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CLIENT ALERT

Supreme Court Again Finds Federal Preemption of Liability for Generic Drug Manufacturers: Will the FDA Finally Step In?

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On June 24, 2013, the United States Supreme Court held 5-4 in *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013),that state law design defect claims against manufacturers of generic pharmaceuticals are preempted by federal law if the claims are based on the adequacy of the drug's warning label. Following its ruling in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the Court once again found that the Federal Food, Drug, and Cosmetic Act and its implementing regulations (FDCA), preempt failure to warn claims against generic pharmaceutical manufacturers because the FDCA requires generic drug labels to mirror the FDA-approved labeling of their branded counterparts. In the underlying *Bartlett* decision, the court of appeals had ruled that the generic drug maker could have avoided the conflict between any state-law duty to warn and federal restrictions on generic drug labeling simply by stopping sales of the drug, *Bartlett v. Mutual Pharmaceutical Co.*, 678 F.3d 30, 37 (1st Cir. 2012), but a majority, led by Justice Alito, rejected this position. Rather, the Court re-affirmed the well-established rule that when it is impossible for an actor to comply with both federal and state law, federal law trumps.

While this ruling once again shut the door on plaintiffs' efforts to hold generic drug manufacturers liable for injuries, the Court expressly left open another option for future plaintiffs to pursue. The Court suggested that federal law might not preempt "state design-defect claims that parallel the federal misbranding statute." *Bartlett*, 133 S. Ct. at 2447 n.4. If, the Court explained, the state law requirements were "equivalent to, and fully consistent with" the federal law requirements, a drug manufacturer could comply with both and thus there would be no basis for preemption. *Id.* In order for liability to attach in such a situation, however, the Court indicated that there must be "new and scientifically significant information that was not before the FDA" when it made its approval decision. *Id.* Although a narrow opening, one should expect plaintiffs to test the boundaries of *Bartlett* by bringing these types of cases where possible.

The *Bartlett* decision furthers an odd dichotomy whereby a plaintiff's ability to maintain a state tort action may turn on whether their pharmacist filled a prescription with a branded drug or its generic alternative. *Compare Bartlett*, 133 S. Ct. 2466, *with Wyeth v. Levine*, 555 U.S. 555 (2009) (permitting a plaintiff to proceed with her state tort action for failure to warn against a branded manufacturer). It appears, however, that Congress and FDA

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will try to reconcile these disparate outcomes with legislative or administrative action. Shortly after the *Bartlett* opinion was issued, Representatives Henry Waxman (CA), Chris van Hollen (MD), Bruce Braley (IA), and Matthew Cartwright (PA), and Senators Tom Harkin (IA), Patrick Leahy (VT), and Al Franken (MN) sent a letter to FDA Commissioner Margaret Hamburg, urging the agency to "expedite its consideration of revisions to the FDA's drug labeling regulations to enable manufacturers of generic drugs to update patient safety labeling in appropriate circumstances." The agency responded quickly, notifying the Office of Management and Budget of its intention to propose a rule by September 2013 that would "create parity" between brand-name and generic pharmaceutical manufacturers as to the requirements for revising a label after FDA approval. Once the proposed rule is published, the public—including industry—will have an opportunity to submit comments. *Bartlett*, it seems, is not the final chapter to this story.

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