

November 30, 2009

Over the Thanksgiving holiday, we and the Center for Constitutional Litigation (CCL) won a big victory against generic drug manufacturers! The U.S. Court of Appeals for the Eighth Circuit held in *Mensing v. Wyeth, Inc.*, that generic drug manufacturers cannot use federal preemption to avoid liability for failing to warn of their drugs' dangers. The court ruled that the approval of a generic drug's label by the U.S. Food and Drug Administration (FDA) does NOT preempt claims against the drug makers for failing to warn consumers of known risks.



Earlier this year, the U.S. Supreme Court held in *Wyeth v. Levine*, as we urged, that the FDA's approval of a drug's label does not preempt - i.e., wipe out - injured consumers' claims against name-brand drug manufacturers for failing to warn of the drugs' dangers. Generic drug manufacturers, however, continue to argue that the FDA's approval of their labels preempts failure to warn claims against them. *Mensing* is the first federal appellate decision since *Levine* to hold that federal preemption does not immunize generic drug manufacturers from liability either.

The decision is crucial to ensuring access to justice for all: as the Eighth Circuit noted in its opinion, seven in ten U.S. prescriptions are now filled with generic drugs.

The case involves Gladys Mensing, who was prescribed metoclopramide to treat her diabetic gastroparesis. The drug caused her to suffer serious and permanent tardive dyskinesia, a neurological disorder that causes facial grimacing, lip twisting, tongue thrusting, gait instability, difficulty swallowing, and difficulty controlling her hands and arms. Ms. Mensing sued several manufacturers of generic metoclopramide, among others, alleging that the manufacturers failed adequately to warn of the drug's side effects.

The generic drug manufacturers moved to dismiss the case, arguing that the failure-to-warn claims conflicted with - and thus were preempted by - an FDA regulation that requires the labels of general prescription drugs to contain the same language as the FDA -approved label for the brand-name version of that drug. The district court agreed. On November 27, 2009, the Eighth Circuit overturned the district court's dismissal and strongly rejected the generic drug companies' preemption arguments.

The Eight Circuit emphasized that generic manufacturers, like name-brand drug companies, "bear primary responsibility for their drug labeling at all times." Lawsuits like Ms. Mensing's, the court said, do not "obstruct the purposes and objectives" of federal drug regulation "in any way." Instead, they help achieve the "fundamental" purpose of federal regulation-ensuring that "all marketed drugs remain safe."

To read the Eighth Circuit's decision rejecting FDA preemption in *Mensing*, [click here](#).

Congratulations and thanks to lead counsel Louis Bograd of the Center for Constitutional Litigation, co-counsel Public Justice Staff Attorneys Leslie A. Brueckner and Claire Prestel, and Wil Fluegel of the Fluegel Law Office in Minneapolis, and plaintiff's trial counsel, Daniel J. McGlynn of McGlynn & Glisson, in Baton Rouge, Louisiana, and Michael K. Johnson and Lucia J.W. McLaren of Goldenberg & Johnson, P.L.L.C., in Minneapolis. Congratulations and thanks to you, too, for making this victory possible.

The victory in *Mensing* is part of our Access to Justice Campaign and Federal Preemption Project, which has been successfully fighting federal preemption for over two decades.

If you are facing, or anticipate facing, a preemption challenge, please don't hesitate to contact Public Justice for help. Together, we can -- and must -- preserve access to justice for all.

Arthur Bryant
Executive Director
Public Justice and the
Public Justice Foundation

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