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Take as Directed
Daniel Fisher 03.10.08, 12:00 AM ET

Can you sue a company for a product the feds approved?

Diana Levine went to the hospital with a headache one spring day in 2000 and wound up losing an arm. Doctors had injected her with an antinausea drug called Phenergan, made by Wyeth, which if used improperly can cause gangrene. Levine sued and the Vermont Supreme Court later upheld $6.8 million in damages. Wyeth has now taken the case to the Supreme Court. Its argument: The drug label already had at least three warnings against injecting Phenergan in an artery, and the Food & Drug Administration wouldn't approve any more. Hadn't Wyeth done enough to protect itself from lawsuits?

The Supreme Court will consider that question in the Levine case and four others now before it. The central issue is whether federal regulation preempts state tort law. Or put another way: When the federal government tells a company how to make and sell a product, down to the exact wording on the label, can a jury in East Dipswitch decide the FDA was wrong? "These cases are saying, 'If the manufacturer had just included one more warning, I wouldn't have taken the drug,'" says Richard Samp, chief counsel of the conservative Washington Legal Foundation.

The stakes are huge, affecting everything from how products are labeled to which new drugs and medical devices will go on the market. Tort lawyers and the advocacy group Public Citizen say there's nothing wrong with letting state law provide a second layer of protection for consumers. Makers say they can't risk selling federally approved products if they are still exposed to unpredictable verdicts.

The justices seemed skeptical about state suits in the first case that was argued before them in Washington in December. A Medtronic balloon catheter burst, causing serious injuries to a patient after a doctor allegedly inflated it past the FDA-approved pressure limit on the label. Allison Zieve, a lawyer for Public Citizen, argued that even if the FDA approved the product, a jury could decide whether it was unreasonably dangerous.

Chief Justice John Roberts didn't seem to buy that argument. What if a company develops an improvement to an FDA-approved product? If state suits were allowed, tort lawyers would argue the old product is defective. That would force companies to remove it from the market until the FDA approves the new one. "What happens to patients in that year?" Roberts asked. "They've got no device."

Merck faced a similar situation after it reported in 2000 higher rates of cardiovascular problems from Vioxx. For two years the FDA dithered over whether to add a stronger warning to the Vioxx label. Merck finally withdrew the arthritis drug from the market and then was deluged with lawsuits claiming the label didn't warn doctors of the higher heart risk. Merck has since announced a $4.9 billion settlement of Vioxx claims.

The Supreme Court's ambivalent rulings haven't helped guide manufacturers through this legal thicket. The court famously decided in the Cipollone case in 1992 that federal cigarette labeling laws preempted state lawsuits over failing to warn consumers of the risks. (The court has recently agreed to hear a similar case over "light cigarette" ads.) The court similarly decided in 2001 that plaintiffs couldn't sue a medical-device manufacturer even though it supposedly got FDA approval through fraud; the court said the government doesn't need civil juries looking over its shoulder. But then in 2005 the court decided it was okay for Texas farmers to sue Dow AgroSciences over government-approved warning labels on a pesticide.

"The Supreme Court seems to make it more confusing every time it issues one of these decisions," says Lawrence Ebner, a Washington lawyer who represents manufacturers.

The fraud-on-the-FDA argument gets another hearing in February in a lawsuit over the Warner-Lambert diabetes drug Rezulin. Two federal appeals courts have split on this case's preemption issue.

How is the court leaning this time? The liberal wing is very protective of the right to sue. But in the Medtronic case, Justice Anthony Kennedy, a swing vote, seemed to lean toward letting government regulators, instead of civil juries, balance the risks and rewards of medical devices. The court ruled similarly last year when it dismissed an antitrust lawsuit over underwriting practices that had been approved by the Securities & Exchange Commission.