Products Liability Law Daily Wrap Up, WARNINGS ISSUES—DRUGS—W. Va. Sup. Ct.: Branded drug company not liable when generic drug allegedly caused injury, (May 14, 2018)

Products Liability Law Daily Wrap Up

Click to open document in a browser

By Susan Smith, J.D., M.A.

In response to a certified question of law ordered by the U.S. Court of Appeals for the Fourth Circuit, the Supreme Court of West Virginia concluded that West Virginia law does not permit a claim of failure to warn and negligent misrepresentation against a brand drug manufacturer when the drug ingested was produced by a generic drug manufacturer. A patient, who had ingested the generic drug levofloxacin and developed acute respiratory distress syndrome, and her husband filed a complaint alleging that Janssen Pharmaceuticals (Janssen) was aware that acute respiratory distress syndrome had been linked to the brand drug Levaquin®, but failed to include this fact in its original label (*McNair v. Johnson & Johnson*, May 18, 2018, Loughry, A.).

Janssen originally trademarked the drug under the brand Levaquin. It produced the warnings on the label that accompanied the distribution. The labels produced by Janssen subsequently were used by generic manufacturers of levofloxacin.

The couple argued that even though the patient took a generic version manufactured by Dr. Reddy's Laboratories Limited, Janssen had exclusive control of the content of the warnings for both the name brand drug and the generic forms. The couple also argued that federal law precluded an action against Dr. Reddy's based on a failure to warn because the generic manufacturer was prohibited from changing the warning on the label prepared by Janssen. Finally, the couple argued that granting Janssen's motion would mean that no party was liable for the alleged misinformation that allegedly caused the injury.

The district court granted summary judgment, concluding that West Virginia law does not permit a plaintiff who consumes a generic to instead sue the brand name manufacturer that produced the original formula of the drug and warning label. Because Janssen did not manufacture the product that was ingested, there was no proximate cause and no basis to hold Janssen liable. On appeal, the Fourth Circuit asked the West Virginia Supreme Court to answer the certified question of whether state 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 [see *Products Liability Law Daily*'s May 31, 2017 analysis].

Supreme Court of West Virginia's reasoning. The state high court stated that when products liability cases are premised on strict liability, the plaintiff must bring his or her claim against the manufacturer or seller of the allegedly injury-causing product. The basis of strict liability is that a manufacturer impliedly represents that its product is reasonably suitable, safe, and fit for the purposes for which it is being sold. A plaintiff cannot recover damages in a strict liability action against the defendant in the absence of showing that the defendant either manufactured or sold the product that allegedly injured the patient.

The court concluded that its product liability law is abundantly clear; liability is premised upon the defendant being the manufacturer or seller of the product in question. Accordingly, when a brand manufacturer neither manufactures nor sells the generic drug, it cannot impliedly represent that the generic drug is free of defects. While West Virginia law provides that manufacturers are subject to the duty to warn about the risks of their products, the generic drug in this case was not a product of the brand manufacturer. Therefore, the brand manufacturer could not be held strictly liable for failure to warn of another manufacturer's product.

Likewise, the court found that a negligent misrepresentation claim against a brand manufacturer for injuries allegedly caused by a generic drug is not viable under West Virginia products liability law. Finally, the court

stated that allowing a generic drug consumer to bring an action against the brand manufacturer for an injury allegedly arising out of the generic drug would be at odds with public policy, which limits the scope of products liability actions to manufacturers and, while now statutorily limited, to sellers. The court determined that the proper remedy for consumers harmed by generic drugs rests with Congress or the Food and Drug Administration.

The case is No. 17-0519.

Attorneys: Leslie A. Brueckner (Public Justice, PC) for Kimmy McNair and Larry McNair. Elbert Lin (Hunton & Williams LLP) and David B. Thomas (Thomas Combs & Spann PLLC) for Johnson & Johnson, Janssen Pharmaceuticals, Inc. and Ortho-McNeil Pharmaceuticals, Inc.

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

Cases: CourtDecisions WarningsNews DrugsNews WestVirginiaNews