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## Practical Implications of *Wyeth v. Levine*

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On March 4 the Supreme Court issued its widely publicized decision in *Wyeth v. Levine,* No. 06-1249. The Court held that the Federal Food, Drug, and Cosmetic Act (FDCA) does not preempt product liability claims alleging that the warnings on a prescription drug's FDA-approved labeling were inadequate.

Any company that produces or sells federally regulated products should read the four separate opinions comprising the 6-3 *Wyeth* decision. They address the subject of "implied conflict preemption" since the FDCA does not contain an express preemption provision relating to prescription drugs. Justice Stevens' majority opinion (joined by Justices Kennedy, Souter, Ginsburg, and Breyer) holds that drug-related failure-to-warn claims are not impliedly preempted because the manufacturer could have strengthened warnings without FDA's prior approval, and because such claims complement, rather than conflict with, FDA's regulation of labeling. Justice Breyer's concurring opinion suggests that federal agencies should act through notice-and-comment rulemaking if they want their views on the impact of state tort claims on a federal regulatory scheme to have preemptive effect. Justice Thomas' opinion concurs in the majority's conclusion that the failure-to-warn claims involved in *Wyeth* are not preempted, but broadly attacks the Court's longstanding jurisprudence on "purposes and objectives" preemption (i.e., the principle that state law is impliedly preempted if it frustrates or obstructs the purposes or operation of federal law). Justice Alito's dissenting opinion (joined by Chief Justice Roberts and Justice Scalia) argues that the plaintiff's failure-to-warn claims are preempted because Congress intended that the FDA - an expert federal agency - not individual juries in 50 States, determine whether the warnings on a drug's labeling are adequate.

Taken together, these opinions illustrate the deep and continuing divisions within the Supreme Court regarding federal preemption doctrine and the particular circumstances under which federal law preempts state law, including state law-based product liability claims.

As a practical matter, it seems clear from *Wyeth* (in which six Justices opposed implied preemption), and from the Court's recent decisions interpreting and applying express preemption provisions (e.g., *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008) (medical devices); *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005) (pesticides)), that the safest—and in the future, perhaps only—route to federal preemption of product liability claims is via a plainly worded preemption provision in a federal statute. Unfortunately, many existing preemption provisions are poorly, ambiguously, and inconsistently drafted. Despite the Obama Administration's presumed aversion to federal tort preemption, product manufacturers and their trade associations should be advocating enactment of new preemption provisions and/or revision of existing provisions so that federal statutes get the task of supplanting state law done without the need for costly and time-consuming judicial interpretations that can produce problematic or conflicting results.

Another practical lesson flowing from *Wyeth* is that a clear, thorough, and easily retrievable record of correspondence or other interactions with federal regulatory agencies on product-specific issues such as labeling, warnings, risks, and safety is *critical* to successful defense of product liability suits, either on preemption grounds or at trial. In *Wyeth* the majority and dissenting opinions appear to disagree about the facts—exactly what label warnings the drug manufacturer proposed, and what risk and labeling issues the FDA considered, and when. Because federal agency personnel often communicate with companies in a way that is less than ideal, such as when they convey decisions orally or in cryptic emails, it is important for companies to engage in "defensive recordkeeping." In other words, companies need to take whatever steps may be necessary to ensure that a federal agency's scientific determinations, and regulatory approvals or rejections, regarding subjects such as label warnings and product risks are well documented and readily accessible in a company's own files.

A copy of the *Wyeth* decision is available on the Supreme Court's website at http://www.supremecourtus.gov/opinions/08pdf/06-1249.pdf.