CLIENT ALERT

Recent Eighth Circuit Ruling Imposes Affirmative Duty On Generic Drug Manufacturers To Propose Label Changes Or Risk 'Failure To Warn' Lawsuits: *Mensing v. Wyeth, Inc., et al.*

Dec.04.2009

On November 27, 2009, the U.S. Court of Appeals for the Eighth Circuit set a remarkable precedent for both generic and brand-name pharmaceutical manufacturers, imposing an affirmative duty on generic manufacturers to provide adequate warning labels, even where it would require deviation from the brand-name drug label. In *Mensing v. Wyeth, Inc., et al.*, the court determined that federal law does not preempt failure-to-warn claims against generic manufacturers; and that brand-name manufacturers cannot be held liable for allegedly inadequate warnings on a generic drug label, where the plaintiff never used the brand name product. The decision is significant in that it represents the first federal appellate court to apply the rationale of *Wyeth v. Levine* to generic drug manufacturers.

In *Mensing v. Wyeth*, the plaintiff brought failure to warn and misrepresentation claims against several generic manufacturers of metoclopramide, a generic form of Reglan®, alleging that the drug caused tardive dyskinesia, a severe neurological movement disorder. The complaint alleged that despite mounting evidence that long-term metoclopramide use carries a risk of tardive dyskinesia, the risk was not adequately indicated on the label and the generic manufacturers failed to amend the label to include this risk. Although she never ingested the brand name drug, the plaintiff also sued brand-name manufacturers Wyeth, Inc. and Schwarz Pharma, Inc. for fraud and negligent misrepresentation on the theory that her doctor relied on the brand label when assessing the risks and proper use of the generic product. The U.S. District Court for the District of Minnesota dismissed her claims against the generic defendants on the basis of federal preemption and against the brand manufacturers on the basis that she had not used their product.

No Preemption for Generics

Reversing the district court, the Eighth Circuit rejected the argument that failure to warn claims against generic manufacturers are preempted because they create an impermissible conflict with federal law. The defendants argued that these claims seek to require generic manufacturers to deviate from the brand name drug label in violation of 21 C.F.R. § 314.150(b)(10). Citing the Supreme Court's recent holding in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), that failure to warn claims against brand manufacturers are not preempted by Section 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355, the Eighth Circuit found persuasive that the Hatch-Waxman Amendments "do not explicitly preempt suits against generic manufacturers." In the Court's view, had Congress wished to craft a preemption provision for generic drugs, it would have done so. Noting that seventy percent of prescriptions in the United States are filled with generic drugs, the court vehemently rejected the notion "that Congress silently intended to grant the manufacturers of most prescription drugs blanket immunity from state tort liability when they market inadequately labeled products." (Slip. Op. at 7).

The generic manufacturers argued that because their labels must be substantively identical to the brand label, even after the product enters the market, they are prohibited from implementing unilateral label changes through "Changes Being Effected" ("CBE") supplements under 21 C.F.R. § 314.70(c)(6)(iii)(A)-(D). Refusing to reach the question of whether generic manufacturers

may unilaterally enhance a label warning through the CBE procedure, the Eighth Circuit found it sufficient that 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." (Slip. Op. at 9; emphasis in original).

No Duty of Brand Manufacturers To Purchasers of Generic Products

As to the name-brand manufacturers, the court affirmed the district court, finding that because the plaintiff did not purchase or ingest the branded drug, it would "stretch the concept of foreseeability too far" to hold the name-brand defendant liable for failure to warn. (Slip. Op. at 17-18).

Far Reaching Implications And Unanswered Questions

Far from an aberration, *Mensing* is indicative of a trend toward increased liability for generic drug manufacturers. In the wake of *Wyeth v. Levine*, a number of courts have held that tort claims against generic manufacturers are not preempted. *See, e.g.*, *Stacel v. Teva Pharm., USA*, 620 F. Supp. 2d 899, 906-07 (N.D. Ill. 2009); *Schrock v. Wyeth*, 601 F. Supp. 2d 1262, 1265-66 (W.D. Okla. 2009); *Bartlett v. Mutual Pharm. Co.*, __ F. Supp. 2d __, No. 08-cv-358-JL, 2009 WL 3126305 (D.N.H. Sept. 30, 2009). *Mensing* also continues the path adopted by the overwhelming majority of courts in refusing to impose liability on a brand-name manufacturer where a plaintiff did not consume the branded product. (A notable exception is the California Court of Appeal's 2008 decision in *Conte v. Wyeth Inc., et al.*)

The Eighth Circuit's ruling leaves many questions unresolved. One question is whether a generic manufacturer possesses sufficient information to determine whether reports of adverse events are isolated incidents or warrant label changes, given the lack of access to premarket safety data exclusively available to the brand manufacturer. Another question is whether FDA would determine that a generic manufacturer's CBE label change rendered the drug product misbranded since the generic label would be substantively different from the brand label, in violation of 21 C.F.R. § 314.150(b)(10). Assuming an FDA determination that such a label change were appropriate, would a brand manufacturer be required to make the same change? If the brand manufacturer refused to make the change, would its product be misbranded? Perhaps more troubling is the possibility that multiple generic manufacturers of the same brand drug could propose or implement a variety of label changes in response to the same or different adverse events, leading to a patchwork of inconsistent labels.

The FDA has yet to weigh in on these issues.

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