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Pliva v. Mensing
U.S. Supreme Court Will Decide Whether People Injured by Generic Drugs Can Hold Manufacturers Accountable

In *Pliva v. Mensing* and *Actavis, Inc. v. deMahy* (consolidated), the Court will decide whether generic drug companies share responsibility with the manufacturers of their brand-name equivalents to update warning labels when significant new risks emerge, and whether people injured by a generic drug may sue in state court for their injuries. The case will be argued on March 30, 2011, and a decision is expected in June 2011.

The case has enormous implications for patients: more than 70 percent of all prescriptions in the U.S. are filled with generics. A win for Pliva could mean generic drug manufacturers receive complete immunity from lawsuits.

Gladys Mensing and Julie deMahy took metoclopramide, the generic equivalent of Reglan, a drug used to treat acid reflux. Both developed tardive dyskinesia, a devastating neurological movement disorder that results in involuntary movements of the mouth, tongue, lips, and extremities.

Both the brand name and generic drug manufacturers are subject to the FDA requirement that they revise their approved labeling to include a warning as soon as there is reasonable evidence of a serious hazard. There were numerous procedures available to the manufacturers to warn patients and their prescribers of the risks associated with long-term metoclopramide use, including two that Defendants themselves concede – and the United States agrees – they could have employed.

Despite the mounting evidence, the manufacturers chose not to do so. While Ms. Mensing and deMahy took the drug, the approved label described tardive dyskenesia as a rare adverse effect of the drug, even though a number of medical studies concluded that the risk was likely far greater than reflected on the label. As many as one in five people who use metoclopramide long-term may develop this disorder, as the Food and Drug Administration recognized when it ordered a black-box warning in 2009.

This warning was too late for Ms. Mensing and Ms. deMahy. Both women sued the manufacturers of the metoclopramide they had taken for failing to provide adequate warnings regarding the risk of tardive dyskinesia from long-term use. In both cases, the manufacturers moved to dismiss based on federal preemption, which was rejected by the Fifth and Eighth Circuits.

In 2009, the Supreme Court ruled in *Wyeth v. Levine* that Congress did not expressly intend to ban failure-to-warn lawsuits when they passed the Drug Price Competition and Patent Term Restoration Act – referred to as the Hatch-Waxman Act. The decision held that despite the fact that brand prescription drugs and their warning labels are regulated by the FDA, the manufacturer is still responsible for their warning labels at all times and can be sued in state court for failure-to-warn claims.