IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

JOYCE FULLINGTON PLAINTIFF

v. No. 4:10CV00236 JLH

PFIZER, INC.; WYETH, LLC; SCHWARZ PHARMA, INC.; PLIVA, INC.; TEVA PHARMACEUTICALS USA, INC.; ALAVEN PHARMACEUTICAL, LLC; MUTUAL PHARMACEUTICAL COMPANY, INC. DEFENDANTS

OPINION AND ORDER

Plaintiff Joyce Fullington alleges that she was injured by consuming the prescription drug metoclopramide. She asserts causes of action under Arkansas law for strict products liability, negligence, gross negligence, fraudulent misrepresentation, negligent misrepresentation, fraudulent concealment, and breach of the implied warranties of merchantability and fitness for a particular purpose. This Court has jurisdiction pursuant to 28 U.S.C. § 1332. Currently before the Court is a motion for summary judgment filed by Pfizer, Wyeth, Schwarz, and Alaven. Fullington has responded, and the motion is ripe for review. For the following reasons, the defendants' motion for summary judgment is granted.

Metoclopramide is a prescription drug approved by the FDA to treat gastroesophageal reflux disease and diabetic gastroparesis. Metoclopramide is available in both brand name and generic formulations. The brand name of the drug is "Reglan." At different times, Wyeth, Schwarz, and Alaven manufactured and distributed Reglan.[1] Pfizer, the parent company of Wyeth, never manufactured or distributed Reglan.

[1] Wyeth manufactured and distributed Reglan from 1989 through December 2001. Schwarz acquired from Wyeth the rights to Reglan in December 2001 and manufactured and distributed it until 2008. In 2008, Alaven acquired the rights to Reglan from Schwarz, and it currently manufactures the drug.

Before marketing and distributing a brand name drug, a pharmaceutical manufacturer must obtain regulatory approval. The producer, or "innovator," of the drug must submit a New Drug Application. 21 U.S.C, § 355(a)-(i) (2010). After the New Drug Application is approved, the innovator has the exclusive right to market the drug for a certain period of time. Once the exclusivity period has expired, other drug manufacturers may market generic versions of the drug if approval has been obtained under the Food, Drug, and Cosmetic Act. Since the adoption of the Hatch-Watchman Amendments to the Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), a generic manufacturer may choose to submit only an Abbreviated New Drug Application. If this choice is made, then the generic manufacturer no longer has to submit independent evidence of safety or efficacy. Instead, it must establish that the generic drug has the same active ingredients and proposed label as the brand name drug. 21 U.S.C. § 355(j)(2)(A)(ii),(v).

Fullington ingested only generic metoclopramide; she did not ingest any metoclopramide, whether generic or brand name, that was manufactured or distributed by Wyeth, Pfizer, Schwarz, or Alaven (the "Brand Name Defendants"). However, she argues that the Brand Name Defendants are liable for her injuries because they failed adequately to warn consumers of the dangers of using metoclopramide. The Brand Name Defendants contend that they are entitled to judgment as a matter of law because they did not manufacture or distribute the metoclopramide that Fullington consumed.

The issue here has been addressed twice by the Western District of Arkansas. The Honorable Robert T. Dawson has held that:

> A basic requirement of products-liability actions under Arkansas law is product identification, i.e. that the actual product manufactured or distributed by the defendant caused injury to the plaintiff. *See Chavers v. General Motors Corp.*, 349 Ark. 550, 563, 79 S.W.3d 361, 370 (2002) (holding plaintiff could not prevail on products-liability action where there was no proof he used defendant's product). Based on the broad definition of a "product liability action," artful pleading simply

> cannot be used to circumvent this requirement. Thus, in order to prevail on her products-liability claims, Plaintiff must meet her product identification burden. *Jackson v. Anchor Packing Co.*, 994 F.2d 1295, 1303 (8th Cir.1993) ("plaintiffs in Arkansas must introduce sufficient evidence to allow a jury to find that more likely than not their exposure to a particular defendant's product was a substantial factor in producing their injuries"); *Lakeview Country Club, Inc. v. Superior Products*, 325 Ark. 218, 226, 926 S.W.2d 428, 432 (1996) (upholding directed verdict on claims for strict liability, breach of warranty of merchantability, and breach of warranty of fitness for a particular purpose where no connection shown between defendant and product supplier).
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> The undisputed facts of this case demonstrate that Plaintiff did not ingest any metoclopramide, whether generic or name brand, that was either produced or distributed by Wyeth or Schwarz. Accordingly, Plaintiff has stipulated that exposure to the products of Wyeth and Schwarz did not cause her injury, and her "product liability action" must therefore fail. *See National Bank of Commerce of El Dorado, Ark. v. Dow Chemical Co.*, 165 F.3d 602, 606-07 (8th Cir.1999) (holding summary judgment appropriate where plaintiff failed to establish product identification).

Fields v. Wyeth, Inc., 613 F. Supp. 2d 1056, 1060 (W.D. Ark. 2009). Following Judge Dawson, The Honorable Harry F. Barnes has held:

> Although Plaintiff has brought this action under various state law theories for recovery, her claims are still product liability claims. *See* Ark. Code Ann. § 16-116-102(5) (defining "product liability action" to include "all actions brought for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging, or labeling of any product."). The question whether a plaintiff can maintain a products liability action in Arkansas against the name brand manufacture[r] of a prescription drug when the consumer only ingested the generic form of the drug has been answered. In *Fields v. Wyeth, Inc., et al*, Judge Robert Dawson held that as a matter of law such an action can not be maintained in Arkansas. 613 F. Supp. 2d 1056, 1058 (W.D. Ark. 2009). The Court agrees with Judge Dawson's reasoning (and the weight of authority considering this issue) and concludes that under Arkansas law a manufacturer of a brand name prescription drug may not be held liable for injuries arising from the use of another manufacturer's generic equivalent of the drug.

Neal v. Teva Pharm. USA, Inc., No. 09-1027, 2010 WL 2640170, at *2 (W.D. Ark. Jul. 1, 2010) (footnote omitted).

This Court agrees with Judges Dawson and Barnes. A plaintiff in a product liability action must allege that the actual product manufactured or distributed by the defendant caused the injury to the plaintiff. Ark. Code Ann. § 16-116-102(5) (2010) (making clear that causation is a required element of a products liability action); s*ee also Jackson v. Anchor Packing Co.*, 994 F.2d 1295, 1303 (8th Cir. 1993) ("Arkansas has . . . retained the traditional requirement of proximate cause in all tort cases."); *Fields*, 613 F. Supp. 2d at 1061 (finding that because the products of the Brand Name Defendants did not give rise to the plaintiff's injury, causation was lacking); *Chavers v. Gen'l Motors Corp.*, 349 Ark. 550, 563, 79 S.W.3d 361, 370 (2002) (finding that the plaintiff failed on her Arkansas product liability claim because she could not prove that her husband was exposed to a particular asbestos-containing product made by the defendants); *see also Mensing v. Wyeth, Inc.*, 588 F.3d 603, 613 (8th Cir. 2009) (determining that name brand manufacturers cannot be held liable for harm caused by generic manufacturers); *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) (rejecting "the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug"); *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R, 2008 WL 2677048, at *3 (W.D. Ky. June 30, 2008) ("Under Kentucky law, when a person[] suffers an injury caused by the advertising and labeling of a product, it is the company that advertised and labeled the product that is responsible, not the company that advertised and labeled the product's competitors."); *Pustejovsky v. Wyeth, Inc.*, No. 4:07-CV-103-Y, 2008 WL 1314902, at *2 (N.D. Tex. April 3, 2008) ("Texas law precludes imposition of products liability on a defendant who did not manufacture or distribute the product that caused the plaintiff's injuries); *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1354-58 (N.D. Ga. 2008) (finding that, under Georgia law, a defendant could only be held liable if the plaintiff was exposed to its products);

LeBlanc v. Wyeth, Inc., No. 04-0611, 2006 WL 2883030, at *6 (W.D. La. Oct. 5, 2006) (rejecting the plaintiff's argument that brand name manufacturers should be liable for injuries caused by generic versions of their drugs). *But see Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 317-18 (Cal. Ct. App. 2008) (departing from the majority of courts and holding that the originator of a warning may be held liable in a product liability case when the ultimate harm to the plaintiff is foreseeable in light of the circumstances).

Fullington did not ingest and was not injured by an product manufactured by Pfizer, Wyeth, Schwarz, and Alaven, so those defendants are entitled to summary judgment. Fullington's claims against Pfizer, Wyeth, Schwarz, and Alaven are dismissed with prejudice.

IT IS SO ORDERED this 17th day of September, 2010.

J. LEON HOLMES
UNITED STATES DISTRICT JUDGE