



## THE SUPREME COURT & BIG BUSINESS

### *Why Favoring Corporate Interests Over Everyday Americans Harms Us All*

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The nation's highest court has undergone an ideological shift to the right. Although this transformation is most often discussed in terms of hot-button social issues, another stark change on the Court is actually a matter of economic policy. Business cases often garner less attention because they often involve dry legal principles, but these cases are in no way less important. In fact, these claims ultimately affect the lives of all Americans.<sup>1</sup>

The Supreme Court's pro-corporate shift is the result of a conservative courtpacking effort that began to take shape during the Reagan administration. At that time, ultraconservatives launched a relatively quiet but significant effort to reshape the American legal system by capitalizing on a growing public wariness of lawyers and litigants. This coalition of ultraconservative business groups and likeminded foundations engaged in a comprehensive campaign to elevate corporate profits and private wealth over social justice and individual rights as the cornerstones of our legal process. The fruits of their labor have now come to pass. Of the 30 business cases heard last term before the Supreme Court, 22 were decided unanimously in favor of big business, or with just one or two dissenting votes, and against the interests of everyday Americans.

Another such case, *Wyeth v. Levine*, will be heard before the Supreme Court on November 3<sup>rd</sup>. The rights of Americans who have been or may be harmed by prescription drugs are at stake. In an effort to protect its profits and avoid responsibility for its wrongdoing, Wyeth Pharmaceuticals is advancing a radical new interpretation of an age-old legal doctrine called "preemption" that has historically been used to vindicate the supremacy of the federal government. If the Supreme Court rules in Wyeth's favor, that will change and every person who takes a prescription drug may be placed at risk.

### Limited Resources Hamstring Oversight

Traditionally, preemption occurs when a federal law or constitutional principle conflicts with a state or local law. When this happens, national law supersedes local law. But the ultraconservatives and Wyeth want to extend this doctrine in two ways: to cover actions taken by federal agencies and to stop juries from holding corporations accountable. Under this approach, once an agency gives its stamp of approval, no state would be able to supplement it with tougher regulations and no jury would be able to assess damages against the corporation.

This new twist is opposed to the protections Congress intended to extend to all Americans. If regulatory action is the ceiling of protection from harmful drugs, people who are injured by those drugs have no recourse after the FDA approves the product. Moreover, the FDA – like so many other regulatory agencies – is constrained. Even former FDA Commissioner David Kessler testified before Congress that, "The FDA has long been hamstrung by resource limitations. Even if FDA's funding were doubled or tripled, its resources and ability to detect emerging risks on thousands of marketed drugs and devices would still be dwarfed by those of the drug and device companies who manufacture those products. For that reason, the tort system has historically provided a critical incentive to drug and device companies to disclose important information to physicians, patients and the FDA about newly emerging risks." The FDA has scant resources compared to the behemoth drug companies it attempts to regulate.

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<sup>1</sup> The scope of shareholder derivative suits, antitrust challenges to corporate mergers, patent disputes, and efforts to reduce punitive damages awards are among the many topics the Court has recently considered and ultimately decided in favor of big business.

To make matters worse, in many cases, the FDA has only the information provided to it by the drug companies to determine product safety. Perhaps that is why Wyeth has issued press materials that paint a misleading picture of the facts in Diana Levine's case. Fortunately, the facts speak for themselves.

**FICTION: "The [Vermont Supreme Court] ruling was in direct conflict with federal law . . . [a]bsent any new evidence, Wyeth could not change Phenergan's labeling to comply with the labeling sought by the Vermont jury without violating federal law."**

**FACT: The Vermont ruling was NOT in conflict with existing federal law.**

Wyeth suggests that FDA labeling requirements create a regulatory ceiling that limits pharmaceutical corporations' obligations to the people who use the drugs they produce. According to Wyeth, any supplemental label changes to enhance consumer safety would be illegal. This is simply untrue. The dangers associated with the IV push administration of Phenergan could have been publicized without prior FDA approval because the label requirements create a floor, not a ceiling. The Food, Drug and Cosmetic Act, which governs the FDA, creates a specific procedure allowing drug manufacturers to change labels that are insufficient to protect consumers.<sup>2</sup> And companies can warn doctors directly of new risks without changing the FDA-approved label. Thus, there is no conflict between federal labeling requirements and state failure-to-warn claims.

**FICTION: "The only claims currently being decided in *Levine* are those where the jury's verdict conflicts with the FDA's considered scientific judgment."**

**FACT: The "considered scientific judgment" Wyeth puts on a pedestal often is based on information that the drug company alone provides.**

The main legal issue in *Wyeth v. Levine* is whether FDA approval of a drug label preempts a more stringent state-law failure-to-warn claim. This is not a matter of questioning the validity of FDA decisions, but rather one of the agency's ability to thoroughly monitor and police an industry that dwarfs the FDA's own regulatory capacity. The "considered scientific judgment" Wyeth puts on a pedestal often consists of information that the drug company alone provides. Once a drug hits the market, the FDA is rarely able to conduct any meaningful further review. Moreover, it is impossible to discover every danger during preliminary clinical trials. To suggest that the FDA should be the only arbiter on drug safety demonstrates a cavalier understanding of the agency's budget and staff resources.

The other, often unspoken, issue in *Levine* is the Bush Administration's aggrandizement of executive power for the benefit of corporate interests. This case is the latest in a series challenging the basic structure of government and separation of powers. Historically, state tort law claims, like the one made by Diana Levine, have served as a backup to federal and state regulatory law. To preempt those claims, Congress could enact a specific "preemption clause." Congress rarely does so, but when it does, Congress usually provides a federal remedy in lieu of the displaced state remedy. Yet, instead of seeking legislation, the Bush Administration has unilaterally placed preemption language in the preambles of a number of regulatory agency rules, sidestepping Congress's role. In the case of the FDA, no federal remedy exists for people, like Diana Levine, who have been harmed by prescription drugs. If Wyeth gets its way, she won't have a remedy at all.<sup>3</sup>

This doomsday scenario recently became a reality for people who have been harmed by dangerous or defective medical devices like heart valves, breast implants, and defibrillators. Earlier this year, the Supreme Court ruled in

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<sup>2</sup> See 21 C.F.R. § 314.70(c).

<sup>3</sup> Wyeth suggests in its Reply Brief that even hiding information from the FDA in a drug application or failing to inform the FDA of dangers learned after a drug's approval might also be preempted under the new analysis. Pet.'s Reply Br. 26-7.

*Riegel v. Medtronic, Inc.*<sup>4</sup> that product manufacturers were immune from state liability suits because the FDA had approved the devices before they were marketed and manufactured. But, because there is no national product-liability law allowing federal suits for personal injuries, people who are injured by these products now have no way of making themselves whole. The companies are off the hook and have little incentive to create the safest product available.

**FICTION: “[The] injury was the result of an improper administration of [the drug] . . . clear indicators of an improper administration were ignored.”**

**FACT: Despite knowing of the clear dangers associated with the “IV push” administration of Phenergan, Wyeth failed to include this warning on the drug’s label.**

Diana Levine was given Phenergan directly by what is known as the “IV push” method. We now know that when Phenergan is given to a patient via an IV push and any part of the drug comes into contact with an artery the result can be irreversible gangrene. This is exactly what happened to Mrs. Levine, who ultimately lost her arm.

This danger was not clearly included in Wyeth’s Phenergan label. According to the label, “When administering any irritant drug intravenously it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily.” Notably, the label does not counsel against the intravenous IV push injection. It is easy to see why medical professionals would not know of its full dangers. But Wyeth had known for years about the dangers associated with the IV push method and chose not to tell doctors and patients about it.

**FICTION: “A Vermont jury . . . rul[ed] that Wyeth should have changed the Phenergan labeling to prohibit physicians from administering the medicine through IV push.”**

**FACT: Under the Vermont Supreme Court ruling, Phenergan can continue to be administered to patients through the IV push method if an adequate warning is provided.**

The jury verdict was only an evaluation of the adequacy of the label, not a complete prohibition. The Vermont Supreme Court stated, “[t]here may have been any number of ways for [Wyeth] to strengthen the Phenergan warning without completely eliminating IV-push administration.”<sup>5</sup>

If the Supreme Court decides in favor of Wyeth, that decision could be extended to other areas of law in which the Bush Administration has sought, through little-noticed agency action, to promote the interests of huge corporations at the expense of Americans. The Bush Administration is likely to spend its last few, lame-duck months in office, issuing even more agency “preambles” and “guidelines” – like the one that is putting Diana Levine’s case in jeopardy – that will seek to promote complete immunity from lawsuits for billion-dollar businesses. Many of these will be difficult for even a new President to undo, but will doubtless be used relentlessly by corporations armed with a favorable decision from the Supreme Court.

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<sup>4</sup> 128 S. Ct. 999 (2008).

<sup>5</sup> 944 A.2d 179,189 (Vt. 2006)

