Sills Cummis & Gross P.C.

Client Alert **Product Liability Law**

Alabama Supreme Court: Brand-Name Pharmaceutical Manufacturer Can Be Sued for Injury Caused by Generic Product

In *Wyeth, Inc. v. Weeks*, No. 1101397, 2013 Ala. LEXIS 2 (Ala. Jan. 11, 2013), the Alabama Supreme Court joined courts in California and Vermont in allowing a lawsuit to proceed against a brand-name manufacturer for injuries caused by a generic alternative. In reaching its decision, the Court found that since the FDA requires a generic manufacturer's label to be identical to the brand-name label, a generic manufacturer cannot proactively change its label, and brand-name manufacturers have a continuing duty to strengthen their warning labels, it is foreseeable that the user of a generic drug might be injured as a result of shortcomings in the brand-name's warning. The Court held that it was therefore not "fundamentally unfair" for brand-name manufacturers to be held liable for fraud or misrepresentation claims even where a plaintiff only ingested the generic. To prevail on such a claim, however, plaintiff must still show that plaintiff's prescribing physician reasonably relied upon the alleged fraud or misrepresentation.

In *Weeks*, plaintiff developed tardive dyskinesia, a disorder that causes involuntary, repetitive muscle movements, allegedly due to the long-term use of metoclopramide, the generic form of Pfizer's heartburn medication, Reglan®. Plaintiff brought fraud, misrepresentation and suppression claims pursuant to Ala. Code § 6-15-101 (1975) against brand-name manufacturers Pfizer, Inc., Wyeth LLC, and Schwarz Pharma, Inc. (collectively "Pfizer"), and generic manufacturers Teva Pharmaceuticals and Actavis Elizabeth in the U.S. District Court for the Middle District of Alabama. Plaintiff alleged that Pfizer failed to disclose the risks associated with the long-term use of

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metoclopramide. Plaintiff had never taken Reglan®, and had only taken metoclopramide, which was not manufactured by Pfizer.

Pfizer moved to dismiss on the grounds that brand-name manufacturers owe no duty to individuals who took a generic drug they did not make. The district court granted in part and denied in part Pfizer's motion, holding that plaintiffs might be able to bring a suit under Alabama law if they could prove the brand-name manufacturer had a duty to warn plaintiff's physician about the risks associated with the long-term use of Reglan®, and that plaintiffs, as third parties to the misrepresentation, had a right to enforce a breach of that duty. The district court also requested certification from the Alabama Supreme Court on the issue of whether a brand-name manufacturer could be held liable for fraud or misrepresentation as a result of an injury caused by a generic drug. The Alabama Supreme Court granted certification due to an intrastate split among the Alabama federal district courts on the issue, the growing number of Reglan® cases nationwide, and the positive impact a definitive resolution would have on pending cases. The Alabama Supreme Court held "Under Alabama law, a brand-name drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company."

In coming to its decision, the Court relied in part on the United States Supreme Court decisions in *Wyeth v. Levine*, 555 U.S. 555 (2009) and *PLIVA, Inc. v Mensing*, 131 S. Ct. 2567 (2011). In *Levine*, plaintiff sued Wyeth, Inc., the manufacturer of anti-nausea medication Phenergan, on the grounds that Wyeth failed to warn of the risks associated with administering Phenergan intravenously. Wyeth argued that plaintiff's state law failure to warn claim was pre-empted by federal drug labeling regulations because the FDA had approved the label that plaintiff alleged was defective. Wyeth argued it was impossible for a manufacturer to comply with both state and federal labeling requirements where state law allowed a failure to warn claim to proceed based upon a label that had been approved by the FDA. The U.S. Supreme Court disagreed with Wyeth and found that not only had the company failed to demonstrate that it was impossible to comply with both state and federal labeling requirements, but that under federal regulations a brand-name manufacturer has a continuing duty to revise and strengthen its warning label while its product is on the market when there is evidence of a serious hazard.

In *PLIVA, Inc. v. Mensing*, the Supreme Court held that under the Hatch-Waxman Act, 21 U.S.C. § 355(j)(2)(A)(v) and (j)(4)(G), and applicable FDA regulations, it was impossible for a generic drug maker to change its warning label without violating the requirement that the warning on a generic drug be identical to the warning on the brand-name version. The Court found that a generic pharmaceutical manufacturer cannot unilaterally change its own warning label to add risks that are not expressly identified in the brand-name label. The generic manufacturer's duty was thus characterized by the Supreme Court as being a "duty of sameness" in contrast to the brand-name manufacturer's continuing duty of accuracy.

Because the generic manufacturer must completely rely upon the brand-name label, and because over time generic products often represent a larger share of the market, the Alabama Supreme Court found it was foreseeable to the brand-name manufacturer that a patient could be injured by a generic drug as a result of the brand-name manufacturer's failure to include appropriate warnings in the brand-name product's labeling.

The Alabama Supreme Court recognized that its ruling was not consistent with the position taken by the majority of courts in other jurisdictions that have rejected similar claims by relying predominantly on *Foster v. American Home Products*, 29 F.3d 165 (4th Cir. 1994). In *Foster*, plaintiffs sued the brand-name manufacturer for negligent misrepresentation as a result of a fatality caused by ingestion of the generic drug. The Fourth Circuit, in its pre-*Mensing* decision, found that a brand-name manufacturer does not owe a duty to warn users of the risks associated with taking the generic product because a generic manufacturer has responsibility for the accuracy of its own warning label. In light of *Mensing's* duty of sameness, the Alabama Supreme Court criticized the *Foster* holding as fundamentally flawed and opted instead to follow the minority, forseeability of injury approach adopted by the California Court of Appeal in *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008), and by the Vermont federal district court in *Kellog v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010).

In *Conte*, the California Court of Appeal held that the brand-name manufacturer knew or should have known that in a large number of cases where Reglan® is prescribed, the prescription would instead be filled with metoclopramide, and that due to the foreseeability that a patient could be injured by metoclopramide, the brand-name manufacturer's duty of care in product labeling extends to those who are injured by the generic version. Similarly, in *Kellog*, the Vermont federal district court held that

a brand-name manufacturer has a duty to use reasonable care to avoid causing injury to those who were prescribed the generic equivalent because, again, it is reasonably foreseeable that a physician will rely upon the brand-name warning label when prescribing the medication to the patient, regardless of whether the prescription is ultimately filled with Reglan® or metoclopramide.

As part of its finding of "foreseeability" on the part of the brand-name manufacturer, the Alabama Supreme Court also concluded that a brand-name manufacturer may owe a duty to plaintiffs for fraudulent representations made to a third party prescribing physician. In making this finding, the Alabama Supreme Court relied on its prior decisions in *Delta Health Group, Inc. v. Stafford*, 887 So. 2d 887 (Ala. 2004), *Thomas v. Halstead*, 605 So. 2d 1181 (Ala. 1992), and *Sims v. Tigrett*, 158 So. 326 (Ala. 1934). In all three cases, which were non-products related, the Alabama Supreme Court found that in certain limited circumstances a plaintiff may bring a fraud claim pursuant to Alabama law for misrepresentations made to a third party when the plaintiff was harmed as a result of the misrepresentation and the representation was reasonably relied upon. The Court emphasized that in bringing their claim for fraud and misrepresentation against Pfizer, plaintiff adequately alleged that the prescribing physician had reasonably relied upon the representations made by the brand-name manufacturer regarding the product's safety, and that as a result of those misrepresentations, plaintiff was prescribed the drug that caused his injury.

Although Alabama has adopted the learned intermediary doctrine in products cases, the Alabama Supreme Court did not find it a bar to plaintiff's claim. Ordinarily, the learned intermediary doctrine would insulate a manufacturer from liability for a patient's failure to warn claim when appropriate warnings have been given to the prescribing physician. However, here the Alabama Supreme Court noted that plaintiff's claims for fraud and misrepresentation may still be actionable, notwithstanding the learned intermediary doctrine, because plaintiff alleged that the warning given to the physician was inadequate and misrepresented the product's actual risks. Plaintiff's fraud and misrepresentation claims would thus survive a learned intermediary defense if plaintiff could prove that the prescribing physician would not have prescribed the product but for the manufacturer's misrepresentation.

At this juncture, because the *Weeks* decision only directly impacts Alabama state fraud and misrepresentation claims, it could remain an outlier. *Weeks*, however, could also be a sign that in light of generic manufacturers' duty of sameness, as established by

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Mensing, courts may be increasingly more inclined to allow suits against brand-name manufacturers for injuries caused by generic drugs.

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