

Wyeth vs. Levine: Supreme Court Leaves the Door Open for Failure to Warn Claims in Drug Labeling Cases, and Shows Agencies How to Weigh in on Conflict Pre-emption Issues.

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In *Wyeth vs. Levine*, 129 S.Ct. 1887 (2009), the Supreme Court handed down a 6-3 decision, in which it held that a major drug manufacturer's compliance with the FDA's drug labeling process was insufficient to shield it from a state tort claim that produced a \$6.57 million verdict. The holding clarified that state failure to warn claims remain viable in the area of drug labeling.¹

Facts and Legal Issues:

On April 7, 2000, Diana Levine, a professional violinist, brought a state tort action against the pharmaceutical company Wyeth, after she had developed gangrene and eventually had no choice but to undergo amputation of her arm. The complaint alleged that Wyeth had failed to take sufficient measures to prevent a clinician at a hospital from injecting the anti-nausea drug Phenergan into her arm through a method called "IV push." While both Wyeth and the FDA knew that using IV push to administer Phenergan was dangerous, the FDA had not banned the method. Further, Wyeth had issued several FDA-approved labels warning clinicians of the precise danger from which Levine suffered. Nonetheless, Levine successfully argued at trial that these warnings were not enough to offset the risk of harm, and that Wyeth's failure to warn in this case had caused her injury.

At trial, Levine introduced evidence that using the "IV drip" method (administration through a saline solution that a clinician places above the patient in a

¹ Prior to *Wyeth*, federal courts came to different conclusions on issues concerning whether the federal drug labeling approval process pre-empted state claims for failure to warn, particularly in instances where, as in *Wyeth*, the FDA filed amici in support of implied pre-emption. (See e.g., *Witczak v. Pfizer*, 377 F. Supp. 2d 726, 729-32 (D. Minn. 2005) (holding that the federal labeling process did not pre-empt a state claim for failure to warn about the risks of suicide associated with the drug Zoloft, and specifically rejecting Pfizer's contentions that (1) the FDA's order in its approval letter to use its labeling "verbatim" made compliance with both state and federal law impossible and (2) a warning about suicide-related risks would have directly and impliedly conflicted with a federal misbranding statute); *Colacicco v. Apotex*, 432 F. Supp. 2d 514, 518 (E.D. Pa. 2006) (holding that the FDCA impliedly pre-empted state tort claims based on inadequate labeling, and affording deference to the FDA's interpretation in support of implied conflict pre-emption under the *Chevron* doctrine)).

plastic bag) rather than IV push would have eliminated her risk of developing gangrene almost completely. Further, she introduced evidence that Wyeth and the drug industry at large had known of similar gangrene and amputation cases resulting from IV push injection of nausea medications for several decades.

The FDA labeling history of Phenergan was also part of the trial record. This included communications between Wyeth and the FDA regarding the risks of inter-arterial injection, and the warnings that Wyeth issued on its labels pursuant to FDA instruction. The last communication between Wyeth and the FDA took place in 1998, when upon approving the labeling application, the FDA instructed Wyeth that the final label “must be identical” to the approved package insert.

Wyeth urged that the FDA’s drug labeling scheme pre-empted Levine’s state tort claim under theories of: (1) impossibility of dual compliance and (2) implied conflict pre-emption.

First, Wyeth contended that the FDCA pre-empted Levine’s claim because Wyeth could not possibly comply with both the FDA’s drug labeling requirements and Vermont’s tort law. In other words, modifying content of the label for Phenergan beyond that which the FDA had approved (e.g. in order to produce a stronger warning about the IV push method) would have constituted unauthorized distribution and misbranding under the FDA’s regulations.

Second, Wyeth contended that the federal drug labeling laws and regulations pre-empted Vermont’s tort law because the latter frustrated the objectives and purposes of the former. Wyeth contended, by analogy, that a state law eliminating IV push administration of Phenergan would have undermined the objectives behind the FDA’s labeling process.

The trial court rejected Wyeth’s pre-emption arguments in denying its motions for summary judgment, and judgment as a matter of law following the verdict. The Vermont Supreme Court affirmed, reasoning that the FDA requirements did not pre-empt Levine’s claim, because Wyeth “could have warned against IV-push administration without prior FDA approval, and because federal labeling requirements create a floor not a ceiling, for state regulation.”² The Supreme Court affirmed.

The Supreme Court Decision:

Justice Stevens wrote the for the 5 justice majority. The opinion relied on “two cornerstones of ... pre-emption jurisprudence,” namely, that: (1) the purpose of Congress is the ultimate authority regarding intent to pre-empt state law and (2) a presumption

² Wyeth v. Levine, 183 Vt. 76, 84 (2006).

against pre-emption applies, particularly when Congress legislates in a field that states have traditionally occupied.³

As a threshold matter, the Court declined to consider the broader question of whether the federal labeling scheme would have pre-empted an actual state statute proscribing the IV push method. It stated that “[t]he narrower question presented is whether federal law pre-empts Levine’s claim that Phenergan’s label did not contain an adequate warning about using the IV-push method of administration.”⁴

In regard to Wyeth’s contention that dual compliance with federal and state standards was impossible, the Court stated that Wyeth failed to demonstrate impossibility, even under the provisions which the FDA had enacted after the injury.⁵ Further, the Court noted that Wyeth never argued that it had tried to issue a strengthened warning (so as to comport with the heightened negligence standard), only to be prohibited from doing so by the FDA. Rather, Wyeth merely argued the FDA *intended* to prohibit it from strengthening the warning about IV-push administration. The Court stated that the trial court and the Vermont Supreme Court had both rejected this contention as a matter of fact. The Court concluded that it could not rule in favor of Wyeth’s impossibility contention absent clear evidence that dual compliance with federal and state law was impossible.

Turning to Wyeth’s second argument, that federal law pre-empted the state claim due to an implied conflict with the objectives and purposes of federal law, the Court determined that Wyeth failed to show evidence that demonstrated such a conflict. It noted that Wyeth’s proffered evidence concerning the FDA’s approval process fell well short of outweighing the presumption against pre-emption. “The most glaring problem with this argument,” the Court stated, “is that all evidence of Congress’ purposes is to the contrary.”⁶ Specifically, the Court reasoned that if the legislative history of the FDCA contained a specific pre-emption provision for medical devices, but not for prescription drugs, Congress most likely did not intend for FDA oversight of drug labeling to pre-empt state tort claims in that area.

³ *Wyeth*, 129 S.Ct. at 1194.

⁴ *Id.*

⁵ *Wyeth and the FDA* (as amicus curie) both argued that the subsequent provisions reflected the policy in place at the time of the injury. The Court ruled that even if this was true, the FDA’s process didn’t bar dual compliance. See *Wyeth*, 129 S.Ct. at 1196-97 (“We need not decide whether the 2008 CBE [changes being effected] regulation is consistent with the FDCA and the previous version of the regulation, as Wyeth and the United States urge, because Wyeth could have revised Phenergan’s label even in accordance with the amended regulation.”)

⁶ *Wyeth*, 129 S.Ct. at 1199.

Wyeth did point to one item with the force of law, although the FDA had issued it well after Levine's injury.⁷ This was a 2006 preamble to a FDA regulation, which expressly provided that the FDCA "establishes both a 'floor' and a 'ceiling,'" so that "FDA approval of labeling ... preempts conflicting or contrary State law."⁸ However, the Court determined that the preamble, which was at odds with the evidence of Congress' purposes to begin with, was not the type of regulatory evidence that could impact the answer to the pre-emption question. This was because rather than demonstrating *how* state laws obstructed the execution of Congress' purposes and objectives, the regulation's preamble merely asserted the FDA's views on the ultimate question of pre-emption. Further, while the FDA had indicated in its initial rulemaking proposal in 2000 that its new regulations would not pre-empt state law, the 2006 preamble "articulated a sweeping position" that was completely to the contrary. The Court noted that this procedural flaw denied states a fair chance to comment on the proposed rulemaking, and made the preamble inherently suspect.

The Court also noted that the FDA has traditionally relied on state tort law to complement its drug labeling process, and that economic and policy considerations support this notion. Specifically, the Court noted that the FDA has limited resources with which to monitor drugs, manufacturers have superior access to information concerning risks, and state tort law claims help to alleviate this imbalance.

Justice Breyer concurred, writing separately to emphasize that agencies may ascertain issues relevant to questions of "conflicting objectives," so long as they do so through regulations bearing the force of law. Specifically, he noted that the FDA could potentially enact "lawful, specific regulations describing, for example, when labeling requirements serve as a ceiling as well as a floor," and that "it is possible such determinations would have pre-emptive effect."⁹ But Justice Breyer agreed that "such a regulation is not at issue in this case."

Justice Thomas concurred only in the judgment, advocating strict adherence to the principle that only Congress – and not agencies – may choose to pre-empt state law. Specifically, he criticized the plurality for furthering the development of the implied conflict pre-emption doctrine, and noted that giving too much deference to federal

⁷ The Court, in analyzing both of Wyeth's pre-emption arguments, considered several statutes and regulations that Congress enacted subsequent to Levine's injury. Wyeth's impossibility argument relied on the notion that subsequent enactments demonstrated how the labeling process actually functioned at the time of the injury. Its implied conflict pre-emption argument relied on the notion that the subsequent enactments demonstrated how the state tort law conflicted with the purposes and objectives of federal law. The timing issue was likely a considerably smaller detriment to Wyeth's implied conflict pre-emption argument, since implied conflict pre-emption is a broad concept, and indications of a conflict can appear gradually over time.

⁸ 71 Fed.Reg. at 3934-3935 (Jan. 24, 2006) (to be codified at 21 C.F.R. pt. 201).

⁹ *Wyeth*, 129 S.Ct. at 1204 (Breyer, J., concurring).

agencies' determinations could violate the bicameral presentment requirement set forth in Article 1, Section 7 of the Constitution.

Justice Alito wrote the dissent, in which Justice Roberts and Justice Scalia joined. The dissent contended that when Congress amended the FDCA in 1962, it expressly charged the FDA with determining whether drug labels were safe. In this case, the dissent argued, the FDA had determined that the label was safe, but Levine's state negligence claim required a determination to the contrary. Thus, because "the ordinary principles of conflict pre-emption turn solely on whether the State has upset the regulatory balance struck by the federal agency,"¹⁰ the dissent reasoned that federal law should have pre-empted the state claim.

Future Implications:

In *Wyeth*, the Supreme Court protected a state common law tort claim from pre-emption by the federal drug labeling process. But it did not determine whether the federal drug labeling scheme could have pre-empted a state statute proscribing IV push administration of Phenergan. Questions like this may arise in future litigation related to drug labeling.

The doctrine of implied conflict pre-emption may also undergo significant development beyond the field of drug labeling, particularly in fields occupied by state and federal statutes where a federal regulatory agency is active. For litigants whose compliance efforts have been complicated by dissimilar state and federal standards, implied conflict pre-emption may be the best-fitting defense. While demonstrating impossibility as a matter of law is extremely difficult, litigants have a wide range of options from which to craft a compelling argument for implied conflict pre-emption. In addition to the text of the statute(s) in question, litigants can look to legislative history, subsequent enactments, and agency regulations to support their arguments.

The Court's implied conflict pre-emption discussion in *Wyeth* may be particularly important for a number of federal regulatory agencies. While the Court determined that the FDA's "new position" on pre-emption was not entitled to deference, it noted that "we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law."¹¹ Now, federal agencies have better guidance on how to influence implied conflict pre-emption cases. *Wyeth* made it clear that it will not suffice to for an agency to file an amicus brief or make a bare assertion in support of implied conflict pre-emption. Going forward, the best way for an agency in any field to influence these types of cases will be to provide detailed descriptions in a regulation, from which a court can draw appropriate inferences. Of course, if agencies are actually *trying* to influence implied conflict pre-emption cases, then perhaps Justice Thomas' concern,

¹⁰ *Wyeth*, 129 S.Ct. at 1220 (Alito, J., dissenting).

¹¹ *Wyeth*, 129 S.Ct. at 1203.

that agencies might essentially run wild, is well-founded. Justice Thomas' caution against giving agencies too much potential power in pre-emption cases is even more significant if agencies are likely to change their positions based on the administration in power.¹²

¹² The Court did not directly state that partisan politics played a key role in the FDA's stance on implied conflict pre-emption. But history certainly seems to indicate that politics affect how agencies function. *Wyeth* illustrates that the FDA's position in support of pre-emption was consistent under the Bush administration. But the Court noted that prior to 2001, the FDA had consistently supported the coexistence of state tort claims. The Court cited to FDA statements under the Clinton administration to this effect. Further, while the *Wyeth* holding was still pending, interest groups urged the incoming Obama administration to work to strengthen the presumption against pre-emption with respect to drug labeling, and to undo the pro pre-emption stance that the FDA had exhibited under the Bush administration. (See e.g., Memorandum from Allan Coukell, Director of Policy, the Prescription Project, to President-Elect Obama HHS Transition Team (Nov. 26, 2008) (on file with author), available at http://www.prescriptionproject.org/tools/solutions_resources/files/0029.pdf; Press Release, American Association for Justice, AAJ Sends Obama Team Strategies to Reverse Bush "Complete Immunity" Regulations (Jan. 12, 2009) (on file with author), available at <http://www.justice.org/cps/rde/xchg/justice/hs.xsl/6157.htm>).