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Impact of Wyeth v. Levine: High Court Refused To Wipe Out Consumers' Rights

by *Leslie A. Brueckner* has been a Staff Attorney at *Public Justice* for over 15 years. Among other victories, Ms. Brueckner served as lead counsel in *Sprietsma v. Mercury Marine Corp.*, 537 U.S. 51 (2002), a federal preemption case unanimously upholding an injury victim's right to sue a manufacturer for failing to install propeller guards on its recreational motor boat engines.

Consumer advocates across America heaved a collective sigh of relief when, on March 4, the U.S. Supreme Court **rejected Wyeth Pharmaceutical's bid to wipe state law failure-to-warn claims** against drug manufacturers off the litigation map. In *Wyeth v. Levine*, 2009 WL 529172 (U.S.Vt.), one of the most high-profile cases decided this term, the Court **held 6-to-3 that federal law** does not preempt lawsuits against prescription drug manufacturers for failing to warn of their drug's dangers. The decision is being hailed as a resounding victory both for victims' rights and for public health and safety.

A Tragedy That Could Have Been Avoided

Wyeth was filed on behalf of a professional guitarist, Diana Levine (right), who lost an arm after an injection of the nausea drug Phenergan, which is manufactured by Wyeth. (She was given the drug to combat nausea associated with migraine headaches.) The injectable form of Phenergan can be



administered intravenously through either the "IV-push" method, whereby the drug is injected directly into a patient's vein, or the "IV-drip" method, whereby the drug is introduced into a hanging intravenous bag and slowly descends through a catheter inserted in a patient's vein. The drug is corrosive and causes irreversible gangrene if it enters a patient's artery.

Levine's injury resulted from an IV-push injection of Phenergan that inadvertently hit an artery. As a result, her arm developed gangrene, and doctors amputated first her right hand and then her entire forearm. In addition to her terrible pain and suffering, Levine lost her livelihood as a professional musician.

A Vermont state court jury ultimately returned a verdict for the plaintiff of \$6.7 million. During the trial, Ms. Levine presented evidence of at least 20 incidents prior to her injury in which a Phenergan injection resulted in gangrene and amputation. The jury found that Wyeth should have analyzed the accumulating evidence regarding the risks of Phenergan and added a stronger warning about IV-push administration of the drug.

On appeal to the Vermont Supreme Court, Wyeth attempted to avoid liability by arguing that Levine's failure-to-warn claim was preempted on the ground that Wyeth could not legally have changed the drug's label without prior approval from the United States Food and Drug Administration (FDA). The Vermont Supreme Court rejected the argument, holding that the jury's verdict did not conflict with the FDA's labeling requirements because, under the agency's "changes being effected" (CBE) regulation, Wyeth could have added stronger warnings against IV-push administration without prior agency approval. See *Levine v. Wyeth*, 944 A.2d 179, 185-86, 188 (2006).

Wyeth sought U.S. Supreme Court review in March 2007. Most Court watchers expected that the petition would be denied, given that the Vermont Supreme Court's ruling did not conflict with the decisions of any federal Courts of Appeals or state high courts. But the Court reached out and took the case anyway, in an ominous move that sent shudders through the consumer rights community.

The U.S. Supreme Court Just Says No

As it turns out, however, these concerns were unfounded. Before the high court, both Wyeth and the United States (as amicus) took the position that Levine's claims were impliedly preempted because they conflicted with the FDA's decision to approve the drug's warning label. (Because the Food Drug and Cosmetic Act, FDCA, lacks an express preemption clause, the sole focus of the case was whether the plaintiff's claims were impliedly preempted because they conflicted with, or frustrated the purposes of, federal law.) The majority opinion, authored by Justice John Paul Stevens, rejected this contention, holding that the mere fact of agency approval of a drug's label does not absolve the manufacturer of its responsibility to add to or strengthen the label to warn the public of its risks. See 2009 WL 29172 at *7-9.

In so ruling, the Court first addressed Wyeth's argument that Levine's claims were preempted because, as Wyeth claimed, "it is impossible for [the drug manufacturer] to comply with both the state law duties underlying those claims and its federal labeling duties." *Id.* at *7. The Court

rejected the company's argument in light of the FDA's CBE regulation, which "permits a manufacturer to make certain changes to its label before receiving the agency's approval." Id. *7-9.

The Court went on to chastise Wyeth for its "cramped reading" of the FDA's regulatory framework. Id. at *8. "Wyeth suggests," Justice Stevens wrote, "that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." Id. (citations omitted; emphasis added).

Justice Stevens was equally adamant in his rejection of Wyeth's argument that Levine's claims would "obstruct the purposes and objectives of federal drug labeling regulation." Id. at *10. The Court rebuffed this argument in plain terms, stating "Wyeth contends that the FDCA establishes both a floor and a ceiling for drug regulation ...The most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary." Id.

In finding no preemption, the Court also went out of its way to reject the FDA's view, as expressed in the preamble to a 2006 labeling regulation, that its approval of a prescription drug's label "preempts conflicting or contrary State law." Id. at *10 (quoting 71 Fed. Reg. 3922, 3934-35 (2006)). Justice Stevens found that the FDA's preamble did not "merit deference" because it was not "an agency regulation with the force of law"; instead, the preamble constituted a "mere assertion that state law is an obstacle to achieving [the agency's] statutory objectives." Id. at *11. The Court also rejected the FDA's preamble on the grounds that it was promulgated without any notice to the public or opportunity to comment; it stated a position "at odds with what evidence we have of Congress' purposes"; and, last but not least, "it reverses the FDA's own long-standing position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence." Id. at *11-12. The majority ultimately concluded that "Congress has repeatedly declined to preempt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight." Id. at *13.

The majority's opinion in Wyeth did leave drug manufacturers a thin reed on which to rest their preemption hopes. In addressing Wyeth's impossibility argument, Stevens noted that, "[o]f course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application." Id. at *9. "But," he wrote, "absent

clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Id.* (emphasis added). Justice Stevens cautioned that the burden of proving such a "clear evidence" defense lies squarely on the drug manufacturer, *id.*, and that "[i]mpossibility pre-emption is a demanding defense." *Id.* In so ruling, Wyeth cut the vast majority of prescription-drug preemption arguments off at the knees.

Why Wyeth Matters:

1. Holding Drug Companies Accountable. The first reason Wyeth matters is because it halted pharmaceutical companies' attempt to wipe out consumers' rights to sue for failing to warn of the true risks of their drugs. If the drug company had gotten its way, no consumer would ever be able to sue for failure-to-warn, regardless of the extent to which the drug's label understates its potential risks.

An opposite outcome in Wyeth would have been a disaster. As Justice Stevens noted, the FDA itself has admitted that it is unable to ensure the adequacy of prescription drug labels. See *id.* at *12 n.11 (quoting, *inter alia*, an FDA Science Board Report concluding that "the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities."). Among other things, the agency, when deciding whether to approve a drug label, is limited to the information that is submitted by the drug manufacturers themselves. Then, when new risks become known after a drug's label has been approved, the agency has only limited authority to force a manufacturer to change its label to reflect the newly discovered risks. As [Public Justice](#) explained in an amici brief filed on behalf of editors and contributing authors of the *New England Journal of Medicine* (NEJM), the upshot is that, in many, many cases, drugs are left on the market with inadequate labels, even as the casualty statistics climb ever higher. See NEJM Brief in Support of Respondent, 2008 WL 3851616; see also David A. Kessler & David C. Vladeck, A Critical Examination of the FDA's Efforts to Preempt Failure-To-Warn Claims, 96 *Geo. L.J.* 461 (2008).

Litigation is often the only way to dig up information regarding the true risks of prescription drugs. This information can, in turn, spur the agency to put pressure on the manufacturers to improve the labels. But without this critical "feedback loop" generated by prescription drug litigation, the agency would not have the information that it needs to pressure drug manufacturers to improve their labels. And, without litigation, the manufacturers would neither compensate victims nor have any financial incentive to correct their labels and provide consumers with adequate warnings. See

id. at 491-96 (discussing how litigation uncovers information within the control of drug companies that is otherwise unavailable to the FDA).

In short, an adverse ruling in Wyeth would have been a catastrophe for public health. Victims of inadequately labeled drugs would have had no recourse to seek compensation for their injuries. The FDA would have been stripped of the invaluable information that is often unearthed during the course of litigation. The only winners in this scenario would have been drug manufacturers themselves, who could have continued to increase their profit margins unrestrained by the risk of litigation, at the direct expense of the hapless victims of inadequately labeled drugs.

Luckily, this parade of horrors was stopped in its tracks. Wyeth makes clear that failure-to-warn litigation against pharmaceutical companies is here to stay. As Stevens put it, "the [drug] manufacturer bears responsibility for the content of its label at all times." *Id.* at *8 (emphasis added). Consumer advocates could not have hoped for a clearer ruling.

But that's just the first reason Wyeth matters. As explained below, the decision could prove valuable in a number of other important respects.

2. Limiting the Scope of Implied Conflict Preemption: Wyeth suggests that the Supreme Court may be backing away from finding implied preemption based on an alleged conflict with the purposes underlying federal regulations. In 2000, in what may come to be viewed as the high water mark of implied conflict preemption rulings, the Court decided *Geier v. American Honda Motor Co.*, [529 U.S. 861](#), which held 5-to-4 that claims that a car was defective because it lacked an airbag were preempted by a federal regulation that permitted - but did not require - airbags to be installed in passenger vehicles. *Geier's* holding has been decried by many (including the four Justices who dissented in the case) as a radical - and unwarranted - extension of implied conflict preemption. See 529 U.S. at 911 (Stevens, J., dissenting) (criticizing the vague and "potentially boundless scope" doctrine of [implied conflict] pre-emption").

Since then, however, the Court has seemed to pull back from the type of "free-form judicial policymaking" engaged in by the *Geier* majority. *Id.* at 911 (Stevens, J., dissenting). In 2002, for example, the Court issued a unanimous decision in *Sprietsma v. Mercury Marine*, [531 U.S. 57](#) (2002), rejecting implied conflict preemption of state law claims that a boat engine was defective because it lacked a propeller guard. And just last year, in *Altria v. Good*, [129 S. Ct. 538](#) (2008), the Court refused to find implied conflict preemption of consumer-fraud claims against manufacturers of so-called "light" cigarettes.

And now comes *Wyeth*, in which six members of the Court (including Justices Stephen Breyer and Anthony Kennedy, who joined the majority decision in *Geier*), rejected implied conflict preemption. In so ruling, the majority narrowly limited *Geier* to its facts, holding that the decision in that case was based on the "complex and extensive" history of the substantive regulation at issue. See 2009 WL 529172 at *13 n.13. (In a remarkable opinion concurring in the judgment, Justice Clarence Thomas went so far as to assert that implied conflict preemption should be abandoned entirely on the ground that it "leads to the illegitimate - and thus unconstitutional - invalidation of state laws..." *Id.* at *25 (Thomas, J., concurring in the judgment)).

If this string of rulings is a portent of things to come, then defendants may be hard-pressed in the future to persuade courts to find implied conflict preemption, particularly in regulatory cases, like *Geier*, that invite courts to "[run] amok with our potentially boundless . . . doctrine of implied conflict preemption based on frustration of purposes ..." *Geier*, 529 U.S. at 907 (Stevens, J., dissenting). That would be very good news for everyone who cares about victims' rights and preservation of the civil justice system.

3. Curbing Federal Preemption by Regulatory Fiat. *Wyeth* may help stem the tide of Executive Branch attempts to achieve preemption by regulatory fiat. Over the past few years, several federal agencies attempted to wipe out tort litigation against the industry they purport to regulate by including pro-preemption language in their regulations stating that, in the agency's view, state law claims against the regulated industry would frustrate federal purposes, and thus are preempted.

The most notorious example of this practice was committed by the FDA itself, when it declared, in the preamble to a 2006 labeling regulation, that it possesses the exclusive authority to determine the content of prescription drug labels, and that state law failure-to-warn claims are impliedly preempted because they would conflict with the agency's labeling decisions. See 71 Fed. Reg. 3922, 3934-35 (2006). Even though this position represented a 180-degree reversal of the FDA's prior views on the matter (before the Bush administration took power, the FDA enthusiastically endorsed tort litigation as complementing the agency's ability to ensure the safety of prescription drugs), a host of courts threw out failure-to-warn claims against prescription drug manufacturers on the ground that the FDA's newly minted preemption view was entitled to "deference." See, e.g., *Colacicco v. Apotex*, 521 F.3d 253 (3d Cir. 2008). (*Colacicco*, happily, was vacated and remanded in the wake of *Wyeth*.) A number of other courts - including the Vermont Supreme Court in *Wyeth* (see 922 A.2d at 193) - rejected the FDA's preamble as inconsistent with the

FDCA and with the agency's own regulations and thus not entitled to any weight. See, e.g., *Perry v. Novartis Pharmaceutical Corp.*, 456 F. Supp. 2d 678 (E.D. Pa. 2006).

Justice Stevens put an end to the debate, holding that "the [FDA's] preamble is at odds with what evidence we have of Congress' purposes and it reverses the FDA's own long-standing position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence." 2009 WL 529172 at *12. Based on this observation, the majority concluded that the FDA's "recently adopted position" is entitled to "no weight." *Id.* at *13.

This holding could prove invaluable in undercutting other agency's attempts to achieve federal preemption by including pro-preemption language in regulatory preambles. Of course, with a new administration in power, these sorts of regulatory power grabs may fall by the wayside. But so long as pro-preemption preambles remain on the books, manufacturers may attempt to exploit them by arguing that the FDA's preamble was uniquely flawed, thereby rendering *Wyeth* inapplicable to cases involving different products (and different preambles). Although any such attempt would face substantial obstacles, given the *Wyeth* majority's stated distrust of "an agency's mere assertion that state law is an obstacle to achieving its statutory purposes," *id.* at *11, there will likely be further litigation in this area. And *Wyeth*'s refusal to defer to the FDA's preamble will provide substantial ammunition in the fight to ensure that preemption remains where it belongs: in the hands of Congress, not the Executive Branch.

4. Recognizing the Value of the Civil Justice System. Finally, at a time when "tort reform" remains a constant threat notwithstanding the transfer of power in the White House, *Wyeth* provides a powerful reminder of the importance of the civil justice system in compensating victims and keeping America safe. With regard to the FDA, Justice Stevens observed that the agency itself has "traditionally regarded state law as a complementary form of drug regulation." *Id.* at * 12. The majority went on to note that "State tort suits uncover unknown hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information." *Id.*

Although Justice Stevens couched this observation in terms of the FDA, his language is broad enough to encompass all litigation involving defective products. And, although consumer lawyers already understand that tort suits help to "uncover unknown hazards" of dangerous products, thereby creating an incentive for manufacturers to make their products safer (and to warn of their risks), *Wyeth*'s ringing endorsement of tort litigation cannot help but reach a larger audience. It is

precisely this sort of public education that is needed to ensure that the civil justice system continues to play its role in making the world a safer place.