Consumer Class Action Nixed in Propulsid Drug Suit; New Jersey Judge Nixes Consumer Class Action Over Drug Propulsid

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Body

A New Jersey judge has refused to certify a nationwide consumer class action on behalf of more than 30 million people who may have suffered heart damage from taking the drug ***Propulsid*** after finding that the case would involve too many individual issues.

The decision in

Cartiglia v. Johnson & Johnson is a significant victory for attorneys MaryCatherine Roper and Susan Sharko of the Florham Park, N.J., office of Drinker Biddle & Shanley because it marks the first ruling on an issue that is currently pending in several courts, including a federal multidistrict litigation action.

In her 36-page opinion, Superior Court Judge Marina Corodemus found that since ***Propulsid***'s warning label was changed seven times before it was taken off the market, the class would have to be divided into seven subclasses.

"Whereas putative class members who initially took ***Propulsid*** when there were no warnings might not have been adequately warned, this is not to say that those who took it in 2000 with the numerous additional warnings were not," Corodemus wrote.

Propulsid was initially marketed in 1993 without any warnings. The label was altered twice in 1995, once in 1997, once in 1998 and once in 2000.

Corodemus found that the four proposed class representatives named in the suit can't adequately represent the class since they "do not represent these different possibilities on behalf of putative class members and their various circumstances under which they consumed ***Propulsid***."

In the suit, plaintiffs' attorneys Lisa Rodriguez of Philadelphia's Trujillo Rodriguez & Richards; Sol Weiss of Philadelphia's Anapol Schwartz Weiss & Cohan; and Christopher Placitella of Woodbridge, N.J.-based Wilentz, Goldman & Spitzer, allege that Johnson & Johnson violated the New Jersey Products Liability Act and the New Jersey Consumer Fraud Act.

The suit seeks medical monitoring for potential health effects, disgorgement of profits, trebling of ascertainable loss and counsel fees.

Propulsid was used in the treatment of serious gastrointestinal disorders. While most drugs used to treat gastrointestinal problems seek to neutralize acid, ***Propulsid*** took a different approach, by a unique treatment that assisted the gastrointestinal system in processing food.

In 1993, the U.S. Food & Drug Administration approved ***Propulsid*** 10 for the treatment of nocturnal heartburn in adults due to gastro esophageal reflux disease or GERD. Many doctors also prescribed ***Propulsid*** for "off-label" uses.

Even before it was launched, the drug's adverse side effects were noticed in clinical trials. Serious cardiac arrhythmias were noted in some patients.

But despite 80 deaths during the drug's testing phase, the FDA granted approval after concluding that almost all of the deaths were caused by underlying disease.

But by February 1995, the FDA's concern was growing. It demanded that contraindications be added to the labeling to include drug interactions and cardiovascular effects.

As concerns continued to grow over the next few years, the FDA called for more warnings to be added, culminating in the January 2000 warning issued to doctors and patients that the drug "can cause dangerously irregular heartbeat and sudden death."

Two months later, Johnson & Johnson's subsidiary, Janssen Pharmaceutical, announced that it would cease marketing of ***Propulsid*** in the U.S. within four months. The FDA noted at the time that the drug had been associated with 341 reports of heart rhythm abnormalities including 80 reports of deaths.

Most of the cases of serious side effects occurred in patients who were taking other medications or suffering from underlying conditions known to increase risk of cardiac arrhythmia.

As a result, the FDA agreed to allow ***Propulsid*** to stay on the market until at least mid-August 2000 to give patients time to switch to alternative therapies. Since that time, ***Propulsid*** has been available only under a "limited access protocol."

In their Consumer Fraud Act claim, the plaintiffs allege that the drug manufacturers created a false market for ***Propulsid*** based on fraudulent and misleading information concerning the efficacy and risks of the drug.

Despite knowing that ***Propulsid*** was no better than over-the-counter products such as "TUMS," the suit alleges that the manufacturer waged an advertising campaign directed towards physicians promoting on and off-label uses of ***Propulsid***.

Defense lawyers disputed the allegations and stressed that ***Propulsid*** was approved by the FDA and was voluntarily withdrawn from the market.

Judge Corodemus found that she had the power to certify a nationwide class for the consumer fraud claim, but that the claim was flawed because the plaintiffs failed to show any form of loss.

"Although reliance is unnecessary under the CFA, the plaintiffs must be able to show ascertainable loss as a result of defendants' conduct and a causal relationship. Without getting to the merits of whether all of these exist ... the fact that the plaintiffs have not identified any kind loss, economic or otherwise, gives this court pause," Corodemus wrote.

Turning to the products liability claims, Corodemus found that the plaintiffs were proposing two theories of liability -- that the drug was defectively designed since its foreseeable risks exceeded its benefits; and that it lacked adequate warnings of the risk of heart injuries.

Corodemus refused to certify the products liability claim as a class action after concluding that it suffered from two key flaws.

"Firstly, the plaintiffs did not show how the numerous warning label changes affected the putative class members at each periodic interval. The plaintiffs failed to demonstrate how the frequency of labeling changes with the marketing scheme resulted in the injuries sustained by the putative class members," she wrote.

"Secondly, the putative class representatives also do not meet the predominance requirement because the drug was prescribed for so many different ailments under assorted circumstances," she wrote.

Corodemus found that the factual background of the four proposed class representatives pointed up why individual issues predominated.

"Not only might there be at least seven different groups of plaintiffs ... based on the number of times the warnings changed, it is also clear that the putative class representatives each have different circumstances that require their cases to be examined individually," she wrote.

Three of the proposed class representatives took ***Propulsid*** while taking other drugs, she noted, and one of the three was taking a drug that was contraindicated while using ***Propulsid***.

"Although the defendants' conduct is at issue here and not the plaintiffs', this putative class and its representatives have too many individual situations to ignore," Corodemus wrote.

"The plaintiffs' claims ... would require this court to analyze each case as to whether each putative class member sustained damages as a result of the alleged inadequacies or failures in the defendants' warnings and alleged design defect. Such an analysis would first require the court to investigate whether each plaintiff who took ***Propulsid*** was adequately warned during the numerous warning changes."

The class definitions, she said, "do not account for the changes in the defendants' warnings."

Corodemus also found that the same sort of "tedious individual investigation" would be required for claims of lack of efficacy and the "risk versus utility" of the product.

"This is because the drug was used for so many different ailments, under so many different circumstances. In fact, there is preliminary evidence that ***Propulsid*** is efficacious for some patients with GERD," Corodemus wrote.

"Prescription drugs are not meant to work the same for everyone. This court cannot simply certify a class with this many variables. The plaintiffs have not drawn the class lines clearly enough," she wrote.

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