Products Liability Law Daily Wrap Up, TOP STORY—DRUGS—Ala. Sup. Ct.: "Innovator liability" may leave brand manufacturer liable for injuries caused by generics, (Aug. 18, 2014)

Products Liability Law Daily Wrap Up

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By Bryant Storm, J.D.

The Alabama Supreme Court decided that Wyeth, Inc., the brand-name manufacturer of the drug, Reglan®, could be held liable for its failure to warn a patient about risks related to the long-term use of Reglan's generic equivalent. The Alabama high court, in a self-proclaimed narrow holding, decided that the highly regulated prescription drug industry gave rise to unique circumstances in which a brand-name drug manufacturer retained a duty to warn consumers of risks in its competitor's product, contrary to that of manufacturers in other industries (*Wyeth, Inc. v. Weeks*, August 15, 2014, Bolin, M.).

Injury. Danny Weeks developed tardive dyskinesia, a neurological movement disorder, as a result of his prolonged use of metoclopramide, the generic equivalent of the drug Reglan. Weeks and his wife brought suit in federal district court against three brand-name drug manufacturers—Wyeth, Inc. (Wyeth), Pfizer, Inc., and Schwarz Pharma, Inc.—contending that those manufacturers deceptively misrepresented or intentionally suppressed information about Reglan and metoclopramide that misinformed Weeks' physician about the risk that Weeks could develop tardive dyskinesia and related movement disorders. In other words, despite the fact that Weeks only ingested the generic version of the drug, his lawsuit was premised upon the theory that Wyeth, the manufacturer of the brand-name version, Reglan, was under a duty to warn his prescribing physician about the risks of tardive dyskinesia.

Federal district court. In response to the failure to warn claims brought by Weeks, Wyeth contended that the case was a products liability action, and that in such an action, an injured plaintiff shoulders the burden of proving that the defendant manufactured the product that caused the plaintiff's injury. Wyeth argued it could not be held liable because it was not the manufacturer of the drug that injured Weeks. The U.S. District Court for the Middle District of Alabama denied Wyeth's initial attempts at dismissal and, because of a lack of controlling precedent, eventually certified a question to the Alabama Supreme Court, asking the state high court to decide whether a brand-name drug manufacturer could be held liable for a failure to warn about an injury caused by a generic version of the drug.

Alabama Supreme Court. In its first attempt at answering the question, the Alabama Supreme Court reasoned that because brand-name drug manufacturers retained a duty to warn physicians about risks relating to the brand-name version of the drug that carried over to generic labels, Wyeth could be held liable by a patient who used a generic version of the drug (see, *Liability of brand name drug maker for failure to warn physicians may extend to consumers of generics*, January 16, 2013). On application for rehearing, the Alabama high court was asked to answer the question again. On its second look at the issue, with a narrower focus, the court reached the same conclusion.

Drug approval. Federal law and Food and Drug Administration (FDA) regulation give rise to a distinction between generic and brand-name drugs that controlled the case. The FDA's approval of new prescription drugs typically begins with an investigational new-drug application (IND), under 21 U.S.C. sec. 355(b), which includes information about the chemistry, manufacturing, pharmacology, and toxicology of a drug. The next step in the FDA's oversight is the submission of a new drug application (NDA). Under 21 U.S.C. sec. 355(d)(5), an NDA is designed to be a mechanism by which a manufacturer can prove to the FDA the safety and effectiveness of the new drug. The drug application process is notoriously long and costly.

Generic drugs. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) (P.L. 98-417), Congress created an exception for generic drugs to the lengthy and costly multi-step drug approval process. Once a patent has expired, generic manufacturers can sell a generic version of the previously approved and patented drug. The Hatch-Waxman Act created the abbreviated new-drug-application (ANDA) process to streamline approval of generic drugs so that they can more quickly get to market. Under an ANDA, a generic drug manufacturer must show the FDA that the generic drug is the same or bio-equivalent to the brand-name drug. The costly measures associated with an NDA are avoided under an ANDA because the FDA has already determined the safety and effectiveness of the brand-name drug, which the generic version has been modeled after.

Labeling. Under 21 U.S.C. secs. 355(b)(1) and (d), a brand-name manufacturer seeking new drug approval is obligated to prove to the FDA the accuracy and adequacy of its label. However, in sharp distinction to the brand-name manufacturer's responsibility, under 21 C.F.R sec. 314.94(a)(8), a generic drug manufacturer seeking approval for its drug is only responsible for ensuring that its label is identical to the brand-name manufacturers label. Additionally, 21 C.F.R. sec. 314.80 mandates that brand-name manufacturers take on a continuing obligation to update labels to reflect reports of any serious and unexpected adverse reactions that users experience related to the use of a drug.

Under the FDA's "Changes Being Effected" or "CBE" rule, found at 21 C.F.R. sec. 314.70(c)(6)(iii)(A), a brand-name manufacturer, upon discovering a risk related to its drug, may modify its label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" without FDA approval. Like the initial labels themselves, generic drug manufacturers do not have the freedom to modify unilaterally their drug's labels in response to newly identified safety concerns. In order for a drug generic manufacturer to modify a generic label, the manufacturer must contact the FDA, which will then work with the brand-name manufacturer to develop a new label for both the brand-name and the generic drug.

U.S. Supreme Court precedent. The treatment of labeling and warning requirements was further modified by two United States Supreme Court rulings, *Wyeth v. Levine*, 555 U.S. 555 (2009), and *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), which decided whether certain state-law claims related to warning labels were preempted by federal law. In *Wyeth*, the Supreme Court held that state-law claims against a drug manufacturer were not preempted to the extent that the manufacturer was technically capable of satisfying both federal and more stringent state law labeling requirements. In *PLIVA*, the Court held that state-law claims against generic drug manufacturers were preempted because it would be impossible for a generic drug manufacturer to comply with more stringent labeling requirements than those required by federal law. The Supreme Court reasoned that a generic drug manufacturer has its hands tied when it comes to labeling because the FDA requires that a generic drug label must mirror the brand-name drug label.

Misrepresentation. The Alabama Supreme Court applied the existing legal reality surrounding prescription drugs to the certified question before it. The court was cautious to distinguish the Wyeth analysis from its own. The distinction, in the eyes of the court, was that a products liability action would impose liability on a manufacturer for the way that the product was manufactured, whereas a failure-to-warn or misrepresentation case against a brand-name drug manufacturer looked at the manufacturer's obligations regarding product labels.

The court held that the claims were premised not on the manufacturing process that produced the drug, but on the labeling and warnings associated with the drug. Because brand-name manufacturers, under the FDA's regulatory scheme, retain the authority and obligation of updating their own labels and, in effect, hold control over the generic drug labels, the Alabama high court held that an injured patient who was injured by a generic drug, could succeed in a suit against a brand-name drug manufacturer alleging inadequacies in the brand-name drug manufacturer's labeling and warnings.

Learned intermediary doctrine. To account for the tangential relationship between Weeks and Wyeth, the Alabama Supreme Court looked to the learned intermediary doctrine—"[t]he principle behind the learned-intermediary doctrine is that prescribing physicians act as learned intermediaries between a manufacturer of a drug and the consumer." The theory holds that the physician stands in the best position to evaluate a patient's

needs and is the most qualified to assess the risks and benefits of a particular course of treatment for the patient. The doctrine limits a manufacturer's duty to that of warning the prescribing physician of "any potential dangers that may result from the use of its product." However, if the warnings from the manufacturer to the learned intermediary are inadequate or misrepresent a risk, the manufacturer remains liable for a failure to warn. Under the learned intermediary theory, a plaintiff is obligated to show that but for the misrepresentative or inadequate warnings to the physician, the physician would not have prescribed the drug and the patient would not have been injured.

Prescribing physician. Weeks alleged that his physician would not have prescribed him Reglan, or, more specifically, its generic substitute, if his physician had known about the risks of tardive dyskinesia that sometimes develop from prolonged use of Reglan. In other words, Weeks contended that because Wyeth was the party in charge of warning physicians about risks related to Reglan and metoclopramide, Wyeth owed him a duty to tell his physician about the risk of tardive dyskinesia, even if Weeks never took the brand-name version of the drug.

Authorship. The court agreed with Weeks' position and held that through the learned intermediary doctrine and Wyeth's obligations related to the Reglan warning labels, Wyeth could be held liable on a failure-to-warn claim by a patient who was injured by a generic. The Alabama court on several occasions in its opinion made clear that Wyeth's potential liability stemmed from the fact that it authored the labels that Weeks alleged were inadequate. Because the generic manufacturers were required to copy Wyeth's labels verbatim, the court reasoned, Wyeth was the party responsible for any failures in the adequacy of the warnings. The court pointed to the *PLIVA* case as an example, noting that in that case, the Supreme Court relied on the fact that generic drug manufacturers are prohibited from changing their own labels as a reason to not levy liability on generic drug manufacturers for inadequate labeling under state law. Using that same analysis, the court looked to Wyeth, as the brand-name drug manufacturer and sole author of the labels, to answer for the alleged failure to properly warn Weeks' prescribing physician.

Innovator liability. The majority opinion also made several references to the phrase "innovator liability" and made arguments to distance its holding from something that would fit into that doctrine. The court reasoned that under an "innovator liability" theory, a manufacturer potentially could be liable for injuries that stemmed from any product copied from its own product. The court expressly indicated its holding created no such liability for drug manufacturers. Continually rejecting Wyeth's argument that the case was one about products liability, the court held that Weeks did not claim the product he ingested was defective. Instead, the court reasoned, Weeks challenged only the labeling of Reglan and metoclopramide. The court determined that because of FDA regulation, Wyeth held relevant control over the labeling and was the one responsible for warning Week's physician about risks associated with Reglan and its generic substitute. As such, the court noted that because its holding rested on the unique nature of the generic and brand-name drug labeling paradigm, and not on any defect in manufacturing, its holding was narrow and would not carry over into the realm of lawn mowers or power drills.

Concurrence: In concurrence, Justice Shaw reiterated the "extraordinarily narrow" focus of the court's holding, stating that it applied only within the highly regulated prescription drug industry. Similarly, Justice Shaw said that the case was about foreseeability and duty, and observed that both were present because Wyeth knew patients and prescribing physicians would rely on the Wyeth-authored labels when taking generic versions of Reglan.

Dissents. The first dissent, authored by Chief Justice Moore, criticized the holding on procedural grounds contending that the court should have declined to answer the question because critical facts necessary to reliably answer the certified question were not before the court. Justice Moore reasoned that although a certified question should dispose of an issue when answered, the way the court answered the question left several issues unresolved because the answer was "undeterminative." As a result, according to Justice Moore, the Alabama Supreme Court did not have proper jurisdiction to decide the case.

Justice Parker dissented on different grounds, contending that nothing in federal law or regulation required the court to stray from traditional principles of duty, which would not have imposed liability on a manufacturer for injuries stemming from the use of a drug manufactured by a competitor.

Murdoch dissent. Justice Murdock acknowledged that the court was put in a compromising position because there was no "good outcome" in the case. However, Justice Murdoch opined that the majority upended traditional notions of tort liability and economic reality in the way it answered the question. His dissent criticized the majority for diminishing the role of foreseeability and duty in tort actions.

Justice Murdoch agreed with the majority that, given the FDA regulatory scheme, "a generic version of a brand-name drug will be consumed in reliance upon labeling disseminated by the brand-name manufacturer." However, Justice Murdoch disagreed that such foreseeability alone gave rise to a duty, as the majority had concluded. Relying on several cases decided before *PLIVA*, in which U.S. Supreme Court had held that state law claims against generic drug manufacturers were preempted, Justice Murdoch pointed to numerous cases which supported the position that claims could not be supported against a brand-name drug manufacturer by a consumer who had no relationship to that manufacturer. The dissent reasoned that *PLIVA* did nothing to change that position. All *PLIVA* did, according to Justice Murdoch, was insulate generic drug manufacturers from liability under state law by preempting certain state-law claims. In Justice Murdoch's opinion, the majority took an unsupported additional step to reach a conclusion that *PLIVA* or any other precedent created a new class of liability for brand-name drug manufacturers.

Justice Murdoch also disagreed with the majority's position that, through the learned intermediary doctrine, the patient who consumes a generic drug somehow develops a relationship with the brand-name drug manufacturer through his or her relationship with a physician. Absent "bootstrapping," Justice Murdoch reasoned that the labeling requirements shouldered by brand-name drug manufacturers imposed a duty to make labels safe for the consumers of the brand-name drug and not for anyone else.

Making a slippery slope argument and a reference to "innovator liability," Justice Murdoch's dissent revolved around a warning that the majority opinion threatened traditional tort law by potentially imposing liability on manufacturers who hold no relationship to the injured party.

The case number is 1101397.

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Companies: Wyeth, Inc.; Pfizer, Inc.; and Schwarz Pharma, Inc.

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