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Legal Side Effects

Can companies be sued even if they follow FDA instructions?

Diana Levine's story is gut-wrenching. It's also the sort of case that makes bad law, which is why Monday's Supreme Court oral argument in *Wyeth v. Levine* is important for consumers and drug development in America.

A professional guitarist who suffered from migraines, Ms. Levine went into a clinic in April 2000 for an injection of Phenergan, an antinausea drug produced by Wyeth Pharmaceuticals. The clinic administered the drug by what the label described as the "preferred" method -- "deep intramuscular injection." When that didn't help her symptoms, the clinic injected another dose directly into her arm -- a technique known as "IV push." As the label warned, this was dangerous. If Phenergan is accidentally injected into an artery instead of a vein, gangrene can quickly set in and lead to amputation. To avoid this, the drug's label described in detail how to administer an intravenous injection.

Even so, the worst happened. Gangrene set in and Ms. Levine lost her right hand and forearm. She sued the clinic, which settled the case. But then she sued Wyeth in Vermont state court. She argued that Wyeth should have warned health-care providers never to attempt IV-push injection because "other, safer methods" were available. She won, and the Vermont Supreme Court upheld the \$6.7 million verdict.

In *Wyeth v. Levine*, the issue is whether a drug company that had sought and received all the necessary approvals from the Food and Drug Administration, and had labeled that drug in accordance with FDA requirements, can still be held liable under state law. This is not a case about whether a drug company concealed evidence or other misconduct. The FDA-approved label for the drug specifically warned against the risk that became Ms. Levine's reality.

But this case is not just about Ms. Levine. It is about a drug-approval system that balances the risks of treatments against the risk of not being treated at all. And a jury, faced with a single sympathetic plaintiff, is in no position to rule on the correctness of those FDA judgments. The Supreme Court ruled as much in February in *Reigel v. Medtronic*, a similar case involving medical devices. Justice Antonin Scalia argued for the 7-2 majority in *Reigel* that a jury "sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."

Though the tort bar lost that case, Ms. Levine's lawyers are arguing that the relevant federal devices statute explicitly mentions pre-emption, while the drug statute does not. But this is a red herring. As Ms. Levine's lawyer admitted at oral argument, the question in *Wyeth* is not whether *any* state-law tort claim was pre-empted by FDA regulation. The question is whether, in a case in which the FDA has made one determination about safety, a state jury should be permitted to come to another. As Justice Scalia put it yesterday, "If you're telling me the FDA acted . . . irresponsibly, then sue the FDA."

Chief Justice John Roberts asked former Solicitor General Seth Waxman, who argued the case for Wyeth, whether this case could be distinguished from *Reigel* on these grounds. Mr. Waxman's response goes to the heart of this case: "A jury was asked to look at the same information [that the FDA had] and conclude that the precise language that the . . . FDA required Wyeth to use rendered that drug unreasonably unsafe." In other words, the jury is being asked to look at a situation where the worst has happened, and the risks have been realized, and to decide whether the FDA made the right call. This would all but guarantee that the drug companies would be sued whenever a known risk becomes actual in a particular case.

The U.S. drug approval system is imperfect, and the FDA makes mistakes -- most of which involve blocking or slowing drug therapies that could save lives. Congress created that system and asks drug companies to spend some \$1 billion per drug and wait years to gain approval. It amounts to double jeopardy to say, even if you do all those things right, and disclose all the known dangers and label the drug as ordered by the FDA, that you can still get sued if something goes wrong because *someone else* made a mistake.

If a known and disclosed medical risk can still lead to a law suit, drug companies can literally be sued for anything. No doubt there are trial lawyers and Democrats in Congress who would prefer it that way. But if we want state juries second-guessing the FDA at every turn, let's pass a law in broad daylight so everyone knows whom to blame when drug innovation stops cold.

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