Products Liability Law Daily Wrap Up, TOP STORY—DRUGS—4th Cir.: Is a branded drug manufacturer liable for failure-to-warn claims against a generic manufacturer?, (May 31, 2017)

Products Liability Law Daily Wrap Up

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By Sheila Lynch-Afryl, J.D., M.A.

The U.S. Court of Appeals for the Fourth Circuit has asked the West Virginia Supreme Court of Appeals to answer the certified question of whether the state's law permits a failure-to-warn and negligent misrepresentation claim against a branded drug manufacturer when the drug ingested was produced by a generic manufacturer. Federal law precludes a suit against the generic manufacturer, which is forbidden to change the warning prepared by the brand-name manufacturer. However, dismissal of the case against the brand-name manufacturer would leave patients who take generic drugs with no legal recourse for injuries caused by inadequate warning labels (*McNair v. Johnson & Johnson*, May 30, 2017, Traxler, W.).

Patent. Janssen Pharmaceuticals held the patent for the drug levofloxacin under the trade name Levaquin® and produced the warnings that accompanied the drug. When Janssen's patent expired, other companies began manufacturing generic versions of levofloxacin using the same warnings Janssen produced, as required by federal law.

Complaint. A patient and her husband filed a complaint in state court against Janssen alleging that she developed acute respiratory distress syndrome after taking generic levofloxacin, which had warning information prepared by Janssen. They claimed that Janssen was aware that acute respiratory distress syndrome had been linked to the use of levofloxacin but failed to include this fact in its warnings. Even though the patient took a generic version manufactured by a different company, she argued that Janssen had exclusive control of the content of the warnings for both the name brand drug and the generic forms.

District court decision. The district court granted summary judgment, concluding that West Virginia law does not permit a plaintiff who consumes a generic drug to instead sue the brand name manufacturer that produced the original formula of the drug and the warning label. Every other court of appeals has arrived at the same conclusion, the district court said, and there was no reason to think the outcome would be any different under West Virginia law (see *Products Liability Law Daily*'s June 29, 2015 analysis).

Certified question. Federal law requires the warning labels of a brand name drug and its generic equivalent to be the same. This "ongoing duty of sameness" makes it impossible for a generic manufacturer to comply with any state law duty to strengthen the warnings on its labels, and where it is impossible for a party to comply with both state and federal requirements, state law is preempted to the extent it conflicts with federal law.

The West Virginia Supreme Court of Appeals has not decided the issue of whether, under West Virginia law, a brand-name manufacturer can be held liable on a failure-to-warn claim when the plaintiff ingested a generic substitute and, therefore, has no remedy against the manufacturer of the generic drug, and the parties reasonably disagree as to how the court would resolve the question. While the overwhelming weight of federal precedent favors no liability against the brand-name manufacturer, there is some support for the patient's position. Thus, the Fourth Circuit has sought the West Virginia high court's guidance through the certification process.

The case is No. 15-1806.

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Companies: Janssen Pharmaceuticals, Inc.; Ortho-McNeil Pharmaceutical, Inc.; Johnson & Johnson

MainStory: TopStory WarningsNews SCLIssuesNews DrugsNews MarylandNews NorthCarolinaNews SouthCarolinaNews VirginiaNews WestVirginiaNews