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RECENT LEGISLATIVE ACTIVITY

Beth A. Diebold

The Pain Relief Promotion Act of 1999: Whose Pain Does It Relieve?

"Terminally ill patients deserve better pain control precisely because they have the same innate worth and dignity as all other human beings. . . . [Physician-assisted suicide]. . . denies the value of their lives and thereby undermines respect for their dignity and their legitimate needs—including their need for the best possible palliative care."

Richard M. Doerflinger, National Conference of Catholic Bishops¹

"Dying is personal. And it is profound. For many, the thought of an ignoble end, steeped in decay, is abhorrent. A quiet, proud death, bodily integrity intact, is a matter of extreme consequence."

Justice William Brennan, *Cruzan v. Missouri Dept. Of Health*²

On October 27, 1999, the House of Representatives passed H.R. 2260, the Pain Relief Promotion Act ("PRPA"), by a margin of nearly 2:1.³ Currently awaiting Senate approval, the bill's primary purposes include the authorization of funding for research and education in the area of palliative medicine, particularly at the end of life, and the clarification of federal law regarding the legitimate use of controlled substances in palliative care.⁴ While the first goal of the bill has received almost unanimous support from both health care providers as

as well as consumers, the second remains controversial.

One concern voiced by opponents is the possible “chilling” effect that the legislation might have on physicians’ tendencies to aggressively treat pain in terminally ill patients.⁵ Under PRPA, physicians would face criminal prosecution for prescribing controlled substances to hasten the death of a terminally ill patient.⁶ Some fear that this legislation could cause doctors to undertreat pain in these individuals in order to avoid possible criminal allegations. In addition, because the regulation of medical practices is the responsibility of the states and their medical boards, and not of the federal government, critics contend that this legislation violates Constitutional principles of federalism. In fact, it has been suggested that the real purpose of PRPA is to override Oregon’s Death With Dignity Act, a law that many PRPA supporters adamantly oppose.⁷

This article will examine the current status of the laws surrounding pain management in medical care and physician assisted suicide. It then identifies the proposed changes that would occur under PRPA. Finally, the federalism and palliative care issues that have been raised by PRPA opponents are addressed, along with the responses to those arguments that have been made by the bill’s supporters.

The Development of Palliative Care Laws

In 1970, Congress passed the Controlled Substances Act (“CSA”), which restricted the use of controlled substances, gave the federal government control over their intrastate as well as interstate traffic, and required the Drug Enforcement Administration (“DEA”), under the Attorney General of the Department of Justice, to oversee a federal system of enforcement and penalties.⁸ Because many of the materials regulated by the CSA are useful in the treatment of pain or injury, Congress authorized their use by physicians for “legitimate

medical purposes" only, requiring that physicians and pharmacists apply to the DEA for a special license authorizing them to administer regulated substances.⁹ Consequently, although physicians receive their licenses to practice medicine from state medical boards and are required to comply with state regulations concerning the lawful practice of medicine, the ability to prescribe controlled substances must be authorized by the federal government.

Due in part to a concern regarding the misuse of prescription drugs in lethal overdoses, Congress amended the CSA in 1984, allowing the DEA to revoke a physician's license to prescribe if such was used to endanger the health and safety of another.¹⁰ Currently, a physician must be prepared to explain to DEA officials her purpose in prescribing controlled substances, and she risks criminal penalties as well as loss of the DEA registration if controlled substances are prescribed for unauthorized purposes.¹¹

In 1997, Congress specifically indicated its position on the issue of physician assisted suicide with the passage of the Assisted Suicide Funding Restriction Act, which prohibited federal funds, health care facilities and health care programs from being used for assisted suicide or euthanasia.¹² Indeed, President Clinton, in signing the bill, stated that the legislation would allow the federal government to "speak with a clear voice in opposing these practices."¹³

That same year, the Supreme Court rendered its decision in *Washington v. Glucksberg*, ruling that the "right" to assistance in committing suicide is not a fundamental liberty interest protected by the Due Process Clause, and thus, the state of Washington's ban on assisted suicide was not unconstitutional.¹⁴ However, the Court went on to acknowledge the uncertainty of the law in this area, inviting the states to "continue to debate and experiment with this issue."¹⁵ Within months of the *Washington* decision, the Death With Dignity Act, a refer-

endum which had passed in 1994 through two separate votes by Oregon residents, became effective in the state of Oregon. Generally, the legislation allows a terminally ill adult, judged by two separate physicians as having less than six months to live and being of sound mind, to request a lethal dose of a controlled substance from a prescribing physician.¹⁶

However, in a November, 1997 letter responding to an inquiry by Judiciary Committee Chairman Henry Hyde, DEA Administrator Thomas Constantine made a determination that physician assisted suicide with the use of federally controlled substances did not constitute a legitimate medical purpose and thus violated the CSA.¹⁷ Because the 1984 amendment to the CSA allows the DEA in such cases to revoke a physician's prescription license and commence criminal proceedings regardless of whether state laws have been violated, the determination effectively quashed the ability of Oregon physicians to provide the very services that state residents had voted to allow. The determination also indirectly prevented all states from "experimenting" with the issue, a process that the Supreme Court had encouraged states to do in its *Washington* opinion.

In response to the public outcry created by the DEA determination, Attorney General Janet Reno issued a subsequent letter in 1998 overruling the 1997 statement. Currently, according to the Attorney General, the federal CSA is enforceable against physicians' use of controlled substances for assisted suicide only to the extent that states have not authorized assisted suicide.¹⁸ Unfortunately, as proponents of PRPA point out, this ruling also rendered a contradictory result, as it allowed state law to limit the applicability of the federal CSA, and indirectly forced the federal government to support the practice of physician assisted suicide by licensing physicians to distribute the federally-regulated drugs used in lethal overdoses.¹⁹

Since 1998, several bills have been introduced in Congress attempting to clarify what is now an extremely unsettled area of the law. The Lethal Drug Abuse Prevention Act ("LDAPA"), introduced in 1998 and approved by both House and Senate Judiciary Committees, was one bill which attempted to overrule the 1998 Attorney General determination. The bill sought to render physician assisted suicide an invalid medical purpose for the administration of controlled substances regardless of state law provisions.²⁰ Seeking to establish a substantive policy against the use of controlled substances for assisted suicide throughout the 50 states, the proposal caused significant concern throughout the health care community regarding the effects it would have on a physician's ability or willingness to prescribe controlled substances even strictly for pain relief.²¹ The bill was never enacted due to critics' fears that this new authority might be construed as a mandate for the DEA to begin scrutinizing medical decisions in order to determine whether assisted suicide had occurred.

PRPA Provisions

Proponents of PRPA contend that the bill is designed to allay the very concerns raised by critics of LDAPA.²² According to Henry Hyde (R-IL), co-author of PRPA, one of its purposes is to "legitimate [the] use of controlled substances in pain management and palliative care."²³ Title I of PRPA officially recognizes palliative care as a legitimate medical purpose, and authorizes prescription of controlled substances to alleviate pain "even if the use of such a substance may increase the risk of death."²⁴ However, the Act also provides that opiate drugs and other controlled substances may not intentionally be used "for the purpose of causing death or assisting another person in causing death."²⁵ Physicians found to be in violation of this section of the Act would be subject to a criminal investigation by the DEA and

possible imprisonment for 20 years to life.²⁶ Furthermore, in determining whether this law has been violated, the US attorney general "shall give not force and effect to state law authorizing or permitting assisted suicide or euthanasia."²⁷

The second purpose of the legislation is to promote research, education and development in this area. Title II of PRPA authorizes \$5 million to be made available on an annual basis for programs providing "education and training to health care professionals in palliative care."²⁸ In addition, the Act instructs the Agency for Healthcare Research and Quality ("AHRQ", formerly the Agency for Health Care Policy and Research) to develop a program to "advance scientific understanding of palliative care."²⁹ The AHRQ would also be responsible for educational directives such as collecting and disseminating palliative care protocols to health care providers, educational institutions and consumers.³⁰

The "Chilling" Issues

PRPA critics argue that the legislation would "chill" the tendency of medical professionals to aggressively treat pain for a number of reasons, the most obvious of which is that they would be threatened with a criminal investigation anytime a terminally ill patient treated with controlled substances dies.³¹ According to testimony given before the House Committee on the Judiciary, "regulatory scrutiny [is] the cause of the unrelieved pain problem."³² In order to avoid the disruption, embarrassment and expense that an investigation would generate, physicians would likely undertreat pain in their terminally ill patients. As a result, these individuals would endure ignoble, needless suffering, opponents conclude.³³

Supporters of the bill argue that it would promote the opposite effect because, in addition to the research and education it would foster in this area, it would

formally recognize the use of controlled substances for pain management as a "legitimate medical purpose" even if large doses were prescribed which unintentionally hastened death.³⁴ Currently, physicians can be faced with a criminal investigation of their prescribing practices under the CSA for administering controlled substances to a patient who later dies as a result, even if the drugs were only intended for palliative purposes.³⁵ In addition, investigations of physicians' prescribing practices already occur when drug diversion, substance abuse and other illegitimate uses of controlled substances are suspected.³⁶ Under PRPA, a doctor would be innocent of any criminal wrong-doing in a situation where the patient dies as a result of controlled substances being administered for pain relief. Thus, according to supporters, the Act would allow doctors to treat pain more aggressively than they might currently feel comfortable with, because they would be less constrained by burdensome legal consequences.³⁷

However, the purpose of a criminal investigation under PRPA would be to determine, in hindsight, the intent of the physician in treating the patient. This is a second reason why PRPA could negatively affect palliative care, particularly in terminally ill patients.³⁸ Under the proposal, intent is established where there was "knowledge that death was substantially certain to occur as a result of the conduct, or where death should have been reasonably expected to occur as a result of the conduct."³⁹ Unfortunately, aggressive treatments are often necessary to relieve a terminally ill patient's feelings of pain and suffocation, and the amount of medication that is effective in one patient may not even begin to alleviate the suffering in another.⁴⁰ Furthermore, controlling pain in dying patients sometimes, though rarely, requires such large doses of drugs that the patient's breathing reflex is suppressed and the dying process is hastened.⁴¹ Even experts in bioethics and health care law disagree as to when palliative care ends and euthanasia

begins.⁴²

Consequently, criminal intent could be found in a circumstance where none existed. How would a court view a physician whose patient, after repeatedly requesting assistance in hastening her own death, subsequently died from an overdose of pain-killing medication that was legitimately administered for palliative purposes?

One supporter of the bill, the National Conference of Catholic Bishops, contends that the difference between consequences which are intended and those which are merely foreseen “. . . is not especially obscure.”⁴³ In testimony given in support of PRPA on behalf of that organization, Richard M. Doerflinger, of the Secretariat’s Office for Pro-Life Activities, pointed out that pain control requires careful titration of the drugs administered in order to alleviate pain with minimal side effects, whereas assisted suicide generally involves one sudden and massive dose of drugs.⁴⁴ Medical practitioners strongly disagree that the determination is as easily discernible as this, however.⁴⁵

Finally, a physician allegedly violating this Act would be subject to a DEA-conducted investigation of her medical decisions under the provisions of the CSA.⁴⁶ Opponents argue that DEA officials are unqualified to distinguish between actions which constitute pain management and those which intentionally hasten death.⁴⁷ Furthermore, physicians have voiced concern with the idea of “medically untrained [bureaucrats] deciding if a doctor is using too much pain medication.”⁴⁸ Indeed, the position echoes a 1998 statement in which the Department of Justice expressed its lack of support for the LDAPA for the same reason.⁴⁹ As Joseph N. Onek testified for the DOJ, “[d]etermination 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 under the original 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."⁵⁰

Supporters counter this position by first pointing out that the DEA already has the authority to revoke a physician's DEA registration for assisting suicide in any of the 49 states where the practice has not been legalized.⁵¹ In addition, they reiterate that the educational programs implemented under PRPA would be designed to enlighten law enforcement personnel, such as DEA officials, as well as health care practitioners, so that investigators would be better able to evaluate the different decisions made under different circumstances.⁵²

Regardless of whether PRPA is enacted into law, physicians in general have expressed support for a training program that would be aimed at helping law enforcement personnel better understand the medical questions that enter into palliative care practices, particularly in terminally ill patients.⁵³ Within the context of PRPA, however, many remain doubtful that such a program would truly allow these individuals to adequately evaluate many of the situations that would be in question.⁵⁴ As indicated in testimony before the House, "[i]t is unrealistic to think the Secretary of Health and Human Services will be more successful at effectively training law enforcement officials than medical schools or Boards of Medical Examiners have been at training physicians."⁵⁵

The Constitutional Issues

Perhaps the best arguments made on both sides for their respective positions are those concerning the Constitutional questions. Although a discussion of the Constitutional issues surrounding the legalization of physician-assisted suicide is beyond the scope of this article, a brief summary of those that have been raised is helpful in order to better evaluate the positions outlined above.

It is no secret that supporters of PRPA also generally support a nation-wide ban on physician-assisted suicide. Considering the Constitution's separation of state and federal powers, the fact that states have long regulated their own medical practices, and the role of the states in the physician-assisted suicide question indicated by the Supreme Court in its *Glucksberg* opinion, however, it is unlikely that federal legislation banning physician-assisted suicide altogether could be enacted and successfully upheld in court. However, the federal government can, and has, indicated that it does not support the practice.⁵⁶ PRPA is simply one more means through which the federal government chooses to further its objective.⁵⁷

As mentioned earlier in this paper, the CSA regulates the dispensing of controlled substances on a federal level.⁵⁸ Therefore, even if a physician is authorized by the state to prescribe medications, she is only able to prescribe controlled substances with a federally-administered license from the DEA and is subject to revocation of that license and possible criminal charges if her prescribing practices "endanger public health and safety."⁵⁹ Supporters of PRPA contend that physicians who prescribe controlled substances intending to hasten the death of a terminally ill patient should be subject to investigation of their actions because they are endangering the health and safety of their patients.⁶⁰ Furthermore, by allowing these doctors to retain their DEA licenses, the federal government is supporting a practice which it specifically opposes and which has never been authorized by Congress or the President.⁶¹ Finally, to allow the 1998 Attorney General's determination to stand is to allow the states to limit the application of federal law, which is specifically prohibited by the Constitution.⁶²

Opponents of PRPA point out that the CSA grants a physician the authority to prescribe controlled substances "if the applicant is authorized to dispense . . . controlled substances under the laws of the State in

which he practices," and thus, if a state legalizes physician assisted suicide, then the DEA license of a doctor who has complied with the state laws regarding practice should not be revoked.⁶³ While this is true, the Act also allows revocation of the DEA license for endangering public health and safety, as stated above. So if one considers such practice "endangerment," then revocation would be authorized.

Perhaps a stronger argument on behalf of those opposing PRPA and federal bans on physician assisted suicide is that such legislation gives the federal government the responsibility to "define appropriate medical practice and regulate such practice through the use of criminal penalties."⁶⁴ Opponents contend that the practice of medicine and its regulation is a responsibility that belongs to the states, not the federal government. Furthermore, the Supreme Court has expressed that the states are the appropriate forum in which this issue must be addressed. In her concurring opinion to *Washington*, Justice Sandra Day O'Connor stated that "[t]hroughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician assisted suicide. Our holding permits this debate to continue, as it should in a democratic society."⁶⁵ Justice O'Connor continued: "There is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who should seek to end their suffering and the State's interest in protecting those who might seek to end life mistakenly or under pressure. . . . In such circumstances, 'the challenging task of crafting appropriate procedures for safeguarding. . . liberty interests is entrusted to the "laboratory of the States."⁶⁶

Conclusion

Everyone, from health care practitioners and consumers to the legislators themselves, agrees on the

need for better palliative care. PRPA effectively fosters that goal through its Title II provisions for research and educational initiatives. However, this intent may be hindered by the punitive measures contained in Title I. Although legislators point out that Title I will clarify the status of the law in this area to protect both physicians as well as their patients, this is precisely what may compromise Title II benefits. It appears to be the legislators, rather than health care consumers, who so strongly desire the clarification provided in Title I. In Oregon, at least, health care consumers have twice stated that they don't want this type of "protection."

Regardless of one's personal views on physician assisted suicide, PRPA provisions beg the question: whose pain is being relieved?

Endnotes

1. *The Medical Use of Controlled Substances, 1999: Hearings on H.R. 2260 Before the Subcomm. on the Constitution of the House Judiciary Comm.*, 106th Cong. (1999) (statement of Richard M. Doerflinger, Associate Director for Policy Development at the Secretariat for Pro-Life Activities, National Conference of Catholic Bishops).
2. *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 at 310 (1990).
3. See 145 CONG. REC. S14774 (daily ed. November 18, 1999) (statement of Sen. Nickles).
4. See H.R. 2260, 106th Cong. § 201, § 101 (1999).
5. *The Medical Use of Controlled Substances, 1999: Hearings on H.R. 2260 Before the Subcomm. On the Constitution of the House Judiciary Comm.*, 106th Cong. (1999) (statement of

Ann Jackson, Executive Director and Chief Executive Officer, Oregon Hospice Association).

6. See H.R. 2260, § 101 (1999).
7. See 145 CONG. REC. H10876 (daily ed. October 27, 1999) (statement of Rep. Rothman).
8. See Controlled Substances Act, 21 U.S.C. §801, §871 (1999).
9. 21 U.S.C. § 823.
10. See 21 U.S.C. § 824.
11. See *id.*
12. See Assisted Suicide Funding Restriction Act, 42 U.S.C. § 14401.
13. 145 CONG. REC. S14774, *supra* note 3.
14. *Washington v. Glucksberg*, 521 U.S. 702 at 728 (1997).
15. *Id.* at 735.
16. See OR. REV. STAT. §§127.800-.897 (1999).
17. See Henry Hyde, "Pain Relief Promotion Act of 1999," CONG. PRESS RELEASES (Federal Document Clearing House, Inc.), Sept. 9, 1999.
18. See *id.*
19. See *id.*
20. See H.R. 4006, 105th Cong. (1998).

21. *See id.*
22. *See Kill the Pain, Not the Patients*, OREGONIAN, July 1, 1999.
23. Hyde, *supra* note 17.
24. H.R. 2260, § 101 (1999).
25. *Id.*
26. *See* 21 U.S.C. § 824.
27. H.R. 2260, § 101 (1999).
28. H.R. 2260, § 201 (1999).
29. *Id.*
30. *See* H.R. 2260, § 201 (1999).
31. *See* David Orentlicher & Arthur Caplan, *The Pain Relief Promotion Act of 1999: A Serious Threat to Palliative Care*, 283 JAMA 255, 256 (2000).
32. Jackson, *supra* note 5.
33. *See id.*
34. Hyde, *supra* note 17.
35. *See id.*
36. *See Pain Management and End of Life Care, 1999: Hearings on S. 1272 Before the Senate Health, Education, Labor & Pensions Comm.*, 106th Cong. (1999) (statement of Yank D. Coble, MD, on behalf of the American Medical Association).

37. *See id.*
38. *See* H.R. 2260, § 101 (1999).
39. Nicholas W. van Aelstyn & Todd G. Glass, *Pain Management at Risk; Proposed Law Could Chill Treatment for the Terminally Ill*, LEGAL TIMES, Feb. 21, 2000, at 68.
40. *See* Orentlicher, *supra* note 31.
41. *See* Doerflinger, *supra* note 1.
42. *See* David Orentlicher, *The Supreme Court and Physician-Assisted Suicide: Rejecting Assisted Suicide but Embracing Euthanasia*, 337 NEW ENGLAND JOURNAL OF MEDICINE 1236 (1999).
43. *See* Doerflinger, *supra* note 1.
44. *See id.*
45. *See Pain Management and End of Life Care, 1999: Hearings on S. 1272 Before the Senate Health, Education, Labor & Pensions Comm., 106th Cong. (1999)* (statement of James P. Rathmell, MD, Director, Pain Management Center, Fletcher Allen Health Care); *see also The Medical Use of Controlled Substances, 1999: Hearings on H.R. 2260 Before the Subcomm. On the Constitution of the House Judiciary Comm., 106th Cong. (1999)* (joint statement of the American College of Physicians and the American Society of Internal Medicine).
46. *See* 21 U.S.C. § 824.
47. *See* Jane Glenn Haas, *When Does Pain Relief Become Suicide?* SAN DIEGO UNION-TRIBUNE, Jan. 15, 2000, at E4; *see also* Orentlicher, *supra* note 31.

48. Haas, *supra* note 47.
49. See *Assisted Suicide, 1998: Hearings on S.2151 Before the Senate Judiciary Comm.*, 105th Cong. (1998) (statement of Joseph N. Onek, Principal Deputy Associate Attorney General, Department of Justice).
50. *Id.*
51. See Nickles, *supra* note 3.
52. See *id.*
53. See *The Use of Controlled Substances, 1999: Hearings on H.R. 2260 Before the Subcomm. On the Constitution of the House Judiciary Comm.*, 106th Cong. (1999) (statement of David E. Joranson, Director, Pain & Policy Studies Group, Comprehensive Cancer Center, University of Wisconsin in Madison); See also Orentlicher, *supra* note 31.
54. See Jackson, *supra* note 5.
55. *Id.*
56. See 145 CONG. REC. S14774, *supra* note 3.
57. See Hyde, *supra* note 17.
58. See 21 U.S.C. § 823.
59. 21 U.S.C. § 824.
60. See *Kill the Pain, Not the Patients*, *supra* note 22; see also Nickles, *supra* note 3.
61. See Nickles, *supra* note 3; see also Hyde, *supra* note 17.
62. See Nickles, *supra* note 3; see also Hyde, *supra* note 17.

63. 21 U.S.C. § 823; *see also* Orentlicher, *supra* note 31.

64. van Aelstyn, *supra* note 39.

65. *Washington v. Glucksberg*, 521 U.S. 702 at 735.

66. *Id* at 737.

