Law and the Public's Health

This installment of *Law and the Public's Health* reviews the recently decided U.S. Supreme Court case of *Wyeth v Levine*, which concerns the power of states to provide protections beyond those found in federal law against defective or misleading drug labeling.

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WYETH v LEVINE: IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

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This installment of *Law and the Public's Health* reviews *Wyeth v Levine*,[1] which concerns the power of states to provide added protections, beyond those found in federal law, against defective or misleading drug labeling. As such, this installment revisits the issue of federalism generally, and specifically, the question of when federal health statutes will be interpreted as preempting state law, a recurring theme in public health policy and practice.[2]

BACKGROUND

The federalism doctrine, which refers to the constitutional distribution of powers between the federal and state governments, has long played an important role in public health. Congress possesses broad constitutional authority to advance population health and has done so through a host of laws ranging from the Federal Food, Drug, and Cosmetic Act (FDCA)[3] to the Social Security Act.[4]

At the same time, states also engage in extensive health and welfare regulation, often in ways that overlap with federal law, frequently supplementing federal safeguards. Thus, for example, federal law establishes standards for preventing unsafe products from entering the market, while state laws may add remedies for people who are injured by unsafe products. In effect, state laws expand on federal standards, creating individual protections that complement federal regulatory schemes.

At times, federal statutes preempt state laws aimed at permitting individuals to seek judicial redress for injuries caused by negligence. These federal statutes expressly bar states from providing additional remedies not recognized under federal law. Perhaps the best known example of a preemptive federal statute in the area of health and health care is the Employee Retirement Income Security Act (ERISA),[5] which has been recognized by the U.S. Supreme Court as preempting any remedies other than those afforded under federal law and, thus, barring state tort remedies for injuries caused by the negligent operation of employee health benefit plans, specifically the negligent denial of coverage for medically necessary care.[6]

In considering preemption, the Supreme Court has recognized three different types of preemption: express preemption, implied field preemption, and implied conflict preemption. In express preemption, a federal statute explicitly supersedes state or local law.[7] In implied field preemption (an example of which is ERISA), the Court concludes that congressional intent, as discerned from the statute and history, is to displace all state laws that may relate to the subject area addressed by the federal legislation. Finally, in implied conflict preemption, the Court determines that compliance with both federal and state regulation is impossible, or that state law poses an obstacle to the accomplishment of congressional objectives.[7] Conflict preemption was the issue in *Wyeth v Levine*.

In recent years, the Supreme Court increasingly has found preemption of state tort remedies for health injuries in areas where federal agencies are involved in product and safety regulation. Setting the stage for *Wyeth* were two pro-preemption cases, *Geier v American Honda Motor Co., Inc.*[8] and *Riegel v Medtronic, Inc.*[9]

In *Geier*, the Supreme Court held that state tort remedies for injuries resulting from a vehicle manufacturer's failure to install airbags in the plaintiff's car were preempted by a comprehensive regulatory scheme, developed by the U.S. Department of Transportation (DOT) through a formal rulemaking process, which

allowed vehicle manufacturers to install alternative safety restraints. Relying on the doctrine of implied conflict preemption, the Court held that permitting state tort remedies in this instance would frustrate the purpose and objectives of DOT's comprehensive scheme.

In *Riegel*, the Court held that the FDCA preempted a state tort suit alleging injury resulting from a Class III medical device that had received U.S. Food and Drug Administration (FDA) approval following the agency's rigorous premarket approval process. Relying on the doctrine of express preemption, the Court determined that in the case of Class III devices subject to premarket approval, the FDCA explicitly forbids states from imposing any requirements in addition to those provided in the statute. A state law duty of care, whose negligent violation would result in liability, represented such an additional requirement in the Court's view.

In 2006, the FDA, reflecting this evolving Supreme Court jurisprudence, announced a significant shift in its position on preemption as it relates to liability actions in connection with FDA-approved drugs. Previously, the FDA had taken the position that federal drug labeling standards represented a legal public health safety floor and that states could expand legal protections by affording individual remedies for negligent conduct, such as a negligent failure to warn, through inaccurate or misleading labeling, of possible drug risks.[1] The FDA's logic in encouraging additional protections was based in both law and policy. From a legal perspective, nothing in the FDCA appeared to preempt additional state legal protections where drugs were concerned. From a policy standpoint, state duty-to-warn statutes could be viewed as providing an added safeguard in the case of drugs in the market, particularly as FDA post-marketing surveillance capabilities are so limited.

The 2006 about-face came in the form of a preamble to a final FDA drug labeling regulation.[10] Stating agency position (regulatory preambles are nonbinding but reflect agency policy), the FDA indicated for the first time that the approval of drug labels preempts state duty-to-warn laws imposing liability for negligent labeling.[10]

WYETH v LEVINE

The facts

In April 2000, Diana Levine sought treatment for recurring severe nausea and headache. As part of the prescribed treatment regimen, the physician's assistant injected Levine with the antinausea drug Phenergan using the intravenous (IV)-push method—one of three methods of administration commonly used to inject the drug. The FDA-approved label for Phenergan did not prohibit this method of administration, but included several warnings and urged caution in administering the drug via IV injection because of the risk of arterial exposure. Although the drug is considered safe and effective when used as directed in the approved labeling, Phenergan is corrosive and can cause irreversible gangrene upon entering a patient's artery. In this case, Phenergan accidentally entered Levine's artery and she subsequently developed gangrene, resulting in amputation of her right forearm. Levine sued Wyeth, the drug's manufacturer, alleging, among other claims, defective labeling in its failure to instruct against use of the IV-push method of administration. The jury awarded Levine $7.4 million (later reduced to take into account a separate recovery against the health-care provider), and the Vermont Supreme Court affirmed the decision. Wyeth appealed, claiming preemption.

The Supreme Court decision

Wyeth argued implied conflict preemption: first, Wyeth claimed that it was impossible to comply with both federal drug-labeling requirements and the state-law duties underlying Levine's claims, as the federal government had approved the Phenergan label; second, Wyeth argued that requiring it to relabel with stronger warnings would obstruct the purposes and objectives of federal drug labeling regulation by interfering with Congress's decision to entrust an expert agency, rather than a lay jury, to make drug labeling decisions.

Writing for a 5-1-3 majority, Justice John Paul Stevens began his opinion by noting that the Court's analysis was guided by two cornerstones of preemption jurisprudence: (*1*) the purpose of Congress is the ultimate touchstone in every preemption case; and (*2*) the historic police powers of the states are not to be superseded by federal law in the absence of a "clear and manifest" congressional purpose, particularly in traditional health and safety areas dominated by states.[11]

In ascertaining congressional purpose, the Court first looked to the history of federal regulation of drugs and drug labeling. Beginning with the 1906 Federal Food and Drugs Act (which supplemented state law by prohibiting the manufacture or interstate shipment of adulterated or misbranded drugs), federal food and drug regulation has been geared toward ensuring consumer protection. The 1930 enactment of the FDCA for the first time required manufacturers to secure FDA premarket approval for new drugs through submission of new drug applications, including reports of investigations and proposed labeling.

In 1962, Congress amended the FDCA to shift the burden of proof from the FDA to manufacturers, who

were required to demonstrate prior to its approval that a drug was both safe for use—as described in the proposed labeling—and effective. The 1962 amendments included a "savings clause" clarifying that state laws would be invalidated only if in "direct and positive" conflict with the FDCA.[12] In 1972, Congress enacted an express preemption provision for certain Class III medical devices (the provision at issue in *Riegel*) but included no similar provision for drugs.[13]

Finally, in 2007, Congress amended the FDCA and granted the FDA legal authority to require labeling changes based on safety information that becomes available following market approval.[14] In doing so, Congress made it clear that manufacturers remain responsible for updating labels (notably, Congress failed to pass a Senate bill that would have required the FDA to pre-approve all changes to drug labels, a revision of FDA duties that might well have served to preempt state-law negligence claims based on labels considered defective by a lay jury).

With this history in mind, the Court turned to Wyeth's first argument that it was impossible for it to comply with both state-law duties and federal labeling requirements. Wyeth contended that under the FDA's premarket approval process, it could not alter Phenergan's label in any way without the FDA's permission.

The Court rejected Wyeth's argument of impossibility, finding that Wyeth could have unilaterally strengthened Phenergan's labeling without the FDA's prior approval pursuant to the FDA's "changes being effected" rule,[15] which permits post-market changes in drug labels without FDA approval in certain circumstances. Specifically, the rule permits manufacturers to add or strengthen a contraindication, warning, or precaution about adverse reaction; add or strengthen dosage or administration information to increase safety; or delete false or misleading information.[16] Thus, Wyeth could have strengthened Phenergan's warning regarding the risks of IV-push administration without first obtaining FDA approval. The Court concluded that Wyeth fundamentally misunderstood the FDCA and its own legal responsibilities: contrary to Wyeth's assertion that the FDA maintains primary responsibility for drug labeling, the FDCA, according to the Court, embodies as a central premise the policy that manufacturers bear responsibility at all times for drug label content.

With respect to Wyeth's second argument—that complying with state law would obstruct the Act's purpose of entrusting drug labeling to experts (who in effect would set both a floor and ceiling for labeling)—the Court noted that congressional intent in fact suggested otherwise. As the Court explained, the FDCA was enacted to bolster consumer protection. Congress could have expressly preempted state tort remedies for drugs as it did for Class III medical devices in the 1976 Medical Device Amendments, but it did not. Moreover, because Congress has never provided a federal remedy for consumers harmed by unsafe or ineffective drugs, this suggested to the Court that Congress determined that widely available state remedial laws represented the appropriate avenue. In the Court's view, Congress's "silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. Rather, Congress has decided to rely on state tort remedies to further consumer protection by motivating manufacturers to produce safe and effective drugs and give adequate warnings."[1]

The Court also discounted the FDA's 2006 Preamble as lacking the force of law and its "mere assertion" that state law is an obstacle to achieving its statutory objectives. In weighing how much deference to give the Preamble, the Court applied a standard of review commonly referred to as "Skidmore deference."[17] This standard of review, which considers "thoroughness, consistency, and persuasiveness," is used when considering the degree of deference to be given to agency interpretations of federal law that have not gone through the formal rulemaking process of notice and comment. Under this standard, the Court concluded that FDA's Preamble did not merit deference, and was entitled to no weight. In the Court's view, the Preamble was not subject to notice and comment for states or other interested parties, appeared to be at odds with Congress's purposes in protecting consumers, and reversed FDA's own longstanding position without reasoned explanation. It was this "dramatic change in position" and the absence of any public due process that, in the majority's view, distinguished the case from its earlier auto safety decision in *Geier*; unlike the FDA's Preamble, the DOT regulations were consistent with DOT's previous position on preemption and were part of a comprehensive regulatory scheme developed through formal rulemaking that allowed for public notice and comment.[1]

IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

As noted by a leading constitutional law scholar, *Wyeth v Levine* is arguably "one of the most important Supreme Court victories for consumers in many years. *Wyeth* takes a strong stand against preemption and preserves the ability of injured consumers to sue pharmaceutical companies for the companies' failure to provide adequate warnings."[18] Because the FDCA provides no

federal remedies for patient injuries, state law provides the only means for redress. Had the Court sided with Wyeth and declared Levine's suit preempted, patients would have been left without any recourse. Of course, the right of redress exists only in those states whose common law or statutory protections are recognized as providing protections against negligent or defective drug warnings. But the decision reaffirms the power of states to provide just such protections without fear of preemption.

Moreover, as the Court itself recognized, the FDA's resources to monitor drugs on the market are limited, particularly with regard to post-marketing surveillance of approved drugs. In the absence of such continuous FDA oversight, state tort suits protect consumers by "uncovering unknown drug hazards and provide incentives for manufacturers to disclose safety risks promptly."[1] The Court's decision in *Wyeth* reaffirmed that this important public health function of state tort law remains in effect with regard to drug-related failure-to-warn claims, and is likely to extend to other areas of public health and consumer protection laws where preemption is an issue.

Recognizing these benefits, lawmakers wasted no time in pushing for equivalent consumer protections for medical devices. One day after the *Wyeth* ruling, Congressmen Frank Pallone (Democrat from New Jersey), Chairman of the Energy and Commerce Subcommittee on Health, and Henry Waxman (Democrat from California), Chairman of the Energy and Commerce Committee, introduced the Medical Device Safety Act of 2009, which negates the Court's ruling in *Riegel* and explicitly clarifies that state product liability lawsuits are preserved with regard to medical devices.[19] The late Senator Edward Kennedy (Democrat from Massachusetts), then Chairman of the Health, Education, Labor, and Pensions Committee, introduced the legislation in the Senate.[20] Both bills, which were referred to committee and are currently pending, have been endorsed by several prominent medical and consumer organizations.

Despite the important public health implications of *Wyeth*, policy makers should remain alert to the concern that Justice Stephen Breyer espoused in his concurring opinion—that tort suits may result in drug companies raising prices to the point where those who are sick are unable to obtain the drugs they need. Moreover, as several commentators noted in "friend of the court" (i.e., *amicus*) briefs filed in the case, fear of state tort suits may impede the development of new, state-of-the-art drugs, many of which are geared toward treating the nation's most chronic and debilitating diseases. In addition, both the FDA[10] and the U.S. Solicitor General[21] have warned that allowing state tort suits based on pharmaceutical-related failure-to-warn claims could lead to excessive warning practices, which may discourage clinicians and consumers from using otherwise beneficial drugs, or result in meaningful risk information losing its significance. While these reasons alone do not outweigh the consumer protections afforded by permitting state tort suits, they are issues that merit careful monitoring.

In addition to its strong stance on protecting consumers, *Wyeth* also cautions federal agencies regarding their duties in the development of policy. In refusing to give any deference to the FDA's 2006 Preamble, the Court made clear its distaste for the FDA's sudden change in position—without notice or comment—regarding drug labeling and preemption, as well as its unorthodox attempt to assert this position through a mere preamble. The Court's reaction underscores the importance of formal regulatory development if agencies expect that the courts will defer to their judgment about the meaning of a law.

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