Law and the Public's Health

GONZALES V. OREGON: IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

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This installment of *Law and the Public's Health* visits two related subjects that are periodically covered in this column: the role of federalism in formulating and enforcing public health policy, and the role of courts in interpreting the reach of public agency powers. These two issues represent classic areas of inquiry in public health policy and practice.[1] Recent installments analyzing food safety regulation[2] and state compassionate use acts[3] focus on these themes, and a recent column examining the power of federal agencies to ensure the cleanliness of the nation's waterways (*Rapanos v. U.S. Army Corps of Engineers*) considers how the United States Supreme Court approaches the question of federal agency claims of power to regulate individual conduct.[4]

This article visits these themes once again, examining the United States Supreme Court's 2006 opinion in *Gonzalez v. Oregon*,[5] which struck down efforts by the U.S. Attorney General, acting under a claimed grant of federal statutory authority, to preempt state medical practice law permitting physician-assisted suicide. The decision offers important insights into how the Court approaches questions involving the extent of federal powers to regulate conduct affecting the public's health, as well as questions involving the point at which federal conduct will be found to encroach on state powers.

BACKGROUND

In 1994, the Oregon electorate voted to legalize physician-assisted suicide under certain circumstances. The Oregon Death With Dignity Act (ODWDA) permits licensed physicians to dispense or prescribe—but not administer—a lethal dose of drugs to patients with incurable and irreversible diseases calculated to result in death within six months under the exercise of reasonable medical judgment. The law imposes a series of safeguards aimed at avoiding abuses. Physicians must ensure that a patient's request is voluntary and informed, and medical conclusions must be confirmed by an examining physician other than the patient's attending physician.[6] In order to fulfill a patient's request under the ODWDA, doctors must be registered with Oregon's Board of Medical Examiners and the federal Drug Enforcement Administration (DEA).

In its 1997 decision in *Washington v. Glucksberg*,[7] the United States Supreme Court ruled that although the Constitution did not create a fundamental right to physician-assisted suicide, decisions regarding whether or not to recognize and protect such a right fell within the legitimate Constitutional purview of states. The original Oregon statute survived a 1997 referendum vote, and evaluations of the law have shown its carefully circumscribed impact.[8] To date, Oregon remains the only state to expressly authorize physician-assisted suicide.

Congress enacted the Controlled Substances Act (CSA) in 1970 to regulate the manufacture, distribution, dispensing, and possession of controlled substances. The statute classifies controlled substances into five schedules based on their accepted medical uses, their potential for abuse, and their physical and psychological effects. The statute also provides that "[n]o provision of this subchapter shall be construed as indicating an intent [to exclude] any State law . . . otherwise . . . within the authority of the State, unless there is a positive conflict between [the CSA] and [state law]."[9] This provision establishes a federal policy of "conflict preemption"; that is, displacement only of state laws that clearly conflict with a provision of the federal law.

The CSA authorizes the U.S. Attorney General to regulate controlled substances prescribing practices and permits the Attorney General to deny, suspend, or revoke a physician's registration with the DEA if such registration is "inconsistent with the public interest."[10] Federal regulations further require that prescriptions for controlled substances "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[11]

Following enactment of the ODWDA, several members of Congress advocated DEA prosecution of physicians who engaged in assisted suicide practice, arguing that even if permitted under state law, such conduct violated the CSA. However, Attorney General Janet Reno determined that CSA did not authorize the agency to "displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate

medical practice."[12] Federal legislation to expressly authorize CSA enforcement against the state failed in Congress.

In 2001, Attorney General John Ashcroft (Janet Reno's successor who, during his Senate term, led the effort to use the CSA to overturn the ODWDA) issued an "Interpretive Rule" declaring that the use of controlled substances to assist suicide violated the CSA, thereby preempting state law to the contrary. Oregon, along with others, sued to enjoin application of the rule, arguing that the Attorney General exceeded his CSA powers. Plaintiffs won at the trial and appellate levels. In its decision, the Ninth Circuit Court of Appeals held that, by attempting to preempt state medical practice law, the Department of Justice rule impermissibly altered the "usual constitutional balance between the States and the Federal Government,"[13] and further, that the rule amounted to an *ultra vires* exercise of federal enforcement powers under the CSA, which precluded federal involvement in matters of medical policy.[13]

THE SUPREME COURT DECISION

By a 6–3 margin, the U.S. Supreme Court affirmed the Ninth Circuit's judgment. Writing for the majority, Justice Kennedy concluded that although the CSA grants broad rulemaking authority to the Attorney General, the Act also prohibits the federal government from "declaring illegitimate a medical standard for care and treatment of patients . . . specifically authorized under state law."[14] The Court carefully examined the scope of federal enforcement powers under the CSA and found that nothing in the Act authorized the Attorney General to define what constitutes legal medical practice. The Court noted that while the CSA authorizes the Attorney General to deny, revoke, or suspend a physician's DEA registration when doing so is consistent with the public interest (e.g., when a physician is determined to be abusing prescription drugs), federal law does not permit the executive branch to criminalize an entire class of lawful prescribing practice.

Furthermore, the Court ruled that despite the fact that the Attorney General has the power to "control" CSA-regulated drugs, the term "control" is defined as the power to "add a drug or other substance, or immediate precursor, to a schedule. . . ."[15] Moreover, the legal exercise of this power requires the Attorney General to act on the basis of evidence developed by the United States Department of Health and Human Services (DHHS) and, further, to utilize an Administrative Procedures Act (APA) rulemaking process. The Interpretive Rule, on the other hand, lacked a DHHS-provided evidentiary base and failed to adhere to APA standards. Indeed, in the Court's view, this mandatory, evidence-based process required when altering the CSA drug schedule underscored Congress' conclusion that medical judgments regarding controlled substances lie outside the purview of "an Executive official who lacks medical expertise."[16]

In the final analysis, the Court majority simply found no basis in either CSA's text or structure for the power claimed by the Attorney General: "[T]he statute manifests no intent to regulate the practice of medicine [which is] understandable given the structure and limitations of federalism, which allows the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."[17]

Three dissenting Justices—Scalia, Thomas, and Roberts—argued for deference to the Attorney General regarding his view of his powers, pointing out that if his claims were erroneous in Congress' view, then Congress always could override them. In this respect, the majority and dissenting opinions echoed a profound theme in evidence throughout the 2005–2006 term, namely, the Supreme Court's role in setting limits on the exercise of power by the Executive Branch of Government. (Strikingly, Justice Scalia took precisely the opposite view of federal executive branch powers when, in *Rapanos,* he cast aside federal agency arguments regarding the scope of their authority to regulate non-adjacent wetlands under the Clean Water Act. Indeed, in *Rapanos,* Congress had effectively validated the agency's rules by reauthorizing the statute without in any way disturbing the reach of federal agency powers, thereby proving Justice Scalia's point.)

IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

Gonzales v. Oregon sheds light on how the Supreme Court approaches controversies involving the exercise of power by federal agencies operating under statutes enacted by Congress pursuant to its broad Commerce Clause powers. Despite the breadth of Congressional power under the Commerce Clause, the Court is zealous about its authority to scrutinize the legal basis on which a federal agency claims to act. In *Oregon v. Gonzales,* the Court found that the Attorney General not only lacked legal authority to regulate medical practice but concluded that, if anything, the CSA denied him the very power he claimed. Similarly, in *Rapanos,* the decision turned on the Court's conclusion that the agency lacked the federal powers it claimed.

Gonzales v. Oregon is also instructive for its view

regarding Congressional power to regulate medical and health professions' practice. As Professor George Annas has pointed out,[18] there is no doubt after both this decision and the Court's previous decision in *Gonzales v. Raich* that the Court considers Congress to have the constitutional power to regulate medical practice. At the same time, this decision suggests that the Court will carefully review agency claims regarding the existence of such far-reaching enforcement powers, given the history of federal/state relationships and Congress' desire to preserve state governments' power to set public health standards.

As a practical matter, of course, Congress is intimately involved in protecting the public's health and welfare through the exercise of its spending, taxing, and regulatory powers. At the same time, *Gonzales v. Oregon* serves as a reminder that the Court is mindful of longstanding power-sharing custom, and thus does not treat lightly federal agency claims regarding their authority to preempt state law in the course of enforcing federal standards.

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10. 21 U.S.C. at 912.
11. Gonzalez v. Oregon, at 912, citing 21 C.F.R. § 1306.04(a).
12. Gonzalez v. Oregon, at 913.
13. Gonzalez v. Oregon, at 914. (Citations and internal quotation marks omitted.)
14. Gonzalez v. Oregon, at 916.
15. Gonzalez v. Oregon, citing 21 U.S.C. § 802(5).
16. Gonzalez v. Oregon, at 921.
17. Gonzalez v. Oregon, at 923. (Citations and internal quotation marks omitted.)
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