



The Big Chill — Inserting the DEA into End-of-Life Care

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On October 5, 2005, the U.S. Supreme Court heard oral arguments in *Gonzales v. Oregon*. On the surface, this case is about the legitimacy of physicians' prescribing of medications under

Oregon's Death with Dignity Act and whether the federal government can overrule the states in defining "legitimate medical practice." Just beneath the surface, however, lies the risk of empowering agents of the Drug Enforcement Agency (DEA) — whose traditional role is to prevent drug abuse and diversion — to evaluate the end-of-life practices of physicians whose patients die while receiving prescribed opioids or barbiturates. A finding in favor of the Justice Department would not only nullify the Death with Dignity Act, permitting the DEA to penalize physicians for providing medications to hasten the deaths of terminally ill patients, but also have a chilling effect on

physicians' willingness to treat patients' terminal symptoms.

Uncontrolled pain and other distressing symptoms are the primary concerns and greatest fears of patients facing serious illness.¹ More than 90 percent of the pain associated with severe illness can be relieved if physicians adhere to well-established guidelines and seek help, when necessary, from experts in pain management or palliative care. For the infrequent instances in which all palliative care alternatives have been exhausted without providing adequate relief from the symptoms of advanced terminal disease, there is a growing consensus that sedation to the point of comfortable sleep is permissible.² Despite the

efficacy of opioids and a commitment by the medical profession to treat pain, abundant evidence suggests that patients' fears of undertreatment of distressing symptoms are justified.¹ Although a lack of proper training and overblown fears of addiction contribute to such undertreatment, physicians' fears of regulatory oversight and disciplinary action remain a central stumbling block.³

Several initiatives have lessened the adverse effects of regulatory constraints on symptom management.⁴ Many legislatures and regulatory boards have adopted model pain statutes that encourage compliance with established standards for the prescribing of pharmacologic agents for pain and other symptoms and that protect physicians who observe these guidelines from regulatory intrusion and possible prosecution. Other states have simplified or eliminated special prescribing

rules (such as those requiring the use of triplicate prescription pads) that were designed to control and monitor prescribing but that had the (presumably unintended) effect of discouraging all prescribing of controlled substances. California now requires training in pain management and palliative care as a condition of licensure.

Two cases in California highlight the legal consequences of physicians' undertreatment of pain, providing a counterweight to the fear of legal vulnerability for the prescribing of controlled substances.⁵ In 2001, in *Bergman v. Chin*, a jury found that a dying patient had received inadequate pain management and convicted the treating physician under the state's elder-abuse statute, awarding the patient's family \$1.5 million. In 2003, in *Tomlinson v. Bayberry Care Center*, charges of inadequate pain management were brought successfully against both the treating physician and the patient's nursing home. Both cases demonstrate that, in addition to representing an unacceptably poor quality of care, the undertreatment of pain may carry legal risks and consequences.

Nevertheless, physicians continue to believe that regulatory oversight translates into a high risk of disciplinary action for prescribing opioids and other controlled substances. Consider the following cases.

Patient 1, a young man, became acutely ill with an aggressive but highly treatable cancer that caused severe acute chest pain. Since he had to make quick and extremely difficult decisions about his treatment options, he

sought advice and pain medication from his trusted primary care physician — only to learn that his physician, wishing to be spared any possibility of regulatory suspicion, had never applied for prescribing privileges for strong opioids. At this critical juncture, the patient, who is himself a physician, had to find a new doctor in

This directive might open to investigation every instance of prescribing of a controlled substance for a dying patient.

order to receive standard pain treatment.

Patient 2, a middle-aged woman with progressive cancer that had metastasized to bone, had accelerating pain requiring increasing doses of morphine. She ran out of pain medicine earlier than anticipated, but her physician refused to refill her prescription for fear that she was using it too much and that he might be reviewed for overprescribing. When she went to the emergency department with a pain crisis, a palliative care consultant recognized that her worsening pain and increased morphine requirements were caused by the progression of cancer. With a moderate increase in her dose, satisfactory pain con-

trol was achieved, and the patient went home to live out her final months in relative comfort.

Patient 3 had advanced metastatic lung cancer and had been receiving opioids at home when he was admitted to the hospital with new metastases to his thoracic spine. He was confused, could not move his legs, had difficulty breathing, and was in excruciating pain — screaming whenever he moved and grimacing with each breath. He was near death, and the primary goal of medical care was to control pain, agitation, and dyspnea. He was given a subcutaneous infusion of opioids at an equianalgesic dose 30 percent higher than his usual dose, and the nurses were instructed to give him another dose, equal to 10 percent of the total daily dose, “as needed” every half hour if he appeared to be in pain (the proper approach, according to standard guidelines). But several nurses and physicians refused to give the “as needed” doses, despite evidence of continuing distress, because they feared hastening his death. Ethics and palliative care consultants were called in, and they refocused the team on the professional obligation to relieve pain and suffering. The patient died hours after receiving the additional doses, and some staff members remained unsettled about whether they might have been legally liable for “causing” his death.

For better or for worse, the DEA sets the tone and drives physicians' perceptions about the legal risk associated with prescribing Schedule 2 drugs (potentially addictive drugs with critical medical uses)

for seriously ill and dying patients. Concerns about regulatory oversight have led some physicians, such as Patient 1's provider, to avoid prescribing opioids entirely and have rendered others, such as the physicians of Patients 2 and 3, fearful or hesitant. It is likely that such physicians will be further intimidated if the role of the DEA is expanded as the federal government proposes — and the risk of the inadequate management of symptoms during serious illness will increase.

Two other attempts by the federal government to invalidate Oregon's Death with Dignity Act preceded *Gonzales v. Oregon*. The first was the Lethal Drug Abuse Prevention Act, which a year later was repackaged as the Pain Relief Promotion Act (PRPA) of 1999. The PRPA contained some valuable provisions that would have encouraged education and research in pain management and palliative care, but the primary purpose of both acts was to make prescribing controlled substances under the Oregon law a violation of the Controlled Substances Act.

Although the regulation of medical practice is the legal province of the states, the PRPA would have allowed the federal government to undermine state law by making it a crime for physicians to provide medications that humanely hasten death. Furthermore, the PRPA would have empowered the DEA to investigate whether or not such a violation had occurred, raising the specter of DEA oversight of every death of a patient who had received barbiturates or

opioids. After an outcry from both advocates and opponents of assisted suicide, all of whom recognized the danger such legislation posed to the practice of pain management and palliative care, the PRPA died in committee.

Then, in November 2001, U.S. Attorney General John Ashcroft issued a directive suggesting that the prescription of Schedule 2 medications under the Oregon law violates the Controlled Substances Act, since "assisting in a suicide is not a 'legitimate medical purpose.'" The State of Oregon and several interested parties challenged this directive, arguing that the definition of legitimate medical practice is a responsibility of the states, not a function of the Controlled Substances Act. If passed, this directive would allow the federal government to overrule established state law, empower the DEA to investigate whether a violation had occurred, and potentially open to investigation every instance of prescribing of a controlled substance for a dying patient. The U.S. Court of Appeals for the Ninth Circuit supported the arguments made by the State of Oregon, and the case was recently heard by the Supreme Court. The Court has not yet announced its decision.

This type of DEA involvement in medical practice would adversely affect far more patients than those few who seek assistance with a hastened death in Oregon. If the government thus oversteps its legitimate role and expertise, allowing DEA agents, trained only to combat criminal substance

abuse and diversion, to dictate to physicians what constitutes acceptable medical practice for seriously ill and dying persons, it will undermine palliative care and pain management for the much larger number of seriously ill patients in all states. Physicians may become hesitant to prescribe the best available medications to manage the pain, agitation, and shortness of breath that sometimes accompany the end stages of illness. As a result, they may, in essence, abandon patients and their families in their moment of greatest need.

An interview with Dr. Quill and Dr. Meier can be heard at www.nejm.org.

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