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PRODUCT LIABILITY ALERT

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# Ohio federal court holds generic drug manufacturer not liable for inadequate warnings where plaintiff's physicians did not read and rely on warnings

In the case *Fulgenzi v. PLIVA, Inc.*, 2015 U.S. Dist. LEXIS 144283 (N.D. Ohio Oct. 23, 2015), the United States District Court for the Northern District of Ohio made clear that the fact of an inadequate warning is not enough to establish a drug manufacturer's liability. Rather, the plaintiff must also establish proximate cause, which can depend on whether the plaintiff's physicians read and relied on inadequate product warnings in prescribing drugs to the plaintiff.

## The Facts

This *Fulgenzi* opinion concludes six years of product liability litigation over plaintiff Eleanor Fulgenzi's claims that she developed the severe neurological movement disorder tardive dyskinesia (TD) after ingesting the drug metoclopramide (brand name Reglan). PLIVA, a generic manufacturer of metoclopramide and the only defendant remaining in the case, moved for summary judgment on the sole remaining claim for failure to warn under Ohio statutory law.

Reglan was first approved by the FDA in 1980 and has been traditionally prescribed to treat a variety of digestive illnesses. As studies revealed the risk of developing TD, the product's labeling was revised. Pursuant to the

federal regulatory scheme's "duty of sameness," generic manufacturers were required to update their generic labels accordingly. It was undisputed that PLIVA failed to revise its general label for metoclopramide to include

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updated 2004 warnings regarding duration of use ("Therapy should not exceed 12 weeks in duration.").

Plaintiff was prescribed Reglan between July 2004 and August 2007 by three separate physicians, and pharmacists filled each of her prescriptions with the generic equivalent. At least some of those prescriptions were filled with metoclopramide manufactured by PLIVA. Each of plaintiff's three physicians testified that they did not read the PLIVA warnings. Plaintiff was thereafter diagnosed with TD.

In 2009, plaintiff sued various generic and brand-name manufacturers. The brand-name manufacturers were dismissed and the case was stayed until the Supreme Court issued its decision in *Mensing*. After that decision, plaintiff amended her complaint, including among other things, a failure-to-warn claim under the Ohio Product Liability Act (OPLA). The Northern District then granted PLIVA's motion to dismiss, finding that plaintiff's failure-to-warn claims were preempted by federal law according to *Mensing*. Plaintiff appealed that dismissal, and the United States Court of Appeals for the Sixth Circuit reversed. The Sixth Circuit issued a narrow opinion that circumscribed plaintiff's claims, requiring her to "argue that PLIVA should have included the language contained in the updated Reglan label by soon after July 2004, and that the failure to include that language proximately caused her injuries."

## The Court's Analysis

On remand, the Northern District of Ohio held that plaintiff could not establish proximate cause as a matter of law because "the record shows

that plaintiff's prescribing physicians did not rely upon PLIVA's deficient 2004 warning label." Under Ohio law, where an inadequate warning is given, a presumption arises in favor of the plaintiff as to proximate cause, but "a defendant can rebut this presumption by showing that 'an inadequate warning would have made no difference in the physician's decision as to whether to prescribe a drug or as to whether to monitor the patient thereafter.'" Because plaintiff's physicians each testified that they did not read the PLIVA warning and plaintiff could not point to any record evidence suggesting otherwise, the Court granted PLIVA's motion for summary judgment. The Court also found it significant that each physician prescribed Reglan, not the generic equivalent, which "dictated that they would have had no reason to seek out an insert from one of several manufacturers of the generic counterpart."

Finally, the Court rejected plaintiff's last-ditch "failure-to-communicate" theory, in which she argued that PLIVA should have found some other way—such as a "Dear Doctor" letter—to communicate the information in the 2004 updated warning to plaintiff's physicians. The Sixth Circuit has recently rejected a similar theory, noting that a generic manufacturer's federal "duty of sameness" would actually prevent it from independently pursuing any means of communication not utilized by the name-brand drug manufacturer.

### Key Takeaways For Drug Manufacturers

PLIVA and its attorneys made several key decisions in developing the facts and law of this case in anticipation of a causation defense to plaintiff's warning claims. First, they got plaintiff's physicians to concede that the physicians did not read and rely on the generic drug's warnings. Second, they developed a persuasive rationale behind this—plaintiff's physicians were well experienced with the brand-name drug and prescribed it to plaintiff; therefore, they had no reason to look at labels from one of several generic manufacturers. Third, they utilized the federal "duty of sameness" as a shield when plaintiff claimed that PLIVA, a generic manufacturer, should have done more to warn consumers.

For more information, please contact Terry Miller, Joyce Edelman, Jason Gerken or any member of Porter Wright's Product Liability Practice Group.