

## Drug companies on the hook for off-label use of generic

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In an apparent case of first impression, a Philadelphia judge has ruled that two pharmaceutical companies may have a legal duty to class members for money spent on the generic version of the companies' name-brand drug allegedly marketed by the companies for uses not approved by federal regulators.

The generic drug in the case was produced by a third-party manufacturer.

Three class action claims alleging that Warner-Lambert Co. and its merger partner, Pfizer Inc., marketed a drug for off-label use to treat medical conditions not approved by the federal Food and Drug Administration have survived partial summary judgment following the judge's ruling earlier this month.

The plaintiffs in the class action allege that the drug company defendants conducted a campaign to promote the prescription of its Neurontin drug and its generic equivalent, gabapentin, for a number of medical uses not approved by the FDA, according to court papers.

Philadelphia Common Pleas Judge Mark I. Bernstein let stand the claims of negligent misrepresentation, negligence and intentional misrepresentation in *Clark v. Pfizer Inc.* regarding the generic gabapentin made by third-party drug manufacturers.

Bernstein said that the legal question presented in Pfizer's and Warner-Lambert's motion for partial summary judgment was whether a drug company, which "negligently or intentionally perpetrates a fraud upon the medical community" by the off-label marketing of its name-brand drug, can be held responsible for money paid to other drug companies that make the generic equivalent of the name-brand drug.

Assuming that the plaintiffs can prove their allegations at trial, "under Pennsylvania law, a defendant may be liable for misrepresentation to foreseeable plaintiffs even without any direct relations between the parties," Bernstein said in his March 14 opinion.

It was foreseeable that the marketing of Neurontin for off-label use would increase the demand for the generic version of the drug, Bernstein said. The defendants themselves estimated that Neurontin would lose 65 to 95 percent of its market once the patents on Neurontin expired, so Pfizer proposed marketing its own generic, the judge said.

"I believe it's the first opinion in the country that expressly says that a brand name manufacturer can be liable for the money spent on drugs manufactured by a third-party manufacturer," said plaintiffs attorney John K. Weston of Sacks & Weston. "There are not a huge number of cases that address this."

Robert C. Heim of Dechert, one of the pharmaceutical defendants' attorneys, said he doesn't know of any other Pennsylvania case that deals with allowing a consumer to get a refund from a company that did not make or sell the drug purchased.

Other courts around the country have found that a manufacturer of a branded drug product does not have a duty to the purchasers of generic versions; in particular, the defense relied upon the 1994 4th U.S. Circuit Court of Appeals decision in *Foster v. American Home Products Corp.*, Heim said.

"While not bound by out-of-state precedent, this court may consider the well-reasoned analysis of the courts from other jurisdictions that have unanimously rejected the theories of recovery advanced by plaintiffs," the defendants' motion for partial summary judgment said. "In the absence of any authority, the court should not accept the plaintiffs' invitation to depart from a long string of precedent from other jurisdictions and expand Pennsylvania law in a way that has been rejected by every other jurisdiction to consider the issue."

The drug maker defendants never realized any profits from the sales of the generic gabapentin, Heim said. Bernstein said a federal Eastern District judge's decision in *Colacicco v. Apotex, Inc.* -- put forth by the defense in support of its position that a name-brand drug maker doesn't have a legal duty to users of the generic version of the drug -- did not accurately reflect Pennsylvania law.

In that case, U.S. District Judge Michael M. Baylson said -- "in dicta," according to Bernstein -- that name-brand pharmaceutical companies did not have that duty with regard to generic users. Baylson also held that state-level plaintiffs should be pre-empted from suing over allegedly inadequate warnings on prescription drugs.

Bernstein concluded that a duty did exist in *Clark* after applying the five-prong test from the Pennsylvania Supreme Court's 2000 decision in *Althaus v. Cohen*.

Bernstein also said that the economic loss doctrine, which prohibits tort recovery only when a contract has been violated, did not bar claims over money spent by consumers on the generic gabapentin. He noted that the Supreme Court's 2005 decision in *Bilt-Rite Contractor, Inc. v. Architectural Studio* found that plaintiffs are not barred from recovering economic losses because the action 'sounds in tort rather than contract law.'"

The defense, in its motion for partial summary judgment, argued that *Clark* didn't fall within the narrow exception carved out from the economic loss rule by the *Bilt-Rite* Court for negligent misrepresentation claims by adopting Section 552 of the Restatement of Torts.

Other judges have applied Section 552 more narrowly, Heim said, and the defense encouraged Bernstein to not apply it broadly because then it would apply to all manufacturing businesses, not just businesses that supply information to others.

"I think it's fair to say there's a split of authority on that subject," Heim said. "We don't see *Bilt-Rite* as eliminating the distinction between tort law and contract law in regards to negligence claims. ... I have a lot of respect for Judge Bernstein. It just shows that you can have respect for a court and just disagree with the court as to the law, and it will eventually be for someone other than Judge Bernstein or me to determine who is right about this."

Weston, the plaintiffs attorney, said he also thinks Bernstein's reading of the *Bilt-Rite* decision's impact on the economic loss doctrine is groundbreaking.

"His reading on *Bilt-Rite* affects a lot of cases," Weston said. "Defendants have been using this economic loss rule very aggressively in the last 10 years."

Bernstein's decision increases the potential class recovery significantly, Weston said, because the patent on Neurontin has expired and Pennsylvania pharmacists are required to substitute the generic unless expressly directed otherwise.

Bernstein granted the defendants' motion for partial summary judgment on the warranty claims, which was stipulated to by both sides during oral argument, according to Weston.

During the class certification hearing, the plaintiffs produced evidence that the defendants unlawfully promoted Neurontin to physicians for off-label use, despite the lack of scientific proof that the drug was effective in treating those conditions, Bernstein said.

A \$40 million promotional budget was devoted to those efforts, including the insertion of anecdotal articles in medical journals, paying physicians considered to be opinion leaders and sponsoring continuing medical education conferences that actually were paid promotional events, Bernstein said. At least 200,000 prescriptions for Neurontin were written in Pennsylvania, and the defendants earned between \$53 million and \$64 million on the drug per quarter in the state, Bernstein said.

"Whether plaintiffs' claims can be proven at trial remain to be seen," Bernstein wrote. "However if plaintiffs can demonstrate at trial a comprehensive marketing scheme to unlawfully promote the off-label use of an FDA approved medication, a class-wide claim has been proven. The claims of plaintiffs class, if ultimately proven at trial, consist of an unlawful manipulation of medical literature, medical opinion, and a fraud upon the medical community of the country."

Neurontin was approved to treat epilepsy in 1993 and neuralgia in 2002, Bernstein said. Pfizer, a Delaware corporation, and Warner-Lambert Co., a limited liability company, merged June 19, 2000, according to the defense's answer to the plaintiffs' amended complaint.

Bernstein granted class certification last June. The class involves all people who purchased Neurontin and gabapentin between 1995 and the present for medical conditions other than adjunctive therapy for epilepsy and management of pain associated with herpes zoster rash outbreaks.

Each class member has damages worth less than \$75,000; the class action members seek a refund for the amount they spent on Neurontin/gabapentin prescriptions given to treat off-label medical conditions not approved by the FDA, according to court papers.

Class representative Gregory Clark of Philadelphia was prescribed Neurontin for knee pain, according to the amended lawsuit complaint. Class representative Linda Meashey of Anville, Pa., was prescribed Neurontin for bipolar disorder, according to the amended complaint.

Warner-Lambert entered a criminal plea agreement in Federal District Court of Massachusetts, which included a \$240 million fine and a cessation of all off-label marketing efforts, Bernstein said.

Bernstein's opinion also touched upon on the issue of whether state-level plaintiffs should be pre-empted from suing over allegedly inadequate warnings on prescription drugs because the FDA approved the warning labels. The 3rd U.S. Circuit Court of Appeals heard arguments in December on two conflicting lower court decisions: Baylson's decision and the decision by U.S. District Judge Jerome B. Simandle in the District of New Jersey in *McNellis v. Pfizer Inc.* that such claims aren't pre-empted.

The *Colacicco* decision found that the plaintiffs couldn't "graft additional requirements for citizen safety onto the FDCA," Bernstein said, and thus allowing the plaintiffs claims to continue would conflict with the FDCA.

Bernstein said the *Colacicco* decision gave "excessive deference" to the FDA's "Pre-emption Preamble," which was disseminated in 2006 and said that allowing state-court actions over drug labels would conflict with federal law and regulations.

Pennsylvania courts are not required to follow federal decisions in all instances and it's the right of the state to protect its citizens, Bernstein said.

"While state courts respect the reasoning of federal courts particularly when interpreting federal law issues of nationwide import which impact upon federal-state relations, the right of each sovereign state to protect its citizens is a matter of state law interpretation protected by the 10th Amendment to the United States Constitution," Bernstein said. "As a Pennsylvania trial court, this court is obligated to enforce state law until such time as the Supreme Court of the United States having actual authority determines that state law has been pre-empted."

The U.S. Supreme Court is slated to take up a pre-emption case, *Levine v. Wyeth*.

Heim said that the defendants believe pre-emption applies here but that they have not yet filed a pre-emption motion.