

Defining “legitimate medical purpose”

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Case Law, a regular AJHP section, is intended to provide pharmacists with timely information about recent court decisions that may affect pharmacy practice. Each installment includes pertinent background information, excerpts from the opinion of the court, and brief commentary. The contributing editor for the section is David B. Brushwood, J.D., Professor, Pharmacy Health Care Administration, University of Florida, Box 100496, Health Science Center, Gainesville, FL 32610.

The U.S. Department of Justice (DOJ) does not have the authority to determine which health care activities constitute a “legitimate medical purpose” under federal Drug Enforcement Administration (DEA) regulations. The U.S. Court of Appeals for the Ninth Circuit has held in *Oregon v. Ashcroft* that this authority rests with state governments.¹

Background. In 1994, the state of Oregon enacted by ballot measure the U.S.’s first law authorizing physician-assisted suicide. Oregon’s Death With Dignity Act permits physicians to prescribe lethal doses of controlled substances to terminally ill residents. The law established procedures designed to protect vulnerable patients and ensure that their decisions are reasoned and voluntary. Oregon voters reaffirmed their support for the Death With Dignity Act on November 4, 1997, by defeating a ballot measure that sought to repeal the law.

Soon after the passage of this law in Oregon, several members of the U.S. Congress, including then-Senator John Ashcroft, urged then-

Attorney General Janet Reno to declare that physician-assisted suicide violated the federal Controlled Substances Act (CSA). She declined to do so. On November 9, 2001, newly appointed Attorney General John Ashcroft reversed the position of his predecessor and issued the “Ashcroft Directive,” which declared that physician-assisted suicide serves no “legitimate medical purpose” under DEA regulations. This directive made it unlawful for a physician to prescribe medications for assisted suicide and for a pharmacist to knowingly dispense medications for that purpose.

A doctor, a pharmacist, several terminally ill patients, and the state of Oregon challenged the issuance of the Ashcroft Directive. They contended that the directive criminalized conduct that is specifically authorized under Oregon law. The case was originally filed in federal district

court, where the judge issued a ruling in favor of the state of Oregon. The case was then transferred to the Ninth Circuit Court of Appeals, which took original jurisdiction of the matter.

Legal reasoning. The appellate court took no position on the merits or morality of physician-assisted suicide. The sole issue considered by the court was whether Congress has authorized the Attorney General to determine that physician-assisted suicide violates the CSA. The court held that the Ashcroft Directive violated the “clear statement” rule, contradicts the plain language of the CSA, and contravenes the express intent of Congress.

The clear statement rule requires that, unless Congress’s authorization is “unmistakably clear,” the Attorney General may not exercise control over an area of law traditionally reserved for state authority. The court noted the principle that state lawmakers, not the federal government, are the primary regulators of professional conduct. The court then ruled that the Ashcroft Directive was invalid because Congress has provided no indication—much less an “unmistakably clear” indication—that it intended to authorize the Attorney General to regulate the practice of physician-assisted suicide. Because Congress has not authorized such an intrusion into state authority, the Ashcroft Directive violated the clear statement rule.

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The court ruled that not only does the Ashcroft Directive lack clear congressional authority, it also violates the plain language of the CSA. The CSA expressly limits federal authority under the act to the “field of drug abuse.” The court said: “To the limited extent that the CSA does authorize federal regulation of medical practice, Congress carefully circumscribed the Attorney General’s role. The Attorney General may not define the scope of legitimate medical practice.”

In addition, according to the court, the legislative history of the CSA confirmed that the Attorney General has exceeded the scope of his authority. Referring to testimony in Congress at the time the CSA was passed, the court noted that the intent of Congress was to limit the CSA to problems associated with drug abuse and addiction. Congress was concerned that the CSA might encroach on a state’s traditional authority to regulate medical practice. According to congressional testimony, all decisions of a medical nature, if made by a federal agency at all, are to be made by the Secretary of Health and Human Services (HHS). Law-enforcement decisions made by the Attorney General are limited to those related to “the security of stocks of narcotic drugs and the maintenance of records on such drugs.”

The court concluded that the CSA was enacted to combat drug abuse. To the extent that the CSA authorizes the federal government to make decisions regarding the practice of medicine, those decisions are delegated to the Secretary of HHS. In summary, the court said: “The Attorney General’s unilateral attempt to regulate general medical practices historically entrusted to state lawmakers interferes with the democratic debate about physician assisted suicide and far exceeds the scope of his authority under federal law.”

Discussion. The ruling in this case is welcome news to those in health

care who provide controlled substances to patients. The implications of this case go beyond terminal illness and physician-assisted suicide. According to this case, the role of DOJ is to prevent drug abuse, not to decide what health care practices are acceptable or unacceptable. The Attorney General is the chief administrator of DOJ, and DEA is an agency of DOJ.

If a physician or pharmacist is engaging in activities outside the realm of health care, such as selling controlled substances to drug dealers with no therapeutic objective, DOJ is authorized to intervene. But DOJ has no business telling physicians or pharmacists what activities constitute acceptable health care practices. If a drug distribution activity is within the realm of health care, even if it is an alternative or novel practice, DOJ has no authority to intervene.

The authority of DOJ is described in a regulation promulgated by DEA. This regulation describes the lawful purpose for issuance of a controlled substance prescription.

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription . . . and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances.²

The key phrases “legitimate medical purpose” and “in the usual course

of his professional practice” are not defined. This omission invites conjecture about the meaning of the phrases. “Legitimate medical purpose” has no meaning unless “illegitimate medical purpose” has meaning. Yet medicine is inherently legitimate; there is no such thing as “illegitimate medicine.” A practice that is not legitimate is not medical. Perhaps conceptual stretching can produce examples of medical practices that might be illegitimate. Using controlled substances to enhance athletic performance or improve academic achievement come to mind. But these uses of controlled substances are not medical, and one should not have to engage in conceptual stretching to find an example to support a core definition. Where this analysis leads is to the conclusion that the words “legitimate” and “medical” are redundant. The phrase “legitimate medical purpose” can be reduced to “medical purpose” without losing any meaning. A practice that is not medical is neither legitimate nor legal under the DEA regulation. A practice that is medical is legitimate and is legal under the DEA regulation. DEA does not regulate within medical practice but simply discerns whether a practice is medical or nonmedical.

The phrase “usual course of his professional practice” is sometimes confused with “scope of practice,” but it has a very different meaning. “Course of practice” refers to the activities of a health care professional in providing care. “Scope of practice” refers to the credentials and qualifications of the health care professional and the limits these credentials may place on his or her activities. For example, a dentist may legally treat pain of the jaw but not pain of the abdomen, because abdominal pain is beyond the scope of a dentist’s practice. Being within the scope of one’s practice does not mean the practice is legal. When prescribing a drug to treat jaw pain, the dentist must en-

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gage in activities usually undertaken by those in the dental profession to remain within the usual course of dental practice. At times there is concern that a health care provider may be practicing outside the usual course of professional practice, because the health care provider has elected a specialty practice that limits its scope. Such concern is misplaced. The DEA regulation has nothing to do with the credentials or qualifications of a health care provider. It has everything to do with the *activities* of the health care provider. If those activities are not professional health care activities, then they are illegal under the DEA regulation; if they are professional health care activities, they are legal. DEA has no authority to pass judgment on the merits of a professional practice. Its role is limited to determining whether a practice is a professional practice.

DEA recognizes that its responsibility is to prevent drug abuse and not to interfere with professional practice. In an article published in 1983, the agency's Associate Chief Counsel said:

Acts of prescribing or dispensing of controlled substances which are done within the course of the registrant's professional practice are, for purposes of the Controlled Substances Act, lawful. It matters not that such acts might constitute terrible medicine or malpractice. They may reflect the grossest form of medical misconduct or negligence. They are nevertheless legal.³

In 2001, another agency commentator stated:

The DEA investigates practitioners and pharmacists when there is suspicion of criminal activity specifically the 'diversion' or sale of controlled drugs or prescriptions without legitimate need. To proceed with criminal or administrative actions, the DEA must have conclusive evidence of wrongdoing such as providing multiple prescriptions to individuals in fictitious names to avoid detection; trading drugs for sexual favors or money; or providing controlled substance prescriptions to known abusers despite awareness of actual harm

or of their arrests for selling the drugs that he had earlier provided.⁴

The Attorney General, DOJ, and DEA are not authorized to regulate within the practice of medicine or pharmacy. Activities performed within professional practice are regulated by state governments. Activities performed by a physician or a pharmacist outside of professional practice are subject to DEA regulation, under the auspices of DOJ and the Attorney General. The role of the federal government is to prevent drug abuse. The quality, character, and boundaries of practice within the professions are not its concern.

References

1. *Oregon v. Ashcroft*, 368 F.3d 1118 (9th Cir. 2004).
2. 21 C.F.R. 1306.04(a).
3. Stone S. The investigation and prosecution of professional practice cases under the Controlled Substances Act. *Drug Enforcement (newsletter)*. 1983; page 21.
4. Houck LK. The Drug Enforcement Administration, controlled substances and pain management. www.dea diversion.usdoj.gov/pubs/nwsltr/spec2001/page10.htm (accessed 2004 Oct 25).