American Society for Pharmacy Law

## PRODUCT LIABILITY – FRAUDULENT MISREPRESENTATION

### *Alabama Supreme Court finds Pfizer/Wyeth could be liable for damages from generic version of Reglan®*

On an application for rehearing by plaintiffs, the Alabama Supreme Court withdrew its January 2013 opinion and found in favor of plaintiffs on a question certified to the Court by the Middle District of Alabama: "Under Alabama law, may a drug company be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture or distribution of a brand-name drug, by a plaintiff claiming physical injury from a generic drug manufactured and distributed by a different company?"

Plaintiffs (Danny and Vicki Weeks) sued 5 current and former manufacturers of metoclopramide, the long-term ingestion of which caused injuries to plaintiff Danny Weeks. They conceded that Mr. Weeks did not take Reglan®, formerly marketed by Wyeth LLC, and subsequently by Schwarz Pharma, Inc., but "nevertheless asset that the brand-name defendants are liable for Mr. Weeks's harm on fraud, misrepresentation, and/or suppression theories because they at different times manufactured or sold brand-name Reglan® and purportedly either misrepresented or failed to adequately warn Mr. Weeks or his physician about the risks of using Reglan® long-term."

The district court denied in part the motion of defendants to dismiss on the basis, *inter alia*, "(1) that the Weekses' claims, however pled, are in fact product liability claims that are barred for failure of 'product identification' and (2) that they had no duty to warn about the risks associated with ingestion of their competitors' generic products," holding that plaintiffs "might be able to state a claim for relief under Alabama law if they could prove that the brand-name manufacturers had a duty to warn Mr. Weeks's physician about the risks associated with long-term use of brand-name Reglan® and, further, that the Weekses, as third parties, had a right to enforce an alleged breach of that duty."

Because federal district courts in Alabama have disagreed on the issues presented in this case, an intrastate split made certification to the Alabama Supreme Court an appropriate action. In its certification, the district court noted that a recent ballooning of Reglan® cases to approximately 3500 nationwide has resulted in "at least 250 Alabama-resident plaintiffs … most [of which] … assert the fraud, misrepresentation, and/or suppression theories asserted here."

The Court recognized the defendants' characterization of the plaintiffs' claims as product liability claims, but noted that under Alabama's adoption of the Alabama Extended Manufacturer's Liability Doctrine (AEMLD), fraudulent suppression claims are a separate cause of action from strict product liability claims under the AEMLD, and chose to treat plaintiffs' claims as fraudulent suppression

claims. It held that the plaintiffs did not "claim that the drug ingested by Danny was defective; instead, [they] claim that Wyeth fraudulently misrepresented or suppressed information about the manner in which (i.e., the duration) the drug was to be taken. In short, the Weekses' claim is based on what Wyeth said or did not say about Reglan and their assertion that those statements or omissions caused Danny's injuries."

The Court noted at the outset that "Alabama's Pharmacy Act … permits a pharmacist to select in place of a brand-name drug a less expensive drug product that is the same pharmaceutical and therapeutical equivalent of the brand-name drug and that contains the same active ingredient or ingredients and is the same dosage-form strength, unless the prescribing physician indicates otherwise on the prescription. … In the present case, it appears that Danny's prescription did not prohibit the pharmacist from substituting a generic drug for the brand-name drug. … That a pharmacist acted under [the Pharmacy Act] and gave Danny a generic drug does not preclude Danny's ability to assert a fraudulent-misrepresentation claim against the brand-name manufacturer of the drug."

The Court then discussed federal preemption of state product liability laws against brand-name and generic manufacturers, and reviewed U.S. Supreme Court decisions in *Wyeth v. Levine* and *Pliva v. Mensing.* Prior federal district court opinions applying Alabama law had held that a consumer of a generic drug product could not sue a brand-name manufacturer based on fraudulent misrepresentation. The lead case, *Mosely v. Wyeth, Inc.,* 719 F.Supp. 2d 1340 (S.D. Ala. 2010), held that the brand-name manufacturer owed no duty to plaintiffs, in part because the manufacturer did not engage in any business relationship with the plaintiffs. The district court also found that "after the ANDA process, generic manufacturers become responsible for their own warning labels and any necessary revisions to those labels."

The Court distinguished *Mosely* from the present case: "The Weekses are not arguing that Wyeth owed them a duty. Instead they are arguing that Wyeth owed Danny Weeks's physician a duty and that, under the learned-intermediary doctrine, the Weekses are entitled to rely on representations made to Danny's physician." The Court also noted that *Mosely* was decided before *Pliva,* and the holding by the U.S. Supreme Court that generic manufacturers could not possibly "comply with both their state-law duty to change the drug label to a safer label adequately warning of the dangers inherent in long-term use and their federal-law duty to keep the label the same as the brand-name manufacturer's label" renders the "reasoning … that a generic manufacturer is responsible for its own warning labels … unsound."

The Court engaged in a thorough discussion of jurisprudence from other jurisdictions, noting that this case may present the first instance where the highest court of a state has been asked to opine on its own laws: the majority of other decisions arose in diversity actions in federal courts. The instant opinion represents an up-to-date summary of significant jurisprudence on the issues presented.

The Court again noted that prior decisions emphasized product liability theories, particularly strict liability, whereas this case is not about the product, but the warnings communicated by the brand-name manufacturer. Ultimately, the Court held that a "brand-name manufacturer could reasonably foresee that a physician prescribing a brand-name drug (or a generic drug) to a patient would rely on the warning drafted by the brand-name manufacturer even if the patient ultimately consumed the generic version of the drug."

The Court then turned to the question whether a plaintiff could maintain a cause of action based on representations to a third party where the plaintiff could not establish "his reliance upon that misrepresentation." In *Thomas v. Halstead,* 605 So. 2d 1181 (1992), the Court had held that in limited circumstances, a third party may claim damages as a result of a fraudulent misrepresentation

it never itself relied upon: “While generally ‘[a] stranger to a transaction … has no right of action [for fraud],’ there is an exception to this general rule: ‘If a third person is injured by the deceit, he may recover against the one who made possible the damages to him by practicing the deceit in the first place’ [alterations in the original].”

The Court observed that under the learned-intermediary doctrine as adopted in Alabama, “a prescription-drug manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug. Once that duty is fulfilled, the manufacturer has no further duty to warn the patient directly. However, if the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for injuries sustained by the patient.”

The Court then recounted Wyeth’s argument that there was no relationship between it and the Weekses: “’Here, the brand-name defendants had absolutely no relationship with the Weekses. The Weekses never met with any representative of the brand-name defendants, transacted any business with the brand-name defendants, or did anything else that could have established the necessary relationship. Most significantly, the Weekses concede that Mr. Weeks didn’t use the brand-name defendants’ products. That concession is fatal. Without some product-use link, the Weekses can’t establish a relationship; and without a relationship, they can’t prove a duty.’” However, the Court held that Wyeth’s argument “completely ignores the nature of prescription medication. The Weekses cannot obtain Reglan or any other prescription medication directly from a prescription-drug manufacturer. … [Under the learned-intermediary doctrine,] When the warning to the prescribing health-care professional is inadequate, however, the manufacturer is directly liable to the patient for damage resulting from that failure. The substitution of a generic drug for its brand-name equivalent is not fatal to the Weekses’ claim because the Weekses are not claiming that the drug Danny ingested was defective; instead, the Weekses’ claim is that Wyeth fraudulently misrepresented or suppressed information concerning the way the drug was to be taken and, as discussed, the FDA mandates that the warning on a generic-drug label be the same as the warning on the brand-name-drug label and only the brand-name manufacturer may make unilateral changes to the label.”

The Court emphasized that its decision is narrowly confined to manufacturers of prescription drugs: “In answering the question of law presented to us by the federal court, we emphasize the following: We are not turning products-liability law (or tort law for that matter) on its head, nor are we creating a new tort of ‘innovator liability’ as has been suggested. Instead, we are answering a question of law involving a product that, unlike any other product on the market, has unprecedented federal regulation. Nothing in this opinion suggests that a plaintiff can sue Black & Decker for injuries caused by a power tool manufactured by Skil based on labeling or otherwise. The unique relationship between brand-name and generic drugs as a result of federal law and FDA regulations, combined with the learned-intermediary doctrine and the fact that representations regarding prescriptions drugs are made not to the plaintiff but to a third party, create the sui generis context in which we find prescription medication. Again, the fraud or misrepresentation claim that may be brought under Alabama law against a drug manufacturer 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 is premised upon liability not as a result of a defect in the product itself but as a result of statements made by the brand-name manufacturer that Congress, through the FDA, has mandated be the same on the generic version of the brand-name drug.” [Wyeth et al. v. Weeks, No. 1101397, S.Ct. Ala., August 15, 2014; http://1.usa.gov/1oKi9jN]