IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
PINE BLUFF DIVISION

SHIRLEY J. BELL **PLAINTIFF**

v. **CASE NO. 5:10CV00101 BSM**

PFIZER INC.;
WYETH LLC;
SCHWARZ PHARMA, INC.;
PLIVA USA, INC.; and
ALAVEN PHARMACEUTICAL LLC **DEFENDANTS**

ORDER

Defendants Wyeth LLC ("Wyeth"), Pfizer Inc. ("Pfizer"), Schwarz Pharma, Inc. ("Schwarz"), and Alaven Pharmaceutical LLC ("Alaven") move for summary judgment. [Doc. No 24]. Plaintiff Shirley J. Bell has responded, [Doc. No. 30] and defendants have replied. [Doc. No.32]. For the reasons set forth below, defendants' motion is granted.

I. FACTUAL BACKGROUND

Viewed in the light most favorable to Bell, the nonmoving party, the facts are as follows. Shirley J. Bell is a resident of Monticello, Arkansas. Defendants Pfizer, Wyeth, Schwarz, and Alaven (collectively, the "brand-name defendants") are pharmaceutical companies who developed, manufacture, and market the drug metoclopramide under the brand name Reglan. Separate defendant Pliva USA, Inc. produces generic metoclopramide and does not move for summary judgment with the brand-name defendants. Metoclopramide is a gastrointestinal stimulant, antiemetic, and dopaminergic blocking agent prescribed as short-term therapy for symptomatic gastrointestinal reflux and acute and recurrent diabetic

gastric stasis.

Wyeth and its predecessors-in-interest manufactured and distributed Reglan from approximately 1989 to 2001. In December 2001, Wyeth sold the rights and liabilities associated with Reglan to Schwarz, which manufactured and distributed Reglan until February 2008, when it transferred its rights to Alaven. None of the brand-name defendants reported clinical findings to the FDA showing a strong correlation between the long-term use of metoclopramide and tardive dyskinesia.

In January 2008, Bell was prescribed metoclopramide at a dosage of 10mg to treat her symptoms of abdominal pain and digestive problems. At all times, Bell ingested only the generic form of metoclopramide. On the advice of her doctor, Bell continued to take metoclopramide on a daily basis through December 2008. This advice was based on information published by the brand-name defendants in the Physicians' Desk Reference (PDR). Bell's long-term use of metoclopramide caused her to develop tardive dyskinesia, a permanent neurological disorder involving involuntary and repetitive movements primarily of the head, neck, and face.

In February 2009, the United States Food and Drug Administration (FDA) mandated that a "boxed warning" be affixed on the label of metoclopramide, stating that "chronic treatment . . . can cause tardive dyskinesia, a serious movement disorder that is often irreversible," and that "prolonged treatment (greater than 12 weeks) . . . should be avoided in all but rare cases."

Bell filed this case on April 12, 2010, stating the following causes of action: failure-to-warn; negligence; strict liability; breach of warranty of merchantability; breach of implied warranty of fitness for a particular purpose; misrepresentation, suppression of evidence, and fraud; and gross negligence. On July 14, 2010, the brand-name defendants moved for summary judgment, arguing that, as a matter of law, Bell is precluded from bringing suit against them because she never ingested their product, Reglan; she ingested only generic metoclopramide. They maintain that Arkansas law provides no alternative theory that extends liability beyond the actual manufacturer of the product that caused her injury. Bell counters that the federal regulatory scheme for prescription drug labels imposes an ongoing responsibility on the brand-name defendants to warn doctors and patients of known risks even after metoclopramide began being produced by generic manufacturers. Therefore, Bell suggests that the brand-name defendants are not immune from liability simply because she ingested a generic form of metoclopramide. Bell further argues that summary judgment is improper because the question whether brand-name defendants owed Bell a duty of care is essentially an issue of foreseeability that should be decided by a jury.

II. LEGAL STANDARD

Summary judgment is proper if, after viewing the evidence and drawing all reasonable inferences in the light most favorable to the nonmovant, no genuine issue of material fact exists and the movants are entitled to judgment as a matter of law. *Christoffersen v. Yellow Book U.S.A.*, 536 F.3d 947, 949 (8th Cir. 2008); Fed. R. Civ. P. 56.

A party seeking summary judgment bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the record which it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The moving party is not required to support its motion with affidavits or other similar materials negating the opponent's claim. *Id.*

Once the moving party demonstrates the absence of a genuine and material factual dispute, the nonmoving party may not rest upon the mere allegations or denials of its pleadings, but its response, by affidavits or as otherwise provided in Rule 56, must set forth specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The plain language of Rule 56(c) mandates the entry of summary judgment against a nonmoving party which, after adequate time for discovery, fails to make a showing sufficient to establish the existence of an element essential to its case, and on which that party will bear the burden of proof at trial. *Celotex Corp.*, 477 U.S. at 322. Further, the nonmoving party's allegations must be supported by sufficient probative evidence that would permit a finding in her favor on more than mere speculation, conjecture, or fantasy. *Mann v. Yarnell*, 497 F.3d 822, 825 (8th Cir. 2007).

The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48

(1985). A genuine issue of material fact exists if: (1) there is a dispute of fact; (2) the disputed fact is material to the outcome of the case; and (3) the dispute is genuine. *RSBI Aerospace, Inc. v. Affiliated FM Ins. Co.*, 49 F.3d 399, 401 (8th Cir. 1995). A dispute is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson*, 477 U.S. at 248.

In considering a motion for summary judgment, all reasonable inferences must be drawn in the light most favorable to the nonmoving party. *Holland v. Sam's Club*, 487 F.3d 641, 643 (8th Cir. 2007). The evidence is not weighed, and no credibility determinations are made. *Jenkins v. Winter*, 540 F.3d 742, 750 (8th Cir. 2008).

III. DISCUSSION

The brand-name defendants' motion for summary judgment is granted.

Bell's primary argument is as follows. Federal law forbids the distribution of any drug until it is approved by the FDA. For manufacturers of new drugs, the first step in this process is the filing of a New Drug Application (NDA), which, among other things, sets forth the risks associated with using the drug. Once the NDA is approved, the brand-name manufacturer may exclusively market its drug for a certain period of time. After this time expires, other manufacturers may produce bio-equivalent versions of the drug called "generics." A generic manufacturer, however, need not complete this process from the beginning. Rather, it need only complete an Abbreviated New Drug Application (ANDA), which relies on the representations made by the original NDA sponsor. Because it is almost

inevitable that a successful drug will eventually be produced in generic form, it is foreseeable to a brand-name manufacturer that the warnings set forth in its label will become the basis for a generic manufacturers' label. Thus, upon discovery of a new risk, the brand-name manufacturer has a duty to update its statement of risks not only to patients who ingest its own product, but also to patients who will ingest a generic form of its product.

Of particular importance to this argument is the fact that the Physicians' Desk Reference, which Bell's physician consulted before prescribing metoclopramide to Bell, contains the original warnings disseminated by the name-brand defendants. So, even though Bell's physician did not specify that she take Reglan, his prescription was based on indications for Reglan in the Physicians' Desk Reference.

To counter the brand-name defendants' position that Arkansas law immunizes them from an action by a plaintiff who did not consume their product, Bell argues that the Arkansas Supreme Court favors a flexible and fact-intensive duty analysis over rigid application of bright-line rules.

Although Bell's position was ably and persuasively argued, it is simply not in accord with general principles of Arkansas tort law. Although foreseeability is an important consideration in determining whether an actor owes a duty to another, it is not the end of the duty analysis. Rather, the inquiry turns on reasonableness. Just because a particular harm is foreseeable, does not mean that the law automatically imposes a duty of care. Indeed, "duty" in the law of negligence is "an expression of the sum total of those considerations of policy

which lead the law to say that the plaintiff is entitled to protection." W. Page Keeton, *Prosser and Keeton on Torts* 358 (5th ed. 1984).

Under Arkansas law, Bell's claim is construed as a "product liability action." *See* Ark. Code Ann. § 16-116-102(5) (LEXIS Repl. 2006). Such a claim depends on product identification, i.e., that the plaintiff's injury was caused by a product manufactured or distributed by the defendant. *See Chavers v. General Motors Corp.*, 79 S.W.3d 361, 369-70 (Ark. 2002). Here, it is undisputed that Bell did not ingest a product manufactured by the name-brand defendants. Therefore, the brand-name defendants are not liable under Arkansas law.

It appears that other districts within the Eighth Circuit have adopted a similar view. In *Mensing v. Wyeth, Inc.*, the Eighth Circuit Court of Appeals affirmed the District Court of Minnesota's finding that brand-name manufacturers of metoclopramide had no duty under Minnesota law to a plaintiff who ingested a generic version made by another manufacturer. 588 F.3d 603, 613 (8th Cir. 2009). Despite Bell's arguments to the contrary, Arkansas law does not appear to extend the concept of duty any further than the law of Minnesota.

Further, from a policy standpoint, if Bell's position were adopted, brand-name drug manufactures would essentially become the insurers of the generic manufacturers. Not only would brand-name manufacturers bear all of the up-front costs associated with developing drugs, navigating the regulatory maze to obtain FDA approval, and then marketing those drugs, but they would also serve as the permanent insurers for the generic manufacturers,

who bear none of the up-front costs. Although it is completely appropriate to hold brand-name manufacturers liable for failing to warn a plaintiff who actually buys and uses their products, it would be totally inappropriate to hold brand-name manufacturers liable when the plaintiff bought and used a generic drug produced by the brand-name manufacturers' competitor. Of course, Bell may still proceed against the generic manufacturer who produced the metoclopramide she ingested.

IV. CONCLUSION

For the reasons set forth above, the name-brand defendants' motion for summary judgment [Doc. No. 24] is granted and all claims against Pfizer, Wyeth, Schwarz, and Alaven are dismissed with prejudice.

IT IS SO ORDERED this 16th day of March, 2011.

UNITED STATES DISTRICT JUDGE