

Who should regulate the practice of medicine?

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Treating pain and suffering is a fundamental duty in the practice of medicine. Mechanisms and strategies for pain management are part of the art of medicine, and substantial clinical skill, experience, and judgment are essential to proper pain management. Unfortunately, the policy issues of pain management are intertwined with the debate on physician-assisted suicide (PAS), to the detriment of patients in pain. The debate around PAS is passionate on both sides, but people directly involved in providing care to patients need to remain focused on keeping the issue of pain management separate.

Adequate pain control remains an important issue for patients in the United States, and evidence indicates that pain is still under-recognized and undertreated.¹ Attempts by the federal government to minimize illegal use of legitimate pain medications and to make PAS under the Oregon Death with Dignity Act (DWDA) illegal have an important impact on pain management practices. Most physicians have no personal involvement with the DWDA, but all physicians are affected by possible (real or perceived) limitations on the prescription of pain medications. Although it is unnecessary for pain management issues to be enmeshed in the debate about the legality of PAS, trying to prohibit use of a medication for one purpose without raising questions about its use for other purposes is a tricky proposition.

The federal government, through the Drug Enforcement Agency (DEA), has taken steps to crack down on physicians prescribing large amounts of OxyContin®, a long-acting morphine derivative.² Attorney General John Ashcroft has also asked the Supreme Court to review *Oregon v. Ashcroft*, a case dealing with the DWDA.³ For physicians to feel safe prescribing adequate pain medication to control pain, even in refractory cases, two issues need to be resolved: 1) Who is the proper regulator of medical practice—the federal government or the states? and 2) Can states or the federal government decide what a legitimate medical practice is?

The US Supreme Court has the opportunity to review the case of *Oregon v. Ashcroft*⁴ at the request of Attorney General John Ashcroft.³ When the Supreme Court has considered cases involving PAS in the past, the Court has expressly endorsed adequate pain control and has emphasized that pain control considerations are separate from PAS considerations. The Supreme Court has considered the issue of assisted suicide in two previous cases, *Washington v. Glucksberg*⁵ and *Vacco v. Quill*.⁶ While neither of these cases directly dealt

with issues of pain control, they do affect the practice of pain control indirectly. *Glucksberg* and *Vacco* include language that expressly approves the use of adequate pain control, even when it might have the effect of hastening death.⁷

Oregon v. Ashcroft deals with the “Ashcroft Directive,” which directs the DEA to enforce the Attorney General’s determination that prescribing controlled substances for the purpose of assisting suicide is not a “legitimate medical purpose.” Therefore, any physician who writes such a prescription violates the Controlled Substances Act (CSA) and is subject to prosecution.⁸ This challenge to the legitimacy of the DWDA through the enforcement powers of the DEA presumes that the CSA⁹ empowers the federal government to regulate medicine. Traditionally, regulation of medical practice has been left to the state governments.¹⁰ States license physicians, describe the acceptable scope of their practice, and set up regulatory strategies for review and discipline. If the DEA is allowed to discipline physicians for practicing medicine in compliance with state law, such as a physician prescribing a lethal dose of medication in compliance with the DWDA, then the DEA is regulating the practice of medicine. Determining which practices constitute “legitimate medical purpose[s]” is the type of determination typically left to state regulatory and disciplinary boards. Historically, when physicians were involved in DEA prosecutions, it was for diverting drugs or prescribing drugs that are trafficked on the street and are not used to treat an actual medical condition. The actions promoted by the Ashcroft Directive cross the line into regulating the practice of medicine.

This issue has another important application in pain management. Some states protect physicians who aggressively control pain from criminal sanctions if they are acting in good faith. Such protections would be suspect if the DWDA could be overridden by federal enforcement agencies.

Many people believe that the Supreme Court will refuse to review *Oregon v. Ashcroft*. The decisions in *Glucksberg* and *Vacco* allowed states to prohibit PAS, finding that the issue of whether to PAS may be prohibited is one that the states have the authority to decide for themselves. Presumably, this leaves the states open to decide to permit it as well, although the Court has not expressly decided this. Refusing to hear the *Oregon v. Ashcroft* case would have the effect of affirming this position. Refusing to hear the case will also protect state sovereignty in the regulation of medical practice.

What constitutes the safe and effective practice of medicine has been typically left to the medical profession to determine. In his directive to the DEA, "Dispensing of Controlled Substances to Assist Suicide,"¹¹ Attorney General Ashcroft made the determination that assisting suicide is not a "legitimate medical purpose" under the CSA. The CSA allows the DEA to regulate controlled substances when they are not used for a "legitimate medical purpose."¹² States have been empowered to allow or disallow certain practices, but generally, the medical profession has determined the validity of a treatment or procedure.

This language in the Ashcroft Directive, as well as the increasing practice of targeting physicians who prescribe high doses of narcotics to manage refractory pain,¹³ makes physicians concerned that their attempts to aggressively treat pain will have legal consequences. The doctrine of double effect holds that an act is proper and ethical if the intent is proper and ethical, despite the fact that the act may have more than one effect.¹⁴ Therefore, it is appropriate to aggressively treat pain, even if that means death may occur sooner, as long as the intent is to treat pain. This was approved by Supreme Court Justice O'Connor in her concurring opinion in *Vacco* and *Glucksberg*.¹⁵ The majority opinion in *Vacco* makes exactly this point, endorsing aggressive pain control and affirming that the decisive issue is the physician's intent to control pain.¹⁶

The Attorney General attempts to divorce the PAS issue from the issue of pain control, titling a paragraph of the memo "Use of Controlled Substances to Manage Pain Promoted."¹⁷ However, the DEA has specifically targeted OxyContin as a drug of abuse and warns that the higher strength versions of the drug should only be used in opioid-tolerant patients.¹⁸ While it is true that only opioid-tolerant patients should be on high doses of the drug, or any opioid, many patients with chronic severe pain become tolerant and require high doses. The concerning issue is that a physician's judgment on the amount of opioid medication needed to control a patient's pain is subject to the federal government's interpretation of what is a "legitimate medical purpose." The Attorney General and DEA are creating a precedent for medical decision making by federal agencies and taking this power out of the hand of physicians. *Oregon v. Ashcroft* may not be heard in the Supreme Court, and the DEA has a multipronged initiative for dealing with OxyContin abuse, but the effects on physicians responsible for managing pain are significant. One-quarter of physicians say that fear of discipline by a medical board or prosecutor has caused them to alter their treatment strategies.¹⁹

Ultimately, practitioners need to honor the duty to help patients and find the moral courage to treat pain adequately in spite of concerns of legal consequences. Fear of pain when dying is a substantial concern for many people, and many patients are in pain at the end of their lives.²⁰ Acting in the patient's best interest requires that physicians treat pain.

Physicians can protect themselves by documenting their decision making and intent to treat pain. Specifically, physicians must document that they have prescribed high doses of pain medication because the degree of pain the patient was experiencing justified the dose, and the need to treat the pain outweighed the risks. Ultimately, physicians need to advocate on behalf of their patients and their colleagues. Pain control is, and always will be, important to patients. Physicians who aggressively treat pain and undertake to help those patients whose pain is most severe deserve respect and admiration. Physicians need to advocate keeping the determination of what constitutes valid medical practice firmly within the hands of practitioners. Even as the sensational issue of *Oregon v. Ashcroft* fades, these problems will persist and continue to impair the quality of people's lives.

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