Establishing a Right to Palliative Care at the End of Life

The following is adapted from an article by Charles H. Wilson, Establishing the Right of the Terminally Ill to Adequate Palliative Care: The Litigation Alternative, published in the April 1999 issue of the Journal of Palliative Medicine.

Introduction

The question of adequate palliative care to ameliorate the pain and suffering of individuals with a terminal illness is infused at every level with legal issues and concerns. One impetus for current efforts to improve such care has been the attempt to create a constitutional right to physician-assisted suicide for individuals who face an agonizing death. At the same time, clinical studies have begun to show that pharmacological and other options are available to relieve most of the pain that often accompanies a final illness.\(^1\)

In federal courts in New York and Washington, proponents of physician-assisted suicide contended that individuals have a constitutionally protected liberty interest in deciding the time and manner of their own deaths and a right to a physician's assistance in achieving death. Eventually, the United States Supreme Court ruled unanimously that there was no such constitutional right,\(^2\) thereby upholding the states' power to make physician-assisted suicide a criminal offense.

Several of the justices found it significant that New York and Washington imposed no legal impediments to adequate pain management for the terminally ill. For example, in her concurring opinion, Justice Sandra Day O'Connor noted:

The parties and amici agree that in these States a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication, from qualified physicians, to alleviate that suffering, even to the point of causing unconsciousness and hastening death.\(^3\)

For Justice O'Connor, the fact that terminally ill individuals could, under existing state laws, receive the pain relief necessary to alleviate their suffering undermined the most compelling argument for physician-assisted suicide. Justice Ruth Bader Ginsburg expressed her full agreement with Justice O'Connor.\(^4\)

Justice Steven Breyer was even more explicit, conceding that a strong argument could be made for a constitutional right to "die with dignity," a right that would include "the avoidance of unnecessary and severe physical suffering."\(^5\) But, like Justice O'Connor, he noted that "the laws of New York and Washington do not prohibit doctors from providing patients with drugs sufficient to control pain despite the risk that those drugs could themselves kill."\(^6\)
Justices John Paul Stevens and David Souter also included adequate palliative care as one of the serious issues confronting the terminally ill and suggested that barriers to such care might require reconsideration of the decisions in the physician-assisted suicide cases.\(^{(7)}\)

Whether the *dicta* of those five justices will eventually become the basis for the Supreme Court's finding a constitutional right to adequate palliative care must await an appropriate future court case. In the meantime, the availability of medications for adequate pain management remains a contentious issue under federal and state laws.

Numerous clinical studies have shown that opioids are an important component of any pain-management regimen for the terminally ill. But opioids are tightly regulated under the federal Controlled Substances Act,\(^{(8)}\) and state regulatory authorities carefully monitor and sometimes challenge the opioid prescription practices of physicians subject to their authority. Such license-revocation or suspension proceedings invariably end up in state courts.

The Bazelon Center seeks to identify legal barriers to palliative care, including pain management, for individuals with a terminal illness and to assess whether litigation is an appropriate means of eliminating or lowering the barriers. Two issues are the focus of initial inquiries: 1) administration of the Medicare Hospice Benefit and 2) state regulatory oversight of the use of opioids in pain management.

### Administration of the Medicare Hospice Benefit

The Medicare Hospice Benefit is available to terminally ill Medicare recipients who have a prognosis of six months or less to live and who waive their right to "curative" treatment under Medicare. Both of those conditions have evoked criticism, but the six-month rule has been the most contentious.\(^{(9)}\)

Congress added the hospice benefit to Medicare by 1982 amendments to the Social Security Act, apparently without giving much thought to the six-month requirement. At the time, the hospice movement was just becoming established in this country, and the patients most likely to choose hospice were those with advanced malignant diseases. Some, but not all, cancers follow a fairly predictable trajectory from the diagnosis of a terminal condition\(^{(10)}\) to death. However, making an accurate prognostication for any *individual* with a nonmalignant terminal condition, such as congestive heart failure, chronic obstructive pulmonary disease or dementia, is extremely difficult, because the pace of dying is affected by many factors over a substantial period of time.\(^{(11)}\)

Neither the legislation nor its implementing regulations provide any significant guidance on application of the six-month rule.

It is not clear whether a 6-month prognosis means that nearly all patients (more than 99%) should expire within 6 months or that 10% or even 50% of patients might still be alive at 6 months (the latter being akin to the usual way of thinking in terms of median survival). Depending on the extent to which hospices might be forced to bear excessive costs when patients live beyond 6 months, ... this lack of definition can have profound effects on the potential hospice population.\(^{(12)}\)

Two other factors have exacerbated the difficulty in administration of hospice benefit. First, in 1995, the Office of Inspector General of the Department of Health & Human Services (HHS) undertook an investigation into allegations of fraud in connection with the operation of the Medicare hospice benefit.\(^{(13)}\) The investigation looked askance at any hospice with more than a few patients who survived...
longer than six months after being certified eligible.

One consequence of the investigation was a precipitous drop in hospice enrollment, indicated by a greatly reduced increase in hospice payments in 1996 "due in part to a lower rate of patient enrollment, after the Office of Inspector General found that some hospices were inappropriately enrolling patients by making inaccurate life expectancy determinations."(14)

Another possible impact of the inquiry was a drop in the average length of Medicare recipients' stay in hospices. While the number of Medicare beneficiaries enrolling in hospice increased by 42% between 1994 and 1997, their average length of stay in hospice declined by 10 days. The decline was attributed in part to the investigation because doctors had become reluctant to certify patients for the hospice benefit until death was imminent.(15)

Oddly, HHS has not attempted to recover money improperly paid to the offending hospices. Such proceedings would provide an avenue for hospices to challenge the inspector general's interpretation of the six-month rule.

One thing is certain: the publicity surrounding the investigations has made doctors reluctant to certify and hospices reluctant to accept Medicare patients until there is no question that death will ensue in fewer than six months and often quite a bit sooner. The effect has been to deprive Medicare recipients and their families of the full range of services available under the hospice benefit, including the development of an appropriate pain-management plan and the time necessary to tie up the loose ends of one's life.

A second issue related to the hospice benefit is concern that inconsistent criteria are being applied to assess compliance with the six-month rule. The Health Care Financing Administration (HCFA) contracts with private entities, each responsible for a geographical region, to carry out many of the tasks associated with administering Medicare. These "Fiscal Intermediaries" (FIs) receive requests for payments from hospices for services provided to Medicare beneficiaries, evaluate the hospices' compliance with applicable statutory and regulatory requirements, and authorize payments for the services provided. The various FIs have adopted local medical review policies for evaluating whether a person diagnosed with a terminal, nonmalignant illness has six months or fewer to live. Since the jurisdiction of each FI is geographical, two individuals in identical stages of a terminal illness can be evaluated differently because of where they live. A court could well conclude that the hospice benefit is being administered in an arbitrary and capricious manner, a classic ground to invalidate administrative actions.

**Pain Management and Government Regulation**

However, litigation cannot address two issues related to inadequate pain management for the terminally ill: the adequacy of medical education and the attitudes of those involved in the dying process. An American Medical Association survey revealed that only five of 126 medical schools in the country required a separate course on the care of the dying and only 26 percent of 7,048 residency programs surveyed offered training on the medical aspects of care at the end of life as a regular part of the curriculum.(16)

The attitudinal problem relates to fears on the part of patients, their families and physicians that the use of opioids in the quantities required to alleviate the pain of a final illness will lead to addiction. These fears are rooted in misconceptions about the nature of addiction and the legitimate medical use of opioids. For example, those who abuse drugs such as opioids do so for the "high" they experience. Yet
one survey showed that more than 85% percent of cancer patients experienced dysphoria rather than euphoria when opioids were administered to treat their pain.\(^{17}\) Attitudes, however, do not have to be well grounded to interfere with proper palliative care.

Apart from those considerations, physicians often encounter significant regulatory barriers when they use opioids to treat pain. Two facts delineate the conundrum faced by physicians engaged in pain management for the terminally ill. First, opioids, and particularly morphine, are the most effective drugs for alleviating the pain experienced by people in their final illnesses. Second, opioids are a major focus of efforts to curb drug abuse. Consequently, physicians who use opioids to treat pain are often scrutinized closely by federal or state regulators.

Opioids are among the drugs listed under Schedule II of the Controlled Substances Act as having a high potential for abuse that may lead to severe psychological or physical dependence, even while having a currently accepted medical use in treatment.\(^{18}\) This tension drives the regulatory problems that face physicians using opioids to alleviate the pain accompanying terminal illness.

The Drug Enforcement Agency (DEA) is the federal enforcement agency charged with preventing the illegal use and abuse of controlled substances. But when a physician who prescribes a controlled substance in the course of professional practice, he or she is outside the DEA's enforcement authority.\(^{19}\) The responsibility for policing prescriptions of these drugs in the course of professional practice rests with state regulatory authorities, such as state medical boards.

State regulation of prescription practices has not been as benign as the federal government's. Until 1970, states' anti-drug laws, more often than not, were driven by perceptions of abuse rather than the realities of medical need. Beginning in 1970, all states replaced their drug control laws with legislation based on a model called the Uniform Controlled Substances Act (UCSA) that was designed to bring more consistency to drug control policies.\(^{20}\)

While the UCSA achieved a degree of consistency among the states, it had two significant shortcomings. First, unlike the federal Controlled Substances Act, the UCSA did not expressly acknowledge the acceptable medical uses of controlled substances. Second, the UCSA left each state to work out its own definition of "addict." In some states, the effect has been to equate drug addiction with drug dependence and/or habitual drug use, two conditions that describe the terminally ill patient whose pain is managed with opioids.

The result has been policies and practices in some states that deter or unduly restrict the ability of a physician legitimately to prescribe the dosage of opioids that terminally ill patients need for pain relief. For example, some states have restricted the number of dosage units that can be dispensed at one time. This causes many patients to ration drugs for fear of running out before a prescription can be refilled; it also costs patients additional dispensing fees. Other states require physicians to use multiple-copy prescription forms provided by state agencies. These forms increase physicians' record-keeping burdens and have been found to discourage the prescribing of the drugs that require such forms.\(^{21}\)

While motivated by the states' desire to reduce drug abuse, such restrictions weigh most heavily on people suffering from the pain that accompanies a final illness. For example, in a 1993 study of 897 physicians caring for cancer patients, 86 percent reported that most patients with cancer were under-medicated for pain. Another study a year later disclosed that patients with nonmalignant diseases received less adequate pain treatment than patients with cancer.
One of the significant impediments is physicians' fear that prescribing an adequate quantity of opioids will result in an investigation... Even members of state medical boards do not have a clear understanding of what is legally and medically acceptable in using opioids to treat pain.(22)

Efforts to reverse these trends began in the early 1990s and have begun to show some progress. For example, the Federation of State Medical Boards, working in cooperation with the Pain and Policy Studies Group at the University of Wisconsin and others, has sponsored a series of educational workshops for members of state medical boards.(23) During the same period, an increasing number of states have enacted intractable pain laws or their medical boards have issued guidelines for physicians using opioids to treat intractable pain.(24) While these actions hold the promise of relaxing the regulatory restrictions that physicians perceive on their opioid prescription practices, fears and inhibitions that have built up over the years will not vanish overnight.

Moreover, state medical boards are not the only entities that pose a threat to physicians who prescribe opioids in appropriately large quantities to alleviate the pain of a final illness. State prosecutors and other actors in the criminal justice system can also be a threat.

For example, a special panel of forensic professionals was appointed in Volusia County, Florida, after the a District Medical Examiner and his associate were suspended for identifying 19 deaths for further investigation because of high blood levels of opioids.(25) The panel reported that none of the deaths warranted further investigation, although some had been attributed to homicide and all had been labeled suspicious. In most of the cases, the panel found that the "toxic" levels of morphine to which the medical examiner attributed death were based on an assumption that the deceased had been "pharmacologically naive," a term that describes individuals not previously treated with opiate narcotics, such as morphine, for pain. In fact, the 19 deceased individuals in Volusia County had either died in hospices where they had been given opioids in appropriately large doses to manage the pain of their terminal illnesses or had died in intensive care units of hospitals from severe trauma after being sedated with opioids for severe pain.

The panel of forensic professionals was unanimous in concluding that none of the deaths warranted further investigation. It criticized the original autopsy reports for failing to consider the clinical treatment of the deceased prior to death and basing conclusions solely on levels of opioids in the blood at the time of death. While the panel vindicated the treatment of the 19 deceased individuals prior to death, it does not require much imagination to understand the chilling effect the initial autopsy reports must have had on physicians engaged in pain management in Volusia County.

As a further example, some nurses at a nursing home in eastern Maryland faced criminal charges because an autopsy disclosed that a patient at the home had opioids in her body at the time of death. The patient, a 90-year-old woman with congestive heart failure, had suffered a stroke and had an irregular heart beat, a fever and a seizure in the days preceding her death. Apart from the presence of opioids in her body, the autopsy disclosed that the patient had suffered an acute stroke and had an acute infection prior to death. Yet the local prosecutor brought criminal charges, including conspiracy to commit first degree murder, against three nurses, based solely on the presence of the opioids. While those charges never went to trial,(26) the prosecutor's action sent a chill through health care professionals in nursing homes throughout Maryland.

The Bazelon Center believes that unduly restrictive state medical board policies on the prescription of opioids and unfounded criminal charges or other punitive actions against health care professionals engaged in appropriate pain management are legitimate targets for preventive litigation.
One difficulty with a state medical board's actions against a particular physician, or the types of inquiries or criminal charges described above in Florida and Maryland, is that they do not always get the public notice that they should. For the most part, they are publicized, if at all, in the local community or among members of the affected health care community. Only if such incidents come under the light of public scrutiny are they likely to be challenged and shown to be what they are: a serious threat to the ability of terminally ill patients to get the palliative care and appropriate pain management they need to ease the burdens of a final illness.

Conclusion

A plethora of problems continues to inhibit the ability of health care professionals to provide adequate palliative care, including effective pain management, to people with terminal illnesses. These problems range from outdated attitudes about the use of opioids, fostered by unfounded concerns about addiction, and inadequate training of physicians, to unnecessarily restrictive regulatory policies. Litigation is not a panacea that will cause all the problems to disappear. However, when the problems arise in a context in which the legal process likely will be directly or indirectly implicated, properly targeted litigation can be a needed antidote to assure terminally ill individuals that they can receive appropriate palliative care.

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ENDNOTES


4. Id., 117 S.Ct. at 2310.

5. Id., 117 S.Ct. at 2311.

6. Id.


9. There is not always a clear demarcation between curative and palliative medicine. For example, surgical procedures are the paradigm of curative medicine, but some surgery can serve a palliative purpose. See G.P. Dunn, Surgery and Palliative Medicine: New Horizons, 1 Journal of Palliative Medicine 215 (1998). Even the requirement that a person be "terminally ill" to be eligible for the Medicare hospice benefit has been criticized. E.g., J. Lynn, Geriatricians, Public Policy, and Practice Standards for the Care of the Dying, 43 Journal of American Geriatrics Society 553 (1995); J. Lynn. F.E. Harrell, F. Cohn, M.B. Hamel, N. Dawson & A.W. Wu, Defining the "Terminally Ill:" Insights from SUPPORT, 35 Duquesne L. Rev. 311 (1996).

10. "Terminal condition," as used in the text, means that the particular disease or condition will no longer respond to attempts to bring about a cure.


18. 21 United States Code § 812(b)(2).
19. D.E. Joranson & A. Gilson, *Controlled Substances, Medical Practice, and the Law*, in Psychiatric Practice Under Fire: The Influence of Government, the Media and Special Interests on Somatic Therapies, pp. 173-94 (H.I. Schwartz, ed. 1994). The authors note that a physician's prescription practices might constitute terrible medicine, the grossest form of medical misconduct or malpractice and still not be subject to DEA jurisdiction as along the prescriptions in question were issued in the course of professional practice.


25. The information reported in the text about the Volusia County situation is from a letter, dated July 30, 1998, to Joan E. Wood, M.D., Acting District 7 Medical Examiner, from Stephen J. Nelson, M.D., who chaired the panel of forensic professionals.

26. The charges against one of the nurses were dropped for lack of evidence. The two other nurses, however, committed an error in judgment that proved quite costly. On the day before the elderly patient's death, she was in great distress because of dyspnea. There was no written order in her chart authorizing the administration of opioids. So the two nurses "borrowed" medicine from another patient and gave it to the dying elderly woman. It was that "borrowed" medicine that was found in that patient's body at the autopsy. In exchange for the prosecutor's dropping all charges, including conspiracy to murder, in the original indictments, the two nurses entered guilty pleas to a charge of administering a controlled substance without proper authorization. They served 30 days in jail, were fined and subsequently lost their nursing licenses for their error in judgment. However, the charge to which they entered their guilty pleas was far removed from the original charge of conspiracy to commit first degree murder. (This information about the Maryland nursing home incident was provided by Dr. Timothy J. Keay, a Soros Faculty Scholar in the Geriatrics Division of the Department of Family Medicine at the University of Maryland School of Medicine in Baltimore.)