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Preemption Strike

By Michael S. Greve

Contrary to its recent reputation of being "probusiness," the Supreme Court, in its Wyeth v. Levine *decision, has gutted "federal preemption," one of the few remaining protections against state interference in the national economy. By ruling that the pharmaceutical company Wyeth is liable for not including a stronger warning on a drug label than the Food and Drug Administration (FDA) required, the Court allows local juries and regulators to preempt federal regulators—which are better equipped to deal fairly with national industries. The* Wyeth *decision will prove disastrous for the American economy.*

Not so long ago, the Roberts Court drew a torrent of commentary—most of it critical—about its supposed probusiness orientation. "Supreme Court, Inc." was the title of an article by law professor Jeffrey Rosen in *The New York Times Magazine*. This year, with a heavily Democratic Congress relieving its pent-up demand for regulation, as well as a financial disaster supposedly caused by "deregulation" and a new administration with a declared intention to reconstruct the American economy, many expected a confrontation between populist politics and the Supreme Court's insistence on a modicum of government restraint and reason. But the justices' recent decision in *Wyeth* suggests just the opposite. The Court's doctrines on the once-arcane subject of federal preemption extend an open invitation to juries, state officials, and tort lawyers to help themselves to even more of the diminishing proceeds of America's productive economy.

Wyeth arose over a tragic injury to a patient whose doctor and nurse, in an act of flagrant malpractice, had administered a drug in direct contravention of the federally approved warning label. The wording of that label conformed with—in fact, was practically dictated by—FDA requirements. This should have sufficed to shield the drug company from liability in state courts in cases of misuse; in legalese, the federal law—in this case, the Food, Drug, and Cosmetic Act (FDCA)—should "preempt" the imposition of state-law liability. But by a six-to-three majority, the court decided against preemption. (Justice Samuel Alito dissented, joined by Chief Justice John Roberts and Justice Antonin Scalia.) The adequacy of drug labels will henceforth be determined not by FDA experts but by random juries with massive hindsight bias.

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Key points in this *On the Issues*:

- *Wyeth v. Levine* overrules *Geier v. Honda Motor Co.*, which established implied preemption when a federal regulator set an optimal standard.
- Because it is so easy to circumvent express preemption, leaving it to Congress to specifically preempt state laws is ineffective.
- Without federal preemption, businesses will have to fit their products to fifty different regulatory regimes, and the most stringent state regulatory regime will determine the market.
- *Wyeth* is a dangerous precedent for the vitality of American business enterprises.

The effects of this ruling reach far beyond the pharmaceutical industry. Federal preemption is the only available defense for virtually any industry against rapacious tort lawyers and ambitious state attorneys general. Without it, a manufacturer will potentially be subject to fifty-odd different sets of rules within the United States, all of them subject to change at the whim of juries and judges. The risk of confusion and balkanization is compounded by a relentless proregulatory bias: in integrated product markets, producers must of necessity comply with the law of the most restrictive state.

Over the past decade, corporations and defense lawyers have refined and coordinated their preemption arguments. Their main focus has been "implied" preemption—the position that a federal statute can trump conflicting state law, including state tort law, even if it does not *expressly* preempt it. The central case for that proposition is, or was, *Geier v. Honda Motor Co.*, a 2000 case involving an accident in a car that was not equipped with airbags. Justice Stephen Breyer's opinion for the majority held that federal health and safety statutes (in that case, the National Traffic and Motor Vehicle Safety Act), along with agency regulations implementing them, preempt state law by implication when the federal standards establish, not a minimum but rather an *optimum* standard. The reasoning was that because excessively strict standards can increase risk just as much as unduly lax ones can (by discouraging or slowing innovation, for example), jury-imposed liability standards beyond the federally determined optimum conflict with federal law and are therefore preempted. (In *Geier*, federal regulators had chosen, for safety reasons, to phase in airbags over a period of years, as opposed to mandating them immediately for the entire new car fleet. The court held that states could not vitiate this policy by means of tort standards.)

After *Wyeth*, however, *Geier* is a dead letter, at least with respect to labeling and disclosure requirements. If any federal statute constitutes an attempt to strike an optimum balance among risks, it is the FDCA. Every medicine has side effects and can be misused, so what is the point of the federal drug-approval process if not to balance these risks against the benefits of a drug that would save lives? What is the point of labeling standards if not to guard against the twin dangers of under- and overwarning? And what remains of the FDA's mission now that any jury can hold any pharmaceutical company liable for any reason—or, so far as federal law is concerned, for no reason at all?

Far worse than Justice John Paul Stevens's majority opinion is Justice Clarence Thomas's concurrence. Incredibly, it berates the majority for an undue solicitude of preemption and makes it hard to conceive of any room at all for implied preemption.

That may sound reasonable: "If Congress wants to preempt, let it say so clearly," rings the refrain. Thomas's opinion is the most extreme expression of that position to date. Yet its obtuseness borders on willful denial. The states have every incentive and myriad ways to circumvent federal law. Because Congress cannot possibly foresee those stratagems, it cannot "clearly" preempt them. For example, the clearest federal preemption provision of all prohibits states from administering "a law or regulation related to fuel economy standards." California's proposed greenhouse-gas standards do not simply "relate to" fuel economy; they *are* fuel-economy standards. Even so, federal courts have upheld them against preemption challenges because California describes them as emission standards instead.

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When a state regulator or judge can evade a clear and explicit preemption by simply relabeling the prohibited conduct, it is hard to see why Congress would bother to enact regulatory statutes in the first place. For this reason (among others), federal statutes must be read to bar not just the directly prohibited conduct but also attempts at evasion. Contrary to Thomas's view, that anticircumvention principle is not some modern judicial extravagance; an anticircumvention "rule against mischief" showed up in British law as soon as there were parliamentary statutes. In American constitutional and statutory interpretation, the rule is as old as *McCulloch v. Maryland* (1819) and *Gibbons v. Ogden* (1824). The *Wyeth* majority's implied-preemption analysis calls the principle in doubt; Thomas's opinion would repeal it outright, under "originalist" pretenses.

Wyeth is a disaster because preemption litigation is highly asymmetric. For business groups, wins mean incremental gains, while losses tend to choke off once-plausible arguments and embolden aggressive state regulators and trial lawyers. Defense lawyers will continue to achieve some victories (for example, under federal statutes that regulate products rather than labels), but they know that the *Wyeth* opinions seriously undermine many of their strongest arguments.

Next on deck for *Wyeth*-style treatment is the banking industry. Ever since the enactment of the National Bank Act in 1864, the banking operations of federally chartered institutions have been shielded against investigation and prosecution by the states. *Cuomo v. Clearing House*, to be argued and decided later this term, may well end that regime. In that event, federal financial institutions stand to "benefit" from expert oversight and impartial investigation by state attorneys general. In seamless cooperation with a dozen sure-footed federal regulators and congressional subcommittees, the attorneys general will contribute greatly to the coherent regulation of our financial system.

That bit of sarcasm points to the true source of the Supreme Court's antipreemption doctrine—the justices' incomprehension of the country's constitutional predicament. The Stevens and Thomas opinions in *Wyeth* teem with encomiums to "federalism" and the need to protect states against federal overreach. The court, they say, should not favor Congress by implying preemption. But the federalism analysis is a fantasy, and the protestations of neutrality are false.

Federal usurpation? Never in our history have the states wielded comparable power, and comparably destructive power, over the commerce of the United States. What "federalism" has come to mean, evidently, is the states' right to exploit the same branch of interstate commerce fifty times over. That absurdity is but a facet of a broader problem—the proliferation of fragmented, semi-autonomous, faction-ridden agencies and entities, from multistate attorney general "investigations" to local juries, all of which exercise public power without coordination or effective control. Implied preemption is, or was, one of the very few checks on that tendency.

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The court's evisceration of that check is not an act of judicial neutrality; it is an abject surrender of constitutional responsibility. We are experiencing a malignant form of institutional competition—a three-branch, fifty-state race for first prize in the gratuitous destruction of American business and industry. After *Wyeth*, the Supreme Court is leading by a nose.