

Affirmation of States' Authority to Define "Legitimate Medical Purpose"

[David B. Brushwood](#), J.D; Am J Health-Syst Pharm; 63(5); 2006. Posted: 2006-03-18.
[Identifier: <http://www.doctordeluca.com/Library/WOD/StateAuthorityLegitMed06.htm>]
[Source: <http://www.medscape.com/viewarticle/524498>]

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Introduction

In *Gonzales v. Oregon*,^[1] the Supreme Court of the United States has affirmed the ruling of two lower federal courts that the states, not the U.S. Department of Justice (DOJ), have the authority to determine what prescriptions have been issued for a "legitimate medical purpose." The context of the case was a challenge to the Oregon Death With Dignity Act, but the legal principles resolved in the case have nothing to do with physician-assisted suicide or a patient's right to decide when to die. If the U.S. Attorney General had won this case, DOJ, through the Drug Enforcement Administration (DEA), would have been given the authority to make decisions about the legality of prescriptions in all situations, not just end-of-life care. DOJ could, for example, have ruled that under all circumstances the prescribing of Schedule II barbiturates for insomnia is not a legitimate medical purpose, that prescribing Schedule II stimulants for attention-deficit/hyperactivity disorder is not a legitimate medical purpose, or that prescribing Schedule II opioids for longer than 60 days is not a legitimate medical purpose. This is not to say that DOJ would have done this, but it could have if the Attorney General had won the case. By ruling in favor of the state of Oregon, the Supreme Court has ensured that states, through their legislatures, professional licensing boards, and citizen initiatives, will continue to decide what uses of medications are for a legitimate medical purpose.

Background

In 1994, the state of Oregon enacted by ballot measure the Oregon Death With Dignity Act, the country's first law authorizing physician-assisted suicide. Oregon voters reaffirmed their support for the Act in 1997 by defeating a measure that would have repealed it. For Oregon residents to be eligible to request a prescription under the Act, they must receive a diagnosis from their attending physician that they have an incurable and irreversible disease that will cause death within six months. Attending physicians must also determine whether a patient has made a voluntary request, ensure that a patient's choice is informed, and refer patients to counseling if they might be suffering from a psychological disorder or depression causing impaired judgment. A consulting physician must examine the patient and the medical record and confirm the attending

physician's conclusions. A specific conscience clause protects the right of refusal by physicians and pharmacists who prefer not to become involved in this process.

Several members of 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). Reno declined to do so. Several years later, having lost his bid for reelection to the Senate and having been appointed Attorney General, Ashcroft issued what came to be known as the "Ashcroft Directive," in which he proclaimed that a prescription for physician-assisted suicide is not a prescription under federal law because it serves no legitimate medical purpose. In response, the state of Oregon, joined by a physician, a pharmacist, and several terminally ill patients, challenged the directive in federal court. A federal district court in Oregon entered a permanent injunction against the directive's enforcement. This ruling was affirmed by the U.S. Court of Appeals for the Ninth Circuit.[2] The case was then appealed to the Supreme Court.

Supreme Court Ruling

The injunction was affirmed by the Supreme Court, in a 6-3 split opinion, with Justices Kennedy, Stevens, O'Connor, Souter, Ginsburg, and Breyer voting to affirm the injunction, and Justices Scalia and Thomas, along with Chief Justice Roberts, dissenting.

The majority opinion relied on basic administrative law in its ruling. It is a general principle of administrative law that courts will defer to the interpretations that administrative agencies give to ambiguous laws they enforce. The reason for this deference is that administrative agencies have specialized expertise, allowing them to understand and apply technical concepts with which the courts are generally far less familiar. This judicial deference to the interpretations of administrative agencies is not absolute.

There are two situations in which courts will defer to the interpretation of a law by an administrative agency. Based on the case of *Auer v. Robbins*, courts grant substantial deference to an agency's interpretation of a regulation it has promulgated itself. This is called "Auer deference." Based on the case of *Chevron v. NRDC*, courts grant substantial deference to an agency's interpretation of an ambiguous statute enacted by the legislature. This "Chevron deference" is applicable when Congress has delegated authority to an agency to make rules that have the force of law and the agency's interpretation claiming deference was promulgated in the exercise of that authority. If neither Auer deference nor Chevron deference apply, a federal administrative agency's interpretation of an ambiguous statute or regulation is subject to judicial reinterpretation. The agency's interpretation will then be respected by the court only if it is based on reasoning that is persuasive to the court.

The Supreme Court ruled in *Gonzales v. Oregon* that Auer deference did not apply because the administrative regulation being interpreted by DOJ was a DEA regulation that merely parroted the language of the CSA. The phrase "legitimate medical purpose" in the DEA regulation is taken directly from the CSA. It is not the agency's phrase; it is

Congress's phrase. The court concluded that an agency "does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected to paraphrase the statutory language."

The Supreme Court likewise ruled that Chevron deference did not apply. The court noted that the Attorney General has rule-making power under the CSA, but this does not authorize the Attorney General to "make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law." The court concluded that the Attorney General has not been granted such authority in the CSA, noting that the structure of the CSA "conveys unwillingness to cede medical judgments to an Executive official who lacks medical expertise." The court acknowledged the importance of deference, but then observed that deference in this case was "tempered by the Attorney General's lack of expertise in this area and the apparent absence of any consultation with anyone outside the Department of Justice who might aid in a reasoned judgment." The court was concerned that the Attorney General's argument was not limited to physician-assisted suicide, explaining that, were his argument accepted, "he could decide whether any particular drug may be used for any particular purpose."

Left unencumbered by either Auer or Chevron deference, the court held that the Attorney General's reasoning was unpersuasive. Looking to the language of the CSA itself, the court said: "The statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally." The Supreme Court interpreted the phrase "legitimate medical purpose" to mean that DEA can regulate the diversion of controlled substances to purposes that are not medical, but the states can regulate the type of conduct to be considered within the realm of medicine. A medical practice is, by definition, legitimate, and DEA has no authority to regulate within medical practices.[3]

Discussion

The traditional authority of states to establish standards of practice in health care has been upheld. This Supreme Court ruling comes at a time of increasing antagonism between health care professionals and DEA. The ruling has the potential to defuse escalating concern over DEA's role in regulating the prescribing and dispensing practices of physicians and pharmacists, particularly in the area of pain management, where physicians and pharmacists have been subjected to heightened scrutiny by the agency. Perhaps now the medical and pharmacy professions can reclaim authority over their standards of practice through their power of self-regulation. The Supreme Court has invited them to do so by declaring that through the authority to regulate the professions, state governments should decide what activities fall within the definition of a legitimate medical purpose.

According to DEA, the primary source of diverted controlled substances is "criminal activity of physicians and pharmacy personnel." [4] This conclusion is reached despite

evidence that theft, robbery, burglary, hijacking, importation, and the Internet are also significant contributors to leaks of the supposedly "closed system" of controlled substance distribution.[5] All responsible physicians and pharmacists support government regulation and enforcement to reduce drug diversion at the physician and pharmacist level. However, regulation should not be so unbalanced that it has a chilling effect on the appropriate use of controlled substances. Strong regulation to prevent diversion must be tempered by the knowledge that legitimate patients will be denied necessary medications if physicians and pharmacists become so fearful of regulators that they adopt overly conservative practices to avoid being mistaken for drug diverters.

Although DEA denies the existence of such an effect,[6] recent encounters between registrants and the agency belie the denial. A recent case from the U.S. Court of Appeals for the District of Columbia illustrates this point.[7]

A Colorado physician was investigated for several months by DEA, after which she was told that her DEA registration would be revoked for violations of the CSA related to appetite suppressants. A hearing was held before an administrative law judge. The DEA investigator was the government's sole witness at the hearing. According to the court, the investigator "conceded that she was aware of no reports of diversion or abuse and no evidence that [the physician] had ever abused drugs or prescribed them for an illegitimate medical purpose." There was evidence that the physician had not kept good records, and the physician admitted that her record keeping was "abysmal." The judge recommended that no action be taken against the physician. After one year, during which the physician was in regulatory limbo, DEA ignored the judge's recommendation and revoked the physician's registration, primarily because she could not produce records to account for missing drugs.

The Court of Appeals reversed DEA's actions, issuing a stinging rebuke. The court said: "In light of the record evidence presented in this case, the DEA's suggestion of 'possible drug use' by [the physician] is both irresponsible and appalling. The suggestion is dangerously arbitrary and entirely unsupported." The court noted also: "The decision does not purport to rest on diversion of controlled substances or drug abuse. Therefore, the deputy administrator's passing comment on possible drug abuse is gratuitous and condemnable." The court concluded: "The agency decision is, in short, stunningly one-sided in focus and, thus, utterly arbitrary and capricious." Revocation of the physician's DEA registration was reversed.

The message of this case, and others like it, is that health care providers who occasionally have lapses in judgment will be shown no mercy by DEA, even if there is no evidence of drug diversion. It is this arbitrary and capricious regulatory perspective that has created a chilling effect on the prescribing and dispensing of controlled substances, particularly high-dose opioids for chronic pain. Health care professionals should certainly adopt practices that avoid abysmal record keeping, but regulators must understand that bad record keeping does not necessarily constitute drug trafficking. Patients are living and dying in pain because their health care providers are intimidated by regulators.

The story of the now-withdrawn DEA pain management FAQ provides further evidence of the high level of interference in medicine by an agency that at one time enlisted health care providers as allies in the prevention of drug diversion.[8] Negotiated over two years with representatives of the health care professions and proudly posted on DEA's Web site in August 2004, the FAQ document was disclaimed and withdrawn by the agency only six weeks later. In declarations following the withdrawal of that document, the agency has sought to micromanage medicine and pharmacy with rules concerning matters such as the number of legitimate prescriptions that can be written for a patient on the same day, as well as restrictions on practices that physicians and pharmacists may develop for the periodic dispensing of medications at designated time periods after they have been prescribed.

The *Gonzales v. Oregon* decision has the potential to bring order out of this chaos. While recognizing that DEA has authority to prosecute health care providers who engage in "illicit drug dealing and trafficking as conventionally understood," the decision makes it equally clear that promulgating standards for the licit use of controlled substances when diversion is not occurring is beyond the scope of the agency's authority. The number of legitimate controlled prescriptions that can be written on a single day, the conditions that can legitimately be treated with controlled substances, and the process through which a prescriber decides to prescribe or a dispenser decides to dispense are considerations for state regulators to address through the appropriate professional licensing agency.

When Congress has unambiguously stated limitations on medical and pharmacy practice to prevent diversion, those CSA provisions must be followed. For example, Schedule II prescriptions may not be refilled. Schedule III and IV prescriptions may not be filled or refilled more than six months after the date of issue. DEA may enforce these unambiguous provisions and has the authority to promulgate unambiguous regulations to amplify these statutory provisions. The role of DEA is to keep controlled substances from being diverted outside of medicine and pharmacy. But Congress has not given DEA or DOJ the authority to regulate by establishing rules for the handling of controlled substances in the care of patients within medicine and pharmacy when no diversion is occurring. Any use of medications within medicine and pharmacy that is "specifically authorized under state law" must be respected by DEA.

The Supreme Court has made it clear that standards of practice for physicians and pharmacists in the use of controlled substances are not a federal issue. The task now is for state boards of medicine and pharmacy to develop meaningful, flexible, practical, and specific standards for the use of controlled substances; they do not exist in most states. In the absence of specific standards at the state level, the federal government has filled the void with unnecessarily restrictive interpretations that do nothing to prevent drug diversion and that build barriers to the treatment of chronic pain and other conditions for which controlled substances are medically necessary. The states now have an opportunity to reassert authority over their professional standards.

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