

DRUG & DEVICE
BULLETIN



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EIGHTH CIRCUIT TACKLES TWO KEY ISSUES IN PRODUCTS CASE INVOLVING NAME BRAND AND GENERIC MANUFACTURERS

The Eighth Circuit held on Friday that name brand manufacturers are not liable under Minnesota law in cases involving generic equivalents and that failure-to-warn claims brought against generic manufacturers are not preempted by federal law. *Mensing v. Wyeth, Inc.*, No. 08-3850, Slip Op. (8th Cir. Nov. 27, 2009).

In *Mensing*, the plaintiff alleged that a generic form of Reglan® caused her to develop tardive dyskinesia (a neurological movement disorder). She sued the name brand and generic manufacturers, arguing that both were liable. The plaintiff never ingested name brand Reglan®, but nevertheless maintained that the name brand manufacturers were liable for various common-law torts including fraud and negligent representation. The Eighth Circuit rejected plaintiff's position, working from the premise that "traditional products liability requires a plaintiff to show that she actually consumed the defendant's product." *Mensing*, Slip. Op. at 16.

Citing *Conte v. Wyeth*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008), the plaintiff argued that her physician had relied on the representations of the name brand manufacturers when prescribing the generic medication to her and, therefore, should be liable for her alleged injuries. The Eighth Circuit disagreed. "[R]egardless of whether her doctor relied upon the Reglan label, [the plaintiff] must show that the name brand manufacturers owed her a duty of care," as duty is a "threshold requirement for all of the tort claims [the plaintiff] asserts." *Mensing*, Slip. Op. at 17. Because the plaintiff did not purchase or use the name brand manufacturers' product, there was "no direct relationship between them, let alone a fiduciary relationship that gave rise to a duty." *Id.*

The plaintiff focused on the foreseeability of harm, though to no avail. "Like the Fourth Circuit, we conclude that holding name brand manufacturers liable for harm caused by generic manufacturers 'stretches the concept of foreseeability too far.'" *Id.* at 18, citing *Foster v. American Home Products Corp.*, 29 F.3d 165, 171 (4th Cir. 1994). The Eighth Circuit affirmed the district court's entry of summary judgment in favor of the name brand manufacturers, rejecting *Conte* and siding instead with the majority position. *Id.*

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The court also considered whether the plaintiff's failure-to-warn claims against the generic manufacturers were preempted by federal law. The district court had concluded that the failure-to-warn claims would require the generic manufacturers to deviate from the name brand manufacturers' label, thereby creating an impermissible conflict with federal law. But the lower court's ruling predated the Supreme Court's decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009). Relying heavily on *Levine*, the Eighth Circuit reversed.

The Eighth Circuit first noted that Congress could have crafted an express preemption provision for generic drugs, as it did for medical devices, but that Congress chose not to do so. The absence of such a provision was viewed as key – especially since, according to the court, seven in 10 prescriptions filled in the United States are now for generic drugs. “After [*Levine*], we must view with a questioning mind the generic defendants' argument that Congress silently intended to grant the manufacturers of most prescription drugs blanket immunity from state tort liability when they market inadequately labeled products.” *Mensing*, Slip Op. at 7. The court likewise noted that post-*Levine* courts considering the issue “have almost uniformly ruled that tort claims against generic manufacturers are not preempted.” *Id.*

The generic manufacturers argued that, because generic labels must be substantively identical to the name brand label even after they enter the market, they are prohibited from implementing a unilateral labeling change without prior FDA approval through the CBE process. “[W]e need not decide whether generic manufacturers may unilaterally enhance a label warning through the CBE procedure because the generic defendants could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved.” *Id.* at 9.

Again citing to *Levine*, the Eighth Circuit stated that, to establish preemption, the generic defendants must show the likelihood of inaction. “The record contains nothing, let alone ‘clear evidence,’ to suggest the FDA would have rejected a labeling proposal from any of them.” *Id.* at 13. The court also stated that, earlier this year, the FDA ordered manufacturers of Reglan® and generic metoclopramide to add a boxed warning regarding the risk of tardive dyskinesia from long-term use of the product.

The court concluded that generic manufacturers are subject to the requirement that their labeling must be revised as soon as there is reasonable evidence of an association of a serious hazard with a drug. “[The Plaintiff] alleges that the Reglan manufacturers did nothing to strengthen the label despite reasonable evidence of the drug's association with a serious hazard. In these circumstances, Section 201.57(e) does not permit generic manufacturers to passively accept the inadequacy of their drug's label as they market and profit from it.” *Id.* at 9.

Finally, the court considered the generic manufacturers' argument that the plaintiff's claims would obstruct the purposes and objectives of federal law. The generic manufacturers argued that proposing a labeling change would require expensive

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clinical trials, thwarting the goal of the Hatch-Waxman Amendments to quickly bring low-cost generic drugs to the market. The court rejected this argument. It stated that, while labeling changes must be supported by “scientific substantiation,” there is nothing to indicate that the information must be acquired through a manufacturer’s own clinical studies. *Id.* at 14.

In reversing, the court concluded that the plaintiff had stated a viable claim against the generic manufacturers. “Far from prohibiting them from taking steps to warn their customers of new safety hazards, federal law requires such action.” *Id.* at 18.

Whether state law failure-to-warn claims against generic manufacturers are preempted by federal law is also pending before the Fifth Circuit in *Demahy v. Actavis Inc.*, No. 08-31204. ■