

CLASS-ACTION CERTIFICATION DENIED IN SUIT OVER DIGESTIVE DRUG PROPULSID

New Jersey Law Journal

May 6, 2002 Monday

Copyright 2002 ALM Media Properties, LLC All Rights Reserved Further duplication without permission is prohibited

New Jersey Law Journal

Section: Pg. 9

Length: 1141 words

Byline: Shannon P. Duffy American Lawyer Media

Body

New Jersey's chief judge of mass-tort litigation has refused to certify a consumer class action on behalf of more than 30 million people nationwide who may have suffered heart damage from taking the digestive drug **Propulsid**.

Superior Court Judge Marina Corodemus, who manages all mass-tort cases in the state courts, found that the case would involve too many individual issues. Prescription drugs are not meant to work the same for everyone, wrote Corodemus in a 36-page opinion, **Cartiglia v. Johnson & Johnson**. This court cannot simply certify a class with this many variables. The plaintiffs have not drawn the class lines clearly enough.

The judge found that the class would have to be subdivided because the class definitions did not account for changes in the drug's warning label before it was taken off the market. **Propulsid** was first marketed in 1993 without any warnings, but the label was altered twice in 1995, once in 1997, once in 1998 and once in 2000. 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, wrote Corodemus, who sits in New Brunswick.

Furthermore, the four proposed class representatives named in the suit couldn'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**, the judge found.

The plaintiffs allege that Johnson & Johnson violated New Jersey's Products Liability Act and Consumer Fraud Act. They seek 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.

CLASS-ACTION CERTIFICATION DENIED IN SUIT OVER DIGESTIVE DRUG PROPULSID

In 1993, the U.S. Food and 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. The FDA granted approval despite 80 deaths during the testing phase, concluding that almost all were caused by underlying disease.

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 United States 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 toward 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 of loss, economic or otherwise, gives this court pause, Corodemus wrote.

Turning to the product-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 product-liability claim as a class action after concluding that it suffered from two key flaws.

CLASS-ACTION CERTIFICATION DENIED IN SUIT OVER DIGESTIVE DRUG PROPULSID

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. 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.

Johnson & Johnson's lawyers are Mary Catherine Roper and Susan Sharko of Florham Park's Drinker Biddle & Shanley. The plaintiffs' lawyers are Lisa Rodriguez of Philadelphia's Trujillo Rodriguez & Richards, Sol Weiss of Philadelphia's Anapol Schwartz Weiss & Cohan and Christopher Placitella of Wilentz, Goldman & Spitzer in Woodbridge.

Classification

Language: ENGLISH

Publication-Type: Newspaper

Subject: LITIGATION (91%); CLASS ACTIONS (90%); JUDGES (90%); SUITS & CLAIMS (90%); TORTS (89%); DRUG INTERACTIONS & SIDE EFFECTS (89%); DISEASES & DISORDERS (89%); GASTROESOPHAGEAL REFLUX DISEASE (89%); PRODUCT LABELING (89%); HEART DISEASE (89%); GASTROINTESTINAL DISORDERS (89%); APPROVALS (78%); BUSINESS TORTS (78%); TRIAL & PROCEDURE (78%); DRUG & MEDICAL DEVICES APPROVAL (77%); ADVERSE DRUG EVENT REPORTING (77%); DRUG LABELING (77%); CLINICAL TRIALS (77%); CARDIOVASCULAR DISEASE (77%); LAW COURTS & TRIBUNALS (73%); PRODUCT LIABILITY (73%); BURN INJURIES (72%); US FDA APPROVALS (69%); MEDICAL TREATMENTS & PROCEDURES (68%); PHYSICIANS & SURGEONS (64%); EDITORIALS & OPINIONS (53%)

Company: JOHNSON & JOHNSON (93%)

Ticker: JNJ (NYSE) (93%)

Industry: LITIGATION (91%); DRUG INTERACTIONS & SIDE EFFECTS (89%); PRODUCT

CLASS-ACTION CERTIFICATION DENIED IN SUIT OVER DIGESTIVE DRUG PROPULSID

LABELING (89%); DRUG & MEDICAL DEVICES APPROVAL (77%); ADVERSE DRUG EVENT REPORTING (77%); GASTROINTESTINAL AGENTS (77%); DRUG LABELING (77%); OFF LABEL DRUG USE (77%); PRESCRIPTION DRUGS (77%); CLINICAL TRIALS (77%); US FDA APPROVALS (69%); PHYSICIANS & SURGEONS (64%)

Geographic: NEW JERSEY, USA (90%); UNITED STATES (79%)

Load-Date: April 19, 2011

End of Document