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Product Liability

Branded Makers Not Liable to Woman In Ohio Who Used Only Generic Drug

An Ohio woman who used only generic metoclopramide has no cause of action against makers of the brand-name drug, Reglan, a federal trial court in Ohio held Sept. 27, lining up with the majority of courts that have considered this brand-name liability question (*Hogue v. Pfizer Inc.,* S.D. Ohio, No. 2:10-cv-00805-MHW-EPD, 9/27/12).

BNA Snapshot

Hogue v. Pfizer Inc., S.D. Ohio, No. 2:10-cv-00805-MHW-EPD, 9/27/12

Key Holding: An Ohio woman who used only generic metoclopramide has no cause of action under the Ohio Product Liability Act against makers of the branded drug, Reglan.

Key Development: Court dismisses woman's suit in its entirety, also ruling federal law preempts her claims against generic drug companies.

The Ohio Product Liability Act (OPLA) governs all of plaintiff Donna Hogue's claims, and requires a plaintiff to prove that the defendant manufactured the product that caused harm, the U.S. District Court for the Southern District of Ohio said.

In a separate opinion, the court granted judgment on the pleadings to makers of generic metoclopramide, ruling Hogue's claims are preempted.

Plaintiff Used Drug for Nearly 10 Years

Hogue took metoclopramide from 2000 until 2009 to treat abdominal pain and digestive problems. She alleged the drug caused her to develop tardive dyskinesia, a neurological movement disorder.

Hogue sued Reglan makers Schwarz Pharma, Pfizer Inc., and Wyeth LLC; and generic metoclopramide makers Pliva Inc., Qualitest Pharmaceuticals Inc., and Teva Pharmaceuticals USA Inc.

She asserted various claims under Ohio law. The crux of Hogue's claims was that despite mounting evidence, the brand-name defendants failed to warn doctors and patients about the risks associated with long-term use (more than 12 weeks) of the drug, the opinion said.

The branded defendants sought summary judgment, arguing the OPLA governed Hogue's claims. Alternatively, they argued even if the OPLA did not apply, the result would be the same under Ohio common law, which requires a plaintiff to show he or she was injured by the defendant's product.

Hogue countered that the defendants were liable for the dissemination of false information regardless of whether they made the actual pills she took.

Product Liability Act Governs Claims

The OPLA abrogates all of Hogue's common law product liability claims or causes of action, the court said. It broadly defines product liability claims as including those where the alleged injuries arise from the "formulation" of a product or "[a]ny warning or instruction, or lack of warning or instruction, associated with that product."

Nonetheless, Ohio courts have reached different conclusions as to whether the OPLA abrogates product-related claims sounding in fraud and misrepresentation, the opinion said.

In *Stratford v. SmithKline Beecham Corp.*, No. 07-639, S.D. Ohio, 6/17/2008), a different judge with the Southern District of Ohio said the OPLA does not necessarily preclude all fraud and misrepresentation claims: specifically, the act does not abrogate fraud claims based on a general duty not to deceive.

However, it does abrogate fraud claims arising from a duty to warn. The *Stratford* court held the OPLA bars claims that a drug manufacturer failed to warn physicians and consumers of the risks involved with taking the antidepressant Paxil during pregnancy.

The court here adopted that approach.

Looking at Hogue's action, the court said her fraud claims are based on a theory of omission and concealment—they are "substantially the same as those the court found abrogated in *Stratford*." The substance of Hogue's fraud claim "is unmistakably failure to warn," the opinion here said.

Judgment Granted to Generic Defendants

In a separate opinion, the court granted judgment on the pleadings for generic manufacturers Pliva Inc., Qualitest Pharmaceuticals Inc., and Teva Pharmaceuticals USA Inc.

Hogue's claims against those companies are preempted under the U.S. Supreme Court's decision in *Pliva Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the court here said.

In *Mensing*, the Supreme Court said impossibility preemption principles bar failure-to-warn claims against generic drug companies, who lack independent means to change labels that must match those of the branded equivalents under federal law (9 PLIR 805, 7/1/11).

Hogue argued her claim for breach of warranty and a negligence claim based on generic defendants' alleged failure to communicate the FDA-approved warning through "Dear Doctor" letters survived premption.

She also contended *Mensing* did not foreclose her design defect claims because that holding was limited to a generic manufacturer's ability to unilaterally change the warning, and did not preclude the possibility the manufacturer could be liable for continuing to sell an unreasonably dangerous product.

But in *Smith v. Wyeth Inc.*, the U.S. Court of Appeals for the Sixth Circuit rejected all these arguments, the court here said. The *Smith* court also deemed preempted the plaintiff's claims that Pliva Inc. failed to update its warning to reflect changes the Food and Drug Administration approved for the branded drug's label. That decision is controlling here.

The Supreme Court declined earlier this year to review the *Smith* decision (10 PLIR 582, 5/4/12).

Judge Michael H. Watson wrote the opinions.

William B. Curtis, of the Curtis Law Group in Dallas, and Terrence J. Donahue Jr., of McGlynn Glisson & Mouton in Baton Rouge, La., represented Donna Hogue.

Henninger S. Bullock and Andrew J. Calica, of Mayer Brown LLP, in New York, represented Schwarz Pharma Inc. Brian D. Goldwasser, of White, Getgey & Meyer, in Cincinnati, represented Qualitest Pharmaceuticals Inc. Lisa Marlo Kuhnell, of Ulmer & Berne LLP, in Cincinnati, represented Pliva Inc. Quentin F. Urquhart, of Irwin Fritchie Urquhart & Moore LLC, in New Orleans, represented Pfizer Inc. Sarah K. Frederick, of Goodwin Procter LLP, in Boston, represented Teva Pharmaceuticals USA Inc.

For More Information

The summary judgment opinion is at http://op.bna.com/pslr.nsf/r?Open=jstg-8yqkk2. The judgment on the pleadings opinion is at http://op.bna.com/pslr.nsf/r?Open=jstg-8yqlqj

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ISSN 1542-9555
Issues prior to 1/17/2003, published as Pharmaceutical Law & Policy Report® use ISSN 1536-1128