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Newsletters

Products Liability Bulletin - February 2010

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Federal Law Requires Generic Drug Manufacturers to Warn of Post-Approval Hazards

The United States Court of Appeals for the Eighth Circuit recently issued a strict ruling against generic drug manufacturers, finding that they could not avoid state tort liability with regard to failure to warn claims by arguing that U.S. Food and Drug Administration (FDA) regulations prohibited them from deviating from the name brand drug label. *Mensing v. Wyeth, Inc., et al.,* 588 F.3d 603 (8th Cir. 2009).

The plaintiff in the case was prescribed Reglan for treatment of diabetic gastroparesis. Instead of taking the name brand drug, she took its generic bioequivalent, metoclopramide. After four years of ingesting the drug, plaintiff developed tardive dyskinesia, a neurological disorder characterized by involuntary movements of the tongue, lips, face, trunk and extremities. She sued the generic drug manufacturers, arguing that they should have taken steps to enhance the label warnings in light of mounting evidence regarding long-term use of metoclopramide and the risk of tardive dyskinesia.

Defendants moved to dismiss, arguing that plaintiff's failure to warn claims were preempted by federal law. Defendants claimed that it would have been impossible to comply with both federal law and the state laws under which plaintiff was proceeding. Specifically, the FDA's regulations state that the agency may withdraw approval of a generic drug if its label is no longer consistent with the name brand label. Defendants argued that this prevented them from implementing a unilateral label change without prior FDA approval. The court rejected this argument, finding that the generic drug manufacturer defendants could have at least proposed a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved. The court stated that the FDA regulations make clear that a generic manufacturer must take steps to warn its customers when it learns that it may be marketing an unsafe drug, and cannot simply rely on matching its labels to the name brand label and passively accept the inadequacy of its drug's label as it markets and profits from the product.

Further, the Eighth Circuit quoted the U.S. Supreme Court's decision in *Wyeth v. Levine,* 129 S.Ct. 1187 (2009), wherein the high court noted the historic co-existence of state tort remedies and federal regulation of prescription drugs, and contrasted Congress' 1976 express preemption provision for medical devices and lack of such a provision for prescription drugs.

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Generic drug manufacturers should be advised not to rely on name brand manufacturer inaction in labeling when they become aware of adverse health affects associated with their products.

For more information, please contact your regular Hinshaw attorney.

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