Washington Legal Foundation

On the Merits:

WYETH, INC., ET AL.,

Defendants-Appellants,

v.

DANNY WEEKS AND VICKY WEEKS,

Plaintiffs-Appellees.

No. 1101397

Supreme Court of Alabama

January 27, 2012

Question Presented: 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?

Summary of the Case: Mr. Weeks developed a neurological disorder following his prescribed use of a generic form of the drug metoclopramide between 2007 and 2009. Mr. Weeks alleges that his neurological disorder was caused by an undisclosed side-effect of his long-term use of the drug. Although he had never taken a brand-name form of the drug, Mr. Weeks and his wife sued both Wyeth, which had stopped manufacturing and marketing brand-name Reglen in 2001, and Schwarz Pharma, which manufactured and sold Reglen from 2001 to 2008. Mrs. Weeks's claim was for loss of consortium. Mr. Weeks's claim alleged that Wyeth negligently misrepresented the dangers of Reglen, its brand-name version of metoclopramide, both on the drug's label and when Wyeth originally applied to the Food and Drug Administration for approval to market the drug back in 1983. Under a theory of "innovator liability," the plaintiffs seek money damages for Mr. Weeks's neurological disorder and for Mrs. Weeks's loss of consortium from both Wyeth and Schwarz Pharma.

Wyeth and Schwarz Pharma moved to dismiss the suit. The U.S. District Court for the Middle District of Alabama denied the motion but recognized that an unresolved question of state law existed as to whether a brand name drug manufacturer could be liable for failure to warn where the plaintiff took only the generic version of the drug. On Defendants' motion, the court certified the above question. The Alabama Supreme Court has since consented to answer the certified question.

On The Merits:
Judgment for Appellants

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Like the overwhelming majority of courts to consider the issue, we reject plaintiffs' novel proposition that a brand name drug manufacturer can be held liable for injuries that an individual sustains from ingesting a generic manufacturer's competing product. Plaintiffs' theory of "innovator liability" is inconsistent with the most fundamental principles of tort law and would undermine the incentive for brand name companies to make further medical

advances by exposing innovators to potentially limitless liability based on harms caused by their competitors' products.

As an initial matter, Mr. Weeks cannot bring a claim against Wyeth or Schwarz because he has not been injured by their product, which is a basic, threshold requirement of any product liability suit. *See Enoch v. Firestone Tire & Rubber Co.*, 534 So. 2d 266, 270 (Ala. 1988). As in other innovator liability suits, Mr. Weeks attempts to avoid this problem by characterizing his claim against Wyeth and Schwarz as one based on their allegedly negligent misrepresentations about Reglen to regulators and to Mr. Weeks' doctor, who prescribed generic metoclopramide to Mr. Weeks as a result. But we look to the substance of a plaintiff's complaint, rather than its form, to determine whether it qualifies as a product liability suit. *See Pfizer, Inc. v. Farsian*, 682 So. 406, 407 (Ala. 1996).

Mr. Weeks's innovator liability suit against Wyeth and Schwarz is almost identical to a traditional product liability failure-to-warn claim: both allege that the plaintiff suffered physical injury as a result of using a product, which the plaintiff would not have used had the defendant changed its warnings about the risk of injury. The only thing that distinguishes Mr. Weeks's suit from a more typical failure-to-warn products liability claim is the fact that Mr. Weeks was not injured by the defendants' product. But that is the very reason Mr. Weeks's claim against Wyeth and Schwarz should fail, rather than a basis for allowing him to circumvent altogether the limits on product liability claims.

Even on the merits, Mr. Weeks's suit for negligent misrepresentation cannot succeed because the brand-name manufacturers owed no duty to disclose information to individuals who never used their products. In one of the few cases that have recognized a claim for "innovator liability," a California appeals court held that it was appropriate to impose a legal duty of care on brand-name manufacturers toward consumers of generic products because brand-name manufacturers could foresee that a negligent misstatement on the brand-name drug's label could cause injury to consumers of the drug's generic equivalent. *See Conte v. Wyeth, Inc.*, 85 Cal . Rprtr. 3d 299 (Ct. App. 2008). But under Alabama law, the imposition of a legal duty requires more than simply that the injury was foreseeable. *See DiBiasi v. Joe Wheeler Elec. Membership Corp.*, 988 So. 2d 454, 463–64 (Ala. 2008).

Recognizing a legal duty represents a policy judgment that the defendant ought to be responsible to the plaintiff in some fashion, and there is no basis for imposing such a duty here. Alabama law does not impose upon one person a duty to disclose information to another in the absence of some kind of relationship or privity between the parties. *State Farm Fire & Cas. Co. v. Owen*, 729 So. 2d 834, 839 (Ala. 1998). In Mr. Weeks's case, there is no relationship between him and Wyeth or Schwartz. If the law imposed a duty to disclose information to every person who might be injured in the absence of the information, there would be no end to potential liability.

Plaintiffs argue that a duty should be imposed on innovator pharmaceutical companies for injuries caused by a generic manufacturer's product because federal law makes the innovator exclusively responsible for the labeling of both the branded drug and its generic version. But federal law provides no basis for departing from the traditional principles of tort law that bar plaintiffs' claims. Rather, federal statutes and regulations hold generic manufacturers responsible for the safety, efficacy, and adequate labeling of their products. Under federal law, generic manufacturers, like innovator manufacturers, are subject to extensive safety monitoring and reporting requirements. *See, e.g.,* 21 C.F.R. § 314.80, 314.81; 314.98 (extending postmarketing reporting requirements to generic drug manufacturers). When a generic drug manufacturer becomes aware of new safety information that supports a labeling change, the generic drug manufacturer, like the innovator manufacturer, must submit that information to the FDA. *See* 21 C.F.R. § 314.70, 314.71; 314.97 (extending requirements concerning supplemental applications to generic drug manufacturers). The FDA will then determine whether the labeling for the generic drug *and* the branded drug should be revised. Both innovator and generic manufacturers have responsibilities to seek FDA approval for labeling changes for the drugs they market under circumstances defined in FDA regulations. Plaintiffs complain that the Supreme Court's decision in *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), precludes plaintiffs from suing the generic companies that manufactured the drugs that Mr. Weeks ingested, but that is no basis for this Court to make the kind of radical departure from settled principles of tort liability that would be required in order to make a brand name manufacturer liable to an individual who never consumed the brand name product.

Mr. Weeks's theory that the brand-name manufacturers somehow had a duty to disclose warnings to Mr. Weeks's *doctor* fares no better. While a manufacturer can satisfy its duty to warn a patient using its product by warning the

patient's doctor, the manufacturer has no duty to warn the doctor independent of a duty to warn the patient. Wyeth and Schwarz had no duty to warn Mr. Weeks, because he was not using their product, and they therefore had no duty to warn Mr. Weeks' doctor either.

Finally, making brand-name drug manufacturers liable for injuries suffered by consumers of competitors' generic products would be bad public policy. Brand-name manufacturers receive none of the revenue earned on sales of generic drugs. Imposing liability for injuries caused by competitors' products would saddle the drug innovator with potentially large liability at precisely the time the company is losing revenues to generic sales. And, if Mr. Weeks's arguments are accepted, a drug innovator could not limit its liability even by exiting the market altogether, as Wyeth did six years before Mr. Weeks took any form of metoclopramide. Such a result is not only unfair, but contrary to the public policy embodied in the federal drug laws, which strongly encourage drug innovation.

Dissenting View:
Michael L. Murphy
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A recent Supreme Court case, *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), held that state law failure-to-warn claims against generic drug manufacturers were preempted because those manufacturers are required by federal law to use the same safety and efficacy labeling as that approved for the brand name drugs. Because generic drugs are often prescribed interchangeably with brand name drugs, *Pliva* leaves a plaintiff injured after taking a generic drug because of failure to warn with no recourse but a suit against the brand-name defendants who were responsible for the drafting of the drug warning label. Faced with this reality, Weeks and his wife sued the brand name manufacturers, not the generic manufacturer whose drugs he ingested, for common law fraud and failure to warn on the theory that it was their failure to warn doctors of this neurological side effect that led to the doctor proscribing the drug which he ultimately took in generic form.

As of the fall of 2011, expenditures on healthcare-related costs exceed 18% of our country's gross domestic product. In other words, of every dollar that is spent in the United States more than 18 cents goes toward a healthcare-related expense. For the 2010 calendar year, American consumers spent approximately $220 billion on retail prescription drugs filling more than 3.7 billion prescriptions at pharmacies in the United States.[1] That is 12 prescriptions for every person in the United States.

In Alabama, residents filled more than 80 million prescriptions in 2010 which amounts to approximately 16.7 prescriptions per capita, the nation's third highest per capita prescription rate, at a cost of almost $4.5 billion. Alabama residents 65 and older filled a whopping 39.2 prescriptions per year, the fifth highest rate in the country.

In an effort to reduce healthcare costs, Alabama permit pharmacists to substitute a brand name drug for a "less expensive pharmaceutically and therapeutically equivalent drug product." Ala. Code § 34-23-8. While some statutes require substitutions and others simply permit it, each regime permits the substitution of a general equivalent that costs less unless the doctor expressly requires that the brand-name drug be dispensed. Even after the introduction of generic drugs doctors typically write prescriptions using the moniker of the brand-name drug, *e.g.* Prozac instead of Fluoxetine, because of the familiarity they developed with that terminology during the lengthy exclusivity period when no generic could be introduced. *See*, *e.g.*, Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies, Federal Trade Commission (Aug. 2005), at xi (noting prescriptions marked as "dispense as written" (DAW), which means that the generic drug cannot be substituted, occur between only 5% and 15% of the time). Doctors typically leave it up to the pharmacist to substitute the generic equivalent. Estimates of how frequently generic drugs are substituted range from approximately one-half to two-thirds of all prescriptions written.

Accordingly, when a patient receives a prescription from his or her doctor the odds are good that the patient will receive a generic drug that has been deemed to be the functional equivalent to its brand-name predecessor. So, if a brand-name manufacturer says (or fails to say) something about its drug to the doctors and pharmacists on the front lines, the normal flow of commerce dictates that this misstatement will impact the sale of a bottle of generic drugs.

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[1] These statistics were produced by the Kaiser Family Foundation and are available at www.statehealthfacts.org. Click on the "50 State Comparisons" tab and then on "Health Costs & Budgets." The study cited here was released on August 30, 2011.

The district court considered three arguments raised by Defendants in their motion to dismiss. First, the court rejected an argument that the Weeks' claims were premised on a non-existent duty of the brand name manufacturers to warn the generic-drug taking injured plaintiff. The court explained that the Weeks' theory of liability hinged on the fact that the brand-name defendants failed to warn the prescribing physician about a risk of neurological harm associated with long-term use of the drug at issue. "When framed in this way, the Weeks would not be required to demonstrate that the brand name manufacturers had a duty to warn about [the generic drug]. The Weeks would not even have to demonstrate that the brand name defendants owed a duty to Mr. Weeks himself, only that the brand name defendants owed a duty to the prescribing physician to adequately disclose and warn about the risks associated with [their drug]." *Weeks v. Wyeth*, Mem. Opinion & Order (Mar. 31, 2011) (Dkt. 86), slip op. at 6.

Second, the court held that a requirement of the Alabama Extended Manufacturer's Liability Doctrine, the state's product liability law, that the plaintiff "must be able to prove that the defendant manufactured the injurious product," did not apply to plaintiff's tort-based claims. *Id.* at 9.

Third, the court considered the question of what relationship, if any, was required between the brand name defendants and the plaintiff to sustain these tort claims. Both parties cited cases in support, but the court found that none were on point. Because it was defendant's burden to show plaintiff failed to state a claim, the tie went to the Weeks and the motion to dismiss was denied. *Id.*

Thus, I believe that the district court issued a well-reasoned opinion that is fully supported by Alabama law. If the Alabama Supreme Court finds that a patient harmed by a misleading drug warning for a generic drug cannot sustain a suit against the brand name manufacturer and thereby guts the plaintiffs' case, I fully expect that the vast majority of Alabama citizens who take drugs will unfortunately be left without any remedy for their failure-to-warn harm. Brand-name drug manufacturers will face no private-action liability when their lack of disclosure leads to a generic drug prescription and resultant injury. Ironically, given that the state of Alabama loudly promotes states' rights, the state's many users of generic drugs will be forced to rely entirely on the Food and Drug Administration to ensure drug warning labels provide full disclosure.

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