

Viability of Preemption Defense for Generic Drug Manufacturers Remains Unclear

By Kelly Savage Day

In *Wyeth v. Levine*, 129 S.Ct. 1187 (2009), the U.S. Supreme Court held that failure-to-warn claims against brand-name drug manufacturers were not automatically preempted by the federal Food, Drug and Cosmetic Act (FDCA) simply by virtue of the fact that the Food and Drug Administration (FDA) had approved the drug's labeling. Since *Levine*, a majority of courts, including the Eighth Circuit Court of Appeals in *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), and the Fifth Circuit Court of Appeals in *DeMahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), have held that the FDCA does not preempt state-law failure-to-warn claims brought against generic drug makers. (For an overview of the current generic drug preemption landscape, see the Washington Legal Foundation's recent [Legal Backgrounder](#) on the topic.)

Only two courts have reached an opposite conclusion. In *Morris v. Wyeth, Inc.*, 582 F.Supp.2d 861 (W.D. Ky. 2008), *aff'd* 642 F.Supp.2d 677 (W.D. Ky. Feb. 20, 2009), *aff'd* 2009 WL 736200 (W.D. Ky. Mar. 4, 2009) the Western District of Kentucky denied the plaintiffs' motion for reconsideration in light of *Levine* after concluding for a second time that the plaintiffs' state law failure-to-warn claims against generic drug makers were preempted because they conflicted with the federal regulation of generic drug labeling. The Northern District of California reached a similar conclusion in *Gaeta v. Perrigo Pharmaceuticals Co.*, 672 F.Supp.2d 1017 (N.D. Cal. 2009).

Recent Actions Suggest the Pendulum Against Preemption May Be Swinging Back

The legal landscape, however, may soon change. The *Mensing* defendants recently filed a petition for certiorari to the U.S. Supreme Court. And the U.S. Supreme Court has invited the solicitor general (or, for now, the acting solicitor general) to "express the view of the United States." (Supreme Court Nos. 09-993, 09-1039, 588 F.3d 603 (8th Cir. Nov. 27, 2009)). Meanwhile, *Morris* was argued in the Sixth Circuit Court of Appeals earlier this month. And the [Sixth Circuit has invited the FDA](#) "to file a brief setting forth its views on the preemption issue ..., and how the issue ought to be resolved."

Implications for Future Cases

Both moves indicate courts' growing awareness of the significant issues at stake. However, until the Supreme Court definitively decides the issue, generic drug manufacturers should anticipate increased product liability litigation and continue to assert the defense.