Products Liability Law Daily Wrap Up, PREEMPTION—DRUGS—5th Cir.: Catch-22 for patients injured by generic drugs, (Jul. 14, 2014)

By Michelle L. Oxman, JD, LL.M.

The intersection of the federal law of preemption and Louisiana's tort law leaves no possibility of a remedy for a patient who developed tardive dyskinesia because of her ingestion of metoclopramide, the generic version of Reglan®. The generic manufacturers' duties to the patient under state tort law were preempted by federal Food, Drug and Cosmetic Act (FDC Act) sec. 505(j), which requires that manufacturers of generic drugs make both their products and the labels the same as the branded product. The patient could not assert a claim against the makers of the branded drug because they did not make the drug that the patient consumed, and the brand name manufacturer did not owe any continuing duty to consumers using the generic version. The court also denied a request to certify to the Louisiana Supreme Court the question of whether the brand-name manufacturer owed any duty to generic consumers under state law (*Johnson v. Teva Pharmaceuticals USA, Inc.*, July 11, 2014, Higginson, S.).

Johnson's use of the drug. Tina Johnson's physicians prescribed metoclopramide for her digestive problems from July 2002 to March 2009. They relied on the approved labels, including package inserts and the Physicians' Desk Reference. She subsequently developed tardive dyskinesia. She sued both generic and brand name makers of the drug, alleging design defect, inadequate warnings, and breach of express warranties.

The brand-name manufacturer changed the label for Reglan in 2004 to recommend against the use of the drug for longer than 12 weeks, but did not issue a "Dear Doctor" letter. None of the generic manufacturers did so, either. In 2009, the label was changed to a "black box" warning of the risk of tardive dyskinesia.

Prior proceedings. The district court had held that the Louisiana Product Liability Act (LPLA), La. Rev. Stat. sec. 9:2800.51*et seq.*, which would have imposed liability on the makers of the generic drug, was preempted by the federal Food, Drug and Cosmetic Act (FDCA). The court also denied Johnson permission to amend her complaint. Johnson appealed, and further proceedings were suspended pending a Supreme Court decision. In June 2011, the Supreme Court ruled in *PLIVA, Inc. v Mensing*(*Mensing*) that product liability claims against the manufacturers of generic drugs were preempted by federal law. The court said that a manufacturer could not comply both with the requirement that its drug and labeling be the same as the brand-name version and with a duty to provide more effective warnings on the labels.

The appeals court ruling. The Fifth Circuit ruled that the claims against the manufacturers of the generic drug were controlled by the *Mensing* decision. It also ruled that the LPLA did not provide for any claim by a patient who took a generic drug against the manufacturer of the branded drug. Therefore, dismissal of Johnson's claims against the brand-name manufacturer was upheld. The appeals court noted that the LPLA specifies that it is the sole remedy for claims involving damage caused by a product.

Johnson asked the appeals court to certify to the Louisiana Supreme Court the question of whether Louisiana law allowed Johnson's claims against the brand name manufacturers. The court declined to do so, noting that it had previously interpreted the LPLA and that Johnson had chosen the federal forum.

Partial dissent. Judge James Dennis agreed with the majority that Johnson's claims against the generic manufacturers must be dismissed. However, he would have certified the question of the brand name manufacturer's potential liability to the Louisiana Supreme Court because that court had never addressed the issue. Moreover, the only Louisiana appellate decision on point pre-dated *Mensing* and reasoned that generic consumers do not rely on the labels created by brand-name manufacturers. Judge Dennis opined that the Louisiana appellate decision was questionable post-*Mensing*.

The case number is 12-31011.

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Companies: Teva Pharmaceuticals USA, Inc.; Qualitest Pharmaceuticals, Inc.; Wyeth, LLC; Schwarz Pharma, Inc.; Alaven Pharmaceutical, LLC; Generics Bidco I, LLC

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