When Can Patients Sue Drug Companies?

Supreme Court Finds That FDA Approval Does Not Stand In the Way

Robert I. Field, JD, MPH, PhD

Dr. Field chairs the Department of Health Policy and Public Health and is Professor of Health Policy at University of the Sciences in Philadelphia, Pennsylvania.

Drugs go through rigorous testing before the FDA approves them. Drug manufacturers may spend as much as $1 billion and up to 12 years to gain permission to sell a new prescription product. Even when permission is granted, an approval still carries numerous limitations, including restrictions on promotional materials and requirements for specific warnings that must appear on the product's labeling.

After running this gauntlet, can manufacturers rest assured that they have met the legal standard for selling their drugs? Or, to put it another way, if a drug maker complies with FDA marketing and labeling restrictions, can an injured patient also sue the company for not making the product safe enough? In a closely watched case, the Supreme Court in early March said definitively "yes;" a company can be sued even after FDA approval.

THE CASE

The case in question is *Wyeth v. Levine*.[1] Diana Levine, a Vermont musician, lost her right hand to gangrene after taking a Wyeth drug, promethazine (Phenergan), for nausea caused by migraine headaches. The preferred methods of administration of this product are through intramuscular (IM) injection and intravenous (IV) drip. However, a physician's assistant who performed the administration used an IV push technique instead. The IV push method allows delivery of the medication more quickly but carries a significant risk. Gangrene can result if the injection is mistakenly inserted into an artery instead of a vein—which is what the assistant did (see the April issue of *P&T*, page 175).

Ms. Levine sued and received a settlement from the clinic where the drug was administered. She also named Wyeth as a defendant, claiming that the drug's label should have more clearly instructed clinicians against using an IV push injection. The label, which the FDA had approved, warned about inadvertent intra-arterial injection but did not explicitly rule it out as a means of administration. The suit claimed that Wyeth had a duty to provide a stronger warning on its own initiative. She was successful at trial and was awarded $6.7 million. Wyeth appealed, and the case went all the way to the U.S. Supreme Court.

ARGUMENTS ON EACH SIDE

In their arguments, both sides raised policy issues related to the appropriate role of the FDA as the arbiter of drug safety. Wyeth stated that the use of an FDA-approved label should be the determining factor and should shield a drug's manufacturer from lawsuits that claim the label's contents were insufficient. The FDA is an expert agency that represents the best forum for weighing a drug's risks and benefits and for determining the kind of warnings and other marketing restrictions that should apply. If the agency permits a label to be used, that action reflects the considered judgment of those most knowledgeable on the subject. Juries composed of lay citizens should not be permitted to second-guess them.

Ms. Levine's lawyers countered that FDA approval represents a floor—not an absolute standard—for determining which safety precautions, such as warnings, are appropriate. Even after the FDA conducts its product review, the manufacturer is still in the best position to decide which patient protections are appropriate. If it is evident that additional steps are needed beyond those that the FDA has mandated, a drug maker has a legal duty to act. The FDA oversees more than 11,000 drugs on the market and does not have sufficient staff to keep tabs on all of them. Tort law provides a needed incentive to keep companies vigilant about safety concerns regarding the products that they sell.

THE LEGAL ISSUE OF PRE-EMPTION

These arguments focus primarily on the policy question of who is best able to police drug safety. Beneath this question lies a legal issue that is more prosaic but more far-reaching in its effect. When Congress enacted the Food, Drug, and Cosmetic Act,[2] which governs drug safety, did it intend for the law to supersede all state authority in the area? The challenge for the Supreme Court was that Congress did not clearly say.

Tort suits for product liability, like the one brought by Ms. Levine, are generally governed by state law, meaning that the standards can be different in each state. If Congress wants to overrule the states and establish national uniformity, it can do so under the Constitution if the area affects interstate commerce, national defense, or a few other enumerated concerns. When Congress acts in this way, its legislative initiative trumps state authority. In legal terms, state laws on the same subject are "pre-empted."

Congress can pre-empt state laws in one of two ways. It can make the action explicit by clearly stating in a statute that it supersedes state pronouncements on the same subject. For example, the Medical Device Amendments of 1976 directly prohibits states from establishing safety requirements for medical devices.[3] In 2008, in the case of *Riegel v. Medtronic, Inc.*, the U.S. Supreme Court found that this language prevented an injured patient from suing Medtronic in state court for harm related to a cardiac catheter.[4]

The other way is implicitly based on the scope of a statute. In some instances, state authority that relates to the same subject as a federal law would be logically

inconsistent with federal intervention and could conflict with the goals that the federal law seeks to accomplish. In these situations, courts may find that state laws are pre-empted by implication. Obviously, this state of affairs is more readily subject to conflicting interpretations, because it requires the court to divine Congressional intent. This makes it prime grist for litigation.

THE PRE-EMPTION ARGUMENTS

Implied pre-emption was the issue in the *Levine* case. Ms. Levine argued that the Food, Drug, and Cosmetic Act neither explicitly pre-empted state authority in this area nor superseded it by implication. State laws that permit suits for harm from prescription drugs are not inconsistent with FDA approval, she contended, because Congress intended that the FDA set a floor for safety precautions, not an absolute standard. The state of Vermont could require a stricter warning about the dangers of using the IV push technique for Phenergan than the wording that the FDA had approved. Her position was supported by several medical groups and by the *New England Journal of Medicine*.[5]

Wyeth argued that the doctrine of implied pre-emption should govern this case. Permitting each state to set a higher standard than the FDA could subject manufacturers to 50 different sets of requirements, creating an onerous legal burden. It contended that this was the kind of situation to which implied pre-emption was intended to apply. The pharmaceutical industry and the Bush administration supported this position.

THE COURT'S DECISION

The majority of Supreme Court justices found Ms. Levine's arguments more persuasive. In writing the Court's opinion, Justice John Paul Stevens declared that the intent of Congress in passing the Food, Drug, and Cosmetic Act was to implement a system of minimum standards for assessing when a drug is safe and effective enough to reach the market. It did not mean to pre-empt states from finding that additional steps are appropriate to protect their citizens. The Court agreed with Ms. Levine that although the FDA has technical expertise, it lacks the resources to continuously oversee all of the thousands of drugs on the market. Congress intended that state tort law serve as a supplement to its oversight.

Based on this reading of Congressional intent, Vermont was free to decide that a stronger warning should have accompanied Phenergan. Thus, its state courts could rule that in light of the risks of using IV push to administer this drug, Wyeth should have requested FDA approval to insert stronger language. In the absence of such action, the company could be held liable for contributing to an injured patient's harm.

THE FUTURE OF DRUG LAWSUITS

The *Levine* decision will open the door for similar lawsuits in which injured patients assert that manufacturers should have gone beyond FDA safety directives. Had the Court ruled differently, such claims could not have proceeded. This outcome will pressure drug companies to be more vigilant in monitoring risks associated with their products.

Beneath the technical legal arguments about pre-emption, policy questions about the role of the FDA as overseer of postmarket drug safety remain. The debate on this point gained public attention in the wake of the controversy over Merck's pain medication rofecoxib (Vioxx) when holes in the monitoring process became apparent. One result of this controversy was passage of the FDA Amendments Act of 2007,[6] which enhanced the agency's postmarket authority and resources. However, this law did not represent a complete solution.

For the foreseeable future, then, drug manufacturers will face two sets of legal requirements regarding drug safety. FDA approval and all of the specifications that go with it serve as a minimum standard. Beyond that, companies will have to consider whether additional measures are warranted, depending on their own assessments. With this state of affairs, product liability for pharmaceuticals promises to provide ample fodder for legal and policy debates for some time to come.

REFERENCES

1. 555 U.S. ___ (2009), Docket No. 06-1249.
2. 21 U.S.C. §§321 et seq.
3. 21 U.S.C. §360k (a).
4. *Riegel v. Medtronic,* 518 U.S. 740 (2008).
5. Brief of *New England Journal of Medicine* Editors and Authors as *Amici Curiae* in Support of Respondent, *Wyeth v. Levine,* No. 06-1249 (U.S. filed August 14, 2008).
6. Public Law 110–85. ■