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Generic-Drug Consumers Get Rare Boost With Ala. Ruling

By **Sindhu Sundar**

Law360, New York (August 20, 2014, 5:58 PM ET) -- The Alabama Supreme Court's decision to uphold its controversial view that brand-name drug makers can be liable for inadequate warnings on generics marks the first such ruling by a state's highest court and endorses a theory of misrepresentation that plaintiffs can now use to persuade other courts, attorneys say.

*The state Supreme Court on Friday **affirmed** a ruling against Wyeth Inc. in a suit by plaintiff Danny Weeks, who claimed the branded-drug maker had provided inadequate warnings about the risks of the heartburn medication metoclopramide, which it sold as Reglan.*

Weeks had only taken the generic version of the medication, but he had brought fraudulent misrepresentation claims against branded-drug makers Wyeth, its parent Pfizer Inc. and Schwarz Pharma Inc., who manufactured Reglan, arguing that they had failed to warn about the drug's risks of causing the chronic movement disorder tardive dyskinesia.

Siding with Weeks, the state Supreme Court ruled that under Alabama law, branded-drug makers can face liability for fraud and misrepresentation even for their drug warnings that appear on the labels of competing generics, since the U.S. Food and Drug Administration requires generics makers to adopt the same labels that are used on branded drugs.

That reasoning will lend a boost to generic-drug plaintiffs amid the vast majority of defense-friendly rulings around the country, including landmark U.S. Supreme Court decisions in Mensing and Bartlett, attorneys say.

"Now [generic-drug injury] plaintiffs have the reasoning and reconsideration of a state Supreme Court, so maybe other courts will be persuaded," said James Huston of Morrison & Foerster LLP. "At least it will give them something to think about."

Generic-drug plaintiffs have not had much success finding recourse for their alleged injuries, as several dozen federal court rulings have ruled against the so-called "innovator liability" theory, the notion that a branded-drug maker is responsible for injuries caused by generic drugs.

"This is not a case about innovator liability; this is about straight-up misrepresentation," said plaintiffs attorney Bill Curtis of the Curtis Group PC. "Wyeth knows its audience includes generic-drug consumers, and it has a duty to get its label accurate. And the court is saying that if consumers are harmed in reliance of that label, Wyeth is responsible — it's as simple as that."

The U.S. Supreme Court held in Pliva Inc. v. Mensing that federal law preempts state law tort claims against generic-drug manufacturers that have to use the same warning labels as brand-name drug companies. And in Mutual Pharmaceutical Co. v. Bartlett, it found that federal law preempts design defect claims against generic-drug makers.

The Alabama Supreme Court is among a handful of courts, including an Illinois federal court and a California court of appeals, in finding that brand-name drug makers can be held liable for alleged generic-drug injuries. But it also does so under theories of misrepresentation that could apply in other states with similar laws, attorneys say.

"I think this is unlikely to cause a real sea change, but now that the Alabama Supreme Court has doubled down, I could see another state, especially one with similar case law to Alabama's, thinking, 'Well, our law looks somewhat similar, so building on Weeks, we can go that way as well,'" said Demoya Gordon of Faegre Baker Daniels.

The Alabama Supreme Court also shot down a common argument that branded-drug makers make in such cases, namely that they do not have any relationship — and therefore owe no duty — to a patient who took a competing generic product. But the court found that this reasoning "completely ignores the nature of prescription medication," observing that patients never get prescription medications directly from drugmakers.

The court then found that it is the "learned intermediaries," in this case doctors, to whom branded-drug makers owe a duty to make a complete and accurate representation of the drug's risks through its label, according to the opinion.

A spokesman for Pfizer Inc. declined to comment Tuesday on whether the drugmaker intends to appeal the decision to the U.S. Supreme Court, saying that it does not discuss legal strategy.

--Editing by Katherine Rautenberg and Philip Shea.