ALERTS AND UPDATES

U.S. Supreme Court Holds That State-Law-Based Failure-to-Warn Claims Are Federally Preempted Against Generic Drug Manufacturers

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On June 23, 2011, the U.S. Supreme Court issued a decision in *Pliva, Inc. v. Mensing*,[1] holding that state-law claims against generic drug manufacturers are federally preempted pursuant to the Supremacy Clause of the U.S. Constitution. The case evaluated the tension between state-law-based duty-to-warn claims of risks inherent in medications and the Hatch-Waxman amendments to the federal Food, Drug, and Cosmetic Act (FDCA), which require generic drug warnings to mirror those of their bioequivalent branded pharmaceutical products. The Court found conflict preemption existed insofar as it was impossible for the defendant generic drug manufacturers to simultaneously comply with federal law and state-law duties.

The Court framed the issue as "whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt. . . state-law claims." In the underlying lawsuits, the plaintiffs alleged that the defendant generic drug manufacturers failed to provide adequate warning labels and were thus liable under state tort law. Conversely, the defendant generic drug manufacturers contended that federal statutes and U.S. Food and Drug Administration (FDA) regulations required their labels to be the "same as" brand drug manufacturers' labeling.

The *Mensing* decision emphasizes that generic drug manufacturers have federal labeling duties that are different from their brand-name counterparts. In particular, the Court focused on what, if any, federal labeling duties apply to generic drug manufacturers after initial FDA approval; the Court concluded that generic warning labels must always be the same as their branded counterparts' labels—both before and after FDA approval. In contrast to its *Levine* decision, the Court held that the FDA's Changes Being Effected (CBE) regulation, 21 C.F.R. § 314.70(c)(6)(iii), was not available to the defendant generic drug manufacturers. Accordingly, the generic drug manufacturers could not have unilaterally strengthened their drug's warnings. Similarly, the Court held that the defendant generic drug manufacturers could not utilize "Dear Doctor" letters as a means of advising prescribing physicians of increased risks.

Even though the FDA had taken the position before the Court that the CBE process and "Dear Doctor" letters could not be used by generic drug manufacturers to strengthen warnings, the FDA posited that an alternative avenue existed for generic drug manufacturers to change their labels. In particular, the FDA asserted that the generic drug manufacturers "could have proposed—indeed, were required to propose—stronger warning labels to the agency if they believed such warnings were needed." Assuming that the FDA agreed with proposed warning changes, the FDA would then work with brand drug manufacturers in creating a new label that would apply to both the brand and generic drug manufacturers' drugs.

The Court emphasized that if the generic drug manufacturers "had independently changed their labels to satisfy their state-law duty to attach a safer label to their generic metoclopramide, they would have violated the federal requirement that generic drug labels be the same as the corresponding brand-name drug labels" at all times. While a generic drug manufacturer making a request of the FDA to strengthen its labeling would satisfy federal requirements, such actions would not have satisfied a state-law duty of actually providing adequate warnings. The Court reasoned that while state law required a safe label, state law "did not instruct the [generic drug manufacturers] to communicate with the FDA about the possibility of a safer label." Therefore, the Court held that it would be impossible for the generic drug manufacturers to "comply with both their state-law duty to change the label and their federal law duty to keep the label the same."

The Court in *Mensing* also reasoned that conflict preemption would be rendered impotent if the generic drug manufacturers were required to prove that "the FDA would not have allowed compliance with state law." Although the Court recognized that it was possible that the FDA may have agreed to strengthen the generic drug manufacturers' labels had a request been made of it, such a hypothetical would not suffice "to prevent federal and state law from conflicting for Supremacy Clause purposes. . . ." The Court found it unacceptable to imagine that generic drug manufacturers would be "required continually to prove the counterfactual conduct of the FDA and brand-name manufacturer[s] in order to establish the supremacy of federal law."

Although the Court recognized that its prior *Levine v. Wyeth* decision could be seen to directly conflict with its current decision, it emphasized that the Hatch-Waxman Act established a different federal regulatory scheme for generic drug manufacturers. Accordingly, the Court refused to distort the U.S. Constitution's Supremacy Clause in an effort to have similar federal preemption results in the context of a dissimilar statutory scheme. The Court, however, recognized that Congress and the FDA have authority to change the federal regulatory scheme. It can be anticipated that there may be efforts in Congress in the near future to address the divergent application of the federal preemption doctrine to state-law-based claims against generic drug manufacturers and brand drug manufacturers. In the interim, trial and appellate courts that are venues for state-law-based suits against generic drug manufacturers now are likely to be confronted with numerous dispositive motions brought by defendant manufacturers on the basis of the federal preemption doctrine as articulated by the Court in *Mensing*.

About Duane Morris

Duane Morris attorneys represent worldwide generic pharmaceutical companies in products litigation, and provide counsel on issues regarding bringing pharmaceutical products to the U.S. markets.

For Further Information

If you have any questions about the information addressed in this *Alert*, please contact Sharon L. Caffrey, Alan Klein, Frederick ("Rick") R. Ball, Paul M. da Costa, any member of the Products Liability and Toxic Torts Practice Group, any member of the Pharmaceutical, Pharmacy & Food industry group or the attorney in the firm with whom you are regularly in contact.

Note

1. Consolidated with the matter of *Actavis Elizabeth, LLC v. Mensing*, on certiorari to the United States Court of Appeals for the 5th Circuit.