



Relieving Pain: What are today's ethical and legal risks?

by David A. Fleming, M.D.

Failure to treat pain is something for which physicians can now be held accountable.



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Abstract

Many physicians have poor understanding about the symptoms of terminal illness. There is also surprisingly little data about treating symptoms compared to treating disease. Subsequently pain and other forms of suffering are often undertreated, despite the availability of effective interventions. Fear of retribution is often coupled with the moral notion that aggressive pain treatment may cause premature death. Legal and ethical obligations may compete but an appreciation of both is needed to inform effective palliative care.

Introduction

In June 2001 a California jury found an internist liable for reckless neglect in under-treating a dying man's pain, and ordered the physician to pay \$1.5 million to surviving family members.¹ The negligence determined in this case was not due to improper diagnosis or treatment of a disease, but was solely on the basis of inadequate pain control. This landmark case is the first time a jury

decided that a physician's neglect constituted elder abuse. The physician's argument in this case was that more aggressive treatment with narcotics would have hastened the patient's death by causing respiratory distress. His fear was that causing the death of the patient in this way would have placed him at risk for civil action, or could have lead to disciplinary, or even criminal charges.

This case has set legal precedent. While physicians in this country historically have worried that they could face criminal prosecution or regulatory action for over-prescribing controlled substances, this verdict means that under-prescribing may be just as risky legally. As observed by a representative of the Compassion in Dying Federation, "Failure to treat pain is something that physicians can now be held accountable for."²

When facing the complexities of care at the end-of-life everyone-patient, nurse, physician, and caregiver alike-endorses the importance of providing adequate relief from pain and suffering.³ This attitude of compassion and care is the grounding principle of the healing profession. Yet, physicians in this country still don't do a good enough job of providing pain relief,

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even when the most modern advancements in medical technology and drugs are available. Patients with terminal illness often fear pain and suffering more than death which is why many express a desire to end life well before the indignity of suffering is upon them.⁴

These fears are well founded. Between 10 percent and 50 percent of patients in programs devoted to palliative care report significant pain shortly before death.⁵ Investigators in an extensive nationwide study of end-of-life care found that after an intervention designed to inform physicians about patient preferences and improve palliative care, there was no improvement in pain control or other aspects of treatment for terminally ill patients.⁶

The barriers to adequate palliative care are substantial. Society as a whole, and subsequently its health care providers, tends to view the subject of death as anathema to good health care. Death as the enemy must be “defeated,” not acquiesced to. Often there are time limitations in a busy medical practice and there may be prognostic uncertainty by the health care team as the patient deteriorates. More often, however, the barriers to aggressive pain control are fear of reprisal, a poor understanding about the use of narcotic drugs and addiction, avoidance of the subject, and otherwise inadequate communication between the patient and physician.⁷

Physicians understand the obligations of their profession and the oath that they took to help the suffering.^{8, 9} However, end-of-life

issues historically have not been emphasized in training and physicians are often ill equipped to meet the challenge of palliative care. Physicians tend to fear reprisal if they are viewed as “giving up” too soon or as prescribing narcotics too heavily. There also may be unavoidable conflict between the expectations of the patient and family who want pain medication, and the fear of professional sanction or of what the Drug Enforcement Agency (DEA) might do when individual prescribing practices are scrutinized. Increasing awareness of this concern has encouraged research and numerous published articles that underscore the need for greater understanding of the ethics and laws governing the use of opioids and other controlled substances, and better pain management skills in physicians.

Increasingly, medical societies, academic think tanks, health care organizations, public health groups, consumer groups, and state and federal governments are identifying pain management as a priority, especially for patients with chronic illness who are dying. In a recent report by the Institute of Medicine, “Approaching Death: Improving Care at the End-of-Life,” there is a call to action at all levels to accept death as a part of life, to improve care at the end-of-life, and to assure people that they will be neither abandoned nor maltreated as they approach death.¹⁰ The expectation of cure at all costs, fears of litigation, and professional regulation have created barriers in clinical practice and in professional training. But there is now an unprecedented

trend to create good policy in order to appropriately regulate medical practice and the use of controlled substances without jeopardizing patient welfare.

The Changing Legal Environment

The federal government’s attempt to regulate potentially addictive and harmful medications has been around for over 30 years. With growing concern about the control and distribution of opioids in this country, and the illegal use and availability of narcotics stemming from the 1960s, the United States Congress passes the Controlled Substance Act (CSA) in 1970, which acknowledged the legitimacy of prescribing narcotics and hypnotics, but also monitored and regulated their use.¹¹ The CSA goes further to confirm that physicians have an obligation to treat patients who are suffering from intractable pain. In order to meet the needs of the elderly and disabled who are terminally ill, Congress provided for Medicare hospice benefits in the Tax Equity and Fiscal Responsibility Act of 1984 (TEFRA). To confirm the patient’s rights to refuse treatment, Congress also passed the Uniform Rights for the Terminally Ill Act in 1989 and the Patient Self-Determination Act in 1990. Both of these laws protected the patient’s right of refusal, but not the right to adequate palliative care or the right to assisted death in the face of terminal illness.

With growing concern over misuse of prescription drugs and the administration



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of lethal overdoses for dying patients, Congress amended the CSA in 1984, which empowered the DEA to revoke a physician's federal drug licenses if controlled substances were used to "endanger health and safety," regardless of whether state law was violated.¹² The status of the DEA had shifted from being a monitoring security agency to being a policing regulatory agency with power to severely sanction practicing physicians. This has had a subsequent chilling effect on the willingness of physicians to prescribe narcotics, even when indicated.

State policies regarding the use of controlled substances may be more restrictive than those of the federal government. Many state laws have not recognized the value of using narcotics, nor that their use is standard in medical practice. Some statutes perpetuate the belief that opioids unduly hasten death.¹³ Missouri has two statutes that address pain management: the Uniform Controlled Substances Act (195.010 R.S. Mo) and the Intractable Pain Treatment Act (195.080 R.S. Mo). The pain treatment statute in Missouri does identify the use of opioids and pain management as being part of medical practice. And, though the controlled substances statute restricts narcotic prescriptions to a thirty-day supply, the supply may be increased to up to three months if the physician describes on the prescription the medical indications for a larger supply.

It is also explicitly stated that,

"No physician shall be subject to disciplinary action by the board solely for prescribing, administering or dispensing controlled substances when prescribed, administered or dispensed for the therapeutic purpose for a person diagnosed and treated by a physician for a condition resulting in intractable pain, if such diagnosis and treatment has been documented in the physician's medical records." The key word is "documentation."¹⁴ As in every aspect of medical practice, physicians should provide good documentation to support their prescribing habits.

Current federal law, Missouri state law, and DEA regulations acknowledge that prescribing opioids is appropriate for the treatment of pain, and that there is no intent to limit physicians prescribing for intractable pain, even if the use of such substances may increase the risk of death.¹⁵ The United States Supreme Court has also recognized that patients suffering from terminal illness have a constitutional right to adequate palliative care even if such treatment hastens death.¹⁶ The Supreme Court stops short, however, of recognizing a patient's "right" to assisted death. The recent statutory trend has been toward improving the knowledge and skill of providers, and encouraging the appropriate use of opioids for intractable pain. Over the past few years, however, several legislative agendas have once again cast fear and doubt on the aggressive use of these medications for pain relief.

In 1995, Oregon became the first government to legally allow

physicians to prescribe controlled substances to assist the suicide of patients with terminal illness and intractable pain who have requested help to die.¹⁷ Oregon's referendum allows physicians to legally act in direct violation of the Controlled Substances Act of 1970. Recognizing Oregon's right to govern itself, an exception was created in 1998 by then United States Attorney General Janet Reno, indicating that no adverse action would be taken against Oregon physicians who were in compliance with state law. This sequence of events brought strong reaction on both sides of the argument regarding physician-assisted death.^{18, 19}

In response members of the United States Congress introduced the Legal Drug Abuse Prevention Act in 1998 with the singular goal of overriding Reno's decision and to halt Oregon's legalization of physician-assisted suicide. This bill, which ultimately became the Pain Relief Promotion Act of 2000, was met with resistance from the American Medical Association (AMA) and other proponents of palliative care fearful of the chilling effect that such a law would have on physicians and their willingness to aggressively treat pain.²⁰ Ultimately the "Pain Bill" was modified to insinuate a more patient-oriented approach to palliative care, which then garnered support from the AMA and hospice organizations, but the strong punitive component remained. Resistance to the punitive aspects of this bill has continued from the private and professional sectors, fearful that patients will suffer for want of pain



-Dying Well-

*It was pain, raw and unyielding that drove him to ask for help.
"Oh my God, I can't take this. I can't do this. I don't want to die
like this. It's so dark, so horrible, it hurts so bad."
The nurse drew up the morphine. "It's a beast, clawing at you,
but we're going to take care of that beast right now."
The needle pierced his skin and in ninety seconds, he relaxed and said,
"You mean it, don't you?"
"Mean what?"
"You'll be here."*

(New York Times, July 6, 1997, Paul Wilkes²⁴)

relief because cautious physicians may hold back when prescribing narcotics.²¹

Presently the Pain Relief Promotion Act is dormant due to the recent actions of United States Attorney General John Ashcroft. In November 2001 Ashcroft removed the Reno exception for Oregon physicians and instructed DEA agents to move against those who used controlled substances in violation of the Controlled Substances Act of 1970.²² The order does not call for criminal prosecution of doctors, but it does permit suspension or revocation of drug licenses. In support of palliative care, the Ashcroft order does stipulate that pain management is a valid medical use of controlled substances.

The legal environment of pain relief remains in flux at both the state and federal level. State statute may conflict with federal law, and both are susceptible to interpretation. In general professional societies, government organizations, and state boards tend to encourage the use of narcotics for pain relief, but the prescribing habits of physicians are still under scrutiny. In today's legal environment the threat of retribution continues to have a chilling effect on physicians' prescribing practices and the effectiveness of palliative care.

The Ethical Conflicts when Treating Pain

One could argue that the norms guiding the treatment of suffering patients are ethically uncontestable.

Physicians, quite simply, should do everything in their power to relieve pain and suffering because that is what they are supposed to do as physicians. This characteristic of serving the patient's welfare is not only in knowing what is best for the patient clinically, but also in having compassion, integrity, and respect for the wishes of the patient. Every activity of medicine is guided by the beneficence and trust discovered in the relationship that is formed between patients and their health care providers.²³ The principal of beneficence obligates the health care professional to ease the burden of suffering during the natural course of disease and death. This duty requires efforts to alleviate both physical and emotional suffering through appropriate means, as established by professional standards and the laws of society.

These words are impressive, even imposing, and can be very useful when doing an ethical analysis of a clinical situation or when making an intellectual argument. But, for the clinician who deals with the intricacies of illness and death there are many competing issues that pertain, and which should be factored into the ethical calculation. Many physicians have strongly held beliefs regarding the use of drugs that can be used to hasten death. The clinical circumstances may

physicians typically want to remain in good standing with their colleagues, the DEA, and with state licensing boards. These entities have review processes, along with by-laws, regulations, and laws that may be unclear or difficult to interpret. These concerns are legitimate because the values and beliefs of the physician also deserve respect. The welfare of physicians is important, because there are many other patients for whom the sustainability of their physician is important.

These arguments for the physician are compelling, but what is the patient's view from the gurney?

The patient and physician exist in a covenant relationship that has one simple understanding. We promise to be there, and they trust that we will keep that promise. This is not to say that physicians and nurses must, or even can be physically at the patient's side continuously, but we can provide the assurance of our knowledge and skill, and that care will be delivered in a coordinated fashion by a skilled team of providers. Incorporate to this pledge is that patients will not be slighted at their time of greatest need. This is a challenging expectation in modern health care systems. Patient care, especially palliative care, requires a

be unclear and analgesics are often minimized until diagnostic accuracy is established. Also,



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delicate balancing of needs and responses that encompass more than the isolated application of principles, personal belief, medical science, or the laws of society. It requires all of that with the singular goal of helping the patient.

Today's physicians no longer have the luxury of being the sole proprietors of health care decisions. Many interested parties now lay claim to the decisions that direct the care of patients. These interests move together in a complex matrix of accountability sharing responsibility for the outcome.²⁵ Integrated health care systems, insurance plans, employers, government regulators, state boards, medical staffs, and provider groups all participate as stakeholders in the "insured lives" of patients. The physician, as one of many "interested patients," is often linked to others through independent contracts that demand accountability independent of the patient.

These outside contracts ethically obligate the physician, but only to the extent that they are capable of providing the needed services contracted for and that in doing so she will not abdicate strongly held moral beliefs or jeopardize the welfare of the patient. From an ethical as well as legal standpoint this means that physicians should document well and communicate effectively with patients and other members of the health care team. A typical

requirement of most physician contracts is that they sustain the knowledge and skill

necessary for their assigned duties, or provide appropriate referral when necessary. As members of society, physicians are also obligated to follow the laws of society, but they must also be willing to advocate for improvements in health policy when necessary.

When using narcotics in terminally ill patients the rule of double effect can be applied if the patient is suffering and beyond hope, and if the intent is to relieve suffering. The ethical argument is that there is good intent in attempting to relieve the patient's suffering, knowing that death may be hastened as a consequence of giving narcotics or other drugs that tend to suppress respiration with higher dosing.²⁶ This premise is well established and accepted both ethically and legally, but many physicians are hesitant to apply this doctrine because of personal beliefs that they will be "overdosing" the patient, even when the patient is suffering terribly with terminal illness. It can also be troublesome when the patient's clinical situation or prognosis is unclear, which may then heighten the concern about accelerating death when there is still hope for clinical improvement. Establishing "intent" is crucial, both legally and ethically. The intention and expectation of the health care providers and the patient can be established with good documentation in the medical record, also providing a reference point for further decision making as the clinical circumstances evolve.

Conclusion

Pain and other forms of discomfort are prominent contributors to suffering in individuals with terminal illness, but they tend to be undertreated. Clinical research on these symptoms holds out the hope of relief for suffering through better understanding of these symptoms and the development of new, more effective treatments.²⁷ Also important are a clear understanding of the legal environment and ethical deliberation that inform palliative care.

The Missouri Board of Healing Arts, like most state and federal agencies, recognizes that controlled substances, including opioids, may be essential in the treatment of acute and chronic pain.²⁸ The model guidelines provided by the Board explicitly state that physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice.

The legal environment in this country continues to offer mixed messages, but it appears to be moving toward encouraging better-trained physicians who know how to use controlled substances appropriately, and who will use them aggressively when they are needed. This is not to say that regulation and scrutiny of prescribing practices will cease to occur, nor the need for good documentation. These requirements will continue as a natural part of regulation.



The ethical dimensions of pain relief for dying patients are complicated and at times difficult to navigate. But, the ethics of palliative care will always challenge the thoughtful physician who considers the primacy of patient welfare in the context of other legitimate obligations. Remaining knowledgeable in the science of medicine and in the laws that pertain will strengthen the ability to act without fear. To inform decisions at the end-of-life physicians must take the time to communicate with patients and the other members of the health care team, to gain understanding of the goals and values that inform end-of-life decisions, and to document well.

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