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Regulating the Safety of Pharmaceuticals

The FDA, Preemption, and the Public's Health

Lawrence O. Gostin, JD

IN 2008, THE US SUPREME COURT HELD THAT THE MEDICAL Device Amendments (MDA) bar common law claims challenging the safety or effectiveness of a medical device approved by the US Food and Drug Administration (FDA).¹ *Riegel v Medtronic Inc*² had broad implications for patient safety because it removed all means of judicial recourse for most consumers injured by defective medical devices. At that time, the Supreme Court agreed to hear *Wyeth v Levine*,³ which consumer safety advocates feared would similarly preempt pharmaceutical lawsuits with far-reaching effects. There are 11 000 FDA-regulated drugs, with nearly 100 more approved each year,⁴ and patients would have no safety net in the event the FDA fails to detect and correct safety hazards. In a recent 6-3 decision, the Supreme Court ruled that the FDA's approval of a drug label does not preempt a state law product liability claim charging the drug maker with failing to warn adequately about the risks.³ The Court, therefore, rejected a major push by the pharmaceutical industry to invoke compliance with federal safety standards as a complete defense to tort liability.

Preemption of State Tort Liability

Wyeth Pharmaceuticals manufactures the anti-nausea drug promethazine hydrochloride. After a clinician injected Diana Levine, a professional guitar player, by the "intravenous (IV) push" method, the drug entered Levine's artery and she developed gangrene, requiring the amputation of her forearm. She brought a state law damages action, alleging that Wyeth failed to adequately warn about the significant risks of the IV push method, as opposed to the safer IV drip method. A state jury awarded Levine \$7.4 million, later adjusted to \$6.7 million, and the Vermont Supreme Court affirmed.

The Supreme Court upheld the verdict, holding that the Food, Drug, and Cosmetic Act (FDCA), which unlike the MDA has no express preemption clause, does not supersede state tort actions. The Court rejected Wyeth's argument supported by the FDA that the FDCA impliedly preempts state product liability claims. Under the implied preemption doctrine, the Court will invalidate state law if compliance with both federal and state law is a physical impossibility, or state law stands as an obstacle to the accomplishment and execution of congressional objectives.

Generally, a manufacturer can change a drug label only after the FDA approves a supplemental application. However, the agency's "changes being effected" regulation permits pre-approval labeling changes that strengthen a warning to improve drug safety. Thus, Wyeth could have unilaterally added a stronger warning about IV push administration, demonstrating that it could comply with both federal and state requirements. Justice Stevens, writing for the Court, said that Wyeth was operating under a fundamental misunderstanding that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling at all times.

The Court also found that Wyeth was laboring under a misimpression about the purposes of drug regulation. Stevens stressed that the principal objective of Congress was to ensure the safety of pharmaceuticals, not simply to entrust an expert agency with drug-labeling decisions. In a preamble to a 2006 FDA regulation, the agency declared that state law failure-to-warn claims threaten its role in overseeing drug labeling.⁵ The Court often defers to agency judgments, but the agency must have acted in a thorough, consistent, and persuasive manner. The George W. Bush Administration reversed a long-standing FDA view that federal regulation complements stronger state safety requirements, and FDA career staff vehemently objected to the agency's ideological shift.⁶ Not only had the FDA failed to give a reasoned explanation for its change in position, but it also failed to grant interested parties notice or opportunity for comment on the merits of the preemption issue. Consequently, in *Wyeth*, the FDA's "dramatic change in position" was entitled to "no weight."³

The Court drew attention to 2 cornerstones of preemption jurisprudence: (1) Congress' intent is the "ultimate touchstone" in every preemption case⁷; and (2) there is a presumption against preemption whenever the state is acting within its historic police powers to protect the public's health and safety. The Court stressed that if Congress thought state lawsuits posed an obstacle to its objectives, "it surely would have enacted an express preemption provision during the FDCA's 70-year history," as it did for medical devices.³ Consumer safety is a classic state function under the police powers, which suggests that the Court should be reluctant to preempt state law in this realm.⁸ Although the Court relied on this presump-

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tion against preemption in *Wyeth*, it failed to even mention it in other cases such as *Riegel*.²

The Pro-Business Orientation of the Roberts Court

The Roberts Court is closely associated with a pro-business stance that is friendly to corporate claims of immunity against state tort actions. The conservative wing of the Court usually has prevailed, as it did in *Riegel*.² *Wyeth*, however, is the second case this term—and the second opinion written by Stevens, the Court's most liberal member—protecting consumer rights and rejecting industry efforts to avoid state public health regulation. In *Altria Group Inc v Good*,⁹ the Court held that the Cigarette Labeling and Advertising Act does not preempt smokers' state unfair trade practice lawsuit against advertisements falsely suggesting that "light" cigarettes are less harmful.

Justice Alito, joined by the Chief Justice and Justice Scalia, wrote a scathing dissent, lamenting that "tragic facts make bad law." In *Wyeth*, clinicians ignored strong warnings against the IV push method making this an "ideal medical malpractice case," but common law tort suits constitute a "frontal assault" on FDA regulation, said Alito.¹⁰ The dissent asserted that juries are ill-equipped to perform the FDA's cost-benefit-balancing function because they see only the "tragic accident" before them, not the overall benefits of a drug's design or label. This pro-business posture focuses on the industry's incentives to innovate rather than on its responsibility to safeguard consumer safety.

The Court's apparently inconsistent decisions in *Riegel*² and *Wyeth*³ are troubling, demonstrating why preemption is a muddled area of the law. Alito said the Court had done an about-face, "turning yesterday's dissent into today's majority opinion." Although it is true that the MDA have an express preemption provision and the FDCA does not, the Court has often used the implied conflict preemption doctrine. It did so in another public safety case, *Geier v Am Honda Motor Co*,¹¹ in which the Court held that federal law preempted a lawsuit against Honda for failure to install an airbag, despite it being squarely within the state's police powers.

The inconsistency is troubling also because there is no rational basis for allowing lawsuits against manufacturers of drugs but not medical devices. Pharmaceuticals and medical devices go through the same FDA approval process, tort litigation is brought on the same grounds, and in some cases it is unclear whether a particular product is a drug or a device. Consequently, Congress is considering legislation to allow tort litigation against medical device manufacturers, which would override *Riegel*.

FDA Oversight and the Role of Tort Litigation

The Supreme Court's conservative wing stresses the potentially adverse market effects of tort litigation: higher health care costs, disincentives to innovate, and delay in introducing products onto the market. Yet litigation also brings advantages for the agency and consumers. The FDA is hampered in its oversight function, with significant resource and informational deficits.

The responsibilities of the FDA are vast, accounting for approximately 25% of all consumer spending, including food, drugs, vaccines, and medical devices. However, it lacks adequate staffing and resources, even as public safety concerns have increased.^{12,13} At the same time, the agency often does not have the information needed for effective oversight. It is reliant on the manufacturer to find and disclose hazards at the time of approval and postmarketing. Approval decisions, moreover, often consider relatively small numbers in clinical trials, almost ensuring that the full safety and effectiveness profile will emerge only after the drug is marketed to a large population.¹⁴ Tort litigants, unlike the FDA, have subpoena power and discovery can be a potent way to inform the agency and public of undisclosed risks.

The civil justice system also can compensate patients who are wrongly harmed by drugs and medical devices. Absent tort litigation, patients who sustain grievous injuries would have no recourse.

The "preemption wars" between consumers and industry raise a vital public health question—should FDA approval set a regulatory ceiling for product safety or can states enforce higher safety standards?¹⁵ *Wyeth* will not be the death knell of the preemption doctrine. The Supreme Court strongly hinted that it would preempt tort litigation if the FDA takes an active role and pays close attention to a particular safety risk, and the manufacturer fully discloses all the pertinent facts. If, however, as too often appears to be the case, industry conceals relevant information and the FDA lacks the capacity to do anything about it, the tort system becomes a failsafe, facilitating effective agency oversight and offering a remedy for patients who are wrongly harmed.

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