Wyeth v. Levine and the Contours of Conflict Preemption Under the Federal Food, Drug, and Cosmetic Act

Introduction

The Supreme Court has decided that the Food and Drug Administration's (FDA) approval of the packaging and labeling for a drug under the Federal Food, Drug, and Cosmetic Act will not preclude a state common law claim for failure to warn where the FDA gave “only passing attention” to the health risk at issue in the underlying state law case. Prior medical device preemption cases by the Court, discussed below, also address the nature and extent of the FDA's review in each case. The decision in Wyeth reinforces the importance to drug manufacturers of engaging FDA on significant health issues pertaining to their products, and of encouraging the development of a robust record of the FDA's consideration of those issues and the basis for the Agency's approval of the product labeling and warnings.

The Court also vacated and remanded two Third Circuit FDA drug preemption decisions for further consideration in light of the holding in Wyeth. The Third Circuit in each case found a state law claim preempted by the FDA's approval of the drug's labeling. As explained further below, the holding in each Third Circuit case appears consistent with the reasoning and holding in Wyeth, and thus it should not be assumed that either case will be decided differently on remand. However, it will be important to keep an eye on these cases.

Congressional Democrats have responded to the Wyeth decision by introducing bills that would over-turn the Court's preemption decision in the Riegel v. Medtronic, Inc. medical device case.

The Supreme Court's Wyeth Decision

Wyeth arose from the labeling of the anti-nausea drug Phenergan. Respondent suffered serious injury following administration of the drug by the “IV-push” method; gangrene developed as a result of arterial blood contamination, necessitating amputation of her forearm. Respondent sued Wyeth, alleging that Wyeth had failed adequately to warn against the risks of the IV-push method of administering the drug. Wyeth argued that Respondent's claims were preempted by the FDA's approval of the drug's labeling and warnings. The trial court rejected Wyeth's preemption defense, finding that “the agency had paid no more than passing attention to the question whether to warn against IV-push
administration of Phenergan."7 A jury awarded damages, and the Vermont Supreme Court affirmed the verdict and judgment, also citing the FDA’s limited review of the relevant issue.8 The US Supreme Court affirmed, finding no implied conflict preemption. Justice Stevens authored the opinion, joined by Justices Ginsburg, Kennedy, and Souter. The Court relied heavily on the trial court’s findings of the Agency’s limited attention to the particular risk.9 The Court found that Wyeth had offered “no . . . evidence” to indicate “that the FDA would not have approved a change to Phenergan’s label.””10 The Court added that “the trial court found ‘no evidence in the record that either the FDA or the manufacturer gave more than passing attention to’ the relevant issue, and that Wyeth “[d]id not argue that it supplied the FDA with an evaluation or analysis concerning the specific dangers posed by the IV-push method.””11 The Court summarized that Wyeth pointed to no evidence that the FDA had considered and rejected a suggestion that the warnings that formed the basis of the state law claim be strengthened, and that the trial court had found the opposite. The Court’s decision was not premised on limitations in the FDA’s review of drug warnings and labeling generally, which is a very rigorous process, but instead was tied to the specific record before it in that case.

The Court emphasized the burden on drug manufacturers to research their products, and found that under the FDA’s “changes being effected” or “CBE” regulation, “as amputations continued to occur, Wyeth could have analyzed the accumulating data and added a stronger warning.””12 The Court stated: “[A]bsent 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.””13

The Court noted that Congress had not enacted an express preemption provision for drugs, as it has for medical devices.”14 At the same time, the Court acknowledged that “an agency regulation with the force of law can preempt conflicting state requirements,” and concluded: “Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case.””15 The Court left room for where the agency, contrary to the FDA in Wyeth, did pay “more than passing attention to the question” at issue or did “consider and reject a stronger warning.””16 The Court made clear that it was not deciding whether a prohibition on the IV-push method, an approved method of administering Phenergan, would have been preempted.”

Justice Breyer concurred, emphasizing that the opinion did not address a situation where the agency had issued a specific regulation describing when “labeling requirements serve as a ceiling as well as a floor.””17 Justice Thomas concurred in the judgment, expressing reluctance with respect to “far-reaching implied pre-emption doctrines.””18 Justice Alito dissented, joined by Chief Justice Roberts and Justice Scalia, reasoning that the state-court standards impermissibly conflicted with federal labeling requirements and would lead to destructive consequences.”19

**Medical Device Cases**

In *Medtronic, Inc. v. Lohr,*20 the Court found against express preemption under the Medical Device Amendments of 1976 or “MDA” where the device at issue had undergone only an “equivalency review” that the Court found ordinarily takes the FDA only about 20 hours to complete.21 The FDA had compared the new product to a similar, grandfathered product that was already on the market and that also had not undergone a safety
The Court contrasted that equivalency review with the more rigorous "premarket approval" or "PMA" process that otherwise applies to Class III medical devices. In the "premarket approval" process, "[m]anufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." The Court relied upon the fact that the medical device at issue in Lohr had undergone only the review that "focused on equivalence, not safety," and that was "by no means comparable to the PMA process" where a safety determination was made.

The Court in Lohr made clear that the facts in that case were "quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." The Court found that the FDA's regulations in Lohr reflected "important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." Justice Stevens, joined by others, authored this language.

In last year's Riegel v. Medtronic, Inc. decision, the Court again addressed the express preemption provision under the Medical Device Amendments, this time in the context of a medical device that had undergone the rigorous "premarket approval" process. The plaintiffs brought design, manufacturing, and labeling defect claims against the manufacturer of a faulty catheter, and the Court held by an 8–1 vote that the state law claims were preempted because they sought to impose different or additional safety and effectiveness requirements from those imposed through the FDA's "premarket approval" process. The Court explained: "Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review—it is federal safety review. Thus, the attributes that Lohr found lacking . . . are present here." Sensitive to the nature of the agency's review, therefore, the Court reached a different outcome.

**Third Circuit Cases**

On March 9, the Court announced its decision to grant certiorari, vacate, and remand two cases involving drugs to the Third Circuit for further consideration in light of Wyeth. Colacicco v. Apotex, Inc. is an implied conflict preemption case involving failure-to-warn claims pertaining to selective serotonin reuptake inhibitors. Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc. is another conflict preemption case that dealt with state consumer fraud claims stemming from advertisements for the drug Nexium, a proton-pump inhibitor.

Pennsylvania Employees described the approval process for drugs and the FDA's central position with respect to drug advertising; it cited Lohr, in part, for the principle that "state laws are preempted when they frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority." In Colacicco, the court accepted similar principles, citing Lohr, and addressed a context of extensive agency action and review. The court noted that it "need not speculate on the rationale of the FDA for its failure to require the . . . warnings" the plaintiffs requested, observing that "the FDA has repeatedly rejected the scientific basis for [those] warnings." Under the circumstances, where the
FDA had publicly rejected the need for the warning, the court held that the state law claims were preempted.\[^37\]

The Third Circuit decisions appear consistent with the holding in \textit{Wyeth}. However, it will be important to see how the Third Circuit proceeds in each case.

**Implications and Best Practices**

\textit{Lohr}, \textit{Riegel}, and \textit{Wyeth} arose under different statutory provisions and only \textit{Wyeth} is a conflict preemption case. Nevertheless, it seems clear from these cases that a strong majority of the Court favors preemption where there is a clear record that the FDA has reviewed and considered the health risks at issue in the state law claim. Under those circumstances, there are numerous justifications for preventing state juries from second-guessing the FDA's determinations. Many states in fact incorporate federal regulatory approvals into their state laws or regulations to ensure uniformity, or exempt agency-approved activities from liability under state consumer protection laws. Companies should seek a clear record of the FDA's consideration of the health risks associated with their products and the basis for the FDA's decisions concerning required labeling and warnings.

The FDA issued a clarification of the "changes being effected" regulation effective September 22, 2008, after \textit{Wyeth}'s conduct that the Supreme Court reviewed in \textit{Wyeth}. The regulation states that "State law claims that 'challenge labeling that FDA approved after being informed of the relevant risk' are preempted."\[^38\] For "newly acquired information," the regulation states that such data "needs to be of a 'different type or greater severity or frequency than previously included in submissions to FDA.'"\[^39\]

Companies should continue to engage the agency with the data they have, and where appropriate seek written responses that the agency does not consider the data sufficient to change anything with respect to that drug labeling or warning.

**Congressional Reaction to \textit{Wyeth}**

The \textit{Wyeth} decision has already prompted responses from Congress. On March 5, Democrats introduced bills to overturn the express preemption case of \textit{Riegel}, which would lift preemption of claims for patients injured by medical devices, rather than drugs. These legislative developments and their effects will be closely monitored.

**Conclusion**

The decision in \textit{Wyeth} must be considered in light of the specific facts in that case, as reflected in the trial record in the state court case. The trial court's determination that the FDA had given "only passing attention" to the possibility of stronger warnings clearly was an important factor in the Court's opinion. Notwithstanding the outcome in the specific \textit{Wyeth} case, conflict preemption remains an important doctrine. The Court's opinion in \textit{Lohr}, also authored by Justice Stevens, makes clear that conflict preemption should remain a viable defense to state law claims where the FDA or another federal agency "has weighed the competing interests . . ., reached an unambiguous conclusion about how those competing considerations should be resolved . . ., and implemented that conclusion."\[^40\]
If you have any questions about this Client Alert, please contact one of the authors listed below or the Latham attorney with whom you normally consult:

**Laura A. Godfrey**  
+1.619.236.1234  
laura.godfrey@lw.com  
San Diego

**Elizabeth G. Wright**  
+1.202.637.2200  
elizabeth.wright@lw.com  
Washington, D.C.

**Buck B. Endemann**  
+1.619.236.1234  
buck.endemann@lw.com  
San Diego

**Scott W. Morris**  
+1.619.236.1234  
scott.morris@lw.com  
San Diego

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**Endnotes**

3. **Wyeth**, slip op. at 1.
4. *Id*. at 2.
5. *Id*. at 2–3.
7. *Id*. at 3–4, 5–6; see also *id*. at 16, 25.
10. *Id*. at 15.
11. *Id*. at 16.
12. *Id*. at 13; see also *id*. at 10, 15.
13. *Id*. at 15.
14. *Id*. at 10, 18, 22.
15. *Id*. at 19 (emphasis added), 25.
17. *Id*. at 8.
18. **Wyeth**, slip op. at 1 (Breyer, J., concurring).
19. **Wyeth**, slip op. at 2 (Thomas, J., concurring).
20. **Wyeth**, slip op. at 1, 3, 23–24 (Alito, J., dissenting).
22. *Id*. at 479.
23. *Id*. at 480.
25. *Id*. at 477.
27. *Id*. at 501; see also *id*. at 493.
28. *Id*. at 501.
29. 555 US ---, 128 S. Ct. 999 (2008); see 21 USC. § 360k(a).
31. *Id*. at 1007.
32. See **Colacicco v. Apotex, Inc.**, No. 06-5148 (3rd Cir. Apr. 8, 2008); **Pennsylvania Employees Benefit Trust Fund v. Zeneca, Inc.**, No. 05-5340 (3rd Cir. Aug. 17, 2007).
33. 521 F.3d 253 (3d Cir. 2008).
34. 499 F.3d 239 (3d Cir. 2007).
35. *Id*. at 250.
36. 521 F.3d at 269.
37. *Id*. at 271–72.
39. *Id*. at 49604.