PUBLICATION

Federal Law Preempts Failure-to-Warn Claims Against Generic Pharmaceutical Manufacturers

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In a 5-4 decision issued today, the United States Supreme Court held that state law failure-to-warn claims against manufacturers of generic pharmaceuticals are preempted by federal law. In the consolidated cases at issue, plaintiffs argued that makers of the metoclopramide (a generic version of the brand-name drug Reglan) that they took failed to adequately warn them of the potential effects of the long-term use of the drug. Finding that it would have been impossible for the manufacturers to have complied with both the FDA's regulations promulgated under the Hatch-Waxman Amendments and their state tort law duties, the Court reversed and remanded the cases to the Fifth and the Eighth Circuits.

The parties agreed that "[a] manufacturer seeking generic drug approval . . . is responsible for ensuring that its warning label is the same as the brand-name's." *Pliva, Inc. v. Mensing*, No. 09-993, slip op. at 6 (U.S. June 23, 2011). The issue in dispute was "whether, and to what extent, generic manufacturers can change their label after FDA approval." *Id*. at 6. The plaintiffs argued that the generic manufacturers could have strengthened their labeling by using the FDA's "changes being effected" (CBE) process or by sending "Dear Doctor" letters to provide additional warnings. The generic manufacturers disagreed, arguing that those avenues were available to manufacturers of brand-name drugs only. The FDA sided with the manufacturers, interpreting its regulations to impose upon generics an on-going federal duty of "sameness" with respect to labeling. The Court, deferring to the FDA's interpretation of its regulations, found that, at most, the generic manufacturers could have proposed (leaving open the question whether they are required to propose) that the FDA work with the brand-name drug to adopt a stronger warning label if it had reason to believe one was necessary. Such action, however, "would have started a Mouse Trap game," but would not have satisfied the manufacturer's duty under state law. *Id*. at 13. "State law demanded a safer label; it did not instruct Manufacturers to communicate with the FDA about the possibility of a safer label." *Id*. at 12.

The Court distinguished its holding in *Wyeth v. Levine*, 555 U.S. 555 (2009)—that state law failure-to-warn claims against a brand-name pharmaceutical manufacturer are not preempted—by noting that FDA regulations place upon the brand-name manufacturers the responsibility for the accuracy and adequacy of the label and provide the means by which they can unilaterally alter the label pending FDA approval. In contrast, generic labeling must be identical to the brand-name's at all times. Because the generic manufacturer "cannot satisfy its state duties [to provide a safer label] without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, [it] cannot independently satisfy those state duties for preemption purposes." *Id*. at 17.

In conclusion, the Court acknowledged that the pharmacist's choice to substitute the generic for Reglan resulted in a seemingly unfair outcome for these plaintiffs, "[b]ut 'it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.'" *Id*. at 19.

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