics that are often required to treat incapacitating levels of pain. Patients will be left to suffer.

Finally, this legislation will not end the practice of physician-assisted suicide. To the extent that supporters of this bill hope to put an end to physician-assisted suicide, they will be disappointed once the bill is put into practice. Physicians will still be able to use non-controlled substances to assist suicides. Because of the ill effects this legislation will have on the well-being of patients and on the rights of the States, we must dissent.

JOHN CONYERS, Jr.

⁴⁶ Letter from L. Anthony Sutin, Acting Asst. Attorney General, Office of Legislative Aff., U.S. Dept. of Justice, to the Honorable Henry J. Hyde (R-IL), Chair, House Comm. on the Judiciary 1 (Aug. 3, 1998).

⁴⁷ June 24, 1999 Subcomm. Hearing (written statement of David E. Joranson, Pain & Policy Studies Group, Univ. of Wisconsin Comprehensive Cancer Center, at 2). If Congress does change current law with respect to the legal uses of drugs, it should amend the Federal Food, Drug and Cosmetic Act, which governs the use of drugs for medical and scientific purposes. *Id.* (written statement of David E. Joranson, at 3).

⁴⁸ *Id.* (written statement of David Orentlicher, MD, Director, Center of Law and Health, Indiana Univ. School of Law, at 3) ("By empowering officials of the Drug Enforcement Administration and other Federal, State and local law enforcement personnel to prosecute physicians to determine their intent, this Act subjects physicians who care for dying patients to the oversight of police with no expertise in the provision of medical care.").

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