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Assisted Suicide [1]

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Assisted Suicide [1]

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Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Assisted suicide

DRAFT - NOT FOR RELEASE

September 11, 1998
(House)

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

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

Pay-As-You-Go Scoring

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

(Do Not Distribute Outside Executive Office of the President)

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

OMB/LA Clearance: _____

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

Background

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

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

Summary of H.R. 4006

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

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

Pay-As-You-Go Scoring

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

LEGISLATIVE REFERENCE DIVISION DRAFT
September 11, 1998 - 11:00 a.m.



NEWS

News from The Oregonian Sept. 25, 1998

Senate panel OKs suicide ban

Sen. Don Nickles, R-Okla., pushes to nullify Oregon's assisted-suicide law before Congress adjourns, but even allies prefer to hold off and have a thorough debate

Friday, September 25 1998

By Jim Barnett and Dave Hogan of the Oregonian staff

Suicide: Possible 'chilling effect' on doctors is a concern

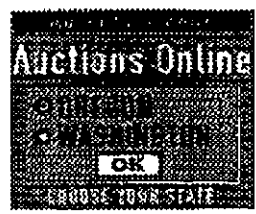
WASHINGTON -- A bill that would block Oregon's physician-assisted suicide law cleared the Senate Judiciary Committee on Thursday. But many who voted in favor said they hoped Congress would proceed slowly and cautiously.

"I will vote to move this process along for now, but I have serious reservations about this bill," Sen. Mike DeWine, R-Ohio, said before the vote. "We need to consider the intended consequences as well as the unintended consequences."

The bill, sponsored by Sen. Don Nickles, R-Okla., would prohibit doctors from prescribing lethal doses of pain-killing drugs to deathly ill patients. It passed 11-6, encouraging Nickles to push for a quick vote by the full Senate.

"It is my intention to help the Senate pass this important bill before we adjourn" on Oct. 9, said Nickles, assistant majority leader and the Senate's No. 2 Republican.

But Judiciary Committee Chairman Orrin Hatch, R-Utah, and other committee members said the full Senate is unlikely to vote on the legislation before next year because of time constraints and procedural roadblocks.



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Several members, including some of the Republicans who supported the bill, had bigger concerns as well.

During a chaotic work session in a crowded Capitol anteroom, some members echoed doctors' objections. Doctors have said the prospect of investigation by federal drug agents would prevent them from prescribing sufficient doses of pain-killing drugs for patients facing death.

In a telling exchange, Sen. Arlen Specter, R-Pa., told Hatch that he had concerns about this "chilling effect" on doctors. Quietly, Hatch replied, "I do, too. I do, too."

Specter then gave Hatch his proxy to vote for the bill. But before leaving the work session, he told the chairman, "I want to make the record explicit that I will oppose it on the Senate floor."

The hourlong debate reached an emotional peak when Sen. Dianne Feinstein, D-Calif., told the committee that several people close to her, including her father and her second husband, required palliative care before dying of cancer.

"I don't think this does a whit for retarding assisted suicide," Feinstein said. "I do sincerely believe that this is going to retard prescribing for terminally ill, deeply suffering patients."

"You may be right," said Hatch, an ardent opponent of assisted suicide.

The bill that passed the Judiciary Committee, in fact, was a version of the Nickles bill that Hatch amended in hopes of allaying doctors' concerns. Among other things, the amended bill would:

- : Increase the prosecutor's burden of proof to show "clear and convincing evidence" that a doctor prescribed medication intended to assist in a suicide.
- : Include officials from the Department of Health and Human Services as part of an advisory board to the Drug Enforcement Administration, with which doctors must register to prescribe certain

drugs.

• Make the bill effective only after the date of enactment, meaning that doctors who participated in an assisted suicide or euthanasia prior to the bill's passage would not be penalized.

In an interview after the Thursday meeting, Hatch said he regarded his version of the bill as an improvement. But he also said he did not consider it to be "the last word."

"We're going to keep our minds open and see what we can do to make sure it's perfected as much as we can," he said. "Anybody can stop any bill right now on the floor . . . and I suspect that unless we have more of a bipartisan consensus, it will be stopped."

Under Senate rules, any member can prevent a floor vote on a bill or nomination by placing it under a procedural "hold." Shortly after the Judiciary Committee voted, Sen. Ron Wyden, D-Ore., did just that, denouncing the Judiciary Committee's vote in a floor speech.

Wyden said he would ensure that the Senate gives the issue of assisted suicide its full attention rather than push through a bill with little debate. But he also said that he was overmatched by Republican leaders who pressed for support in the Judiciary Committee and could easily pass the bill by adding it to other legislation.

"I think certainly Senator Nickles is busily looking for vehicles to attach it to this year," Wyden said. "We're going to have to be vigilant to be sure this isn't going to be railroaded through."

Sen. Gordon Smith, R-Ore., said he and Hatch had discussed the bill and concluded that they shared a dilemma: Both would rather go slowly but would support Nickles' bill if pressed.

"I have had long talks with Senator Hatch now, and I think he is trying to be sensitive to the complexities involved," Smith said. "But like Senator Hatch, if you push me to vote, I cannot as a matter of personal conscience vote to kill people in these circumstances."

The debate about assisted suicide has come to a head in Congress in the past two weeks, thanks to an end-of-session push by Republican leaders, including Nickles and Rep. Henry Hyde, R-Ill., the House Judiciary chairman.

Hyde began turning up the heat on the assisted suicide issue in early June, when he introduced a bill that served as the model for Nickles' proposal. The Hyde bill has been awaiting a floor vote since Sept. 17.

But in the House, some members also have had second thoughts about moving too quickly on an issue that many have not had to confront and know little about. Opponents of the Hyde bill think they have raised enough questions to delay a vote at least until next year.

In the Senate, Smith said caution and further study would be a better course. Now, he just has to convince Republican leaders.

"I think perhaps some in leadership can be accused of pushing it too fast," Smith said. "But I think with the passing of time, many are seeing the complexity and the shades of gray in this issue and want to think it through."

Assisted-suicide activists in Oregon continue to watch the issue in Congress.

Barbara Coombs Lee, executive director of the Compassion in Dying Federation and a co-author of Oregon's law, was buoyed by Hatch's prediction that the bill is not likely to be voted on this year.

"When the chair of the committee that considered the bill says that essentially he doesn't support it, I think that sends a strong message that this is a bad piece of legislation," Lee said.

But Gayle Atteberry, executive director of Oregon Right to Life, said she thinks the mission of stopping assisted suicide has not been derailed.

"I am quite positive they will work something out at some point," Atteberry said. "I'm really not dismayed at all."

HealthMATTERS

health - have health care
and
health - avoided suicide

Fighting Medicare Fraud: Easier Said Than Done

By Julie Rovner

■ IT SOUNDS SO EASY. Just get rid of the fraud in Medicare and we could save as much as 10 percent of the massive program's annual spending, auditors say. But in practice, it always seems to get messy.

A case in point is the fix Congress now finds itself in over Medicare's home health benefit. Long near the top of the Medicare fraud and abuse rogues' gallery, Congress took tough steps in the 1997 Balanced Budget Act to bring home health spending back in line.

But cracking down on the bad guys always seems to hurt good guys, too. For example, Congress originally required home health agencies to post "surety bonds" to prevent fly-by-night agencies from setting up shop, collecting a lot of money and skipping town. But almost immediately agencies began complaining that the bonds were too expensive or too difficult to obtain. Congress and the Health Care Financing Administration quickly backed down on the surety bond requirement.

Now the problem is the new payment system the 1997 act imposed. What was supposed to be a temporary system, to be replaced with a "prospective payment" system similar to how Medicare pays hospitals, now may have to stay in place longer — thanks to HCFA's year 2000 computer problems. But the "Interim Payment System," which bases payment on 1994 spending, penalizes those who acted efficiently back then, particularly if they are now serving sicker patients.

There is significant dispute over just how bad the situation is — whether only a few hundred agencies have closed their doors, or 1,200 as the industry's trade group, the National Association for Home Care contends. But home care has indisputably become a political problem. Most members of both the House and Senate have cosponsored at least one of more than a dozen bills to alter the payment system, and last week a demonstration on the Capitol's West Front featured a 2 1/2-mile long petition urging the payment system be fixed.

The bipartisan members who wrote the health section of the BBA have tried — unsuccessfully — to head off changes that would again encourage open-ended spending on home health care. The same day as the demonstration, they issued a CBO estimate that going back to the old payment system would cost more than \$20 billion over five years. But on Tuesday, those same members of the Ways and Means Health Subcommittee unanimously approved a bill that would add back at least \$1.4 billion in home health payments. And given that it is an election year with a key element of a popular program in peril, that may just represent an opening offer.

■ THE RIFT BETWEEN THE American Medical Association and the congressional GOP leadership continues to widen. Formerly among Republicans' most loyal and generous backers, the AMA has of late been in an ugly war of words with the joint Republican leadership over physicians' endorsement of the Democratic-backed "Patients' Bill of Rights."

Now, organized medicine for the second time this year is opposing a bill being pushed by Republicans at the behest of social conservatives. Back in February, medical groups, the AMA among them, helped block legislation to ban the cloning of humans. The problem with that bill was not its intent — virtually the entire medical community opposes the idea of cloning a human, at least at this point — but rather its potential for "collateral" damage; i.e., inadvertently banning more than cloning.

That is the situation with the Lethal Drug Abuse Prevention Act. The bill, which could reach the House floor as early as today, would make it illegal for physicians to prescribe drugs on the federal government's list of controlled substances for the purpose of assisting in a suicide. Intended at the moment to override Oregon's landmark "Death With Dignity Act," the measure is also an effort by groups opposing assisted suicide to nip the legalization movement in the bud.

But physician groups — led by the AMA — that oppose assisted suicide also oppose the bill. One problem, they say, is that legal controlled substances, including barbiturates and opiate painkillers, are not the only way to assist in a suicide. Assisted suicide physician Jack Kevorkian, for example, has used carbon monoxide — not even a drug, much less a controlled one.

But the heart of the medical community's opposition is survey after survey has shown that many terminal patients die in needless pain because doctors are loathe to prescribe adequate medication. They say the specter of an investigation by the Drug Enforcement Administration is not going to make physicians more likely to use appropriate means to control pain — and could, ironically, make assisted suicide more attractive to the terminally ill.

"We fear the 'real world' consequences of the bill would be to discourage the kind of appropriate aggressive palliative care that can dissuade patients in pain from seeking just such an early death," AMA President-elect Thomas Rendon told the House Judiciary Committee this summer. If the bill is passed, he said, "Recent promising advancements in the care of people at the end of life could be set back dramatically, to the detriment of patient care."

— HEALTHMATTERS CAN BE REACHED BY E-MAIL AT: JROVNER@NJDC.COM

NEW INSERT FOR 2nd PARAGRAPH. (This would be added onto the 3rd paragraph.)

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 H.R. 4006 represents a flawed approach to the Federal regulation of medicine. We are particularly concerned that the insertion of the Drug Enforcement Agency (DEA) into the role of overseer of the practice of the medicine would inevitably divert agency attention away from the core mission of strictly controlling Schedule I drugs and preventing the diversion of and trafficking in all scheduled drugs.

Determination of whether... (Start new paragraph here)

cj

Assisted suicide

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Determination of whether... (Start new paragraph here)

cj

Assisted suicide**U. S. Department of Justice****Office of Legislative Affairs**

Office of the Assistant Attorney General

Washington, D.C. 20530

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

Dear Mr. Chairman:

As the Committee prepares to consider H.R. 4006, as amended by the Subcommittee on the Constitution, I write to provide the views of the Department of Justice on this bill. We appreciate this opportunity to provide comments and look forward to working with you as the bill progresses through the legislative process.

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 H.R. 4006 represents a flawed approach to the sensitive area of Federal regulation of medicine. We are particularly concerned that the insertion of the Drug Enforcement Agency (DEA) into the role of overseer of the practice of medicine would inevitably divert agency attention away from the core mission of strictly controlling Schedule I drugs and preventing the 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 H.R. 4006 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. 2(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. 2(a), stating a new basis for action against a practitioner's registration under § 824(a)(4), and Sec. 2(c), setting forth the

responsibility of the new "Medical Advisory 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. 3, 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, s.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 ..."

Thank you for this opportunity to provide comments. The Office of Management and Budget has advised that there is no objection from the standpoint of the Administration's program to presentation of this report.

Sincerely,

Anthony L. Sutin
Acting Assistant Attorney General

cc: The Honorable John Conyers, Jr.
Ranking Minority Member



U.S. Department of Justice

002

Office of Legislative Affairs

Assisted suicide

Office of the Assistant Attorney General

Washington, D.C. 20530-0001

Draft

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

Dear Mr. Chairman:

As the Committee prepares to consider H.R. 4006, I write to provide the views of the Department of Justice on this bill. We appreciate this opportunity to provide comments and look forward to working with you as the bill progresses through the legislative process.

While this Administration remains opposed to assisted suicide and any Federal support for that procedure, and is open to working with you and other interested members of Congress on this complex but extremely important issue, we are concerned that this bill represents a dangerous foray -- with unpredictable results -- into the federal regulation of the practice of medicine. States, not the Federal Government, are the primary regulators of the health professions; regulation of controlled substances, by virtue of their interstate impact, is a shared federal-state responsibility. The Controlled Substances Act (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. The fact that the citizens of one state have taken the controversial initiative to legalize, within narrow confines, the practice of physician-assisted suicide, should not be leveraged into an invitation for federal overreaching into an area traditionally and properly reserved to the states.

We are further concerned that insertion of DEA into this novel role would inevitably divert agency attention and resources away from the core mission of strictly controlling Schedule I drugs and preventing the 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 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 H.R. 4006 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. 2(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.

- 3 -

There is an apparent inconsistency between Sec. 2(a), stating a new basis for action against a practitioner's registration under § 824(a)(4), and Sec. 2(c), setting forth the responsibility of the new "Medical Advisory 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.

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Finally, in Sec. 3, 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 Senator Wyden, 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 . . . "

Thank you for this opportunity to provide comments. The Office of Management and Budget has advised that there is no objection from the standpoint of the Administration's program to presentation of this report.

Sincerely,

Anthony L. Sutin
Acting Assistant Attorney General

cc: The Honorable John Conyers, Jr.
Ranking Minority Member

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.

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.**

Jonathan Schmitz

514-9308

Fx

Joe G

305-2643

Greg King
514-5331

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.

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Assisted suicide

THE PRESIDENT HAS SEEN
5-20-98

THE WHITE HOUSE

WASHINGTON

May 18, 1998

MEMORANDUM FOR THE PRESIDENT

FROM: PHIL CAPLAN *Phil*

SUBJECT: Assisted Suicide Legislation

*Concur
DOJ/HHS
Garcia
Ruff
POSITIVE*

*copied
Reed
Ruff
LOS
Kagan*

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

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

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

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

Option 1 Option 2 Option 3 (recommended) Discuss

THE WHITE HOUSE
WASHINGTON

May 11, 1998

MEMORANDUM TO THE PRESIDENT

FROM: Bruce Reed
Charles Ruff

SUBJECT: Assisted Suicide Legislation

The Justice Department has determined that the Drug Enforcement Administration (DEA) has no authority under the Controlled Substances Act (CSA) to take adverse action against physicians who assist patients in ending their lives by prescribing controlled substances pursuant to Oregon's "Death with Dignity Act." The Department conducted its legal analysis in response to letters sent by Senator Hatch and Congressman Hyde urging the Department, through DEA, to invoke the CSA against physicians who assist in patient suicide under the Oregon law.

The Justice Department has completed draft letters to Congressman Hyde and Senator Hatch explaining its legal conclusions. The letters will not be forwarded to Congress until we have developed a roll-out strategy, including a position on federal legislation prohibiting physician-assisted suicide.

As you will recall, the Catholic Health Association (CHA) has informed us that Hatch and Hyde are prepared to introduce legislation amending the CSA in the event the Attorney General concludes that the CSA does not authorize the DEA to pursue physicians who assist patients in committing suicide. They may even introduce this legislation before receiving the Department of Justice's opinion letter. In assessing the possible options for responding to Hatch's and Hyde's likely initiative, we held meetings within the White House and with the Departments of Justice and Health and Human Services (including the FDA).

Justice believes that the Administration should not support the Hatch/Hyde proposal. Justice thinks that DEA's approach to enforcing the narcotics laws is inconsistent with the kind of sensitivity that would be needed in pursuing doctors who are assisting terminally ill patients to commit suicide. Justice is also concerned with the resource drain on the DEA if that agency were tasked with enforcement duty. Justice also worries that this new task would damage DEA's relationship with the medical profession, on which it often relies in pursuing narcotics law violations.

The Justice Department also cites principles of federalism in support of its position against a legislative change. The federal government has deferred to the states as the primary regulators of the medical profession. Especially on such a hotly contested issue as assisted suicide, Justice believes there is good reason to continue this tradition of deference to local

decisionmaking.

HHS/FDA concurs with Justice's position, stressing especially the historic deference given to states in regulating the medical profession. HHS/FDA also worries that a new federal law authorizing the federal government to take adverse action against doctors who assist their patients to commit suicide would exacerbate the problem of physicians' underprescribing pain medications for terminally ill patients.

Your longstanding opposition to the practice of assisted suicide is not necessarily inconsistent with the agencies' positions. You could argue that assisted suicide is wrong, but that it is not a matter that should be handled by federal narcotics agents. Or more broadly, you could argue that it is not a matter to be dealt with by the federal government at all, but instead should be left to state and local decisionmaking. Nor is last year's "Assisted Suicide Funding Restriction Act" inconsistent with a refusal to support a legislative change. The Funding Restriction Act bans the use of federal funds to pay for or promote assisted suicide. Nothing in the Act authorizes the federal government to take adverse action against a private physician for assisting in a suicide in a non-federal facility.

We detail below four options for responding to the expected Hyde/Hatch initiative. These options are: (1) support the Hyde/Hatch legislation; (2) oppose the Hyde/Hatch DEA approach, but suggest openness to alternatives and work with Hatch and Hyde to develop a better bill; (3) engage in a "Kick the Can" strategy, suggesting openness to alternatives, but attempting to ensure that no congressional action is taken; and (4) oppose the Hyde/Hatch legislation outright.

1. **Endorse Hyde/Hatch Legislative Alternative.** After the Justice Department's legal interpretation is released, we could endorse the expected introduction of the Hatch/Hyde legislation authorizing the DEA to pursue criminal actions against physicians prescribing medications for assisted suicides.

Pros

- Appears consistent with your longstanding opposition to assisted suicide.
- Avoids inevitable conflict with the Congress, where the Hatch/Hyde legislation is likely to be popular.

Cons

- Conflicts with historic practice of allowing states to regulate the medical profession, and does so with regard to a hotly contested and emotional issue on which local decisionmaking may be particularly appropriate.

- Places authority to act against doctors in an agency ill-equipped to perform this function, in a way that could interfere with the agency's primary mission.
- Ignores danger, noted by many physicians' groups and even the Catholic Health Association, that a federal law of this kind will lead doctors to under-medicate terminally ill patients for fear of federal prosecution.

2. **Oppose Hatch/Hyde legislation, but suggest openness to alternatives.** Under this option, you would welcome the intent of the Hatch/Hyde bill, based on your longstanding opposition to assisted suicide, but raise concerns about using federal drug agents and resources to address this issue. You would advise Republicans of ways to implement the intent of their legislation in a more workable fashion, perhaps suggesting alternative enforcement agencies (such as FDA) or alternative enforcement mechanisms (such as reducing Federal support for Medicaid for states permitting assisted suicide). You would try seriously to find common ground with the Republicans on a workable legislative alternative to DEA enforcement.

Pros

- Appears consistent with your longstanding opposition to assisted suicide and shows that you are seriously concerned about this issue.
- Takes an approach that recognizes the problems with using DEA resources and agents to address this issue.

Cons

- Assumes that we can develop a workable alternative approach, when we may not be able to do so. For example, direct regulation of doctors through HHS/FDA also raises serious issues, and enforcement mechanisms directed toward states, such as reduction of Medicaid dollars, would raise widespread protests of federal micro-management and intrusion.
- Raises expectations that a legislative solution can be achieved, when it may be virtually impossible to reach consensus.

3. **"Kick the Can" Strategy.** Under this option, you would also express openness to addressing this issue through federal legislation, but rather than trying to reach agreement, you would attempt to forestall legislative action. You would try to delay long enough to allow the medical groups, states, and others to communicate that federal approaches in this area are ill-advised. These objections could make Congress conclude that it does not have time to draft thoughtful legislation this year.

Pros

- Allows you to reiterate your strong position against assisted suicide, while preventing problematic federal legislation.
- Provides sufficient time to air the many issues surrounding assisted suicide legislation, perhaps even educating physicians and the public about the problem of undermedicating terminally ill patients

Cons

- May make us look indecisive and weak.
- May be viewed with skepticism on the Hill and make us vulnerable to the charge that we are trying to have it both ways.

4. **Oppose Hatch/Hyde legislation outright.** Under this option, you would tell the Hill that, although you believe that assisted suicide is immoral, you cannot support legislation that intrudes on state responsibility over this issue and diverts limited law enforcement resources for this purpose.

Pros

- Takes a strong position consistent with agency views on the undesirability of federal legislation in this area: respects federalism principles; protects law enforcement priorities; and prevents further undermedication of patients due to physicians' fear of criminal prosecution.

Cons

- May appear inconsistent with your longstanding opposition to assisted suicide.
- Risks major confrontation with the Congress, which almost certainly will pass federal legislation over your objection.

The Departments of Justice and Health and Human Services support Option 4 and strongly oppose Option 1. Of the middle options, they would prefer Option 3 to Option 2. The Counsel's office agrees with the agencies: Chuck believes both that the DEA should not regulate medical practice and that federal legislation in this area conflicts with federalism principles. The DPC agrees that federal legislation in this area makes little sense, but believes that the "Kick the Can" strategy may be the best way to prevent it; the DPC therefore recommends Option 3.

ELIZABETH FURSE
1ST DISTRICT, OREGON
COMMITTEE:
COMMERCE
SUBCOMMITTEE ON
ENERGY AND POWER
SUBCOMMITTEE ON
HEALTH AND ENVIRONMENT
SUBCOMMITTEE ON
FINANCE AND HAZARDOUS MATERIALS

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House of Representatives
Washington, DC 20515-3701

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FAX NUMBER: (202) 225-9497
PHONE NUMBER: (202) 225-0855

Date: 5/15

To: Elena Kagan

From: Rep. Elizabeth Furse to Clerk Porter

Number of pages, including cover pages: 7

IF YOU DID NOT RECEIVE THIS TRANSMISSION IN ITS ENTIRETY OR IF YOU HAVE RECEIVED THIS TRANSMISSION IN ERROR, PLEASE CALL US IMMEDIATELY AT (202) 225-0855. THIS TRANSMISSION MAY INCLUDE CONFIDENTIAL INFORMATION AND IS INTENDED ONLY FOR THE INDIVIDUAL OR ENTITY NAMED ABOVE. ANY OTHER PERSON THAN THE INTENDED RECIPIENT (OR OTHERS AUTHORIZED BY THE INTENDED RECIPIENTS) IS PROHIBITED FROM READING, COPYING, OR DISTRIBUTING THIS TRANSMISSION.

COMMENTS:

Elena - Rep. Furse wanted you to have a copy of these letters we sent to my Deems. on the assisted suicide issue. Please give us a heads-up on any Administration activity on the issue. Ryback.

Congress of the United States

Washington, DC 20515

May 8, 1998

The Honorable John Conyers
 Ranking Member, Committee on the Judiciary
 2136 Rayburn HOB
 Washington, D.C. 20515

Also to:-

Frank
 Schumer
 Berman
 Archer
 Nadler

Scott
 Watt
 Lofgren
 J. D. Dingell
 Wicker
 Meekins
 Delahunt
 Wexler
 Rothman

Dear Mr. Conyers:

We are writing to ask your assistance in a matter that has profound legal implications for Oregon and our entire nation.

As you may know, the state of Oregon has twice passed by public referendum -- most recently with 60% of the vote -- the Death with Dignity Act (DDA). First passed in 1994, this statute has survived a plethora of legal and political challenges, including the U.S. Supreme Court's ruling to lift a legal injunction.

Within days of the second successful referendum, the Drug Enforcement Agency (DEA) issued an opinion which declared DEA Administrator Constantine's view that the DEA had the authority to prosecute doctors in Oregon who, in compliance with the DDA, prescribed drugs at the request of terminally ill patients. This opinion is contrary to the traditional incorporation of state and community medical standards into state medical practice regulations. Immediately following the issuance of the DEA's opinion, Attorney General Janet Reno announced a Justice Department review of that opinion. It is not certain when that ruling will take place.

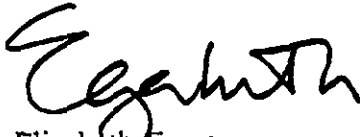
Regardless of the timing or substance of the Attorney General's ruling, we are concerned that later this year Chairman Hyde and Chairman Hatch will introduce legislation to undermine or overturn the DDA and force a vote on this issue in Congress. It seems wholly inappropriate, if not unconstitutional, for federal policy makers to reverse the four-year, intensive process which has led to the implementation of the DDA simply because they do not agree with the people of Oregon's decision.

We believe the intrusion of a federal law enforcement agency or Congress into Oregon's public health matters represents a dangerous interference with our state's lawmaking capabilities. Oregon, over a lengthy period of time, has engaged in exactly the process outlined in the Supreme Court's unanimous opinion (written by Chief Justice Rehnquist) in support of states' roles in making law in the difficult area of death and dying. Oregon has conducted a thoughtful, deliberative, and convincing process. It is our belief that dealing directly with a difficult public health issue should be commended, not punished by federal usurpation of a state's authority. Obviously, this case has crucial implications for the concept of federalism and the relationship between the states and federal government.

We ask you, as a member of the Judiciary Committee and regardless of your personal position on physician-assisted suicide, to assist our state in resisting the potential federalization of proper state law. First, we ask that you insist Chairman Hyde conduct full and open hearings on any legislation which is designed to have an impact on Oregon's DDA. Secondly, we ask that you vigorously defend in the Judiciary Committee and on the House floor the right of our constituents to make their own decisions in this serious public health matter.

We are terribly concerned that our voters and state governing procedures will be eviscerated by a politically-motivated federal intervention. Thank you for your assistance, and we would be happy to provide you with any necessary information.

Sincerely,



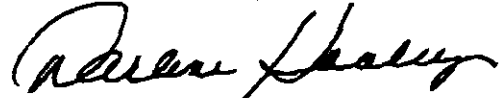
Elizabeth Furse
Member of Congress



Peter DeFazio
Member of Congress



Earl Blumenauer
Member of Congress



Darlene Hooley
Member of Congress

Congress of the United States

Washington, DC 20515

May 8, 1998

Also to:
Skaggs
Dixon

The Honorable Alan Mollohan
Ranking Member, Appropriations Subcommittee
on Commerce, Justice, State, and Judiciary
H-147 - The Capitol
Washington, D.C. 20515

Dear Alan:

We are writing to ask your assistance in a matter that has profound legal implications for Oregon and our entire nation.

As you may know, the state of Oregon has twice passed by public referendum -- most recently with 60% of the vote -- the Death with Dignity Act (DDA). First passed in 1994, this statute has survived a plethora of legal and political challenges, including the U.S. Supreme Court's ruling to lift a legal injunction.

Within days of the second successful referendum, the Drug Enforcement Agency (DEA) issued an opinion which declared DEA Administrator Constantine's view that the DEA had the authority to prosecute doctors in Oregon who, in compliance with the DDA, prescribed drugs at the request of terminally ill patients. This opinion is contrary to the traditional incorporation of state and community medical standards into state medical practice regulations. Immediately following the issuance of the DEA's opinion, Attorney General Janet Reno announced a Justice Department review of that opinion. It is not certain when that ruling will take place.

Regardless of the timing or substance of the Attorney General's ruling, we are concerned that later this year Chairman Hyde and Chairman Hatch will introduce legislation to undermine or overturn the DDA and force a vote on this issue in Congress. It seems wholly inappropriate, if not unconstitutional, for federal policy makers to reverse the four-year, intensive process which has led to the implementation of the DDA simply because they do not agree with the people of Oregon's decision.

We believe the intrusion of a federal law enforcement agency or Congress into Oregon's public health matters represents a dangerous interference with our state's lawmaking capabilities. Oregon, over a lengthy period of time, has engaged in exactly the process outlined in the Supreme Court's unanimous opinion (written by Chief Justice Rehnquist) in support of states' roles in making law in the difficult area of death and dying. Oregon has conducted a thoughtful, deliberative, and convincing process. It is our belief that dealing directly with a difficult public health issue should be commended, not punished by federal usurpation of a state's authority. Obviously, this case has crucial implications for the concept of federalism and the relationship between the states and federal government.

-2-

We ask you, as a member of the Appropriations Subcommittee with jurisdiction over the DEA and Justice Department, and regardless of your personal position on physician-assisted suicide, to assist our state in resisting the potential federalization of proper state law. First, we ask that you insist Judiciary Chairman Hyde conduct full and open hearings on any legislation which is designed to have an impact on Oregon's DDA. Secondly, we ask that you vigorously defend in the Subcommittee and on the House floor the right of our constituents to make their own decisions in this serious public health matter.

We are terribly concerned that our voters and state governing procedures will be eviscerated by a politically-motivated federal intervention. Thank you for your assistance, and we would be happy to provide you with any necessary information.

Sincerely,



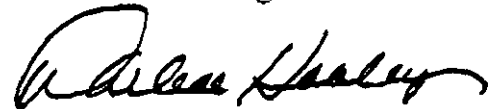
Elizabeth Furse
Member of Congress



Earl Blumenauer
Member of Congress



Peter DeFazio
Member of Congress



Darlene Hooley
Member of Congress

Congress of the United States

Washington, DC 20515

May 8, 1998

The Honorable Richard Gephardt
Democratic Leader
H204 - The Capitol
Washington, D.C. 20515

Also to:
Senator C. Edwards
DeLarco B. Mendez
J. Lewis

Dear Mr. Leader:

We are writing to ask your assistance in a matter that has profound legal implications for Oregon and our entire nation.

As you may know, the state of Oregon has twice passed by public referendum -- most recently with 60% of the vote -- the Death with Dignity Act (DDA). First passed in 1994, this statute has survived a plethora of legal and political challenges, including the U.S. Supreme Court's ruling to lift a legal injunction.

Within days of the second successful referendum, the Drug Enforcement Agency (DEA) issued an opinion which declared DEA Administrator Constantine's view that the DEA had the authority to prosecute doctors in Oregon who, in compliance with the DDA, prescribed drugs at the request of terminally ill patients. This opinion is contrary to the traditional incorporation of state and community medical standards into state medical practice regulations. Immediately following the issuance of the DEA's opinion, Attorney General Janet Reno announced a Justice Department review of that opinion. It is not certain when that ruling will take place.

Regardless of the timing or substance of the Attorney General's ruling, we are concerned that later this year Chairman Hyde and Chairman Hatch will introduce legislation to undermine or overturn the DDA and force a vote on this issue in Congress. It seems wholly inappropriate, if not unconstitutional, for federal policy makers to reverse the four-year, intensive process which has led to the implementation of the DDA simply because they do not agree with the people of Oregon's decision.

We believe the intrusion of a federal law enforcement agency or Congress into Oregon's public health matters represents a dangerous interference with our state's lawmaking capabilities. Oregon, over a lengthy period of time, has engaged in exactly the process outlined in the Supreme Court's unanimous opinion (written by Chief Justice Rehnquist) in support of states' roles in making law in the difficult area of death and dying. Oregon has conducted a thoughtful, deliberative, and convincing process. It is our belief that dealing directly with a difficult public health issue should be commended, not punished by federal usurpation of a state's authority. Obviously, this case has crucial implications for the concept of federalism and the relationship between the states and federal government.

-2-

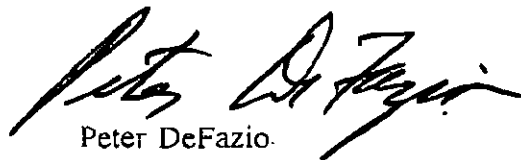
We ask you, as Democratic Leadership, and regardless of your personal position on physician-assisted suicide, to assist our state in resisting the potential federalization of proper state law. First, we ask that you insist Judiciary Chairman Hyde conduct full and open hearings on any legislation which is designed to have an impact on Oregon's DDA. Secondly, we ask that you vigorously defend in Leadership meetings and on the House floor the right of our constituents to make their own decisions in this serious public health matter.

We are terribly concerned that our voters and state governing procedures will be eviscerated by a politically-motivated federal intervention. Thank you for your assistance, and we would be happy to provide you with any necessary information.

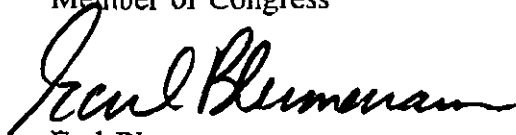
Sincerely,



Elizabeth Furse
Member of Congress



Peter DeFazio
Member of Congress



Earl Blumenauer
Member of Congress



Darlene Hooley
Member of Congress

THE WHITE HOUSE
WASHINGTON

May 11, 1998

MEMORANDUM TO THE PRESIDENT

FROM: Bruce Reed
Charles Ruff

SUBJECT: Assisted Suicide Legislation

The Justice Department has determined that the Drug Enforcement Administration (DEA) has no authority under the Controlled Substances Act (CSA) to take adverse action against physicians who assist patients in ending their lives by prescribing controlled substances pursuant to Oregon's "Death with Dignity Act." The Department conducted its legal analysis in response to letters sent by Senator Hatch and Congressman Hyde urging the Department, through DEA, to invoke the CSA against physicians who assist in patient suicide under the Oregon law.

The Justice Department has completed draft letters to Congressman Hyde and Senator Hatch explaining its legal conclusions. The letters will not be forwarded to Congress until we have developed a roll-out strategy, including a position on federal legislation prohibiting physician-assisted suicide.

As you will recall, the Catholic Health Association (CHA) has informed us that Hatch and Hyde are prepared to introduce legislation amending the CSA in the event the Attorney General concludes that the CSA does not authorize the DEA to pursue physicians who assist patients in committing suicide. They may even introduce this legislation before receiving the Department of Justice's opinion letter. In assessing the possible options for responding to Hatch's and Hyde's likely initiative, we held meetings within the White House and with the Departments of Justice and Health and Human Services (including the FDA).

Justice believes that the Administration should not support the Hatch/Hyde proposal. Justice thinks that DEA's approach to enforcing the narcotics laws is inconsistent with the kind of sensitivity that would be needed in pursuing doctors who are assisting terminally ill patients to commit suicide. Justice is also concerned with the resource drain on the DEA if that agency were tasked with enforcement duty. Justice also worries that this new task would damage DEA's relationship with the medical profession, on which it often relies in pursuing narcotics law violations.

The Justice Department also cites principles of federalism in support of its position against a legislative change. The federal government has deferred to the states as the primary regulators of the medical profession. Especially on such a hotly contested issue as assisted suicide, Justice believes there is good reason to continue this tradition of deference to local

decisionmaking.

HHS/FDA concurs with Justice's position, stressing especially the historic deference given to states in regulating the medical profession. HHS/FDA also worries that a new federal law authorizing the federal government to take adverse action against doctors who assist their patients to commit suicide would exacerbate the problem of physicians' underprescribing pain medications for terminally ill patients.

Your longstanding opposition to the practice of assisted suicide is not necessarily inconsistent with the agencies' positions. You could argue that assisted suicide is wrong, but that it is not a matter that should be handled by federal narcotics agents. Or more broadly, you could argue that it is not a matter to be dealt with by the federal government at all, but instead should be left to state and local decisionmaking. Nor is last year's "Assisted Suicide Funding Restriction Act" inconsistent with a refusal to support a legislative change. The Funding Restriction Act bans the use of federal funds to pay for or promote assisted suicide. Nothing in the Act authorizes the federal government to take adverse action against a private physician for assisting in a suicide in a non-federal facility.

We detail below four options for responding to the expected Hyde/Hatch initiative. These options are: (1) support the Hyde/Hatch legislation; (2) oppose the Hyde/Hatch DEA approach, but suggest openness to alternatives and work with Hatch and Hyde to develop a better bill; (3) engage in a "Kick the Can" strategy, suggesting openness to alternatives, but attempting to ensure that no congressional action is taken; and (4) oppose the Hyde/Hatch legislation outright.

1. **Endorse Hyde/Hatch Legislative Alternative.** After the Justice Department's legal interpretation is released, we could endorse the expected introduction of the Hatch/Hyde legislation authorizing the DEA to pursue criminal actions against physicians prescribing medications for assisted suicides.

Pros

- Appears consistent with your longstanding opposition to assisted suicide.
- Avoids inevitable conflict with the Congress, where the Hatch/Hyde legislation is likely to be popular.

Cons

- Conflicts with historic practice of allowing states to regulate the medical profession, and does so with regard to a hotly contested and emotional issue on which local decisionmaking may be particularly appropriate.

- Places authority to act against doctors in an agency ill-equipped to perform this function, in a way that could interfere with the agency's primary mission.
- Ignores danger, noted by many physicians' groups and even the Catholic Health Association, that a federal law of this kind will lead doctors to under-medicate terminally ill patients for fear of federal prosecution.

2. **Oppose Hatch/Hyde legislation, but suggest openness to alternatives.** Under this option, you would welcome the intent of the Hatch/Hyde bill, based on your longstanding opposition to assisted suicide, but raise concerns about using federal drug agents and resources to address this issue. You would advise Republicans of ways to implement the intent of their legislation in a more workable fashion, perhaps suggesting alternative enforcement agencies (such as FDA) or alternative enforcement mechanisms (such as reducing Federal support for Medicaid for states permitting assisted suicide). You would try seriously to find common ground with the Republicans on a workable legislative alternative to DEA enforcement.

Pros

- Appears consistent with your longstanding opposition to assisted suicide and shows that you are seriously concerned about this issue.
- Takes an approach that recognizes the problems with using DEA resources and agents to address this issue.

Cons

- Assumes that we can develop a workable alternative approach, when we may not be able to do so. For example, direct regulation of doctors through HHS/FDA also raises serious issues, and enforcement mechanisms directed toward states, such as reduction of Medicaid dollars, would raise widespread protests of federal micro-management and intrusion.
- Raises expectations that a legislative solution can be achieved, when it may be virtually impossible to reach consensus.

3. **"Kick the Can" Strategy.** Under this option, you would also express openness to addressing this issue through federal legislation, but rather than trying to reach agreement, you would attempt to forestall legislative action. You would try to delay long enough to allow the medical groups, states, and others to communicate that federal approaches in this area are ill-advised. These objections could make Congress conclude that it does not have time to draft thoughtful legislation this year.

Pros

- Allows you to reiterate your strong position against assisted suicide, while preventing problematic federal legislation.
- Provides sufficient time to air the many issues surrounding assisted suicide legislation, perhaps even educating physicians and the public about the problem of undermedicating terminally ill patients

Cons

- May make us look indecisive and weak.
- May be viewed with skepticism on the Hill and make us vulnerable to the charge that we are trying to have it both ways.

4. **Oppose Hatch/Hyde legislation outright.** Under this option, you would tell the Hill that, although you believe that assisted suicide is immoral, you cannot support legislation that intrudes on state responsibility over this issue and diverts limited law enforcement resources for this purpose.

Pros

- Takes a strong position consistent with agency views on the undesirability of federal legislation in this area: respects federalism principles; protects law enforcement priorities; and prevents further undermedication of patients due to physicians' fear of criminal prosecution.

Cons

- May appear inconsistent with your longstanding opposition to assisted suicide.
- Risks major confrontation with the Congress, which almost certainly will pass federal legislation over your objection.

The Departments of Justice and Health and Human Services support Option 4 and strongly oppose Option 1. Of the middle options, they would prefer Option 3 to Option 2. The Counsel's office agrees with the agencies: Chuck believes both that the DEA should not regulate medical practice and that federal legislation in this area conflicts with federalism principles. The DPC agrees that federal legislation in this area makes little sense, but believes that the "Kick the Can" strategy may be the best way to prevent it; the DPC therefore recommends Option 3.

Assisted suicide

**U.S. Department of Justice
Office of Legal Counsel
Washington, D.C. 20530**

Facsimile Transmission Sheet

Date: April 27, 1998

From: Paul Oetken

Office Phone: 202/514-3865

To: Karen Popp
Associate Counsel to the President

Office Phone: 202/456-7594

Facsimile Number: 202/456-5055

Number of Pages: 6 (including cover sheet)

Remarks:

Karen --

Attached are (1) proposed talking points addressing the legal authority to take adverse action against physician-assisted suicide under the Controlled Substances Act, and (2) the letter addressing the same issue, with a slightly revised final paragraph. Please call with any questions.

Paul

Controlled Substances Act and Physician-Assisted Suicide

- The Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-971, 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 Drug Enforcement Administration ("DEA"), and the unauthorized distribution of drugs is generally subject to criminal and administrative action. The CSA provides criminal penalties for physicians who dispense controlled substances beyond "the course of professional practice," 21 U.S.C. § 802(21), and provides for the revocation of 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).
- 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.
- There is also 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. The CSA was not intended to give DEA the task of determining 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 -- questions that are not susceptible of scientific or factual resolution, but rather are fundamental questions of morality and public policy.
- 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 pursuit of such adverse action against a physician in Oregon who has fully complied with that state's Death with Dignity Act would go beyond anything Congress intended in crafting the CSA.

N:\UDD\OETKEN\JPASPTS.CSA

LETTER #2 (resolving statutory authority question,
but not addressing policy)
DRAFT

Dear Congressman Hyde:

This is in response to your letter urging the Department of Justice, through the Drug Enforcement Administration ("DEA"), to invoke the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801-971 (1994), 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, the chairmen of the House and Senate Judiciary Committees 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 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 CSA provides criminal penalties for physicians who dispense controlled substances beyond "the course of professional practice," 21 U.S.C. § 802(21), and provides for the revocation of 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 pursuit of such adverse action against a physician in Oregon who has fully complied with that state's Death with Dignity Act would go beyond anything Congress intended in crafting the CSA.

Sincerely,

Janet Reno

N:\UDD\OETKEN\JPASLET.X

Assisted suicide

DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE GENERAL COUNSEL
PHONE: 202/690-7741
FAX: 202/690-7998

TO: KAREN POAP
DATE: 4/24/98
DEPARTMENT/OFFICE: WHITE HOUSE COUNSEL'S OFFICE
PHONE: 456-7594
FAX: 456-5055

FROM: HARRIET S. RABB
GENERAL COUNSEL

COMMENTS: As you can see, our chances of success
have been improved when we pursue
"quacks" promoting unapproved drugs.

The enclosed is a list of every reported case
[we believe] in the past 20 years. There maybe 2-3
unpublished opinions in this area, but we can't get
our hands on them. [There may be fewer than 2-3, but
not more than 2-3].

There were categories of cases tenuously related
to these [but not here listed] that we can discuss.

HSR

PAGES INCLUDING COVER: 4

FDA ENFORCEMENT ACTIONS AGAINST PHYSICIANS

Off-label Prescribing/Dispensing of Approved Drugs

1. *Dr. Evers*

- (E.D. La. 1976). FDA obtained an injunction against Dr. Evers to prevent him from administering an approved drug, disodium edetate, for the treatment of arteriosclerosis, for which indication the drug was not approved. In fact, the drug, which was approved to treat lead poisoning, specifically identified arteriosclerosis as contraindicated. Dr. Evers, who was not licensed to practice medicine in Louisiana, was actively promoting the drug, through press conferences and promotional literature, for cardiovascular therapy and arteriosclerosis. Several patients' deaths were attributed to the administration of the drug.
- (M.D. Ala. 1978). In this second case against Dr. Evers (who was licensed in Alabama), the court denied injunctive relief to prevent him from promoting and administering calcium disodium versenate. Dr. Evers was promoting and administering this drug (also approved for lead poisoning) to treat arteriosclerosis and other cardiovascular problems. Although not approved, neither of these indications were specifically contraindicated. The court held that FDA lacks jurisdiction when the intention to use the drug off-label is formed after the drug has been shipped in interstate commerce and that Dr. Evers' actions were within the practice of medicine and thus beyond the reach of federal power.
- (5th Cir. 1981). On appeal, the court affirmed the Alabama district court's denial of the injunction on the grounds that the drugs were not misbranded by Dr. Evers' extensive promotion and off-label administration of calcium disodium versenate for arteriosclerosis and other cardiovascular problems. The court held that the drug was not rendered misbranded by Dr. Evers' promotion or off-label administration because the statutory provision (21 U.S.C. 352(f)(1)) cannot be read to require a physician to provide adequate directions to himself.

Unapproved Drugs

1. *Dr. Burzynski*

- (S.D. Tex. 1983). The court enjoined Dr. Burzynski from distributing in interstate commerce his unapproved cancer drug, antineoplastons, but did not prohibit him from continuing to manufacture and prescribe the drug in Texas. Dr. Burzynski was heavily involved in the nationwide promotion of the drug from which he derived substantial profit.
- (S.D. Tex. 1997). Dr. Burzynski was tried for distributing antineoplastons in interstate commerce (outside the state of Texas), including doing this act in contempt of the 1983 injunction. The jury failed to reach a verdict. The contempt count was retried, and Dr. Burzynski was acquitted on that count.

2. *Dr. Najarian*

- (D. Minn. 1996). Dr. Najarian was prosecuted for, among other charges, selling an investigational drug that was being studied pursuant to an investigational new drug application, for which such sales were prohibited by FDA regulations. Between 1989 and

1992, gross sales of the drug were estimated to be \$24 million. Dr. Najarian was acquitted of all charges.

3. *Drs. Jacobs & Takhar*

- (E.D. Cal 1989). Veterinarians, Drs. Jacobs and Takhar, were successfully prosecuted for manufacturing unapproved animal drugs containing chloramphenicol. Jacobs and Takhar were selling their unapproved chloramphenicol drug for use in food-producing (i.e., edible) animals. The use of this drug in food-producing animals created a significant public health risk because the drug residue left in food is known to be toxic to humans.

Unapproved Devices

1. *Dr. Tang & Century Clinic*

- (D. Nev. 1993). Dr. Tang and Century Clinic entered into a consent decree enjoining them from using unapproved devices, including the "EAV Dermatron," which was used to diagnose various conditions, including "Nevada underground radiation" and bubonic plague.
- (D. Nev. 1998). The court upheld FDA's administrative finding that Dr. Tang was in contempt of the injunction based on the continued use of various unapproved devices for various diseases and conditions including the excessive exposure to aluminum. Defendants received a fine of \$400,000.

2. *Liquid Injectable Silicone Cases*

- (C.D. Cal. 1992) (S.D.N.Y. 1992) (S.D. Fla. 1993). Drs. Fulton, Aronsohn, Orentreich, and Samitier separately entered into consent decrees (or were the subject of default judgments issued by the court) enjoining them from promoting, distributing, or injecting unapproved injectable liquid silicone. The doctors, dermatologists and a cosmetic surgeon, were injecting the unapproved medical device into patients for cosmetic enhancement.

3. *Dr. Metcalf*

- (W.D. Okl. 1995). Dr. Metcalf was convicted, among other violations, of smuggling unapproved silicone gel breast implants into the U.S. and selling them to his patients for implantation.

SELECTED FDA AND CONGRESSIONAL STATEMENTS ON OFF-LABEL USE AND THE PRACTICE OF MEDICINE

1972 Proposed Rule (never finalized or withdrawn)

1. Federal Register: Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the FDA (excerpt)

- "Once (an approved) new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the FDA." 37 FR 16503 (Aug. 15, 1972).

Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. 105-115

1. FDAMA sec. 214 (excerpt)

- "Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." Pub. L. 105-115, § 214, 111 Stat. 2296, 2348 (1997).

2. Conference Report Language Regarding FDAMA sec. 214 (excerpt)

- "Specifically, the conferees note that the off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient is not the province of the FDA." H.R. Conf. Rep. No. 105-399, at 97 (1997).

3. House and Senate Report Language Regarding FDAMA sec. 401 (excerpt)

- "The Committee emphasizes that it has been the long held view of Congress that the FDA should not regulate the practice of medicine. In general, the FDA has no authority to regulate how physicians prescribe approved drugs in the context of their medical practice. Physicians prescribing off-label uses of approved drugs is not within the jurisdiction of the FDA." H.R. Rep. No. 105-310, at 60 (1997); See also almost identical language in the Statement of the Managers for S: 830, 143 Cong. Rec. S9838 (September 24, 1997).

Assisted suicide

DRAFT

FDA TALKING POINTS ON PHYSICIAN ASSISTED SUICIDE

- The FDCA prohibits causing the introduction or delivery for introduction into interstate commerce of any new drug for which the necessary FDA approval has not been obtained. While each time an FDA-approved drug is promoted for an unapproved purpose, it becomes an unapproved new drug for that purpose, we know that physicians do prescribe approved drugs "off-label."
- FDA generally relies on States to regulate physicians who prescribe approved drugs for off-label uses. FDA has only very rarely brought enforcement actions against physicians, and, in fact, there is legislative history to the effect that the FDCA is not intended--at least not directly--to regulate the practice of medicine.
- The suits brought by FDA have almost exclusively involved physicians who have promoted, sold, or distributed, with a sufficient interstate nexus, drugs or devices that are unapproved for any purpose--not physicians engaged in the ordinary practice of medicine who merely recommend or prescribe a particular approved drug for an unapproved use.
- FDA has only very rarely attempted to bring an enforcement action against a physician who was prescribing approved drugs off-label, and those few cases have involved physicians who were widely promoting the off-label use.
- Regulating physician conduct in assisted suicide in a State that permits the practice would be an inappropriate use of the Agency's authority. FDA's core function is the public health mission of regulating foods and medical products. The current debate about the morality of physician-assisted suicide is not an issue that can be resolved by science or according to ordinary public health principles.
- FDA's decision not to act against States' use of drugs for lethal injection--a similarly morally contentious issue--has been upheld by the Supreme Court.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN - 7 1998

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

Dear Mr. Chairman:


This is in response to your letter of September 19, 1997, requesting the Food and Drug Administration's (FDA) views regarding use of a controlled substance in assisted suicide and supersedes our prior letter to you dated October 29, 1997. You asked for FDA views on whether delivering, distributing, dispensing, prescribing, filling a prescription, or administering a controlled substance with the deliberate intent of assisting in a suicide would violate the Federal Food, Drug, and Cosmetic (FDC) Act, applicable regulations, or other Federal law subject to FDA enforcement.

In order to market a new drug, a sponsor must demonstrate (generally through a new drug application) that the product is safe and effective for its intended uses. See, §§ 201(p), 505, FDC Act. The intended uses for which a drug has been determined to be safe and effective (approved uses) appear in the product's package insert (the approved labeling). Approved drugs may only be labeled and promoted for their approved uses.

Numerous prescription drugs approved by FDA potentially could be considered not safe and effective, or potentially could endanger human life, if these drugs are used for purposes other than the specific uses approved by FDA (off-label uses) or not used in the manner described in the approved labeling. While an argument could be made that off-label uses of prescription drugs for physician-assisted suicide would violate the FDC Act, physician off-label uses generally are regulated by individual state licensing boards and authorities. We believe that regulating drugs for physician-assisted suicide through FDC Act enforcement actions also would be inappropriate in the context of current state regulation and the national debate over this practice.

We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,


Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Page 2 - The Honorable Tom Bliley

**cc: The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 29 1997

Food and Drug Administration
Rockville MD 20857

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

Dear Mr. Chairman:

This is in response to your letter of September 19, 1997 requesting the Food and Drug Administration's (FDA) views on whether delivering, distributing, dispensing, prescribing, filling a prescription, or administering a controlled substance with the deliberate intent of assisting in a suicide would violate the Federal Food, Drug, and Cosmetic (FDC) Act, applicable regulations, or other Federal law subject to FDA enforcement.

In order to market a new drug, a sponsor must demonstrate (generally through a new drug application) that the product is safe and effective for its intended uses. See, §§ 201(p), 505, FDC Act. The intended uses for which a drug has been determined to be safe and effective (approved uses) appear in the product's package insert (the approved labeling). Approved drugs may be labeled and promoted only for their intended uses.

Numerous prescription drugs approved by FDA potentially could be considered not safe and effective, or potentially could endanger human life, if these drugs are used for purpose other than the specific uses approved by FDA (off-label uses) or not used in the manner described in the approved labeling. While an argument could be made that off-label uses of prescription drugs for physician-assisted suicide would violate the FDC Act, physician off-label uses generally are regulated by individual state licensing boards and authorities. We believe that regulating drugs for physician-assisted suicide through FDC Act enforcement actions also would be inappropriate in the context of current state regulation and the national debate over this practice.

We hope this information is helpful. If we may be of any further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

cc: The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce

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**U.S. House of Representatives
 Committee on Commerce**

Room 2125, Rayburn House Office Building
 Washington, DC 20515-6115

September 19, 1997

JAMES E. DERDERIAN, CHIEF OF STAFF

Michael A. Friedman, M.D.
 Lead Deputy Commissioner
 Food and Drug Administration
 5600 Fishers Lane
 Rockville, MD 20857

Dear Dr. Friedman:

As Chairman of the House Commerce Committee, I write seeking the Food and Drug Administration's view as to whether delivering, distributing, dispensing, prescribing, filling a prescription, or administering a controlled substance with the deliberate intent of assisting in a suicide would violate the Federal Food, Drug, and Cosmetic Act, applicable regulations, rulings, or other federal law subject to FDA enforcement, notwithstanding the enactment of a State law such as Oregon's Measure 16 rescinding State penalties against such prescriptions for patients with a life expectancy of less than six months:

Drugs used to assist in a suicide include such controlled substances as amobarbital, codeine, diazepam, flurazepam, glutethimide, chloral hydrate, hydromorphone, meprobamate, methyprylon, meperidine, methadone, morphine, phenobarbital, secobarbital, and pentobarbital. This list has been derived from Derek Humphrey's *Final Exit: The Practicalities of Self-Deliverance and Assisted Suicide for the Dying* (Hemlock Society 1991), at 117-120.

Interpretations of other agencies suggest that assisted suicide is not a legitimate medical practice within the meaning of federal law. The Health Care Financing Administration, for example, has written that physician-assisted suicide is not "reasonable and necessary" to the diagnosis and treatment of disease or injury and is therefore barred from reimbursement under Medicare. (See enclosed letter of May 1, 1996 from Debbie I. Chang, Director of HCFA's Office of Legislative and Inter-Governmental Affairs.) In addition, under existing regulations of the Drug Enforcement Administration, a lawful prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04.

Michael A. Friedman, J.

September 19, 1997


Page 2 of 2

The American Medical Association, the American Nurses Association, the American Psychiatric Association, and at least 43 other national specialty and State medical societies have condemned assisted suicide, stating that it has "[l]ong [been] viewed as outside the realm of legitimate health care" and is "fundamentally incompatible with the physician's role as a healer..." [See Briefs Amici of the American Medical Association, *et al.*, at 4-5, in *Washington v. Glucksberg*, No. 96-110 (U.S.) and *Vacco v. Quill*, No. 95-1858 (U.S.), citing Code of Medical Ethics, § 2.211 (App. 11a).]

In my view, the prescription and use of drugs deliberately to assist a person to commit suicide cannot be consistent with FDA standards regarding "health," "legitimate medical use," and "safe and effective use" of drugs [*e.g.*, 21 U.S.C. §§301 (U), 353 (b)(1)(B), 355; 21 C.F.R. §§312.22(a), 312.2(b)(iii)] especially when the practice of assisted suicide is not reasonable and necessary to the diagnosis and treatment of disease and injury, legitimate health care, or compatible with the physician's role as healer. Past FDA action as upheld by the United States Supreme Court indicated that the agency's interest in ensuring that drugs are "safe and effective" and do not endanger human life is no less compelling in the case of patients with life-endangering illnesses. [*United States v. Rutherford*, 442 U.S. 544 (1979).]

As you know, this is an area of special interest to the Congress. On March 20, the Committee that I chair, by a 45-to-2 vote, approved legislation (H.R. 1003) to prohibit any use of federal funds, programs or facilities to perform or advocate assisted suicide. The bill was approved by the full House of Representatives on April 10 by a vote of 398-to-16, passed by the Senate on April 16 by a vote of 99-to-0, and signed by the President on April 30. Clearly, Congress would have serious concerns were any federal agency to construe the intentional prescribing of lethal drugs for suicide as a legitimate medical practice. Therefore, I would be grateful for your prompt response.

Sincerely,


Tom Bliley
Chairman

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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
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DEPARTMENT OF HEALTH & HUMAN

MAY 11 - 1998

Mr. John Neithercut

P6/(b)(6)

[001]

Dear Mr. Neithercut:

Rep. John Olver has referred your letter on recent Administration and Congressional proposals to restructure the Medicare program to my office for a response. In your letter you express opposition to Medicare paying for physician assisted suicide. You also asked Mr. Olver to vote in favor of changes to Medicare that would allow Medicare beneficiaries "to add their own money to be able to get unmanaged fee for service plans under MedicarePlus". We refer to such plans as "private fee for service plans".

In regard to your first issue, in general, the Medicare statute limits Medicare coverage to items and services that "are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Physician assisted suicide, even if allowed under state law, does not meet these statutory criteria. As such, the program is prohibited from making payment for it. Further, there is no provision in the President's balanced budget proposal to change Medicare so that it would cover physician-assisted suicide, either under the fee for service program or through a contracting managed care plan.

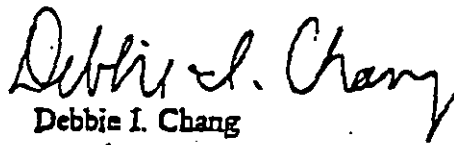
In regard to your second concern, the President has been clear that he does not support private fee for service plans as an option for Medicare beneficiaries because such an option could hurt many beneficiaries while helping none. The rationale for the President's position is as follows:

- o Currently, the law places limits on what doctors, hospitals and others can charge either the Medicare program or Medicare beneficiaries. For instance, if the Medicare approved charge for a physician visit is \$100, the beneficiary's share of the cost is limited to somewhere between \$20 and \$35 (depending on whether or not the doctor is a Medicare "participating physician"). Physicians are prohibited from billing for more than the "limiting charge" which is 115 percent of the Medicare payment amount.
- o Similarly, when a beneficiary goes to the hospital, whether the hospital charges \$5,000 or \$10,000 for the stay, the hospital can charge the beneficiary only certain established deductible and coinsurance amounts and it must accept Medicare's payment as payment in full.

- o However, under the Congressional plan, there are no provisions limiting what physicians and hospitals can charge enrollees of private fee for service plans. Therefore, beneficiaries enrolled in such plans would potentially face enormous additional charges. For instance, if a hospital charged \$10,000 and the private fee for service plan paid \$6,000, the beneficiary would be liable for the other \$4,000. Or if a surgeon charged \$5,000 for an operation and the private fee for service plan paid \$3,000, the beneficiary would be liable for the remaining \$2,000.
- o Given the ability to obtain extra revenue from beneficiaries in private fee-for-service plans, doctors and hospitals could decide they will only serve beneficiaries who choose their Medicare coverage through such plans. In other words, they would no longer serve beneficiaries who chose fee for service Medicare. This would mean that beneficiaries would face significantly higher costs for the same level of care that they receive today.

Thank you for sharing your concerns on the matters of physician assisted suicide and the availability of private fee-for-service plans in Medicare.

Sincerely yours,



Debbie I. Chang
Director

Office of Legislative and Inter-Governmental Affairs

*Assisted suicide***"Assisted Suicide Funding Restriction Act of 1997"**

- The Assisted Suicide Funding Restriction Act of 1997, Pub. L. No. 105-12 (April 30, 1997), bans the use of federal funds to pay for or promote assisted suicide. The central restriction in the Act is phrased in the following terms: "[N]o funds appropriated by Congress for the purpose of paying (directly or indirectly) for the provision of health care services may be used" (1) to provide, (2) to pay for, or (3) to pay for health benefit coverage including, any "item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing." Sec. 3(a).
- The only provision of the Act that restricts the actual furnishing of services (as distinguished from funding) is applicable only to federal employees and to services provided in federal facilities. That provision states that "no such item or service may be furnished for the purpose of causing" death by assisted suicide, and applies to items and services furnished (1) "by or in a health care facility owned or operated by the Federal government," or (2) "by any physician or other individual employed by the Federal government to provide health care services within the scope of the physician's or individual's employment." Sec. 3(c).
- Nothing in the Act authorizes the federal government to take adverse action against a private physician for assisting in a suicide in a non-federal facility.

"Assisted Suicide Funding Restriction Act of 1997"

- The Assisted Suicide Funding Restriction Act of 1997, Pub. L. No. 105-12 (April 30, 1997), bans the use of federal funds to pay for or promote assisted suicide.
- The Act does not have any effect on the Controlled Substances Act (CSA), and nothing in the Act is inconsistent with the conclusion that the CSA was not intended to authorize DEA to take adverse action against a physician who assists in a suicide in compliance with state law.
- Congress found in section 2(a)(3) of the Act: "Because of recent legal developments, it may become lawful in areas of the United States to furnish services in support of such activities [assisted suicide, euthanasia, and mercy killing]."
- In his signing statement, President Clinton stated: "The restrictions on the use of funds contained in [section 5(a)(3)], properly construed, will allow the Federal Government to speak with a clear voice in opposing these practices." 1997 U.S.C.C.A.N. 58 (April 30, 1997). He was addressing a portion of the Act ensuring that federal funds "not be used to subsidize legal assistance or other forms of advocacy in support of legal protection for assisted suicide, euthanasia, or mercy killing." Id. He proceeded to emphasize that the First Amendment required a narrow construction of this provision as covering only activities with the purpose of advocating assisted suicide, and not those providing "forums for the free exchange of ideas." Id.
- Nothing in President Clinton's signing statement is inconsistent with the conclusion that the CSA was not intended to authorize DEA to take adverse action against a physician who assists in a suicide in compliance with state law, or with the conclusion that such adverse action is unwarranted for reasons unrelated to opposition to assisted suicide (such as federalism concerns).

Oregon Initiative Procedure

- The Oregon Constitution provides that "[t]he people reserve to themselves the initiative power, which is to propose laws . . . and enact or reject them at an election independently of the Legislative Assembly." Or. Const. art. IV, § 1(2)(a). The Oregon Death With Dignity Act was enacted through the initiative process.
- The legislature apparently has the authority to repeal an act passed by initiative just as it can repeal an act passed by the legislature itself. Although neither the Constitution nor statutes specifically address repeal of initiatives, the Oregon Supreme Court has stated that "the Legislative Assembly, when convened, may amend or repeal a law passed by the people." State ex rel. Carson v. Kozex, 270 P. 513, 514 (Or. 1928).
- However, the Oregon legislature apparently has never repealed an initiative. Out of 99 voter-approved initiatives since 1904, the Secretary of State reports that none has been repealed by the legislature. Portland Oregonian, March 1, 1997, p. D1. "Many legislators consider it heresy to override the will of the people." Id.
- After efforts in the legislature to repeal Oregon's Death With Dignity Act failed last year, an initiative to repeal the Act was placed before voters. Voters rejected the repeal initiative on November 4, 1997.