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The Pain Relief Promotion Act of 1999

by Christian Downs

With the recent media focus on end-of-life issues, several members of Congress have recently weighed in with legislation known as the Pain Relief Promotion Act of 1999 (PRPA). Both the House version (H.R. 2260, introduced by Congressman Henry Hyde [R-Ill.]), and the Senate companion bill (S. 1272, introduced by Senator Don Nickles [R-Okla.]), would amend the Controlled Substances Act (CSA) to promote pain management and palliative care without permitting assisted suicide and euthanasia. The bill explicitly states that intentionally using a controlled substance to assist in a suicide is not authorized by the CSA. Violators would lose their Drug Enforcement Administration (DEA) license.

In the past, federal legislation that attempted to address this issue has been viewed by many in the cancer care and patient advocacy communities to be an unacceptable intrusion of the federal government into the role of medical decision making. Many advocates have been concerned that physicians—especially oncologists—would be reluctant to use aggressive palliative care, especially at the end of life, for fear of civil or criminal prosecution.

The Pain Relief Promotion Act, which several major medical associations have tacitly supported, is an attempt to address the gray ethical area between euthanasia and appropriate end-of-life care. The bill would add a provision to the Controlled Substances Act, acknowledging the legitimate medical purpose of controlled substances in the management of pain or discomfort, even if their use increases the risk of death for the patient. It states that, under federal law, any state law authorizing or permitting assisted suicide or euthanasia would be superseded by this federal law.

This bill is a direct attempt to circumvent Oregon's Death with Dignity Act and other future state legislation that may address the issue of physician-assisted suicide.

The bill would provide for education and training programs for law enforcement personnel on the appropriate and necessary use of controlled substances in pain management in an attempt to draw clear lines between assisted suicide and appropriate medical care. In another provision of the bill, the Agency of Healthcare Research & Quality (AHRQ) would be authorized to collect and disseminate protocols and evidence-based practices regarding palliative care. In addition, AHRQ would provide grants for the Department of Health and Human Services for the development and implementation of training in palliative care.

Many believe this bill is a significant departure from last year's aborted Lethal Drug Abuse Prevention Act. According to the American Medical Association, the addition of the language explicitly acknowledges the medical legitimacy of the "double effect," where use of controlled substances is intended for pain management with the foreseen consequence of an increased risk of death. Thus, such a bill provides a new and important statutory protection for physicians prescribing controlled substances for pain. Many advocates are confident that identifying the "double effect" in the bill's language will address concerns that language in the Lethal Drug Abuse Prevention Act would have chilled appropriately aggressive prescriptions for pain management.

The Pain Relief Promotion Act takes a different approach from last year's Lethal Drug Abuse Prevention Act regarding the role of the DEA. Last year's bill cited participation in physician-assisted suicide as a reason to revoke a physician's DEA registration, and specifically permitted revocation or denial of registration if the DEA had reason to suspect a physician's intention to assist a suicide. Conversely, the Pain Relief Promotion Act focuses on whether the state law is in the public interest. This distinction would seem to allow the United States Attorney General to ignore state laws similar to that in Oregon. While the PRPA would not technically overturn such laws, it would severely hamper the ability of patients to invoke them, since physicians would be unable to prescribe intentionally lethal doses of federally controlled substances.

At press time, H.R. 2260 had 153 co-sponsors in the House and the Senate version twenty-five. Some providers and patient advocates remain concerned about language regarding education and training programs for law enforcement personnel. They argue that the language must be fine-tuned to clearly communicate to the law enforcement community the legitimate use of controlled substances for pain management.

Finally, even if the bill passes both houses of Congress and is signed by the president, it is unclear whether the law meets constitutional standards. Many constitutional lawyers believe that the implicit conflict between state laws

continued on page 37

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continued from page 7
such as Oregon's and the PRPA could subject the law to constitutional review.

OFF-LABEL INDICATIONS & LAWS

If you ever wondered how important your state off-label laws are, consider this piece of information. In a study recently completed by ACCC staff, forty-three new cancer drugs with forty-nine initially approved indications have been approved by the FDA since 1992. Over that same period of time, 171 new off-label indications were added by the three (now two) reference compendia.

Just this past legislative cycle, five states adopted off-label laws using language found in ACCC's model legislation. At this time, thirty-seven states currently have off-label laws. These states include Alabama, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Virginia, and Washington.

In other off-label news, a federal judge has ruled the FDA Modernization Act (FDAMA) violates the First Amendment by prohibiting drug companies from distributing peer-reviewed publications containing information on the off-label use of drugs. This ruling strikes down an FDAMA requirement that pharmaceutical companies file supplemental NDAs within six months of starting to distribute peer-reviewed materials on off-label uses of drugs.

THE PRESIDENT'S DRUG BENEFIT PLAN

On July 2, 1999, President Clinton unveiled his proposal to modernize and strengthen Medicare for the twenty-first century. One of the largest and probably most expensive pieces of his proposal is the development of a Medicare prescription drug benefit. According to the White House, this proposal would create a new and voluntary prescription drug benefit that would be called Part D. The administration theorizes all Part D beneficiaries would be able to purchase their prescriptions at prices that private-sector benefit managers are able to negotiate. In addition, the new benefit would have no deductible and would pay half of the participant's drug costs, up to a limit of $5,000 ($2,500 in Medicare payments). Premiums are estimated to be $24 in 2002 and $44 in 2008 when fully implemented. Beneficiaries would receive their benefits through private pharmacy benefits managers or other qualified entities. According to the proposal, prescription drugs currently covered under Medicare Part A or B would still be covered under current arrangements and would not be counted against the Part D benefit limit.

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There already is some dispute as to the cost of such a program. According to an analysis performed by the Congressional Budget Office, the Clinton administration underestimated the cost of providing a Medicare prescription drug benefit by roughly $50 billion. The CBO analysis took into account new, higher projections of drug spending from HCFA. HCFA's projections include increased spending on drugs for the institutionalized population and the effect of Medicare reforms on participation in the Medicaid program.

Unfortunately, while every cancer care provider and patient advocate would want increased access to prescription drugs, we need to be watchful of how such a benefit would be paid for. Any trade-off that would reduce current cancer coverage would certainly be unacceptable.