Wyeth v. Levine: U.S. Supreme Court refuses to swallow "Big Pharma's" preemption pill

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By Leslie A. Brueckner

Consumer advocates across America heaved a collective sigh of relief when, on March 4, 2009, 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, 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.

Ms. 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, Ms. 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 Ms. 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 this 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* (2006) 944 A.2d 179, 185-86, 188.) The Vermont Supreme Court wrote: "The litigation at issue here does not pose a direct and positive conflict with federal law, and, thus, there is no basis for federal preemption." (*Id.* at 192.)

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. Even the United States Solicitor General's Office, which filed an *amicus* brief in favor of FDA preemption, urged the Court to deny review given this lack of a split. 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 unwarranted. In the U.S. Supreme Court, both Wyeth and the United States (as *amicus*) took the position that Ms. Levine's claims were impliedly preempted because they conflicted with the FDA's decision to ap-

prove 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 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 reaffirmed the strong presumption against federal preemption in cases involving the historic police powers of the States.

The Court wrote:

> In all pre-emption cases, and particularly in those in which Congress has legislated. . .in a field which the States have traditionally occupied, . . .we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

(*Id.* at *5 (citations, internal quotations, and footnote omitted).)

In light of this presumption, the majority went on to hold that the FDCA does not preempt Ms. Levine's claims. The Court first addressed Wyeth's argument that Ms. Levine's claims are preempted because, said Wyeth, "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 this 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*. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug on the market." (*Ibid.* (citations omitted; emphasis added).) On this basis, the Court rejected Wyeth's attempt to shirk its responsibility for the content of its warning labels.

Justice Stevens was equally adamant in his rejection of Wyeth's argument that Ms. 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." (*Ibid.*)

The Court went on to emphasize the important role damage suits play in protecting the public, stating:

> [t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug 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. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times.

(*Id.* at *12 (footnote omitted).)

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. (2006) 3922, 3934-35).) 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, Justice 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." (*Ibid.*) (emphasis added). Justice Stevens cautioned that the burden of proving such a "clear evidence" defense lies squarely on the drug manufacturer, (*Ibid.*), and that "[i]mpossibility pre-emption is a demanding defense." (*Ibid.*) In so ruling, *Wyeth* cut the vast majority of prescription-drug preemption arguments off at the knees.

Why *Wyeth* matters

•Holding drug companies accountable

The first – and most important – reason *Wyeth* matters is because it halted Big Pharma's attempt to wipe out consumers' rights to sue for failing to warn of the true risks of their drugs. If Wyeth 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.

This 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 *horribles* was stopped in its tracks. *Wyeth* makes crystal clear that failure-to-warn litigation against pharmaceutical companies is here to stay. As Justice 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.

•Limiting the scope of implied conflict preemption

Wyeth is also important because it suggests that the U.S. Supreme Court may be backing away from finding implied preemption based on an alleged conflict with the purposes underlying federal regulations. Back 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.* (2000) 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* (2002) 531 U.S. 57, 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* (2008) 129 S. Ct. 538, 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 Breyer and 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 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.

•Reaffirming the presumption against preemption

Wyeth also should put the final nail in the coffin of the argument that there is no presumption against preemption in cases involving "the historic police power of the States." In recent years, conservative forces have repeatedly argued that the presumption against preemption should not be applied in any preemption cases involving state law damage claims. (See, e.g., *Altria v. Good,* Brief of Washington Legal Foundation as *Amicus Curiae* in Support of Petitioners, 2008 WL 976401 at *4 (arguing that the presumption against preemption "ought to be laid to rest"); *Warner-Lambert v. Kent*, Brief of the Chamber of Commerce of the United States of America as *Amicus Curiae* in Support of Petitioners, 2007 WL 4205141 at *14 (arguing that "there is no basis in the text of the Constitution for a presumption against preemption in any circumstance.").) The Supreme Court recently rejected these arguments in *Altria v. Good*, which applied a presumption against preemption in a consumer-fraud case involving so-called "light" cigarettes. (See (2008) 129 S. Ct. 538, 543.) By reaffirming the presumption against preemption yet again – this time in a case involving personal injury claims – *Wyeth* hopefully puts the issue to rest once and for all.

•Curbing federal preemption by regulatory fiat

Wyeth also 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. (See, e.g., Thomas O. McGarity, *The Perils of Preemption*, Trial Magazine (September 2008) (discussing pro-preemption preambles published by the FDA, the National Highway Traffic Safety Administration, and the Consumer Product Safety Commission); Catherine M. Sharkey, *Preemption by Preamble; Federal Agencies and the Federalization of Tort Law*, 56 DePaul L. Rev. 227 (Winter 2007) (same).)

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. (2006) 3922, 3934-35.) 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* (3d Cir. 2008) 521 F.3d 253 (*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.* (E.D. Pa. 2006) 456 F. Supp. 2d 678.)

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.

•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." *(Ibid.)*

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.


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