

Assisted
Suicide

Karen Popp

File Assisted
Suicide

Dear Mr. Chairman:

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

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

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

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

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

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

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

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

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

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

Beltr. continues in this position

11 1997

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

Sincerely,

Janet Reno

cc:

Ranking Minority Member

TALKING POINTS FOR CALL TO SENATOR WYDEN

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

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



AMA in Washington

Letters to Congress

Letter to Judiciary Committee Chairman Rep. Henry Hyde (R-IL) re: support for HR 2260, the "Pain Relief Promotion Act of 1999."

Also sent to Sen. Don Nickles (R-OK), supporting compatible Senate legislation, S. 1272.

June 28, 1999

The Honorable Henry J. Hyde
U.S. House of Representatives
2110 Rayburn House Office Bldg.
Washington, DC 20515

Dear Representative Hyde:

The American Medical Association (AMA), representing 300,000 physician and medical student members, is pleased to be able to support H.R. 2260, 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.

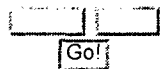
Thus, we are very pleased to note that your bill would recognize the "double effect" as a potential consequence of the legitimate and necessary use of controlled substances in pain management, and explicitly include this as a provision of the Controlled Substances Act. This is a vital element in creating 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,



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E. Ratcliffe Anderson, Jr., MD

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Published Jun 30 1999

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June 5, 1998

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

Dear Mr. Chairman:

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Sincerely,

Janet Reno



[Judiciary Homepage](#)

June 5, 1998

The Honorable Henry J. Hyde

Chairman

Committee on the Judiciary

U.S. House of Representative

Washington, D.C. 20515

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circumstances. Adverse action under the CSA may well be warranted in other circumstances: for

example, where a physician assists in a suicide in a state that has not authorized the practice under any conditions, or where a physician fails to comply with state procedures in doing so. However, the federal government's pursuit of adverse actions against Oregon physicians who fully comply with that state's Death with Dignity Act would be beyond the purpose of the CSA.

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

Sincerely,

Janet Reno



Judiciary Homepage

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

to the United States Senate
Committee on the Judiciary

July 31, 1998

Mr. Chairman and Members of the Committee:

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

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

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

expertise. Moreover, as noted below, the board's insertion in the context of a contested administrative proceeding could well complicate rather than elucidate matters surrounding physician-assisted suicide.

In addition to the above-noted concerns, the proposed revision of the Controlled Substances Act through S. 2151 would not necessarily accomplish the intended effect of banning all assisted suicides, as there are several plausible means of assisted suicide or euthanasia that do not involve the use of controlled substances. Typically, a controlled substance is used as a sedative; a non-controlled substance is used to actually bring about death. Thus, the CSA offers at best only a partial fix. If amendments to the CSA force physicians to use non-controlled substances to assist a patient to hasten a desired death, a procedure that would not explicitly be banned by the CSA, it will not save lives, but merely will increase the amount of pain suffered by those taking their lives.

The flaws of this proposed ban on assisted suicide are visibly apparent by examining the plausible scenario of a patient who has legally obtained a controlled substance from a physician for palliative purposes without disclosing an intent to commit suicide. Once that patient has decided to end his or her own life, they would need only to employ the services of a second physician, who would agree to assist in the suicide so long as the patient agrees to self medicate. As long as the second physician does not "dispense or distribute" a controlled substance, it is difficult to imagine how they could be subject to a revocation action under the proposed changes to the CSA. Moreover, if the bill were modified broadly to reach those who merely assist in a suicide, including by providing their patients with truthful information, it would likely invite serious constitutional challenges.

In addition to the foregoing concerns, the proposed bill raises several technical concerns. First, Sec. 3(a) would amend 21 U.S.C. § 823 to require denial of registration, as inconsistent with the public interest, of any application for registration that had either been revoked within the preceding five years under § 824(a)(4) or for which there is "clear and convincing evidence" that it is sought "with the intention of using the registration" to assist a suicide or commit euthanasia. This latter provision may be unworkable. We are concerned that it is not practical to determine in advance an applicant's "intent" as to how he/she will use a registration; much less can this be determined by clear and convincing evidence. Certainly, few if any applicants will seek the controlled registration with assisted suicide as a primary intended use; even fewer would admit as much on an application. For most physicians, whether they use controlled substances for this purpose will depend on the circumstances, which cannot be foreseen in advance.

There is an apparent inconsistency between Sec. 3(a), stating a new basis for action against a practitioner's registration under § 824(a)(4), and Sec. 3(c), setting forth the responsibility of the new "Medical Review Board on Pain Relief" to issue an opinion under new § 824(c)(3)(C)(i). Under the latter, the Board would review, for appropriateness as a means to relieve pain, "any potential action" (as opposed to "intended" action) by an applicant. Review of "potential" action is even more speculative than "intended" action. Moreover, this section does not mention the clear and convincing evidence standard; it is not clear whether a different level of proof is intended.

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

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

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

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Kern Popp

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

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

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

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

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

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

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

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

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

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

Sincerely,

Janet Reno

cc: Ranking Minority Member

TALKING POINTS FOR CALL TO SENATOR WYDEN

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

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

MEMORANDUM

TO: Jonathan Schwartz

June 4, 1998

FR: Chris Jennings

RE: Outstanding Qs & As vis a vis assisted suicide

cc: Gregory King, Gary Grindler, and Joe Graupensterger

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

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

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

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

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

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

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

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

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

OREGON ASSISTED SUICIDE Q&As

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

- Q. Why did it take so long to reach this conclusion?
- A. There are many complex issues involved and an appropriate amount of time was taken for a full review?
- Q. Does the DEA agree with this decision?
- A. Yes.
- Q. Did the White House review this decision?
- A. While the White House has examined the policy issues surrounding assisted suicide, they did not participate in our legal review.
- Q. Is that unusual?
- A. No, the White House office regularly looks at the policy implications of legal decisions of major importance.
- Q. Was this decision influenced by pressure from Capitol Hill?
- A. No, the decision was based on a careful and thorough review of the state and federal statutes that apply in this area.
- Q. Do you think the DEA should be given statutory authority to intervene in this area?
- A. Not necessarily. Because of the complex moral, legal and practical issues involved -- issues normally reserved to the states -- that issue needs to be carefully examined before we can reach a determination.
- Q. Will you be sending legislation to the Hill on this subject?
- A. We don't anticipate sending legislation at this time, however, we will be happy to work with members of Congress to determine if further actions are necessary.
- Q. How is this situation different than the one in California where the federal government says the use of marijuana for medical patients violates federal law?
- A. Marijuana is a Schedule I controlled substance that cannot be prescribed by physicians under any circumstances. Physicians are not barred from prescribing the drugs that are at issue in Oregon.

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

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

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

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

9 REASONS TO DEFEAT H.R. 4006/S. 2151

NO. 1: THE FEAR OF DEA INVESTIGATION WILL DETER MANY PHYSICIANS AND PHARMACISTS FROM DISPENSING STRONG PAIN MEDICINES - THAT MEANS PATIENTS IN PAIN WILL SUFFER

A host of studies published in peer-reviewed journals document how the fear of disciplinary action by state medical boards for dispensing large amounts of federally controlled substances - like morphine - to treat intense pain deter many physicians from prescribing adequate doses or prescribing them at all. For similar reasons, some pharmacies decline to even stock these medicines.

The DEA has a well-deserved reputation as an aggressive law enforcement agency. This bill instructs the DEA to add an additional layer of review and second-guessing to pain management decisions, and threatens penalties that include loss of DEA registration and banishment from Medicare/Medicaid. That will only give doctors and pharmacists more reasons to avoid dispensing these drugs, which for many patients are the only medicines available to control severe pain.

NO. 2: THE REVIEW PROCEDURES IN THE BILL DON'T CURE THIS PROBLEM

The bill was drafted by attorneys, not health professionals. Thus on paper the bill appears to protect from prosecution physicians and pharmacists who dispense large amounts of controlled substances to relieve pain. But the reality of how dispensing decisions are made is different. Physicians and pharmacists are deterred not just by DEA action but the mere threat of action. And the cost, time, logistics, stigma, and adverse publicity involved in being investigated by armed DEA agents will only add to their reasons for avoiding Schedule II drugs.

NO. 3: PHARMACIES AND HOSPITALS MUST PREDICT DOCTORS' INTENT AND WILL FORFEIT DISPENSING ALL CONTROLLED DRUGS IF THEY GUESS WRONG

The bill requires pharmacists in free-standing and hospital pharmacies to determine the physician's intended use of the medication prior to use. This is literally impossible. But the penalty for guessing wrong is draconian. Because pharmacies, rather than individual pharmacists, hold the DEA registration, the entire pharmacy could lose the ability to dispense all federally controlled drugs, not just the one in question. Fearing such an overwhelming loss, some pharmacists will refuse to fill prescriptions for large but needed doses of strong pain medications. Again, the patients will suffer.

NO. 4: THE DEA HAS LITTLE MEDICAL EXPERTISE AND VAGUE CRITERIA TO DETERMINE WHEN TO OPEN AN INVESTIGATION

The DEA recently testified before the Senate that if the bill passes, it will investigate doctors and pharmacists "on a case-by-case basis" and will consult standard medical texts to guide them in picking out suspects. The DEA stated it had little medical expertise in pain management. That was one reason cited by the U.S. Dept. of Justice, which sets overall federal law enforcement policy, in opposing the bill.

NO. 5: PATIENT AND FAMILY PRIVACY WILL BE INVADED THOUGH NO WRONGDOING HAS OCCURRED

To determine a physician's "intent" a DEA investigator must interview grieving family members just after their loved one's death. Some will be asked to reveal communications between the patient and his or her doctor which were meant to be confidential. The DEA may also subpoena medical records arguably protected by state medical privacy laws. Forcing the family to recount the final days of a loved one's death in this manner is an unconscionable intrusion into the family grieving process.

All of this will interfere with the mandate under federal law for hospices to assist surviving family members with bereavement services. A subsequent ruling by the DEA finding the doctor innocent will not undo the emotional harm the investigation caused the family.

Pay Bala

THE NEED FOR LEGAL CLARIFICATION: USING FEDERALLY REGULATED DRUGS TO ASSIST SUICIDES

- On November 5, the day after Oregon voted to retain its law allowing physician-assisted suicide, the U.S. Drug Enforcement Administration stated that the federal Controlled Substances Act still forbids doctors to prescribe controlled substances (morphine, barbiturates, etc.) for the purpose of assisting a suicide, because current federal law does not authorize deliberately causing a patient's death as a "legitimate medical purpose" for such drugs (sec 21 CFR §1306.04).

- DEA Administrator Thomas K. Constantine issued this interpretation in response to an inquiry from the chairmen of the House and Senate Judiciary Committees (Rep. Henry Hyde and Sen. Orrin Hatch).

- Mr. Constantine's answer is the only responsible answer under current law. The Controlled Substances Act holds that physicians may lose their federal license to prescribe controlled substances if they use these drugs for something other than a "legitimate medical purpose." The American Medical Association, World Medical Association, and the laws of the other 49 states do not recognize assisted suicide as a legitimate medical procedure. The Assisted Suicide Funding Restriction Act signed by President Clinton last April forbids any federal health program or facility to treat assisted suicide as a medical procedure. To authorize use of federally regulated drugs to assist suicides as part of medical practice is a bizarre aberration in the law.

- Oregon officials have attacked the DEA policy on the grounds of "states' rights." But the Controlled Substance Act provides a uniform national standard for the control of potentially dangerous drugs, and a system of enforcement and penalties that is independent of state law. The DEA did not forbid Oregon to drop its own state penalties against assisting a suicide -- it simply said that Oregon cannot unilaterally rescind this separate federal law.

- Nevertheless, on June 5, 1998, U.S. attorney general Janet Reno reversed the DEA's policy and announced that federal drug laws establish no policy against assisted suicide. She said the DEA may only penalize physicians who assist suicides in violation of state laws -- including Oregon physicians who assist suicides of people who are ineligible for death under Oregon law. This ruling distorted the purpose and history of the Controlled Substances Act, and disregarded letters from 169 House members and 37 Senators urging Ms. Reno to uphold the DEA policy.

- The legal effect of reinstating Mr. Constantine's original interpretation of November 1997 would be quite limited. It would not require any specific enforcement activity, and indeed would not require that a physician lose his or her DEA registration if he or she has used a controlled substance to assist a suicide. Even if a particular misuse of controlled substances is seen as a threat to "public health and safety," for example, this is one factor that must be weighed against others in determining whether a registration is revoked or retained. Thus Mr. Constantine said in November 1997 that "DEA must examine the facts on a case-by-case basis" to determine whether a physician's unauthorized use of controlled substances merits a penalty. But such a provision would ensure that even as discussion continues on a more comprehensive federal approach to the issues of assisted suicide and palliative care, the federal government in the meantime is not actively facilitating assisted suicides in Oregon by endorsing the killing of patients as a "legitimate" medical practice.



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.

Page 2 - The Honorable Tom Bliley

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.

Page 2 - The Honorable Tom Bliley

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.

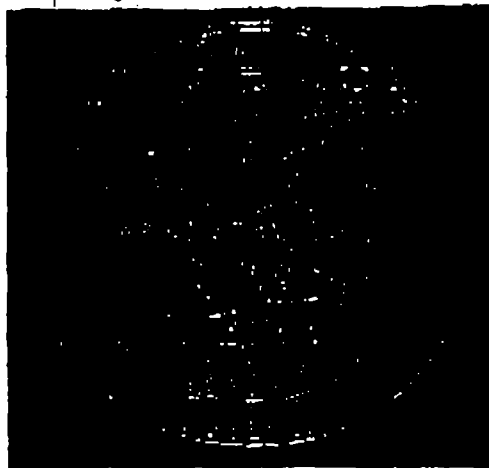
I hope that this information satisfies your request. Please contact Bonnie Washington of my staff at (202) 690-5960 if you have any additional questions.

Sincerely,

Nancy-Ann Min DeParle

5747
7/15/99
Redundant
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:

**Arthur Eugene Chin, M. D.
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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 of 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%
	<u>median</u>	<u>range</u>	<u>media</u> <u>n</u>	<u>range</u>	<u>median</u>	<u>range</u>
Prescription Time-Line (days)						
First and second oral requests	18	(15-66)	30	(16-83)	20	(15-83)
First oral request and death	20	(15-75)	93	(26-101)	26	(15-10)
Prescription receipt and death	1	(0-22)	28	(8-66)	4	(0-66)

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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)	<0.00

1996 Oregon Physician-assisted

Death Cohort Suicide Deaths

	(N=5604)	(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

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Table 3: Characteristics of case patients and matched controls

Demographics	Case-Patients (N=15)		Control-Patients (N=43)		Matched Odds Ratio	95% Confidence Interval
	N	%	N	%		
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

<u>median</u>	<u>range</u>	<u>median</u>	<u>range</u>	<u>P value</u>
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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 specialties defined as family practice, internal medicine, obstetrics and gynecology

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Age (years)	<u>69</u>		<u>74</u>	0.70
Patient-physician relationship (days)	69	15-3780	720	0.03
			35-728	
			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

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Assisted Suicide – Priority of Senator Nickles and Congressman Hyde

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

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

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

Suggested Talking Points:

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

9 REASONS TO DEFEAT H.R. 4006/S. 2151

NO. 1: THE FEAR OF DEA INVESTIGATION WILL DETER MANY PHYSICIANS AND PHARMACISTS FROM DISPENSING STRONG PAIN MEDICINES - THAT MEANS PATIENTS IN PAIN WILL SUFFER

A host of studies published in peer-reviewed journals document how the fear of disciplinary action by state medical boards for dispensing large amounts of federally controlled substances - like morphine - to treat intense pain deter many physicians from prescribing adequate doses or prescribing them at all. For similar reasons, some pharmacies decline to even stock these medicines.

The DEA has a well-deserved reputation as an aggressive law enforcement agency. This bill instructs the DEA to add an additional layer of review and second-guessing to pain management decisions, and threatens penalties that include loss of DEA registration and banishment from Medicare/Medicaid. That will only give doctors and pharmacists more reasons to avoid dispensing these drugs, which for many patients are the only medicines available to control severe pain.

NO. 2: THE REVIEW PROCEDURES IN THE BILL DON'T CURE THIS PROBLEM

The bill was drafted by attorneys, not health professionals. Thus on paper the bill appears to protect from prosecution physicians and pharmacists who dispense large amounts of controlled substances to relieve pain. But the reality of how dispensing decisions are made is different. Physicians and pharmacists are deterred not just by DEA action but the mere threat of action. And the cost, time, logistics, stigma, and adverse publicity involved in being investigated by armed DEA agents will only add to their reasons for avoiding Schedule II drugs.

NO. 3: PHARMACIES AND HOSPITALS MUST PREDICT DOCTORS' INTENT AND WILL FORFEIT DISPENSING ALL CONTROLLED DRUGS IF THEY GUESS WRONG

The bill requires pharmacists in free-standing and hospital pharmacies to determine the physician's intended use of the medication prior to use. This is literally impossible. But the penalty for guessing wrong is draconian. Because pharmacies, rather than individual pharmacists, hold the DEA registration, the entire pharmacy could lose the ability to dispense all federally controlled drugs, not just the one in question. Fearing such an overwhelming loss, some pharmacists will refuse to fill prescriptions for large but needed doses of strong pain medications. Again, the patients will suffer.

NO. 4: THE DEA HAS LITTLE MEDICAL EXPERTISE AND VAGUE CRITERIA TO DETERMINE WHEN TO OPEN AN INVESTIGATION

The DEA recently testified before the Senate that if the bill passes, it will investigate doctors and pharmacists "on a case-by-case basis" and will consult standard medical texts to guide them in picking out suspects. The DEA stated it had little medical expertise in pain management. That was one reason cited by the U.S. Dept. of Justice, which sets overall federal law enforcement policy, in opposing the bill.

NO. 5: PATIENT AND FAMILY PRIVACY WILL BE INVADED THOUGH NO WRONGDOING HAS OCCURRED

To determine a physician's "intent" a DEA investigator must interview *grieving family members just after their loved one's death*. Some will be asked to reveal communications between the patient and his or her doctor which were meant to be confidential. The DEA may also subpoena medical records arguably protected by state medical privacy laws. Forcing the family to recount the final days of a loved one's death in this manner is an unconscionable intrusion into the family grieving process.

All of this will interfere with the mandate under federal law for hospices to assist surviving family members with bereavement services. A subsequent ruling by the DEA finding the doctor innocent will not undo the emotional harm the investigation caused the family.

NO. 6: THE BILL WILL NOT STOP SUICIDES, AND WILL INSTEAD HAVE THE PERVERSE EFFECT OF INCREASING REQUESTS FOR ASSISTED SUICIDE

Numerous medical experts have testified how easily a physician could circumvent this law and still assist a suicide by prescribing a non-controlled substance, an over-the-counter drug, or a common chemical like carbon monoxide (which Jack Kevorkian uses). Thus the bill won't achieve its goal.

In fact, it will increase the demand for assisted suicide because it will reduce the use of the strongest class of pain-relieving drugs available to the seriously ill: narcotics and opioid analgesics.

NO. 7: THIS BILL IGNORES THE ROOT CAUSES AND POTENTIAL SOLUTIONS FOR REDUCING THE DEMAND FOR ASSISTED SUICIDE

This bill totally fails to attack the underlying reasons why patients request help in committing suicide in the first place. Exhaustive research shows that patients commit suicide for several reasons. Chief among them are severe and chronic pain, depression, fear of being a burden, and no access to palliative and hospice care. The undertreatment of pain in the U.S. has been repeatedly documented yet persists for a host of reasons: lack of medical training, an antiquated fear of addiction, concern about regulatory oversight, lack of routine pain assessments, and misunderstandings about side effects. This bill does nothing to attack these admittedly huge and complex problems.

NO. 8: STATE MEDICAL AND PHARMACY BOARDS ALREADY FULLY REGULATE THE UNAUTHORIZED USE OF CONTROLLED SUBSTANCES

All 50 states license physicians and pharmacists. All 50 states have boards of medical experts to review and discipline practitioners who violate state law, the standards of medical practice, licensing requirements, and ethics codes. This includes dispensing of controlled substances. In 45 states, physician assisted suicide is already clearly prohibited by law. In four other states, physician assisted suicide remains a violation of state medical board provisions. Thus in 49 states this bill is completely redundant. But in an effort to overturn the recent voter referendum in Oregon, Congress wants to add a new and unnecessary layer of bureaucracy on medical practice in all 50 states.

NO. 9: HOW TO ELIMINATE THE DEMAND FOR PHYSICIAN ASSISTED SUICIDE IS TOO COMPLEX AND IMPORTANT A QUESTION TO RUSH A BILL THROUGH IN 4 WEEKS

As this is written, Congress has only four weeks left in the 1998 session. Deciding how to address the many underlying causes behind why seriously ill Americans ask for assistance in committing suicide is an important and complex policy question. Trying to answer that question with a hastily-drafted three page bill is short-sighted and short-changes the millions of Americans suffering from pain.

Prepared by:
The National Hospice Organization
Dept. of Government Relations
1901 N. Moore St. - Suite 901
Arlington, VA 22209
703-294-4435

8/17/98

THE NEED FOR LEGAL CLARIFICATION: USING FEDERALLY REGULATED DRUGS TO ASSIST SUICIDES

- On November 5, the day after Oregon voted to retain its law allowing physician-assisted suicide, the U.S. Drug Enforcement Administration stated that the federal Controlled Substances Act still forbids doctors to prescribe controlled substances (morphine, barbiturates, etc.) for the purpose of assisting a suicide, because current federal law does not authorize deliberately causing a patient's death as a "legitimate medical purpose" for such drugs (see 21 CFR §1306.04).

- DEA Administrator Thomas K. Constantine issued this interpretation in response to an inquiry from the chairmen of the House and Senate Judiciary Committees (Rep. Henry Hyde and Sen. Orrin Hatch).

- Mr. Constantine's answer is the only responsible answer under current law. The Controlled Substances Act holds that physicians may lose their federal license to prescribe controlled substances if they use these drugs for something other than a "legitimate medical purpose." The American Medical Association, World Medical Association, and the laws of the other 49 states do not recognize assisted suicide as a legitimate medical procedure. The Assisted Suicide Funding Restriction Act signed by President Clinton last April forbids any federal health program or facility to treat assisted suicide as a medical procedure. To authorize use of federally regulated drugs to assist suicides as part of medical practice is a bizarre aberration in the law.

- Oregon officials have attacked the DEA policy on the grounds of "states' rights." But the Controlled Substance Act provides a uniform national standard for the control of potentially dangerous drugs, and a system of enforcement and penalties that is independent of state law. The DEA did not forbid Oregon to drop its own state penalties against assisting a suicide -- it simply said that **Oregon cannot unilaterally rescind this separate federal law.**

- Nevertheless, on June 5, 1998, U.S. attorney general Janet Reno reversed the DEA's policy and announced that federal drug laws establish no policy against assisted suicide. She said the DEA may only penalize physicians who assist suicides in violation of state laws -- including Oregon physicians who assist suicides of people who are ineligible for death under Oregon law. This ruling distorted the purpose and history of the Controlled Substances Act, and disregarded letters from 169 House members and 37 Senators urging Ms. Reno to uphold the DEA policy.

- The legal effect of reinstating Mr. Constantine's original interpretation of November 1997 would be quite limited. It would not require any specific enforcement activity, and indeed would not require that a physician lose his or her DEA registration if he or she has used a controlled substance to assist a suicide. Even if a particular misuse of controlled substances is seen as a threat to "public health and safety," for example, this is one factor that must be weighed against others in determining whether a registration is revoked or retained. Thus Mr. Constantine said in November 1997 that "DEA must examine the facts on a case-by-case basis" to determine whether a physician's unauthorized use of controlled substances merits a penalty. But such a provision would ensure that even as discussion continues on a more comprehensive federal approach to the issues of assisted suicide and palliative care, the federal government in the meantime is **not actively facilitating assisted suicides in Oregon by endorsing the killing of patients as a "legitimate" medical practice.**

MEMORANDUM

TO: Jonathan Schwartz

June 4, 1998

FR: Chris Jennings

RE: Outstanding Qs & As vis a vis assisted suicide

cc: Gregory King, Gary Grindler, and Joe Graupensterger

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

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

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

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

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

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

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

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

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

OREGON ASSISTED SUICIDE Q&As

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

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

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

Q. Does the DEA agree with this decision?

A. Yes.

Q. Did the White House review this decision?

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

Q. Is that unusual?

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

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

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

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

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

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

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

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

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

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

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

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

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

THE WHITE HOUSE

WASHINGTON

To : Bruce Reed

From : Sarah Wilson

Re : Proposed bill to amend Controlled
Substances Act to create safe harbor
for physicians providing palliative
care who permitting assisted
suicide ("Pain Relief Promotion Act of
1999")

Eldre Acheson from DOJ asked me
to pass along the attached DOJ views
letter on the above-referenced bill.
She wants to make sure that it
doesn't run afoul of WH policy
on assisted suicide. Please
call when you get a chance to discuss
or have someone on your staff call.
Thanks- Sarah Wilson 6-2144

Don wants to send
CBO letter w/ or without
our comments by 10/15.

1/0

I have many comments

PHOTOCOPY
PRESERVATION



U.S. Department of Justice

Office of Legislative Affairs

CURIS

need to have statement

Office of the Assistant Attorney General

Washington, D.C. 20530

EXPLICITLY opposing

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

(301)

480 2255

LD Atcherson
Brian Hofstad
Jane Horvath
David Horowitz
Patrick
Sarah Wilson

Dear Mr. Chairman:

Jane → AMA
on provider groups

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.

Stephanie?

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

Comments
EARLY Monday

supposed to be marked up next week;
not asked to submit a views
letter, but we did anyway.
affirmatively go out & oppose —?

DOJ says no; b/c supportive
of palliative care part. enough ambiguity
about the bill that it's not worth opposing.
Nickles ~~in~~ staff is nervous that palliative
care provision provides cover for as. &
they see the CSA provisions as the necessary
hook. would we issue a SAP? try to make
sure that palliative care provisions are
strong.

"although strong concerns, we do not
oppose."
Where Wyden is? Chris doesn't want
to explicitly talk
about FDA in this
letter.

not ambiguity to Ag authority →
operate state laws.

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

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).

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

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

² 21 U.S.C. § 823 (emphasis added).

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

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

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 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).

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 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

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

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

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.

this #
toned
down.

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 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

from Congress to State legislatures).

⁹ See Assisted Suicide Funding Restriction Act (1997).

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

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

should stay its hand to allow reasonable legislative consideration [of this difficult issue]").



Office of the Attorney General
Washington, D.C. 20530

June 5, 1998

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

Dear Mr. Chairman:

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

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

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

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

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

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

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

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

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

Finally, notwithstanding our interpretation of the CSA as it applies to the Oregon Act, it is important to underscore that the President continues to maintain his longstanding position against assisted suicide and any Federal support for that procedure. This position was recently codified when he signed the Assisted Suicide Funding Restriction Act last year. While states

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ordinarily have primary responsibility for regulating physicians, the President and the Administration nonetheless remain open to working with you and other interested members of Congress on this complex but extremely important issue.

Sincerely,

A handwritten signature in cursive script, appearing to read "Janet Reno".

Janet Reno

cc: The Honorable Patrick J. Leahy, Jr.
Ranking Minority Member

HR 2260 IH

106th CONGRESS

1st Session

H. R. 2260

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

IN THE HOUSE OF REPRESENTATIVES

June 17, 1999

Mr. HYDE (for himself, Mr. STUPAK, Mr. ADERHOLT, Mr. BAKER, Mr. BALLENGER, Mr. BARCIA, Mr. BARTON of Texas, Mr. BLUNT, Mr. BRYANT, Mr. BURR of North Carolina, Mr. BURTON of Indiana, Mr. CANADY of Florida, Mr. CHABOT, Mr. COBURN, Mr. COLLINS, Mr. CUNNINGHAM, Mr. DICKEY, Mr. DOOLITTLE, Mr. DOYLE, Mrs. EMERSON, Mr. EVERETT, Mr. FOSSELLA, Mr. GRAHAM, Mr. GOODE, Mr. GOODLATTE, Mr. HALL of Texas, Mr. HAYES, Mr. HERGER, Mr. HOEKSTRA, Mr. HUTCHINSON, Mr. ISTOOK, Mr. JOHN, Mr. KING, Mr. KNOLLENBERG, Mr. LAFALCE, Mr. LAHOOD, Mr. LARGENT, Mr. LEWIS of Kentucky, Mr. LUCAS of Kentucky, Mr. LUCAS of Oklahoma, Mr. MCINTYRE, Mr. MILLER of Florida, Mrs. MYRICK, Mr. NUSSLE, Mr. NETHERCUTT, Mr. PETERSON of Pennsylvania, Mr. PETERSON of Minnesota, Mr. PHELPS, Mr. PICKERING, Mr. PITTS, Mr. PORTMAN, Mr. RAHALL, Mr. ROGAN, Mr. ROGERS, Mr. SALMON, Mr. SCHAFER, Mr. SENSENBRENNER, Mr. SHIMKUS, Mr. SHOWS, Mr. SKELTON, Mr. SMITH of Texas, Mr. SMITH of New Jersey, Mr. SPENCE, Mr. STEARNS, Mr. TANCREDO, Mr. TERRY, Mr. WALSH, Mr. WAMP, and Mr. WELDON of Florida) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, 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

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:

“(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 section:

‘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 upon the date of the enactment of this Act, whichever occurs later.

END

Bill Summary & Status for the 106th Congress

NEW SEARCH | HOME | HELP | ABOUT STATUS

H.R.2260

SPONSOR: Rep Hyde, Henry J. (introduced 06/17/99)

STATUS: Detailed Legislative Status

House Actions

Jun 17, 99:

Referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, 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.

Referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, 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.

UNITED STATES CODE ANNOTATED
TITLE 21. FOOD AND DRUGS
CHAPTER 13--DRUG ABUSE PREVENTION AND CONTROL
SUBCHAPTER I--CONTROL AND ENFORCEMENT
PART C--REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF
CONTROLLED SUBSTANCES

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Current through P.L. 105-394, approved 11-13-1998

§ 823. Registration requirements

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

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(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he

practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications

Practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(1) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(2) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (A) security of stocks of narcotic drugs for such treatment, and (B) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(3) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under section 802(39)(A)(iv) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider--

- (1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than

legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

CREDIT(S)

1981 Main Volume

(Pub.L. 91-513, Title II, § 303, Oct. 27, 1970, 84 Stat. 1253; Pub.L. 93-281, § 3, May 14, 1974, 88 Stat. 124; Pub.L. 95-633, Title I, § 109, Nov. 10, 1978, 92 Stat. 3773.)

1999 Pocket Part

(As amended Pub.L. 98-473, Title II, § 511, Oct. 12, 1984, 98 Stat. 2073; Pub.L. 103-200, § 3(c), Dec. 17, 1993, 107 Stat. 2336.)

HISTORICAL AND STATUTORY NOTES

References in Text

Schedules I, II, III, IV, and V, referred to in text, are set out in § 812(c) of this title.

1993 Amendments

Subsec. (h). Pub.L. 103-200, § 3(c), added subsec. (h).

1984 Amendment

Subsec. (f). Pub.L. 98-473, substituted provisions relating to registration authority of Attorney General respecting dispensation or conduct of research with controlled substances and separate authority of Secretary respecting registration, for provisions relating to general registration requirements respecting dispensation or conduct of research with controlled or nonnarcotic controlled substances.

1978 Amendment

Subsec. (f). Pub.L. 95-633 added provision relating to the construction of the Convention on Psychotropic Substances.

1974 Amendment

Subsec. (g). Pub.L. 93-281 added subsec. (g).

Effective Date of 1993 Amendments

Amendment to this section by Pub.L. 103-200, to take effect on the date that is 120 days after the date of enactment of Pub.L. 103-200, which was approved Dec. 17, 1993, see section 11 of Pub.L. 103-200, set out as a note under section 802 of this title.

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Effective Date of 1978 Amendment

Amendment by Pub.L. 95-633 effective on the date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see § 112 of Pub.L. 95-633, set out as an Effective Date note under § 801a of this title.

Effective Date

Section effective the first day of the seventh calendar month that begins after the day immediately preceding Oct. 27, 1970, see § 704(a) of Pub.L. 91- 513, set out as an Effective Date note under § 801 of this title.

Provisional Registration

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of § 822 of this title who are registered on such date under § 360 of this title or former § 4722 of Title 26, see § 703 of Pub.L. 91-513, set out as a note under § 822 of this title.

Legislative History

For legislative history and purpose of Pub.L. 91-513, see 1970 U.S.Code Cong. and Adm.News, p. 4566. See, also, Pub.L. 93-281, 1974 U.S.Code Cong. and Adm.News, p. 3029; Pub.L. 95-633, 1978 U.S.Code Cong. and Adm.News, p. 9496.

For legislative history and purpose of Pub.L. 98-473, see 1984 U.S. Code Cong. and Adm. News, p. 3182. See, also, Pub.L. 103-200, 1993 U.S. Code Cong. and Adm. News, p. 2983.

21 U.S.C.A. § 823

21 USCA § 823

END OF DOCUMENT

UNITED STATES CODE ANNOTATED
TITLE 21. FOOD AND DRUGS
CHAPTER 13—DRUG ABUSE PREVENTION AND CONTROL
SUBCHAPTER I—CONTROL AND ENFORCEMENT
PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF
CONTROLLED SUBSTANCES

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Current through P.L. 105-394, approved 11-13-1998

§ 824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant--

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of Title 42.

A registration pursuant to section 823(g) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g) of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) Service of show cause order; proceedings

Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of Title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this

subchapter or any other law of the United States.

(d) Suspension of registration in cases of imminent danger

The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(e) Suspension and revocation of quotas

The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 826 of this title.

(f) Disposition of controlled substances or list I chemicals

In the event the Attorney General suspends or revokes a registration granted under section 823 of this title, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 881(e) of this title. All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

(g) Seizure or placement under seal of controlled substances or list I chemicals

The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance or list I chemical seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

CREDIT(S)

1981 Main Volume

(Pub.L. 91-513, Title II, § 304, Oct. 27, 1970, 84 Stat. 1255; Pub.L. 93-281, § 4, May 14, 1974, 88 Stat. 125.)

1999 Pocket Part

(As amended Pub.L. 98-473, Title II, §§ 304, 512, 513, Oct. 12, 1984, 98 Stat. 2050, 2073; Pub.L. 100-93, § 8(j), Aug. 18, 1987, 101 Stat. 695; Pub.L. 103-200, § 3(d), Dec. 17, 1993, 107 Stat. 2337; Pub.L. 103-322, Title XXXIII, § 330024(e), Sept. 13, 1994, 108 Stat. 2151.)

HISTORICAL AND STATUTORY NOTES

References in Text

"This subchapter", referred to in subsecs. (a)(1), (2), and (c), was in the original "this title" which is Title II of Pub.L. 91-513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the "Controlled Substances Act". For complete classification of Title II to the Code, see Short Title note set out under § 801 of this title and Tables.

"Subchapter II of this chapter", referred to in subsec. (a)(1), (2), was in the original "title III", meaning Title III of Pub.L. 91-513, Oct. 27, 1970, 84 Stat. 1285. Part A of Title III comprises subchapter II of this chapter. For classification of Part B, consisting of §§ 1101 to 1105 of Title III, see Tables.

1994 Amendments

Subsec. (g). Pub.L. 103-322, § 330024(e), inserted "or chemical" after "such substance".

1993 Amendments

Subsec. (a). Pub.L. 103-200, § 3(d)(1), inserted "or a list I chemical" following "controlled substance" wherever appearing, and inserted "or list I chemicals" following "controlled substances".

Subsec. (b). Pub.L. 103-200, § 3(d)(2), inserted "or list I chemical" following "controlled substance".

Subsec. (f). Pub.L. 103-200, § 3(d)(3), inserted "or list I chemicals" following "controlled substances" wherever appearing.

Subsec. (g). Pub.L. 103-200, § 3(d)(4), inserted "or list I chemicals" following "controlled substances" wherever appearing, and inserted "or list I chemical" following "controlled substance" wherever appearing.

1987 Amendment

Subsec. (a)(5). Pub.L. 100-93 added par. (5).

1984 Amendment

Subsec. (a)(3). Pub.L. 98-473, § 512(1), added provisions relating to suspension, etc., recommended by competent State authority.

Subsec. (a)(4). Pub.L. 98-473, § 512(2), added subsec. (a)(4).

Subsec. (f). Pub.L. 98-473, § 304, added provisions relating to vesting of right, title, and interest in the United States.

Subsec. (g). Pub.L. 98-473, § 513, added subsec. (g).

1974 Amendment

Subsec. (a). Pub.L. 93-281, § 4(a), provided for revocation or suspension of a registration pursuant to § 823(g) of this title for failure of a registrant to comply with standards referred to in such § 823(g).

Subsec. (d). Pub.L. 93-281, § 4(b), added provisions relating to treatment as grounds for immediate suspension of registration the failure to comply with a standard referred to in § 823(g), and substituted "A suspension under this subsection" for "Such suspension".

Effective Date of 1994 Amendments

Amendment by Pub.L. 103-322 effective 120 days after Dec. 17, 1993, see section 330024(f) of Pub.L. 103-322,

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set out as a note under section 802 of this title.

Effective Date of 1993 Amendments

Amendment to this section by Pub.L. 103-200, to take effect on the date that is 120 days after the date of enactment of Pub.L. 103-200, which was approved Dec. 17, 1993, see section 11 of Pub.L. 103-200, set out as a note under section 802 of this title.

Effective Date of 1987 Amendment

Amendment by Pub.L. 100-93 effective at the end of the fourteen-day period beginning on Aug. 18, 1987, and inapplicable to administrative proceedings commenced before the end of such period, see section 15(a) of Pub.L. 100-93, set out as a note under section 1320a-7 of Title 42, the Public Health and Welfare.

Effective Date

Section effective the first day of the seventh calendar month that begins after the day immediately preceding Oct. 27, 1970, see § 704(a) of Pub.L. 91- 513, set out as an Effective Date note under § 801 of this title.

Provisional Registration

Applicability of this section to provisional registrations, see § 703 of Pub.L. 91-513, set out as a note under § 822 of this title.

Legislative History

For legislative history and purpose of Pub.L. 91-513, see 1970 U.S. Code Cong. and Adm. News, p. 4566. See, also, Pub.L. 93-281, 1974 U.S. Code Cong. and Adm. News, p. 3029.

For legislative history and purpose of Pub.L. 98-473, see 1984 U.S. Code Cong. and Adm. News, p. 3182. See, also, Pub.L. 100-93, 1987 U.S. Code Cong. and Adm. News, p. 682; Pub.L. 103-200, 1993 U.S. Code Cong. and Adm. News, p. 2983; Pub.L. 103-322, 1994 U.S. Code Cong. and Adm. News, p. 1801.

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**CODE OF FEDERAL REGULATIONS
TITLE 21--FOOD AND DRUGS
CHAPTER II--DRUG ENFORCEMENT
ADMINISTRATION, DEPARTMENT OF
JUSTICE**

**PART 1306--PRESCRIPTIONS
GENERAL INFORMATION**

Current through June 1, 1999; 64 FR 29522

§ 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be

subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for "detoxification treatment" or "maintenance treatment" as defined in Section 102 of the Act (21 U.S.C. 802).

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974]

< General Materials (GM) - References, Annotations,
or Tables >

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