New Jersey Law Journal

Drugmakers Face Suits Linking Diabetes Med to Heart Failure

Charles Toutant, New Jersey Law Journal

May 3, 2017

AstraZeneca Pharmaceuticals and Bristol-Myers Squibb were hit with 14 suits in the District of New Jersey on Tuesday claiming that users of diabetes drug saxagliptin face elevated risks of heart failure as a result of using the drug.

According to the plaintiffs, the defendants failed to warn users that the drug—sold under the names Onglyza and Kombiglyze XR—can cause cardiac arrest, congestive heart failure and death.

The filings follow an April 2016 U.S. Food and Drug Administration announcement calling for stronger warnings about heart problems on saxagliptin labeling.

The group of 14 cases were brought on behalf of plaintiffs from across the United States by Napoli Shkolnik of New York, which has promised additional filings targeting saxagliptin.

Suits attempting to link the drug to heart failure were first filed in state court in San Francisco in September 2016, but re-filed in New Jersey after a judge there on Feb. 1 granted a motion by Bristol-Myers Squibb and AstraZeneca to sever and dismiss non-California plaintiffs from that case on forum non conveniens grounds.

In the New Jersey suits, which are virtually identical, the plaintiffs claim the defendants began selling saxagliptin in 2009 without conducting clinical trials to determine if it increased cardiac risk in users—despite a 2008 FDA bulletin calling on developers of diabetes drugs to demonstrate that their products don't increase such risks.

In 2015 an FDA committee recommended the agency require the addition of a heart failure warning on the label for saxagliptin after reviewing the defendants' own internal study finding a significant increase in the risk of being hospitalized for heart failure, the suits claim. That recommendation was followed in 2016 by an FDA announcement stating that users of saxagliptin have an increased risk of heart failure, and requiring a revised warning label on the drug.

The plaintiffs claim AstraZeneca and Bristol-Myers Squibb knew of saxagliptin's risks but failed to notify doctors or consumers.

The suits allege a design defect and seek to recover on grounds of negligence, failure to warn, breach of warranty of merchantability, and breach of express warranty and implied warranty. The plaintiffs seek to recover for pain and suffering, economic damages, emotional distress, lost wages and medical expenses.

The accrual of any applicable statute of limitations should be tolled by the defendants' fraudulent concealment, the suits contend.

Hunter Shkolnik of Napoli Shkolnik said his firm will file additional saxagliptin cases in state court in New Jersey, and anticipates the litigation will be coordinated on both state and federal levels.

According to Shkolnik, between 150 and 200 saxagliptin cases are pending nationwide, and could ultimately number in the thousands.

He said his firm picked New Jersey as a venue after the cases were dismissed in California because Bristol-Myers Squibb, in an unrelated case, stipulated jurisdiction in the state.

He said all of the plaintiffs have congestive heart failure or other cardiac symptoms, and a handful of cases were brought on behalf of saxagliptin users who died, he said.

According to Shkolnik, individual case values could be high "depending on how healthy the person was before," Shkolnik said.

Representatives of AstraZeneca and Bristol-Myers Squibb did not respond to phone or email messages seeking comment about the suits.

Contact the reporter at ctoutant@alm.com*. On Twitter:* @ctoutantnjlj.
