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09/08/99- Updated 11:43 PM ET

Pain bill could undo assisted suicide law

By Wendy Koch, USA TODAY

WASHINGTON - Congress is moving ahead with a bill that could undo Oregon's pioneering law allowing physician-assisted suicide and affect how doctors nationwide treat their patients' pain.

The controversial bill is expected to pass the House Judiciary Committee as early as Thursday.

It would effectively overturn the Oregon law, the first in the nation that allows doctors to help terminally ill patients who meet certain criteria take their own lives.

The bill would allow doctors to use federally controlled drugs such as morphine to relieve pain, even if the unintended result is death, but would not allow such prescriptions if meant to cause death.

Supporters of the legislation - including the National Conference of Catholic Bishops, right-to-life groups and the American Medical Association (AMA) - say the bill would encourage doctors to treat pain aggressively, which would create less demand for assisted suicide. "It's a step forward to recognize the aggressive treatment of pain," says Thomas Reardon, AMA's president.

But opponents, including many health-care and pain-relief groups, say the legislation would make doctors more nervous about prescribing pain medication because they would fear investigation by federal law enforcement authorities.

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Oregon Gov. John Kitzhaber and other critics also say it would violate states' rights.

"How are you going to determine a doctor's intent?" asks Susan Wincler, director of policy and advocacy for the American Pharmaceutical Association. Her group says a dose needed to relieve major pain in one patient could be lethal in another.

The bill, revised since it was proposed last year, has gained considerable bipartisan support. Its authors are powerful House and Senate members who are determined to pass it, although they might run out of time to do so this year.

The issue reflects a growing movement, at the state and national levels, to address prickly end-of-life issues, especially pain management.

The growing interest is largely a response to Oregon's law, which did not take effect until 1997 because of a court challenge. It's also the result of the graying of the baby boomers, many of whom have elderly parents and are starting to feel their own aches and pains.

Oregon is the only state that allows assisted suicide, and some states have criminal penalties for doctors convicted of it.

The bill's authors say their legislation, which deals strictly with drugs on the federal Controlled Substances List such as narcotics and opiates, would not bar Oregon's doctors from using other drugs or means to cause death. But backers of Oregon's law say it would nullify what they've done. "Only controlled substances are reliable and predictable" for assisting suicide, says Barbara Coombs Lee, executive director of the Compassion in Dying.

Other drugs would cause more suffering, she says.

All 15 people who used the Oregon law to die last year took barbiturates, which are controlled drugs.

Oregon's law appears to have emboldened doctors to treat pain more aggressively.

Doctors there prescribe twice as much morphine per capita as do doctors nationwide, according to data for the first quarter of this year from the Drug Enforcement Administration.

And last week , in what might be the first such action nationwide, the Oregon Board of Medical Examiners disciplined a doctor for treating his patients' pain insufficiently.

Rep. Bart Stupak, D-Mich., a sponsor of what's being called the Pain Relief Promotion Act, says he thinks the bill will attract enough votes to pass the House of Representatives.

The Senate has yet to take action on the bill, but the main sponsor there, Sen. Don Nickles of Oklahoma, is the chamber's second-ranking Republican. He could take the bill directly to the

Senate floor after House passage. "It's one of his highest priorities for this year," says his spokeswoman, Gayle Osterberg.

Sen. Ron Wyden, D-Ore., who has written a bill that would try to improve pain management without revoking Oregon's law, plans a filibuster against Nickles' bill.

The Clinton administration has yet to take a position on the legislation.

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U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

you wanted to look at this — comments due at 2pm

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 President ~~Administration~~ is strongly ~~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

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.

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[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

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[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]

Chris— is this ¶ okay with you?

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

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[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.

are you okay with this?

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,

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[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,"[6] 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

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[6] Washington v. Glucksburg, 117 S. Ct. 2258, 2275 (1997).

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OREGON MEDICAL ASSOCIATION

July 19, 1999

Honorable Ron Wyden
U.S. Senate
717 Hart Building
Washington, DC 20510

Dear Senator Wyden:

Senator Nickles (OK) and Congressman Hyde (IL) have introduced the '*Pain Relief Promotion Act of 1999*,' which continues the federal debate over the controversial Oregon law permitting physician assisted suicide, twice approved by Oregon voters. Proponents have suggested the new bill will improve and enhance "pain management" throughout the country and directly neuter Oregon's unique law. As you know, OMA opposed the 1998 Nickles/ Hyde version based on its implications to appropriate pain management for terminally ill patients and the potential for physicians to face criminal, charges, administrative penalties and loss of licensure.

The OMA continues to have these same substantive concerns regarding the 1999 legislation and its impact on appropriate medical treatment, not only in Oregon but throughout the country. Because of this, the Oregon Medical Association opposes the 'Pain Relief Promotion Act of 1999.' Regardless of one's position on the issue of physician assisted suicide, the Nickles/Hyde legislation fails to resolve a number of issues raised by a variety of national organizations that opposed the 1998 bill. Those concerns are as follows:

1. In a letter to Jonathan Schwartz, U.S. Department of Justice, regarding the Controlled Substances act, Oregon Deputy AG David Shuman stated that "....all indications are that Congress not only did not intend the DEA to interfere in matters of state law, but that it intended to address a completely different problem, the so-called 'war on drugs.' The Supreme Court long has recognized that "direct control of medical practice in the States is beyond the power of the federal government."
2. 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.
3. The OMA concurs with Thomas A. Constantine's outline of the procedural aspects for determination of a violation of the CSA as outlined in his letter to Congressman Hyde and agrees that any prescription which may have a double effect "....would add a new and different application of the CSA.... The DEA would have to examine the facts on a case-by-case basis to determine whether a physician's actions conflict...."
4. Congress has the legitimate authority to consider whether federal law should outlaw "physician assisted suicide." We have no quarrel with legislation which would clearly and directly prohibit Oregon's law; however, the Nickles/Hyde bill fails in that regard, hiding behind the

curtain of improving "pain management" and, in our opinion, fails in that area as well. The Association believes the current proposal will also have a chilling effect on aggressive pain management and would give authority to federal, state, and local law enforcement officials to investigate and determine a physician's state of mind when prescribing medications which could cause a patient's death.

5. The Nickles/Hyde bill would establish for the first time federal authority to determine the standard of practice, which has historically been left to the states. On July 14 the AMA stated before the Constitution Subcommittee of Judiciary (regarding the proper roles of state and federal government on HR 4006), "No federal action is needed; the states are addressing the issue of assisted suicide through their legislatures, their medical boards and their courts." AMA went on to say, "It is the state legislatures, through the police powers, that determine the scope of medical practice. State medical boards are universally authorized by their state statutes to investigate reports of improper prescribing as possible evidence supporting suspension or revocation of a physician's license to practice medicine. This is the purview of the state."
6. In regard to the ability of physicians to rely on state standards, the terms and intent of Nickles/Hyde fly in the face of previous objections to federal legislation, which are best stated by the 1998 testimony of the AMA, "....the AMA believes that expanding the DEA's authority in this matter would be an unacceptable federal intrusion over matters of state law regarding the practice of medicine."
7. The new legislation does not add new protection for American physicians. Instead, it establishes in federal law, regulation and enforcement the authority for the Department of Justice or the DEA to determine on a case by case basis whether a physician has violated the federal law. It 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.

Enclosed a copy of our legal counsel's analysis of the implications and impact of the "Pain Relief Promotion Act of 1999" which outlines additional concerns raised by this bill. We recognize that many interest groups have signed off on it as an "improvement" and enhancement of appropriate pain management with a monetary "carrot" for hospice, but we believe it is an ill advised and dangerous precedent which will do more harm than good for the treatment of patients. We would appreciate your support for opposing this legislation and will be happy to respond to any questions you may have.

Sincerely,

Richard G. Kincade
President

cc: Senator Gordon Smith
Representative David Wu
Representative Greg Walden
Representative Earl Blumenauer
Representative Peter DeFazio
Representative Darlene Hooley

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July 9, 1999

PERSONAL AND CONFIDENTIAL

Via Facsimile 241-7148
Mr. Scott Gallant
Director of Governmental Affairs
Oregon Medical Association
5210 S.W. Corbett Avenue
Portland, OR 97201

Re: Federal Pain Relief Promotion Act of 1999

Dear Scott:

The purpose of this correspondence is to follow up on our initial June 23, 1999 analysis of the Federal Pain Relief Promotion Act of 1999 (S. 1272) which was introduced by Senator Don Nickles (R-Okla.) on June 23, 1999. A similar version was introduced in the House by Representative Henry Hyde (R-Ill.) (H.R. 2260). The main purpose of these bills is to define when dispensing pain medication is a legitimate medical purpose and to prohibit dispensing of controlled substances for the purpose of causing the death of an individual. Contrary to earlier opposition of similar proposed legislation, the American Medical Association (AMA) apparently supports passage of this particular bill. Consequently, you wanted to know whether the current legislative proposal radically differs from earlier bills addressing this issue (which would explain the AMA's change in position), or is the AMA now simply contradicting earlier statements which questioned the authority of the federal government to regulate directly the practice of medicine.

Question Presented

Does the Pain Relief Promotion Act of 1999 raise similar legal issues regarding the authority of the federal government to regulate the practice of medicine as did the Lethal Drug Abuse Prevention Act of 1998?

Short Answer

Compared to earlier proposed legislation, the current legislative proposal to amend the Controlled Substances Act raises similar legal issues regarding the authority of the federal government to regulate the practice of medicine.

Discussion

In July 1998, members of Congress debated the Lethal Drug Abuse Prevention Act which would have prohibited the dispensing of a controlled substance with a purpose of causing the suicide of an individual.[1] At that time, the AMA testified in opposition to the bill before a House subcommittee. The main concerns voiced by the AMA were that the bill might discourage appropriate aggressive palliative care and that the legislation represented an unacceptable federal intrusion of the DEA into state regulation of the practice of medicine.[2]

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[1] HR 4006, 105th Congress, 2d Session (Jun. 5, 1998). Specifically, the bill would have amended the Controlled Substances Act to state that a physician's Drug Enforcement Administration (DEA) license could be revoked upon a finding that the physician:

> has intentionally dispensed or distributed a controlled substance with a *purpose of causing, or assisting in causing, the suicide or euthanasia of any individual, except that this paragraph does not apply to the dispensing or distribution of a controlled substance for the purpose of alleviating pain or discomfort* (even if the use of the controlled substance may increase the risk of death), so long as the controlled substance is *not* also dispensed or distributed for the purpose of causing, or assisting in causing, the death of an individual for any reason. (Emphasis added.)

[2] Hearing on HR 4006, before the Subcommittee on the Constitution of the House Committee on the Judiciary (Jul. 14, 1998) (presented by Thomas R. Reardon, MD). With respect to palliative care, the AMA stated that:

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

Regarding the proper roles of state and federal governments, the AMA concurred with the Attorney General's June 5, 1998 opinion which provided that neither the language of the Controlled Substances Act or its legislative history supported the Act's application to physicians who are in compliance with state law. The AMA stated that:

> Any other reading makes the DEA an arbiter of the practice of medicine. This is an unacceptable conclusion. It is the state legislatures, through the police powers, that

Now in 1999, Congress is revisiting this issue with the Pain Relief Promotion Act. While not identical to earlier legislative proposals, the bill effectively has the same effects. The Controlled Substances Act would be amended to state that alleviating pain or discomfort is a legitimate medical purpose for dispensing, distributing, or administering controlled substances, but the bill would not authorize intentionally dispensing, distributing, or administering controlled substances for the purpose of causing death.[3] Simply put, the bill would prohibit the current legal practice of prescribing controlled substances pursuant to Oregon's Death With Dignity Act.

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determine the scope of medical practice. State medical boards are universally authorized by their state statutes to investigate reports of improper prescribing as possible evidence supporting suspension or revocation of a physician's license to practice medicine. This is the proper purview of the state.

[3] S. 1272, 106th Congress, 1st Session (Jun. 23, 1999). Instead of amending the provision which sets forth grounds for disciplinary action (as with former H.R. 4006), this bill would amend the registration requirements for a DEA license to state:

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

As a direct attempt to preempt Oregon's law, the bill states:

> 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.

Finally, the education provisions of the Controlled Substances Act would be expanded to include programs:

> [f]or local, State and Federal personnel . . . 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.

Upon introduction, Senator Nickles indicated that the House of Delegates of the AMA voted to support the bill.[4] Because the current legislative proposal to amend the Controlled Substances Act raises similar legal issues as those found in an earlier bill directly opposed by the AMA, the AMA appears to have departed from its views which sought to protect appropriate palliative care and support the role of the states in determining the scope of the practice of medicine. Both the threat against appropriate palliative care and the traditional role of the states remain in the current bill.

With respect to palliative care, the authority of the DEA to regulate the legitimate use of controlled substances would be expanded under the 1999 Act. Specifically, the Act provides that alleviating pain in the usual course of professional practice is a "legitimate medical purpose," and authorizes agency rulemaking to implement this new federal definition. Furthermore, the Act creates programs to train law enforcement personnel (both federal and nonfederal personnel) on the "legitimate use of controlled substances in pain management." A logical consequence of such federal expansion into determining standards of care for pain management would be closer scrutiny of clinical decisions to administer pain medication when those decisions may increase the risk of death in order to provide adequate comfort of the patient. As the AMA rightly pointed out in 1998, physicians may think twice about aggressive drug therapies for pain management due to fear of federal investigations. The AMA also pointed out that states are beginning to adopt guidelines for palliative care and this type of proposed legislation could undo such efforts.[5] What would happen if a state's legislative standards regarding palliative care conflicted with rules adopted by the DEA? At the very least, a debate would be created about the preemption of the state standards by the federal standards.

With respect to state regulation of the practice of medicine under this 1999 Act, the federal Department of Justice (through the DEA) clearly would become involved in the creation and enforcement of rules governing when dispensing pain medication is a legitimate medical purpose.[6] Furthermore, the Act specifically instructs the Attorney General to ignore state law.[7] Granted the main consequence of the Act effectively would prohibit physician-assisted suicide in Oregon, but another consequence would be that the federal government may create pain management standards that directly conflict with existing state efforts to address palliative care. In theory, under the Act only the DEA would have the authority to decide when prescribing controlled substances is for a legitimate medical purpose. This is direct federal involvement in setting standards of medical care. From a

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[4] Statement on Introduction of Pain Relief Promotion Act of 1999 (Sen. Nickles) (Jun. 23, 1999).

[5] *See, e.g.*, ORS 677.474 (stating that a physician shall not be subject to disciplinary action by the Board of Medical Examiners for prescribing or administering controlled substances in the course of treatment of a person for intractable pain).

[6] S. 1272, Section 101.

[7] S. 1272, Section 101.

constitutional perspective, direct control of the practice of medicine traditionally has been left up to the states under their police powers.[8] Even the Controlled Substances Act requires the federal government to take into account state law.[9] But here, not only does the proposed bill expand the DEA's authority to regulate the practice of medicine, the bill explicitly requires the federal government to ignore state law altogether. Again, in 1998 the AMA strongly urged Congress to reconsider the wisdom of making the DEA "an arbiter of the practice of medicine." This bill does just what the AMA cautioned against in 1998.

Conclusion

Putting aside the moral and ethical considerations with respect to Oregon's Death With Dignity Act and physician-assisted suicide in general, the recent federal proposal to legislate palliative care standards and give authority to federal, state, and local law enforcement officials to monitor and investigate the legitimate use of controlled substances in pain management clearly puts the federal government in the business of regulating the practice of medicine. Neither the current language of the Controlled Substances Act nor the U.S. Supreme Court support this role for the federal government.[10]

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[8] *Linder v. United States*, 268 U.S. 5, 18 (1924).

[9] 21 U.S.C. §903 states:

> No provision of this subchapter shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

While this provision does not prevent Congress from enacting new legislation which would create a positive conflict with a state law, even the factors considered in DEA registration are supposed to take into account state law. For example, in registering physicians in order to permit them to distribute controlled substances, consideration shall be given to "compliance with applicable State and local law." 21. U.S.C. §823(b)(2) and (e)(2). This bill completely ignores state law.

[10] 21 U.S.C. §903; 21 U.S.C. §823; *Linder v. United States*, 268 U.S. 5 (1924).

COONEY & CREW, P.C.

Scott Gallam
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Please let us know if you have further questions or concerns regarding the Pain Relief Promotion Act of 1999.

Sincerely,

Mark A. Bonanno

MAB:mab
cc: Thomas E. Cooney

TOTAL P.09

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July 21, 1999

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Via Facsimile & U.S. Mail

The Hon. Ron Wyden
717 Senate Hart Office Building
Washington, DC 20510-3703

Re: **S. 1272, The "Pain Relief Promotion Act of 1999"**

Dear Senator Wyden:

On behalf of clients who are deeply concerned with Senator Nickles' recently proposed Pain Relief Promotion Act of 1999 (the "PRPA"), S.1272, I write to bring to your immediate attention a particularly troublesome effect wrought by the bill as currently drafted. As this firm did last year with respect to similar proposed legislation, we have analyzed the legal implications of the PRPA. While we have not yet completed our analysis, one aspect of it is glaringly apparent and deeply troubling: the PRPA 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. We believe that this dangerous consequence of the PRPA needs to be brought to the attention of your colleagues without delay. For this reason alone, as discussed more fully below, we urge you to use all means available to your office to defeat S.1272.

In short, the legal effect of S.1272 is at odds with its innocuous sounding title. Although proponents of the legislation purport to have included new statutory support for aggressive pain management, its language criminalizes the decision making process at the heart of the practice of physician assisted suicide that was approved by the citizens of the State of Oregon. Further, if enacted, S.1272 potentially would expose to criminal prosecution physicians ***in every state*** who prescribe pain management drugs in dosages that they knew would or could increase the likelihood of the patient's death. Moreover, because the PRPA's proposed amendment to the Controlled Substance Act (the "CSA") does not imbue the U.S. Drug Enforcement Agency with any additional powers to enforce the PRPA's new requirements, such enforcement will fall upon state and local authorities with no medical or palliative care expertise. This will result in the possibility of

prosecutorial hindsight being applied to complex end of life and palliative care medical decisions. Knowing this cannot help but color the decision making of every physician who provides care in what are often both medically and ethically difficult circumstances. This aspect of the PRPA emerges when the subtle language of S.1272 is read in the context of the entire regulatory regime governing federally controlled substances.

As mentioned above, the bill carries the effect of criminalizing a course of action currently made available to physicians in the State of Oregon by virtue of the democratic process. As you know, S.1272 is drafted as an amendment to the CSA, which itself is drafted as a broad prohibition on the distribution and dispensing of federally controlled substances; specifically, Section 841(a) of the CSA contains this prohibition. The ability of physicians to use such federally controlled substances — which include the drugs necessary to ease the pain of patients — in the course of their practices is found in Section 823, a so-called safe harbor for the medical profession.

As currently drafted, S.1272 adds to the end of that safe harbor section two new elements of law that, when read in the context of the CSA, radically affect the ability of physicians to practice medicine. First, the amendment includes the deceptively physician-friendly support for aggressive pain management that "may increase the risk of death." The amendment next adds, however, a provision removing from Section 823 the use of such federally controlled substances to *intentionally cause or assist in the causing of a patient's death*. This notion of *intent*, and the unclear manner in which it is used in S.1272, is particularly troubling for physicians, whether or not they plan to engage in physician assisted suicide. Legally, *intent* is considered to be established where there is knowledge that the death is substantially certain to occur as a result of the conduct; however, *intent* also can be found where death should have been reasonably expected to occur as a result of the conduct. The PRPA would mandate that those difficult, subjective questions be resolved by the criminal process after the fact.

Thus, the PRPA not only removes physician assisted suicide from the safe harbor section, it also would leave physicians exposed to the general criminal penalties associated with Section 841(a) if they potentially *should have known* that the dosage they prescribed would result in death — even if their subjective intent in fact was to provide palliative care. By comparison to this unclear new standard, physicians' actions previously have been kicked out of the safe harbor provision and into the general criminal prohibition only if their dispensing of federally controlled substances occurred outside of the usual course of their professional practice. The PRPA would have prosecutors intervening in the core practice of medicine

Professor Orentlicher, Director of the Center for Law and Health at the University of Indiana School of Law, has cautioned that since such intent to cause death can be

HELLER EHRMAN WHITE & McAULIFFE
ATTORNEYS

inferred from the drug or dose ordered, the potential exists that physicians can be incarcerated for up to 20 years if the local authorities view, in retrospect, the dosage received by the patient as excessive.

The PRPA provides little assurance that all of these state and local authorities — armed with new powers in an area they've not previously been asked to police — will enforce the proposed new federal law in a fair or uniform manner. S.1272 includes authorization for the Attorney General of the United States to create education and training programs for local, state and federal personnel "on the necessary and legitimate use of controlled substances in pain management and palliative care." Because the essential element in distinguishing a physician's legal use of federally controlled substances from a criminal use is the intent of the physician, local authorities with only the Attorney General's education program as background will be called upon to second guess the thought processes of formally, medically trained physicians and revisit difficult, stressful and often time-sensitive decisions made at the end of a patient's life — all in a thinly veiled effort to affect Congress' social policy through a cumbersome new regulatory regime.

While the issue of physician assisted suicide is being debated seriously in state houses throughout the nation, one consideration in this debate has enjoyed near unanimous agreement: no one beyond the Beltway wants local police and prosecutors second-guessing physician's decisions on the provision of medications to alleviate the pain of their terminally ill patients. Yet, in criminalizing the intimately private decision making process embarked upon by the physician and her patient — and by empowering local authorities to review those decisions after the fact — that is exactly what the PRPA proposes to do.

We urge you defeat this proposed legislation before it undermines not only the will of the people of the State of Oregon, but also the provision of good pain care to dying patients nationwide.

Very truly yours,

Nicholas W. van Aelstyn

cc: Todd G. Glass, Esq. (Portland Office)

American Medical Association

Physicians dedicated to the health of America

E. Ratcliffe Anderson, Jr., MD
Executive Vice President, CEO

515 North State Street
Chicago, Illinois 60610

312 464-5000
312 464-4184 Fax

June 28, 1999

The Honorable Don Nickles
Assistant Majority Leader
United States Senate
S-208 Capitol Building
Washington, DC 20510

Dear Senator Nickles:

The American Medical Association (AMA), representing 300,000 physician and medical student members, is pleased to be able to support S. 1272, the "Pain Relief Promotion Act of 1999."

The AMA, as you know, is squarely opposed to physician-assisted suicide and believes it is antithetical to the role of physician as healer. We strongly advocated against the Oregon public initiative that has legalized physician-assisted suicide in the State. Nevertheless, we have found past federal attempts to control such activities to be an unacceptable intrusion of federal government into medical decision-making, with the potential to chill appropriately aggressive palliative care for patients, particularly at the end of life.

Physicians have been deeply concerned that such legislation must recognize that aggressive treatment of pain carries with it the potential for increased risk of death, the so-called "double effect." The threat of criminal investigation and prosecution for fully legitimate medical decisions is unacceptable to the AMA.

Thus, we are very pleased to note that your bill would recognize the "double effect" as a potential consequence of the legitimate and necessary use of controlled substances in pain management, and explicitly include this as a provision of the Controlled Substances Act. This is a vital element in creating a legal environment in which physicians may administer appropriate pain care for patients and we appreciate its inclusion.

Under the terms of the bill, in determining the "public interest," the Attorney General would give "no force or effect" to any state law authorizing or permitting assisted suicide, when evaluating DEA registrants. We do not view this as an expansion of DEA authority. We believe your bill takes the correct approach in addressing assisted suicide primarily as a question of the "public interest," rather than as a law enforcement evaluation of legitimate medical decision-making.

We have some concern regarding the language of Section 102 of the bill, regarding education and training programs for law enforcement personnel. We believe this language should be fine-tuned to make explicit that law enforcement investigative and enforcement activities would be required to recognize and abide by the language of Section 101 recognizing the legitimate use of controlled substances for pain management, even if such

use may hasten death. We look forward to working with you and your staff to strengthen and clarify this provision and, further, to assure that development of these programs include input from physicians regularly engaged in a pain management practice.

We greatly appreciate the time and care you have demonstrated in crafting a bill that makes a strong statement against assisted suicide, while minimizing the potential for inappropriate federal intrusion into patient care decisions.

Respectfully,

E. Ratcliffe Anderson, Jr., MD

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Press Office
200 Independence Ave., S.W.
Room 303-D
Washington, D.C. 20201
(202) 690-6145 Phone
(202) 690-7159 Fax

FAX TRANSMISSION

To: CHRIS JENNINGS **Date:** 6/8/99

Fax: 456-5557 **Pages:** 4 **including this cover sheet.**

Phone:

From: **Chris Peacock** / 202-690-6149

Subject: ASSISTED SUICIDE - OREGON

PER OUR DISCUSSION TODAY:

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

Dear Chairman Bliley,

I am writing to provide you with additional information pertaining to Oregon's compliance with the Assisted Suicide Funding Restriction Act of 1997 (ASFRA). Secretary Shalala and I remain committed to ensuring that Oregon complies with Federal law and that no Federal funds are spent on physician assisted suicide-related services. The Health Care Financing Administration (HCFA) has performed a review in Oregon to ensure the State's compliance with ASFRA. We expect to complete a similar review next year to ensure continued compliance.

As I indicated in my letter on April 6, Oregon identified $99 that had been inappropriately spent on physician assisted suicide-related services in 1998, and I immediately required Oregon to refund the $61 in Federal expenditures. Further, in order to ensure that Oregon was in full compliance with ASFRA, I also directed my staff to verify Oregon's assertion that only $99 had been spent for physician assisted suicide. To that end, HCFA staff performed an on-site, comprehensive audit of Oregon's procedures for processing claims for physician assisted suicide-related services. I have enclosed a copy of the results of that review for your information.

In the course of completing this work, HCFA staff identified $2,334 in Medicaid administrative expenditures for physician assisted suicide-related services beyond the original $99. Specifically, these expenditures were for salary and payroll costs in addition to the rental of a post office box. Upon learning of these unallowable claims, I immediately directed Oregon to refund $1,167 in Federal funds through an adjustment to their Federal expenditures for Spring 1999. The State has already refunded this money.

HCFA will continue to closely monitor Oregon's compliance with ASFRA. As a result of our review, we have identified additional safeguards that the State must adopt to ensure that the State does not claim Federal funds for physician assisted suicide-related services. These additional steps include earlier physician reporting to the State of persons intending to utilize these services as well as clearer pharmacy billing instructions. In addition, Oregon will conduct an annual analysis of Medicaid claims to ensure that no Federal funds are claimed for physician assisted suicide-related services. We will work with Oregon to ensure that these steps are implemented.

The President and Congress have been clear that no Federal funds should be used to pay for physician assisted suicide. I am committed to ensuring that this direction is carried out. As noted in the enclosure on page 3, one aspect of our review remains ongoing. If any additional inappropriate claims exist, HCFA will contact the Committee immediately, and I will direct the State to refund funds as needed. Also, as indicated at the beginning of the letter, I have directed my staff to complete a comprehensive review of Oregon's process and expenditures for physician assisted suicide next year in order to monitor and maintain the State's compliance with ASFRA.

I hope that this information is helpful. Please contact Bonnie Washington of my staff at (202) 690-5960 if you have any additional questions.

Sincerely,

Nancy-Ann Min DeParle
Administrator

Enclosure

State refunds $1,167 to feds for assisted suicide costs
By BRAD CAIN
The Associated Press
06/08/99 3:47 AM Eastern

SALEM, Ore. (AP) -- Continuing its close scrutiny of Oregon's Death with Dignity Act, a federal agency says the state mistakenly spent $1,167 in federal money on assisted suicide, not just $60 as the state first reported.

The federal Health Care Financing Administration has been keeping watch on Oregon to make sure the state doesn't violate a congressional ban on using federal dollars for assisted suicides.

Oregon is the only state that allows terminally ill people who are deemed to have six months or less to live to ask their doctors for lethal prescriptions.

In March, Oregon health officials refunded $60 in federal money that had apparently been spent to help two people commit suicide.

Last Friday, the federal health care agency told a congressional committee that Oregon apparently violated the ban by spending an additional $2,334 in Medicaid money to administer the Death with Dignity Act.

The state was directed to refund $1,167 -- which represents the share of Medicaid covered by the federal government.

"The President and Congress have been clear that no federal funds should be used to pay for physician assisted suicide. I am committed to ensuring that this direction is carried out," said Nancy-Ann Min DeParle, head of the federal health care agency.

Oregon's Medicaid Director, Hersh Crawford, said state officials have set up safeguards to separate federal and state funds so only state money is used on assisted suicide.

"We recognize that Congress and President Clinton have taken a very strong line," he said. "We are trying to be as careful as possible not to spend federal dollars on Death with Dignity services."

State Sen. Eileen Qutub, a key lawmaker who opposes assisted suicide, said she thinks both state and federal officials need to step up their scrutiny to make sure federal dollars aren't being improperly spent.

"They really need to obey the law," said Qutub, a Beaverton Republican who is head of a Joint Ways and Means subcommittee.

After the state issued a report showing that 15 people used the law to end their lives last year, the Health Care Financing Administration asked the state to double-check to see if any federal dollars were involved.

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

Dear Chairman Bliley,

This is a second response to your request to Secretary Shalala for information pertaining to Oregon's compliance with the Assisted Suicide Funding Restriction Act of 1997 (ASFRA). I remain personally committed to ensuring that Oregon complies with Federal law and that no Federal funds are spent on physician assisted suicide-related services. The Health Care Financing Administration (HCFA) has performed a review in Oregon to ensure the State's compliance with ASFRA and expects to complete a similar review next year.

As I indicated previously in my letter on April 6, Oregon identified a total of $99.33 that had been inappropriately spent on physician assisted suicide-related services in 1998, and I immediately required Oregon to refund the $61 in Federal expenditures. Further, in order to ensure that Oregon was in full compliance with ASFRA, I also directed my staff to verify Oregon's assertion that only $99.33 had been spent for physician assisted suicide. They performed an on-site, comprehensive audit of Oregon's procedures for processing claims for physician assisted suicide-related services. I have enclosed a copy of the results of that review for your information.

In the course of completing this review, HCFA staff identified $2,334 in Medicaid administrative expenditures for physician assisted suicide-related services. Specifically, these expenditures were for salary and payroll costs in addition to the rental of a post office box. Upon learning of these unallowable claims, I immediately directed Oregon to refund $1,167 in Federal funds through an adjustment to their Federal expenditures for Spring 1999. The state has already refunded this money.

HCFA will continue to closely monitor Oregon's compliance with ASFRA. As a result of our review, we have identified additional safeguards to ensure that the state does not claim Federal funds for physician assisted suicide-related services. These additional steps include earlier physician reporting to the state of persons intending to utilize these services as well as clearer pharmacy billing instructions. In addition, Oregon will conduct an annual analysis of Medicaid claims to ensure that no Federal funds are claimed for physician assisted suicide-related services. We will work with Oregon to ensure that these steps are implemented.

I am committed to ensuring that no Federal funds are spent on physician assisted suicide. As indicated above, I have directed my staff to complete a comprehensive review of Oregon's process and expenditures for physician assisted suicide next year to maintain the State's compliance with ASFRA.

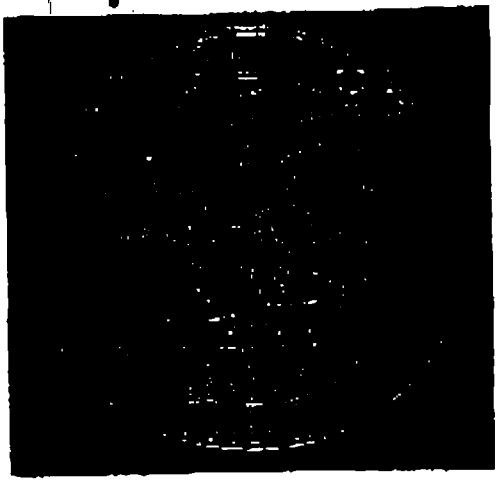
I hope that this information satisfies your request. Please contact Bonnie Washington of my staff at (202) 690-5960 if you have any additional questions.

Sincerely,

Nancy-Ann Min DeParle

Enclosure

Oregon's Death with Dignity Act: The First Year's Experience



Department of Human Resources
Oregon Health Division
Center for Disease Prevention and Epidemiology

February 18, 1999

Oregon's Death with Dignity Act:

The First Year's Experience

Prepared by:

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INTRODUCTION

On October 27, 1997 physician-assisted suicide became a legal medical option for terminally ill Oregonians. The Oregon Death with Dignity Act requires that the Oregon Health Division (OHD) monitor compliance with the law, collect information about the patients and physicians who participate in legal physician-assisted suicide, and publish an annual statistical report.1 This report describes the monitoring and data collection system that was implemented under the law, and summarizes the information collected on patients and physicians who had participated in the Act through December 31, 1998. To better understand the impact of physician-assisted suicide on the care of and decisions made by terminally-ill Oregonians, we also present the results of two studies conducted by the OHD. Each study compared the characteristics of physician-assisted suicide participants with a sample of Oregon patients and physicians who did not participate in the Death with Dignity Act.

THE OREGON DEATH WITH DIGNITY ACT

The Oregon Death with Dignity Act, a citizens' initiative, was first passed by Oregon voters in November 1994 by a margin of 51% in favor and 49% opposed. Immediate implementation of the Act was delayed by a legal injunction. After multiple legal proceedings, including a petition that was denied by the United States Supreme Court, the Ninth Circuit Court of Appeals lifted the injunction on October 27, 1997 and physician-assisted suicide then became a legal option for terminally ill patients in Oregon.. In November 1997, Measure 51 (authorized by Oregon House Bill 2954) was placed on the general election ballot and asked Oregon voters to repeal the Death with Dignity Act. Voters chose to retain the Act by a margin of 60% to 40%.

The Death with Dignity Act allows terminally-ill Oregon residents to obtain from their physicians and use prescriptions for self-administered, lethal medications. The Act states that ending one's life in accordance with the law does not constitute suicide.1 However, we have used the term "physician-assisted suicide" rather than "Death with Dignity" to describe the provisions of this law because physician-assisted suicide is the term used by the public, and by the medical literature, to describe ending life through the voluntary self-administration of lethal medications, expressly prescribed by a physician for that purpose. The Death with Dignity Act legalizes physician-assisted suicide, but specifically prohibits euthanasia, where a physician or other person directly administers a medication to end another's life.1

To request a prescription for lethal medications, the Death with Dignity Act requires that a patient must be:1

- An adult (18 years of age or older);
- A resident of Oregon;
- Capable (defined as able to make and communicate health-care decisions);
- Diagnosed with a terminal illness that will lead to death within 6 months.

Patients who meet these requirements are eligible to request a prescription for lethal medication from a licensed Oregon physician. To receive a prescription for lethal medication, the following steps must be fulfilled:1

- The patient must make two verbal requests to their physician, separated by at least 15 days
- The patient must provide a written request to their physician
- The prescribing physician and a consulting physician must confirm the diagnosis and prognosis. The prescribing physician and a consulting physician must determine whether the patient is capable. If either physician believes the patient's judgment is impaired by a psychiatric or psychological disorder, such as depression, the patient must be referred for counseling
- The prescribing physician must inform the patient of feasible alternatives to assisted suicide including comfort care, hospice care, and pain control
- The prescribing physician must request, but may not require, the patient to notify their next-of-kin of the prescription request.

To comply with the law, physicians must report the writing of all prescriptions for lethal medications to the OHD.1, 2 Reporting is not required if patients begin the request process, but never receive a prescription. Physicians and patients who adhere to the requirements of the Act are protected from criminal prosecution, and the choice of legal physician-assisted suicide cannot effect the status of a patient's health or life insurance policies. Physicians and health care systems are under no obligation to participate in the Death with Dignity Act.1

THE REPORTING SYSTEM

The Death with Dignity Act requires that the OHD develop a reporting system to monitor and collect information on physician-assisted suicide.1 To fulfill this mandate, the OHD implemented a reporting and data collection system with two components. The first involves physician prescription reports. When a lethal prescription is written, the physician must submit specific information to the OHD that documents compliance with the law.2 We review all physician reports and contact reporting physicians regarding missing or discrepant data.

The second component of the reporting system involves death certificate review. All Oregon death certificates are screened by the OHD Vital Records staff. Death certificates of all lethal prescription recipients are reviewed by the OHD State Registrar and matched to the prescribing physician reports. In addition, OHD Vital Records files are searched periodically for death certificates that correspond to physician reports, but that may have been missed by initial death certificate screening.

For 1998, we enlarged the scope of our data collection system to include in-person or telephone interviews with all prescribing physicians after receipt of their patients' death certificate. Physicians were asked to confirm whether the patient took the lethal medications, and were then asked a series of questions to collect data not available from physician reports or death certificates (e.g., insurance status, end-of-life care, end-of-life concerns, medications prescribed, and medical and functional status at the time of death). In instances where the patient took the lethal medication, we collected information on the rapidity of the medication's effect and on any unexpected adverse reactions. Many terminally-ill patients have more than one physician

providing care at the end of life. To maintain consistency in data collection and to protect the privacy of the patient and the prescribing physician, interview data were only collected from prescribing physicians. All physician interviews were performed after the patients' death. We did not interview or collect any information from patients prior to their death, nor did we collect data from patients' families at any time. Reporting forms and the physician interview questionnaire are available at www.ohd.hr.state.or.us/cdpe/chs/pas/pas.htm.

DATA COLLECTION

Data on all prescription recipients were collected from physician reports, death certificates, and prescribing physician interviews using the reporting system just described. We collected information on request dates and consultations from the prescription reports submitted to the OHD. Demographic data (e.g., age, place of residence, level of education) were obtained from death certificate reviews. Using physician interviews, we collected additional information about prescription recipients that was not available from either physician reports or death certificates as well as information about prescribing physician characteristics such as age, sex, number of years in practice, and medical specialty.

COMPARISON STUDIES

We collected information on all patients who received a prescription for lethal medications and died in 1998. Prescription recipients died either by ingesting their lethal medications or from their underlying illnesses. Because there may be differences in the characteristics of patients who completed the physician-assisted suicide process and those who received lethal medications but never used them, we did not classify or analyze the prescription recipients as a single group. Instead, our comparison studies focus only on those persons who chose physician-assisted suicide and died after taking their lethal medications. We did not conduct similar analyses of persons who received lethal medications, but chose not to use them, because of the small number of patients (six) in this group.

For our comparison studies, we included all persons who 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 compared persons who chose physician-assisted suicide with two control groups. First, we compared persons who chose physician-assisted suicide with all Oregonians who died from similar underlying illnesses (e.g., lung cancer, ovarian cancer, congestive heart failure) in 1996 (the most recent year that finalized Oregon mortality data are available). Next, we compared persons who chose physician-assisted suicide with a sample of matched control patients, Oregonians who died in 1998 and were similar with respect to age, underlying illness, and date of death. Matched control patients who would not have met the requirements of the Death with Dignity Act were excluded from the study (e.g., control patients who were not Oregon residents, or who were not capable of making health care decisions). Finally, we compared the characteristics of physicians for patients who chose physician-assisted suicide with the characteristics of the physicians for the matched control patients.

RESULTS

Results of our data collection and comparison studies are presented in two formats. In addition to this report, the results are also presented in a manuscript published in the *New England Journal of Medicine* (Title: "Legalized physician-assisted suicide in Oregon: The first year's experience") on February 18, 1999.3 These data are published in a peer reviewed medical journal for two reasons. First, legalized physician-assisted suicide is unique to Oregon. As such, the reporting system implemented by the OHD under the Death with Dignity Act has no precedent. We believe that a new reporting system which is responsible for collecting data on a controversial issue, such as the Death with Dignity Act, should be subject to the scrutiny of peer review in the medical literature. Such critique may lead to future improvements in the way data are collected. Second, the data and analyses presented in these reports will be of interest and used by parties on all sides of this issue. Again, we believe that the methods, results, and analyses that we present can only benefit from the critique offered by the peer review process.

Characteristics of Prescription Recipients

Twenty-three persons who received legal, lethal prescriptions in 1998 were reported to the Oregon Health Division. Of these twenty-three persons, fifteen died after taking their lethal medications, six died from their underlying illness, and two were alive as of January 1, 1999. Table 1 presents information on the 21 prescription recipients who died in 1998 and further subdivides this information into two categories: patients who took their lethal medications, and prescription recipients who died of their underlying illnesses. The median age of the 21 prescription recipients was 69 years and ranged from the third to the tenth decade of life. All 21 patients were white, 11 (52%) were male, and 11 (52%) lived in the Portland Tri-county area. Of the 21 recipients, 20 had been residents of Oregon for longer than 6 months when they received their prescriptions. One patient had moved to Oregon 4 months prior to death to be cared for by her family and not because of legalized assisted suicide. Four of the twenty-one prescription recipients had a psychiatric or psychological consultation and all patients were ultimately determined to be capable in the context of the Death with Dignity Act. All physician reports were in full compliance with the law.

Twenty (95%) of the twenty-one prescription recipients who died in 1998 were prescribed nine grams of a fast-acting barbiturate, either secobarbital or pentobarbital. One patient was prescribed one gram of secobarbital to be taken with an oral narcotic. Most patients also received a number of nonlethal medications to be taken in conjunction with the lethal medications. These included medications to increase stomach emptying and to prevent nausea and vomiting.

The Physician-Assisted Suicide Process

Fifteen prescription recipients chose physician-assisted suicide and died after taking their lethal medications. The median time from medication ingestion to unconsciousness (available for 11 patients) was 5 minutes (range 3-20 minutes). The median time from medication ingestion to

death (available for 14 patients) was 26 minutes (range 15 minutes to 11.5 hours). For eight of the 15 persons who chose physician-assisted suicide, the prescribing physician was at the bedside when they took the lethal medications. For 6 or the 15 patients, the physician was also at the bedside when they died. In instances where the physician was not present for the medication ingestion or death, times to unconsciousness and death, as well as reports of complications, were provided to the physician by persons present at the bedside. No complications, such as vomiting or seizures were reported by any physician.

Comparison Studies

We first compared the 15 persons who chose physician-assisted suicide with all deaths in Oregon in 1996, the latest year for which finalized mortality data are available. The 15 persons who chose physician-assisted suicide accounted for 5 of every 10,000 deaths in Oregon, based on the 28,900 deaths that occurred in 1996.4 The 13 persons with cancer who chose physician-assisted suicide accounted for 19 of every 10,000 cancer deaths, based on the 6,784 persons who died of cancer in Oregon in 1996.4 Next, we compared the 15 persons who chose physician-assisted suicide with the 5,604 Oregonians who died in 1996 from similar underlying illnesses. Age, race, sex, and Portland Tri-county residence status did not predict participation in physician-assisted suicide (Table 2). Twelve of the fifteen persons who chose physician-assisted suicide had at least a high school diploma. Four of these twelve had graduated from college. The proportions of high school and college graduates were similar among persons who chose assisted suicide and the 5,604 controls. In contrast, marital status was associated with participation in physician-assisted suicide. Persons who were divorced and persons who had never married were 6.8 times and 23.7 times, respectively, more likely to choose physician-assisted suicide than persons who were married.

For our second comparison study, the case-control study, we identified control patients who had not participated in the Death with Dignity Act but who were similar to the persons who chose physician-assisted suicide with regard to age, underlying illness, and date of death. Using 1998 death certificates, we identified 81 potential control patients who met these criteria. Of these 81 persons, 17 were disqualified from the study because we could not contact the physician who provided end of life care or because we could not identify an end of life care provider. We were able to obtain physician interviews for 64 potential control patients. Of these 64 persons, 21 were disqualified because they would not have been eligible for a prescription under the law: 10 were deemed incapable of making health care decisions by their physicians; 2 were not Oregon residents; 2 could not take oral medications, and for 7 patients, the time between when the physician determined that the patient had less than 6 months to live and death was less than the 15 day required waiting period. Ultimately, we collected data on 43 controls, 3 matched controls for each of 14 case patients and 1 matched control for a single patient.

Results of the case-control study are similar to the comparison with 1996 Oregon deaths just described. Persons who chose physician-assisted suicide and 1998 matched controls did not differ statistically by race, sex, Oregon resident status (greater than 6 months), Portland Tri-county resident status, or education level (Table 3). Although not statistically significant, there was a trend in that persons who chose physician-assisted suicide were more likely to be

divorced than controls. Persons who chose physician-assisted suicide were more likely than controls to have never married.

No patients who chose physician-assisted suicide or matched control patients voiced concern to their physician about the financial impact of their illnesses. Both groups contained similar proportions of patients insured through Medicare, Medicaid, or private insurance, or who lacked health insurance. One patient who chose physician-assisted suicide (7 %) and 15 (35 %) controls expressed concern about end-of-life pain, although this difference was not statistically significant. Patients who chose physician-assisted suicide and controls were equally likely to have been enrolled in hospice, to have had advance medical directives, and to have died at home. The proportion of patients in each group who expressed concerns about being a physical or emotional burden, or about the inability to participate in activities that made life enjoyable, were similar. However, patients who chose physician-assisted suicide were 7.3 times more likely than controls to express concern to their physicians about loss of autonomy, and 9.0 time more likely to express concern about loss of control of bodily functions (e.g., incontinence, vomiting) due to their illness. At death, patients who chose physician-assisted suicide were 10 times less likely than controls to be completely disabled and bedridden.

Physician Characteristics

Fourteen physicians wrote prescriptions for lethal medications for the 15 patients who chose physician-assisted suicide. Forty physicians were the end-of-life providers for the 43 control-patients. The two groups of physicians were similar with respect to age, sex, specialty, and years-in-practice, although there was a trend for prescribing physicians to have been older and in practice longer (Table 4).

For some physicians, the process of participating in physician-assisted suicide had a great emotional impact. In response to general, open-ended inquiries, prescribing physicians offered comments such 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."

Not all Oregon physicians were willing to participate in physician-assisted suicide in 1998. Six patients who chose assisted suicide had requested lethal medications from one or more providers before finding a physician who would begin the prescription process. Physicians for 67% (29/43) of control-patients would have refused to write a prescription for lethal medications had the patient asked; physicians for 21% (9/43) of control patients would have provided prescriptions; and physicians for 12% (5/43) of control patients were unsure. Six control-patients (14%) had discussed physician-assisted suicide with the physician we interviewed, but none had begun the formal request process.

DISCUSSION / CONCLUSIONS

Currently, Oregon is the only place in the world where physician-assisted suicide is legal. Physician-assisted suicide was briefly legalized in the Northern Territory of Australia between July, 1996 and March, 1997.5 In the Netherlands, physician-assisted suicide has been practiced for many years; although technically illegal, it has been rarely prosecuted.6

The Death with Dignity Act continues to be the focus of highly charged ethical, legal, and medical debates.7-13 The role of the Oregon Health Division is neither to take sides nor to settle these controversies; however, we believe that the data collected on 1998 participants in the Death with Dignity Act and on patients who chose physician-assisted suicide are important to parties on all sides of these debates. Among the important findings from our 1998 data collection and comparison studies are:

- Physician-assisted suicide accounted for approximately 5 of every 10,000 deaths in Oregon in 1998. Patients with cancer who chose physician assisted suicide accounted for 19 of every 10,000 cancer deaths in Oregon in 1998.

- Patients who chose physician-assisted suicide in 1998 were similar to all Oregonians who died of similar underlying illnesses with respect to age, race, sex, and Portland residence.

- Patients who chose physician-assisted suicide were *not* disproportionately poor (as measured by Medicaid status), less educated, lacking in insurance coverage, or lacking in access to hospice care.

- Fear of intractable pain and concern about the financial impact of their illnesses were not disproportionately associated with the decision to choose physician-assisted suicide.

- The choice of physician-assisted suicide was most strongly associated with concerns about loss of autonomy and personal control of bodily functions.

- In 1998, many hospitals and physicians in Oregon were unable or unwilling to participate in physician-assisted suicide.

- Physicians who wrote lethal prescriptions for patients who chose physician-assisted suicide represented a wide range of specialties, ages, and years in practice.

Considerable debate has focused on the characteristics of terminally-ill patients who choose physician-assisted suicide. Some feared that patients who were minorities, poor, or uneducated would more likely be coerced into choosing physician-assisted suicide. Others feared that terminally-ill persons would feel pressured, either internally or through external forces (e.g., family members or health care systems), to choose assisted suicide because of the financial impact of their illnesses.9, 11, 14, 15 To date, the Oregonians who have chosen physician-assisted suicide have not had these characteristics. Patients who chose physician-assisted suicide and our two comparison groups were similar with respect to age, sex, race, education level, and health insurance coverage. No person who chose physician-assisted

suicide expressed a concern to their physician about the financial impact of their illness. The proportion of patients with private insurance and medicaid were similar among those who chose physician-assisted suicide and among controls. This provides some evidence that socioeconomic status was not associated with the decision to take lethal medications.

End-of-life care has made great strides in Oregon in recent years. Oregon ranks third, nationally, in the rate of hospice admissions.15 More than two thirds of the patients who chose physician-assisted suicide were enrolled in a hospice program when they died. A similar proportion of control patients were also enrolled in hospice. Of the four patients who chose physician-assisted suicide, but who were not receiving hospice care, three had repeatedly refused enrollment offers. To date, lack of access to hospice care has not been associated with the decision to take lethal medications. Fear of intractable pain was also an end of life care issue not associated with physician-assisted suicide. Only one person who chose physician-assisted suicide expressed concern to her physician about inadequate pain control at the end of life (compared with 15 of 43 control patients). This may reflect confidence in one's end of life care. Alternatively, recipients of lethal medications may not have been concerned about end-of-life pain because physician-assisted suicide offered them the option of avoiding intractable pain.

The primary factor distinguishing persons in Oregon selecting physician-assisted suicide is related to the importance of autonomy and personal control. Patients who chose physician-assisted suicide were seven times more likely to be concerned about loss of autonomy and nine times more likely to be concerned about loss of control of bodily functions than control patients. Autonomy was a prominent patient characteristic in physicians' answers to open-ended questions about their patients' end-of-life concerns. Many prescribing physicians reported that their patients decision to request a lethal prescription was consistent with a long-standing philosophy about controlling the manner in which they died. The fact that 79% of persons who chose physician-assisted suicide did not wait until they were bedridden to take their lethal medication provides further evidence that controlling the manner and time of death were important issues to these patients. Thus, in Oregon the decision to request and use a prescription for lethal medications in 1998 appears to be more associated with attitudes about autonomy and dying, and less with fears about intractable pain or financial loss.

There are several limitations that are important to consider when interpreting these results. First, the number of patients who chose physician-assisted suicide in 1998 was relatively small. This limits our ability to detect, from a statistical standpoint, small differences between the characteristics of persons who chose physician-assisted suicide and control patients. Second, the possibility of physician bias must be considered. Prescribing physicians may have spent more time exploring end of life concerns and care options with patients who requested lethal medications. Because of the unique nature of lethal prescription requests, prescribing physicians may have recalled their conversations and interactions with requesting patients in greater detail than physicians of terminally ill patients who did not request such prescriptions. Finally, the Death with Dignity Act requires the OHD to collect data on patients and physicians who participate in the Act.1, 2 However, the OHD must also report any noncompliance with the law to the Oregon Board of Medical Examiners for further investigation.16, 17 Because of this obligation, we cannot detect or collect data on issues of noncompliance with any accuracy. A

1995 anonymous survey of Oregon physicians found that 7% of surveyed physicians had provided lethal prescriptions to patients prior to legalization.18 We do not know if covert physician-assisted suicide continued to be practiced in Oregon in 1998.

Considerable debate has also surrounded the interpretation of very limited data on the medications prescribed for physician-assisted suicide and the rapidity of their effects.19-22 With one exception, all of the lethal prescriptions were similar. This may reflect information available from Oregon physician-assisted suicide advocacy groups. Although all patients were unconscious within 20 minutes of medication ingestion, the time from ingestion to death ranged from 15 minutes to 11.5 hours. In four instances, patients died more than 3 hours after taking the medications, including the one patient who died 11. 5 hours afterward. The last patient fell asleep 5 minutes after taking all 9 grams of barbiturate, the same prescription given to 14 of the 15 persons who chose physician-assisted suicide. Physicians, patients, and their families should be aware that the time from medication ingestion to death is not always rapid or predictable.

In 1998, not all hospital systems or physicians in Oregon participated in physician-assisted suicide. Federal law prohibits participation by patients or physicians within federal health care systems such as Veterans Hospitals and Indian Health Service clinics.23 Some health care systems, including at least one Catholic medical system in Oregon, have placed similar restrictions on patients and staff within their facilities because of ethical concerns. Although some physicians are unable to participate in the Death with Dignity Act because of restrictions by their employers, other physicians have chosen not to participate in physician-assisted suicide because of other concerns. Six of the patients who chose physician-assisted suicide had to approach more than one physician before finding one that would start the prescription process. Two-thirds of otherwise eligible control patients, had they asked, would not have received lethal prescriptions from the physician that we interviewed. Both findings provide evidence that a substantial proportion of Oregon physicians are not willing to participate in legalized physician-assisted suicide.

Physicians who wrote lethal prescriptions for the patients who chose physician-assisted suicide represented a wide range of medical specialties, ages, and years in practice and were similar to physicians for control patients with respect to these characteristics. Several Oregon physicians have publically acknowledged their participation in the Death with Dignity Act, but the majority of prescribing physicians have remained anonymous. Several physicians commented that despite the emotional impact of participating in a physician-assisted suicide, they were unwilling to share their experience with others because they feared repercussions from colleagues or patients if they did not keep their identity as a Death with Dignity Act participant anonymous.

In publishing this report, we recognize that the Death with Dignity Act has been and remains a focal point for ethical, legal, and medical debate. As required by the Act, we will continue to collect information regarding compliance with the statute, and we emphasize that our role is to do so as a neutral party. In accordance with the Act, we will make available to the public an annual statistical report of the information collected. Future reports may not, however, contain the level of detail provided in this first study.

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Table 1: Characteristics of patients who received prescriptions for lethal medications and timing of events.

Demographics	Death after Lethal Medication Ingestion (N=15)		Death from Terminal Illness (N=6)		All Lethal Prescription Recipients (N=21)	
Age - median (years)	69		47		69	
Race - white	15	100%	6	100%	21	100%
Sex - male	8	53%	3	50%	11	52%
Oregon resident greater than 6 months	15	100%	5	83%	20	95%
Residence - Portland-Metro	7	47%	4	67%	11	52%
Legal Requirements						
Psychiatric/psychological consultation	4	27%	0	0%	4	19%
Full compliance	15	100%	6	100%	21	100%
Underlying Illness						
Cancer (all types)	13	87%	5	83%	18	86%
Lung, ovarian, or breast cancer	9	60%	3	50%	12	57%
Acquired Immune Deficiency Syndrome	0	0%	1	17%	1	5%
Congestive heart failure	1	7%	0	0%	1	5%
Chronic obstructive pulmonary disease	1	7%	0	0%	1	5%
PAS Lethal Prescription						
secobarbital 9 grams	13	87%	6	100%	19	90%
phenobarbital 9 grams	1	7%	0	0%	1	5%
secobarbital 1 gram/morphine 1 gram	1	7%	0	0%	1	5%
anti-emetic agent	14	93%	5	83%	19	90%
gastric pro-motility agent	6	40%	5	83%	11	52%
chlorpromazine	1	7%	0	0%	1	5%
beta blocker	3	20%	3	50%	6	29%
	median	**range**	**median**	**range**	**median**	**range**
Prescription Time-Line (days)						
First and second oral requests	18	(15-68)	30	(16-83)	20	(15-83)
First oral request and death	20	(15-75)	93	(26-101)	26	(15-101
Prescription receipt and death	1	(0-22)	28	(8-66)	4	(0-66)

Table 2: Characteristics of case patients and Oregon residents who died from similar illnesses in 1996.

Demographic Characteristic		Deaths	Physician-Assisted Suicide Cases	Rate Physician-Assisted Suicides per 10,000 deaths	Risk Ratio (95% CI†)	2-tailed P value
race* -	non-white	116	0	0.0	referent	
	white	5450	15	27.4	undefined	1.00
sex -	female	3026	7	23.1	referent	
	male	2578	8	30.9	1.3 (0.5-3.7)	0.57
Residence -	rural	3582	8	22.3	referent	
	urban (Portland-metro)	2022	7	34.5	1.6 (0.6-4.3)	0.39
Education*						
	did not graduate high school	1540	3	19.4	referent	
	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*						
	married	2703	2	7.4	referent	
	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

	1996 Oregon Death Cohort (N=5604)	Physician-assisted Suicide Deaths (N=15)	P value
median Age (years)	74	69	0.40

*Of the 5,604 persons who died in 1996 from illnesses that matched the case-patients' underlying illnesses, data on race were available for 5,566; data on education were available for 5,441; and data on marital status were available for 5,584.

†CI denotes confidence intervals

Table 3: Characteristics of case patients and matched controls

Demographics	Case-Patients (N=15) N	%	Control-Patients (N=43) N	%	Matched Odds Ratio	95% Confidence Interval
race - white	15	100%	43	100%		
sex - male	8	53%	15	35%	4.5	0.6-32.1
Oregon resident >6 months	15	100%	43	100%		
Portland-Metro resident	7	47%	16	37%	1.4	0.4-4.9
Education*						
did not graduate high school	3	20%	11	27%	referent	
high school graduate	12	80%	30	73%	1.4	0.3-9.7
college graduate	4	27%	7	17%	undefined	
Marital Status at Death						
married	2	13%	20	47%	referent	
widowed	5	33%	14	33%	1.7	0.1-24.7
divorced	4	27%	7	16%	7.5	0.7-354.5
never married	4	27%	2	5%	undefined	
Insurance Coverage at Death ¶						
Private Insurance	8	53%	28	65%	referent	
Medicare only	4	27%	7	16%	6.0	0.3-288.4
Oregon Medicaid	2	13%	7	16%	0.8	0.1-7.7
No Insurance	1	7%	0	0%	undefined	
Unknown	0	0%	1	2%	undefined	
Hospice/Advance Directives at Death						
Enrolled in Hospice†	10	71%	32	74%	0.8	0.2-4.2
Written Advance Directives‡	11	79%	37	93%	0.4	0.1-3.3
Place of Death						
Private Home	12	80%	29	67%	3.5	0.4-29.7
Patient End-of-Life Concerns*						
Financial cost of treating/prolonging illness	0	0%	0	0%		
Burden on family/friends/caregivers	2	13%	15	35%	0.2	0.0-1.5
Inability to participate in activities	10	67%	26	60%	1.2	0.3-4.3
Inadequate pain control	1	7%	15	35%	0.2	0.0-1.4
Loss of autonomy due to illness	12	80%	17	40%	7.3	1.5-35.9
Loss of control of bodily function	8	53%	8	19%	9.0	1.6-51.4
Functional Status at Death						
completely disabled	3	21%	32	84%	0.1	0.0-0.4

Table 3 continued on next page

Table 3 continued from previous page

	median	range	median	range	P value

Table 4: Characteristics of physicians who prescribed lethal medications and physicians who provided care at the end of life for controls.

	Case Physicians (N=14)		Control Physicians (N=40)		O.R.	95% Confidence Interval
Sex - male	11	79%	35	88%	0.5	0.1-3.4
Specialty - primary care*	9	64%	22	55%	1.5	0.4-6.6
Median age - years (range)	51	(37-69)	44	(30-62)		
Median years in practice - years (range)	18	(1-45)	12	(1-36)		

*primary care specialities defined as family practice, internal medicine, obstetrics and gynecology

Age (years)	69		74		0.70
Patient-physician relationship (days)	69	15-3780	720	35-728	0.03
				4	

* education data were available for 15 case-patients and 41 controls
† hospice data were available for 14 case-patients and 43 controls
‡ advance directives data were available for 14 case-patients and 40 controls
§ Functional status data were available for 14 case-patients and 38 controls
¶ column totals may not sum to 100% due to multiple responses for a single patient

Assisted Suicide -- Priority of Senator Nickles and Congressman Hyde

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

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

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

Suggested Talking Points:

- As you know, the President strongly opposes assisted suicide. He reiterated this position when he signed the Assisted Suicide Funding Restriction Act just last year.

- However, as the Justice Department made clear in a letter to the Senate Judiciary Committee less than a month ago, we cannot support the Nickles/Hatch/Hyde bill -- or something that resembles it -- because we believe it has great potential to exacerbate the current problem of under prescribing pain medications designed to <u>appropriately</u> alleviate the suffering of the terminally ill.

- Our opposition to this bill is shared by many respected national health organizations, many of which also oppose assisted suicide, including the AMA, the Nurses Association, the American College of Physicians and numerous other national health care groups.

- As we have repeatedly said, we are willing to spend the time necessary to determine if appropriate legislation or other interventions can be designed. But this is the wrong policy, on the wrong vehicle, at the wrong time.

* Staff Contact: Chris J./6-5560

U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

September 16, 1998

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

Dear Mr. Chairman:

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

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

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

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

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

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

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

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

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

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

Sincerely,

L. Anthony Sutin
Acting Assistant Attorney General

cc: The Honorable Patrick J. Leahy
Ranking Minority Member

UNITED STATES DEPARTMENT OF JUSTICE

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2986

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NUMBER OF PAGES INCLUDING THIS SHEET: 1 3 4 4 8

TELEPHONE NUMBER OF PERSON TO CONTACT UPON RECEIPT:

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

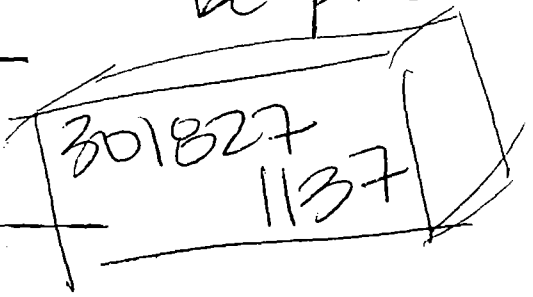
REMARKS: FYI

Nic

• all that can happen is that you lose your license & b/c you can't be prosecuted

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pain Relief Promotion Act of 1999".

TITLE I—USE OF CONTROLLED SUBSTANCES CONSISTENT WITH THE CONTROLLED SUBSTANCES ACT

SEC. 101. REINFORCING EXISTING STANDARD FOR LEGITIMATE USE OF CONTROLLED SUBSTANCES.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

"(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.".

SEC. 102. EDUCATION AND TRAINING PROGRAMS.

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

(1) by striking "and" at the end of paragraph (5);

(2) by striking the period at the end of paragraph (6) and inserting "; and"; and

(3) by adding at the end the following:

"(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.".

TITLE II—PROMOTING PALLIATIVE CARE

SEC. 201. ACTIVITIES OF AGENCY FOR HEALTH CARE POLICY AND RESEARCH.

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

"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 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.".

SEC. 202. ACTIVITIES OF HEALTH RESOURCES AND SERVICES ADMINISTRATION.

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

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

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

"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.

"(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.".

(b) AUTHORIZATION OF APPROPRIATIONS; ALLOCATION.—

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

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

SEC. 203. EFFECTIVE DATE.

The amendments made by this title take effect October 1, 1999, or on the date of the enactment of this Act, whichever occurs later.

Sara Wilson 62144

U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

add language on POTUS has long standing objections to physician assisted suicide

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 makes it clear that controlled substances may be used to alleviate pain in the course of providing palliative care to terminally ill patients. The bill complements this authorization by funding 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 strongly implies — but does not explicitly state — that the use of controlled substances to assist a terminally ill person in committing suicide is not authorized by federal law. The Department is concerned about this aspect of the bill in two respects — its impact on the Attorney General's discretion in regulating controlled substances and its use of the Controlled Substances Act as the instrument of federal policy with respect to physician assisted suicide.

We will address these aspects of the bill separately.

Palliative Care

Section 101 of H.R. 2260 amends section 303 of the Controlled Substances Act, 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 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 effectively creates a "safe harbor" against administrative and criminal sanctions when controlled substances are used for palliative care. Sections 102, 201 and 202 amend the Controlled Substances Act 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 Controlled Substances Act by requiring the Drug Enforcement Agency (DEA), the Department's primary enforcement agency in such matters, by making that discretion subject to any guidelines that the Health and Human Services Department promulgates on the proper use of controlled substances for palliative care purposes. While we agree that clear, easy-to-follow guidelines are important, we do not think it is good policy to have an agency not charged with the administration of the Controlled Substances Act tie the hands of the agency that is charged with enforcing the Act. Nor is such a provision necessary 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.

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

Physician Assisted Suicide

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[1] See, e.g., 21 C.F.R. § 1306.04(a) (authorizing prescriptions only for "legitimate medical purposes"); 21 U.S.C. § 802(21) (defining "legitimate medical purpose" for purposes of the Controlled Substances Act).

Section 101 amends section 303 of the Controlled Substances Act 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."[2]

This language could be read to curtail the Attorney General's authority under the Controlled Substances Act and to subject physicians to administrative and criminal sanctions in the event they prescribe controlled substances to assist a suicide. Because the proposed amendment refers to "this section" – and not merely to the newly added subsection (i) - the amendment would apply more broadly to all of section 303, which is the section that directs the Attorney General to register individuals to authorize them to manufacture and dispense controlled substances under certain circumstances. By modifying the entire section, H.R. 2260 would restrict the scope of the registration granted by the Attorney General under section 303 of the Controlled Substances Act, by providing that no registration allows a physician to dispense controlled substances for the purpose of assisting in a suicide.

Because the DEA's power to revoke a physician's registration under 21 U.S.C. § 824 relies in part upon "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances," H.R. 2260 would also appear to give the Attorney General the power to revoke or suspend registrations of physicians who have prescribed controlled substances for the purpose of assisting in suicides. H.R. 2260 might also authorize criminal prosecution because the Controlled Substances Act makes it a crime "for any person knowingly or intentionally" to dispense a controlled substances "[e]xcept as authorized by this subchapter."[3] If a physician's registration did not permit dispensing for the purpose of assisting a suicide (as it would not under H.R. 2260), then such dispensing would not be "authorized by this subchapter."[4]

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[2] 21 U.S.C. § 823 (emphasis added).

[3] 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).

[4] The net effect of this amendment is 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

H.R. 2260 further provides that the policies of the States on physician assisted suicide would be of no consequence when the DEA assesses whether to bring administrative actions against a physician for assisting a suicide using controlled substances. Section 101 would add a new subsection (i)(2) to section 303 of the Controlled Substances Act, which 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." The "public interest" is a touchstone inquiry in a registration revocation proceeding under 21 U.S.C. § 824(a). H.R. 2260 would therefore undermine the Attorney General's prior position that the Controlled Substances Act did not authorize administrative action against a physician who assisted a suicide pursuant to a state law authorizing such assistance, such as Oregon's Death with Dignity Act.[5]

Like the section 101 amendment discussed above, however, this amendment does not affirmatively prohibit physician-assisted suicide. It is a neutral statement that state policies should not influence federal policy. If the goal of these two amendments is to establish a clear federal policy against physician-assisted suicide, they serve this goal poorly.

More fundamentally, 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. The Act is a complex regulatory system, 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

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controlled substances to assist suicide under the guise of alleviating pain because the state law requires a paper trial 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).

[5] Letter from Attorney General Janet Reno to Sen. Orrin Hatch (June 5, 1998).

substances.[6] 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,"[7] 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.[8]

The Controlled Substances Act is also 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.

We are not, however, suggesting a federal law prohibiting physician-assisted suicide. We are not convinced that this would be a wise policy at this time. While we support legislation that bans federal funding of physician-assisted suicide,[9] a federal policy on physician-assisted suicide would raise serious federalism concerns. Such a law would, for example, clearly overturn the judgments of Oregon voters that physician-assisted suicide is appropriate under certain conditions and after certain procedures have been met.

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

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[6] 21 U.S.C. § 811(h).

[7] Washington v. Glucksburg, 117 S. Ct. 2258, 2275 (1997).

[8] See New York v. United States, 505 U.S. 144, 182-83 (1992) (striking down federal law shifting political accountability for deciding where toxic dumps should be located from Congress to State legislatures).

[9] See Assisted Suicide Funding Restriction Act (1997).

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.[10]

For these reasons, we think the time is not yet ripe for federal intervention.

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

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[10] 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]").

June 17, 1999

Ban Proposed on Drugs for Suicides

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

Filed at 3:16 p.m. EDT

By The Associated Press

WASHINGTON (AP) -- Senior Republican lawmakers proposed legislation Thursday to promote the use of restricted drugs to ease pain among the gravely ill while rejecting the use of those drugs to help patients commit suicide.

The measure could directly affect doctors in Oregon, the first and only state to legalize physician-assisted suicide.

Alleviating pain for those with advanced and terminal diseases should be a public health priority, said Sen. Don Nickles, R-Okla., the second-ranked Senate Republican, who is sponsoring the bill with House Judiciary Committee Chairman Henry Hyde, R-Ill.

``But we want to make sure we don't subsidize suicide,'' Nickles said.

The measure, first introduced last year with Oregon's legalized assisted suicide in mind, affirms that doctors may use federally controlled substances to alleviate pain, even if the use of the medication increases the likelihood of death.

But it also makes clear that the use of controlled drugs for the purpose of assisting in suicide is not allowed.

The legislation would not overturn the Oregon assisted-suicide law, but it would bar doctors from using drugs listed under the federal Controlled Substances Act to help a patient die. Under Oregon's law, a doctor must state his intent when writing a prescription.

While modified this year to meet some objections to last year's bill, Sen. Ron Wyden, D-Ore., said he would again vigorously oppose it.

The bill, he said, is ``clearly aimed at overturning Oregon's law.'' Wyden said he voted against that law twice but ``I think it is wrong

for a member of Congress, thousands of miles from the state of Oregon, to substitute his own personal judgment on a matter like this."

The measure gives the Drug Enforcement Agency no new regulatory authority, unlike the Nickles-Hyde bill last year that allowed the DEA the right to deny doctors registrations to prescribe controlled drugs if they participate in assisted suicides.

A proposed medical advisory board to review assisted suicide cases was also taken out of this year's bill.

David Simpson, board chairman of the National Hospice Organization, said the elimination of the oversight board, which he said would have a ``chilling effect'' on medical practice, was a major reason his group, which opposed last year's bill, now supports it.

But Barbara Coombs Lee, the sponsor of Oregon's initiative law, said in a prepared statement issued in Salem that Nickles' bill would allow the federal government for the first time to define a legitimate medical practice and permit law enforcers to investigate the intent of doctors in furnishing pain drugs to terminally ill patients.

In 1997 Congress overwhelmingly passed and President Clinton signed into law a bill barring the use of federal funds to assist in suicide or euthanasia.

105TH CONGRESS
2D SESSION

H. R. 4006

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 5, 1998

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

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

SEC. 2. LETHAL DRUG ABUSE PREVENTION.

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

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

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

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

(b) SUSPENSION OR REVOCATION OF REGISTRATION.—

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

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

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

"(4) has intentionally dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual, except that this paragraph does not apply to the dispensing or distribution of a controlled substance for the purpose of alleviating pain or discomfort (even if the use of the controlled substance may increase the risk of death), so long as the controlled substance is not also dispensed or distributed for the purpose of causing, or assisting in causing, the death of an individual for any reason;".

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

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

(1) by striking "(c) Before" and inserting the following:

"(c) PROCEDURES.—

"(1) ORDER TO SHOW CAUSE.—After any hearing under paragraph (2), and before"; and

(2) by adding at the end the following:

"(2) MEDICAL REVIEW BOARD ON PAIN RELIEF.—

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

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

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

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

"(C) DUTIES OF BOARD.—

"(i) HEARING.—If an applicant or registrant claims that any action (or, in the case of a proposed denial under section 303(i)(2), any potential action) that is a basis of a proposed denial under section 303(i), or a proposed revocation or suspension under subsection (a)(4) of this section, is an appropriate means to relieve pain that does not constitute a violation of subsection (a)(4) of this section, the applicant or registrant may seek a hearing before the Board on that issue.

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

SEC. 3. CONSTRUCTION.

(a) IN GENERAL.—Nothing in this Act or the amendments made by this Act shall be construed to imply that the dispensing or distribution of a controlled substance be-

fore the date of enactment of this Act for the purpose of causing, or assisting in causing, the suicide or euthanasia of any individual is not a violation of the Controlled Substances Act (21 U.S.C. 801 et seq.).

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

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August 20, 1998

Dear Senator/Representative:

The undersigned organizations are writing to express our opposition to HR 4006/S. 2151 the "Lethal Drug Abuse Prevention Act".

This legislation will seriously harm patient care. Many patients with terminal illnesses suffer debilitating pain every day. The foundation of good end of life care for these patients includes appropriate pain relief. Unfortunately, as recently noted by the Institute of Medicine, pain is currently undertreated, in part because of the existing laws and regulations.

We are concerned that the proposed bill will exacerbate this problem. Faced with the possibility of a Drug Enforcement Administration investigation, physicians will be hesitant to prescribe, and pharmacists will be hesitant to dispense, large doses of narcotics. Patients who are in the most pain, and therefore in need of the largest doses of narcotics, are the most likely to be affected.

An additional concern is that the bill threatens a patient's right to privacy since any government review of a physician's action will require the physician to disclose details of patient care that should be held in confidence.

Improving end-of-life care is a priority for all our organizations. In its attempt to prevent certain behavior, HR 4006/S.2151 will have the opposite effect. Rather than passing the proposed bill, therefore, we urge the Congress to engage in a meaningful and thoughtful debate on this complex issue. Our organizations stand ready to work with the Congress as it undertakes this task.

Thank you for your consideration.

Sincerely,

Academy of Managed Care Pharmacy
American Association for Geriatric Psychiatry
American Association of Colleges of Pharmacy
American College of Clinical Pharmacy
American College of Physicians–American Society of Internal Medicine
American Geriatrics Society
American Medical Association
American Pharmaceutical Association
Americans for Better Care of the Dying
American Society of Clinical Oncology
American Society of Consultant Pharmacists
American Society of Health System Pharmacists
Choice In Dying
Hospice and Palliative Nurses Association
National Hospice Organization
National PACE Association

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

Dear Chairman Bliley,

This is a second response to your request to Secretary Shalala for information pertaining to Oregon's compliance with the Assisted Suicide Funding Restriction Act of 1997 (ASFRA). I remain personally committed to ensuring that Oregon complies with Federal law and that no Federal funds are spent on physician assisted suicide-related services. The Health Care Financing Administration (HCFA) has performed a review in Oregon to ensure the State's compliance with ASFRA and expects to complete a similar review next year.

As I indicated previously in my letter on April 6, Oregon identified a total of $99.33 that had been inappropriately spent on physician assisted suicide-related services in 1998, and I immediately required Oregon to refund the $61 in Federal expenditures. Further, in order to ensure that Oregon was in full compliance with ASFRA, I also directed my staff to verify Oregon's assertion that only $99.33 had been spent for physician assisted suicide. They performed an on-site, comprehensive audit of Oregon's procedures for processing claims for physician assisted suicide-related services. I have enclosed a copy of the results of that review for your information.

In the course of completing this review, HCFA staff identified $2,334 in Medicaid administrative expenditures for physician assisted suicide-related services. Specifically, these expenditures were for salary and payroll costs in addition to the rental of a post office box. Upon learning of these unallowable claims, I immediately directed Oregon to refund $1,167 in Federal funds through an adjustment to their Federal expenditures for Spring 1999. The state has already refunded this money.

HCFA will continue to closely monitor Oregon's compliance with ASFRA. As a result of our review, we have identified additional safeguards to ensure that the state does not claim Federal funds for physician assisted suicide-related services. These additional steps include earlier physician reporting to the state of persons intending to utilize these services as well as clearer pharmacy billing instructions. In addition, Oregon will conduct an annual analysis of Medicaid claims to ensure that no Federal funds are claimed for physician assisted suicide-related services. We will work with Oregon to ensure that these steps are implemented.

I am committed to ensuring that no Federal funds are spent on physician assisted suicide. As indicated above, I have directed my staff to complete a comprehensive review of Oregon's process and expenditures for physician assisted suicide next year to maintain the State's compliance with ASFRA.

I hope that this information satisfies your request. Please contact Bonnie Washington of my staff at (202) 690-5960 if you have any additional questions.

Sincerely,

Nancy-Ann Min DeParle

Enclosure

Mindy E. Myers

05/03/99 07:26:52 PM

Record Type: Record

To: Christopher C. Jennings/OPD/EOP@EOP, Devorah R. Adler/OPD/EOP@EOP

cc:

Subject: Did you see this?

(Source: Congress Daily - 5/3/99)

HEALTH

Ganske's Top Health Policy Adviser Resigns After Fracas

The top healthcare policy adviser to Rep. Greg Ganske, R-Iowa, has resigned following last week's dispute with House Commerce Chairman Bliley over the premature release of a managed care draft bill. A Ganske spokeswoman denied that the aide, Jon Traub, is leaving as a result of Ganske's surprising release of the discussion draft. Traub, who has not yet lined up a new job, could not be reached for comment. "He felt that after four and a half years [with Ganske] it was time to move on," the spokeswoman said. Traub's departure comes on the heels of Ganske's chief of staff, John Barnes, announcing two weeks ago he is leaving to become legislative director of the American Academy of Dermatology. Ganske already has hired a new chief of staff. Ganske last week infuriated House GOP leaders when he released — without permission from Bliley — the draft of managed care legislation being developed for the committee by Ganske and GOP Reps. Tom Coburn of Oklahoma and Charles Norwood of Georgia.

On another healthcare front, Sen. Ron Wyden, D-Ore., and Senate GOP Conference Chairman Connie Mack of Florida today introduced legislation to increase research and information about pain management for terminally ill patients. The bipartisan bill, also sponsored by Sen. Gordon Smith, R-Ore., requires that HHS establish standards for measuring the quality of pain management care, establish an Internet site to provide guidelines for pain treatment, and require all patients in federal health plans and Medicare to receive information about pain management. The bill directs the surgeon general to issue a report on the legal and regulatory barriers to pain management, and calls for other government studies, including one on the impact of controlled substances laws on pain management. Wyden said the bill would cost $18 million.

It is the latter issue that sparked Wyden, Mack and Smith to author the bill. Last Congress, Senate Majority Whip Nickles introduced legislation on controlled substances that would have the effect of prohibiting physician-assisted suicide. Mack said advocates for patient pain management are concerned the legislation could have the unintended effect of curbing doctors' treatment of severe pain. Wyden praised Nickles for working with them on the bill introduced today, but said they could not come to agreement on issues surrounding physician-assisted suicide, which Wyden said he also opposes. Wyden said the demand for physician-assisted suicide can be reduced if doctors can better manage pain for terminally ill patients. — by Matthew Morrissey

ASSISTED SUICIDE

Nickles working on introducing it;
- provision authorizing $ for AHCPR to improve palliative care
- something in there to ensure that in Oregon, you can't use Federal controlled substances to assist in suicide

What does this do for people who utilize controlled substances in that context? —

This law is aimed to intent; if your intent is to ease pain not to cause death you're okay.

Linchpin in AG's argument — can't allow passage of state law to determine Fed authority.

restorative bill b/c they disagree w her legal analysis.

added since 1986 to assist in suicide violation of public health & suicide

What AG did is "I am not making call on public health & safety; that's determined by the people in those States.

Clear laws in 46 States

Open to process & oversight boards.

Wyden ⇒ problem

DEA as enforcer; Nichols doesn't care why/who → just wants enforcement agency.

Catholics for Free Choice