

Brand-Name Drug Cos. Not Liable For Generics' Tags In W.Va.

By **Emily Field**

Law360 (May 14, 2018, 10:05 PM EDT) -- The West Virginia Supreme Court has held that, under state law, a consumer cannot bring failure-to-warn claims against a maker of a brand-name drug when a generic drug manufacturer made the drug, siding with Janssen Pharmaceuticals Inc. in a suit over a generic version of an antibiotic.

The state's high court, in answering a certified question from the Fourth Circuit on Friday, found that brand manufacturers cannot be held liable for failure to warn of another manufacturer's product. In its majority opinion, the West Virginia Supreme Court aligns with the majority of other courts that have addressed this issue and have declined to hold brand-name manufacturers liable for generic versions of drugs made by another manufacturer.

"Requiring the defendant in a products liability case to be either the manufacturer or the seller of the product is the majority rule in this country," the state high court said. "Where the brand manufacturer neither manufactured nor sold the generic drug, it cannot impliedly represent that the generic drug is free of defects."

The case arises from a 2012 suit filed by Kimmy and Larry McNair alleging that she developed acute respiratory distress after using the generic drug levofloxacin made by Dr. Reddy's Laboratories Ltd. Levofloxacin was originally sold by Johnson & Johnson unit Janssen under the brand name Levaquin.

Janssen had produced the warnings on Levaquin's label, which were then used by subsequent generic manufacturers, according to the opinion.

Generic manufacturers are required by federal law to make sure that the labels for a generic drug match the labels for the brand-name version, according to the opinion. Under the U.S. Supreme Court's 2011 decision in PLIVA Inc. v. Mensing, product liability claims against generic drugmakers are preempted by federal law for that reason.

They claimed that Janssen knew that acute respiratory distress had been linked to the antibiotic, but negligently failed to include a warning, according to the opinion.

A West Virginia federal court granted summary judgment in favor of Janssen, on the basis that every federal court of appeals to weigh the issue, both before and after the Mensing decision, has rejected the argument that a brand-name drug manufacturer's statements about its drug could make it liable for

injuries caused by another manufacturer's drug.

The McNairs appealed to the Fourth Circuit, which then asked the state high court to weigh in.

A representative for Janssen told Law360 on Monday that the company is pleased with the decision.

"For decades, it has been universally recognized that a consumer may only sue the manufacturer of the product that allegedly caused a plaintiff's injury, not manufacturers who produce similar or name-brand products," spokeswoman Sarah Freeman said. "This ruling will help us continue to focus on innovation, research and developing new, life-saving medicines."

The majority opinion was penned by Justice Allen H. Loughry II. In a dissenting opinion, Justice Margaret Workman, joined by Justice Robin Davis, slammed the majority's decision as "short-sighted and ill-advised."

"The failure to impose liability will necessarily invite inattention and neglectfulness by brand-name manufacturers, a transgression for which our citizens will have no legal recourse," Justice Workman wrote.

Leslie Brueckner of Public Justice, counsel for the McNairs, told Law360 on Monday that they plan to file a petition for rehearing.

"This was a closely divided vote," Brueckner said. "We think the decision is wrong as a matter of law and policy and will try to get the court to rehear the case and reverse."

Janssen is represented by Elbert Lin of [Hunton Andrews Kurth LLP](#), David B. Thomas and Daniel R. Higginbotham of [Thomas Combs & Spann PLLC](#) and John D. Winter and Jonah M. Knobler of [Patterson Belknap Webb & Tyler LLP](#).

The McNairs are represented by Leslie A. Brueckner of Public Justice and Richard D. Lindsay of Tabor Lindsay & Associates.

The case is McNair et al. v. Johnson & Johnson et al., case number 17-0519 in the Supreme Court of Appeals of West Virginia.

--Editing by Nicole Bleier.