

# Pharmaceutical Legal Advisory

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## Fifth Circuit Joins Eighth in Holding that State-Law Failure to Warn Claims Against Generic Drug Manufacturers are Not Preempted by Federal Regulation

By Deborah A. Little, Counsel, Buchanan Ingersoll & Rooney's Products Liability Practice

On January 8, 2010, the United States Court of Appeals for the Fifth Circuit held that state law failure to warn claims against generic drug manufacturers are not preempted by federal regulation. *Demahy v. Actavis, Inc.*, 2010 WL 46513 (C.A. 5 (La.)). This decision is consistent with that of the Eighth Circuit in *Mensing v. Wyeth*, 588 F.3d 603 (8th Cir. 2009) and was guided by the Supreme Court's decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), holding that such claims are not preempted against name brand drug manufacturers. The Fifth Circuit noted that "[a]ppeals involving materially identical preemption claims are now pending before the Sixth Circuit," citing *Smith v. Wyeth*, No. 09-5460 (6th Cir.); *Wilson v. Pliva*, No. 09-5466 (6th Cir.); and *Morris v. Wyeth*, No. 09-5509 (6th Cir.).

In *Demahy*, the drug at issue was the generic form of Reglan (metoclopramide) manufactured by Actavis. Plaintiff alleged that her long-term ingestion of the drug caused her to develop a neurological movement disorder called tardive dyskinesia. She asserted personal injury claims under the Louisiana Products Liability Act for, *inter alia*, failure to warn of the risks of the drug's long-term use.

As noted by the Fifth Circuit, preemption of state law can be either found in express statutory language or implied from the aim and structure of federal law. Implied preemption occurs where the federal law is so pervasive that it leaves no room for state supplementation (field preemption) or when state law actually conflicts with federal law (conflict preemption).

Actavis unsuccessfully argued that Demahy's claims were conflict preempted in that it was impossible for Actavis to comply with both federal and state law because, under the Food, Drug and Cosmetics Act, ("FDCA"), a generic manufacturer cannot unilaterally change a drug's label but, rather, must use the same label as the name brand. Rejecting that argument, the Fifth Circuit stated that, while the generic's label must be the same as that of the name brand when seeking approval, nothing in the FDCA bars generic labeling modifications following initial approval. Further, the Fifth Circuit agreed with Demahy that Actavis could have strengthened its label warning before receiving FDA approval through the "changes being effected" or CBE process, or could have proposed label changes through the prior approval process or suggested that the FDA send "Dear Doctor" letters to prescribing physicians on its behalf.

The Fifth Circuit rejected the argument that compliance with state duties to warn would burden generic manufacturers with duplicative drug trials, noting that clinical studies are not prerequisites to labeling changes and reports of adverse drug reactions can substantiate the need for a heightened warning. The Fifth Circuit's decision was grounded in the belief that a central premise of federal drug regulation is that the manufacturer bears responsibility for the content of its label at all times.

We will continue to watch the Sixth Circuit cases cited above to see if that court rules consistently with the Fifth and Eighth Circuits on this important issue.

For more information, email the author(s) at [litigationadvisory@bipc.com](mailto:litigationadvisory@bipc.com).

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