



Pliva v. Mensing, 131 S. Ct. 2567 (2011)

Topics Covered: Drug Manufacturers

Outcome: Very Unfavorable

Issue

The issue in this case was whether generic drug manufacturers could be liable for state tort claims based on inadequate labeling that failed to warn of the possible side effects associated with the drugs.

AMA Interest

Physicians and patients should be aware of medication side effects.

Case Summary

Gladys Mensing's physician prescribed medication to treat her diabetic gastroparesis. Her pharmacist filled the prescription with a generic drug, metoclopramide. After four years of taking the metoclopramide, Mensing developed a neurological disorder, tardive dyskinesia.

Mensing sued the metoclopramide manufacturer in the United States District Court. She contended that the label on her medication gave inadequate notice of the risk of developing tardive dyskinesia, despite mounting evidence within the pharmaceutical industry of such risk, and the manufacturer had therefore violated a state law of product liability.

The district court entered judgment for the generic drug manufacturer. It found that Mensing's failure to warn claims created an impermissible conflict with federal law, as the Hatch-Waxman Amendments of the Food, Drug, and Cosmetic Act (FDCA) mandated different and inconsistent labeling requirements from those of state law. The state law was therefore preempted. Mensing appealed to the Eighth Circuit, which reversed.

The generic drug manufacturer appealed to the United States Supreme Court. It contended that the Hatch-Waxman amendments impliedly preempt state lawsuits based on such claims. It further asserted that it would be economically impractical to sell generic drugs without such preemption. The case was consolidated with *Demahy v. Actavis*, a Fifth Circuit decision based on similar facts.

The Supreme Court found it was impossible for the generic drug manufacturers to comply simultaneously with their legal obligations under state and federal law. Thus, the state law was preempted, and the suits were remanded for dismissal.

Litigation Center Involvement

The Litigation Center, along with several state medical associations and insurance companies that represent physicians, filed an *amicus curiae* brief urging non-preemption of state law.

United States Supreme Court brief