UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

ROSEMARY KEFFER,

Plaintiff,

v. Civil Action No. 2:04-0692

WYETH, d/b/a Wyeth, Inc.;
WYETH PHARMACEUTICALS, INC.;
and PHARMACIA & UPJOHN COMPANY,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending is the motion for summary judgment of defendant Pharmacia & Upjohn Company ("Upjohn"), filed March 28, 2011. (Doc. No. 121).[1]

I. Background

This is a pharmaceutical products liability action in which plaintiff Rosemary Keffer alleges that she developed breast cancer as a result of ingesting hormone replacement therapy ("HRT") medications. HRT consists of two medications, estrogen and progestin, which are commonly used in combination to treat

[1] Also pending is the unopposed motion of Upjohn and the Wyeth defendants for a "hearing" on dispositive motions, filed April 20, 2011. (Doc. No. 156). Inasmuch as the court concludes that the parties' briefings adequately present the legal and factual issues discussed herein, it is ORDERED that defendants' motion for a hearing be, and it hereby is, denied to the extent Upjohn seeks a hearing on its motion for summary judgment.

symptoms of menopause. Upjohn manufactured and distributed Provera, a progestin drug. The chemical name for Provera is medroxyprogesterone acetate ("MPA").

In the early 1980s, plaintiff's physician began prescribing HRT drugs to treat her menopausal symptoms. Plaintiff claims that Provera was one of the HRT drugs that her doctor prescribed for her, and that she ingested the drug from October 16, 1991, to approximately November 7, 1999.

After being diagnosed with breast cancer in 1999, plaintiff stopped taking HRT drugs. She thereafter instituted this action on July 7, 2004, invoking the court's diversity jurisdiction. Her complaint asserts claims against defendants for negligence, strict liability (design defect and failure to warn), and breach of implied warranties.

Defendant Upjohn[2] moved for summary judgment on March 28, 2011, asserting that plaintiff has failed to carry her burden of showing that she ingested Provera or any other Upjohn product. Plaintiff responded in opposition to the motion on April 11, 2011, and Upjohn replied on April 27, 2011.

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[2] Although Pfizer also moved for summary judgment, the parties have since stipulated to the dismissal of any claims against Pfizer. (Doc. Nos. 160, 162, 169). The court accordingly dismissed Pfizer from this action by order dated May 12, 2011. (Doc. No. 171).

II. Motion for Summary Judgment

A. Governing Standard

A party is entitled to summary judgment "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Material facts are those necessary to establish the elements of a party's cause of action. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

A genuine issue of material fact exists if, in viewing the record and all reasonable inferences drawn therefrom in a light most favorable to the non-moving party, a reasonable fact-finder could return a verdict for the non-movant. Id. The moving party has the burden of showing -- "that is, pointing out to the district court -- that there is an absence of evidence to support the nonmoving party's case." Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). If the movant satisfies this burden, then the non-movant must set forth specific facts as would be admissible in evidence that demonstrate the existence of a genuine issue of fact for trial. Id. at 322-23. A party is entitled to summary judgment if the record as a whole could not lead a rational trier of fact to find in favor of the non-movant.

Williams v. Griffin, 952 F.2d 820, 823 (4th Cir. 1991).

A court must neither resolve disputed facts nor weigh the evidence, Russell v. Microdyne Corp., 65 F.3d 1229, 1239 (4th Cir. 1995), nor make determinations of credibility. Sosebee v. Murphy, 797 F.2d 179, 182 (4th Cir. 1986). Rather, the party opposing the motion is entitled to have his or her version of the facts accepted as true and, moreover, to have all internal conflicts resolved in his or her favor. Charbonnages de France v. Smith, 597 F.2d 406, 414 (4th Cir. 1979). Inferences that are "drawn from the underlying facts . . . must be viewed in the light most favorable to the party opposing the motion." United States v. Diebold, Inc., 369 U.S. 654, 655 (1962).

B. Product Identification

To succeed in a products liability action, a plaintiff must show that the defendant manufactured the product that injured her. See Foster v. American Home Prods. Corp., 29 F.3d 165, 168 (4th Cir. 1994) (holding that "a plaintiff seeking to recover for an injury by a product [must] demonstrate that the defendant manufactured the product at issue" under Maryland law); Meade v. Parsley, No. 09-388, 2009 WL 3806716, at *3 (S.D. W. Va. Nov. 13, 2009) (following Foster in case applying West Virginia law and concluding that "[b]ecause neither Wyeth nor Schwarz

manufactured the product that injured plaintiffs, there is no proximate cause."). And so, as both parties seem to acknowledge, Upjohn is not a proper party to this action if plaintiff did not ingest any of its drugs.

The only issue before the court is whether plaintiff has offered sufficient evidence to show that she ingested Provera. In support of her claim that she ingested Provera from October 1991 until November 1999, plaintiff relies on her prescribing doctor's medical records and her own deposition testimony. The medical records document six doctor visits -- occurring from October 16, 1991 to July 30, 1998 -- that all note prescriptions to plaintiff for "Provera" in varying doses. (See Pl.'s Opp., Ex. 12, Keffer Medical Records). And plaintiff's deposition testimony indicates that she always received Provera, not a generic substitution, from her pharmacist:

> Q. Do you remember if the amount that you would pay [for the medications] depended on whether you got a generic brand versus a name brand drug?
>
> A. There was never generic.
>
> Q. You never got generic drugs?
>
> A. No.
>
> Q. So with respect to Provera, you always got the name brand Provera drug, correct?
>
> A. Yes.
>
> Q. Did you -- was there a reason for that? . . .

*** * * ***

A. That's what they give me. There was no discussion on generic.

(Pl.'s Opp., Ex. 13, Keffer Dep. at 288).

Upjohn argues that plaintiff has not carried her burden of establishing product identification based upon the following grounds: (1) there are no pharmacy records confirming that she was prescribed Provera and her "sworn Fact Sheet" does not "provide any National Drug Codes" for Provera; (2) her deposition testimony shows that she could not "sufficiently recall" her HRT regimen; and (3) West Virginia law requires pharmacists to fill prescriptions with generic drugs unless the physician specifically notes "Brand Medically Necessary" on the prescription form, and there was no such notation in this case. (Def.'s Mem. at 3-5). For the reasons that follow, the court finds none of these grounds persuasive at this stage.

First, plaintiff explains that there are no pharmacy records confirming her Provera prescriptions because her pharmacies did not maintain such records. (Pl.'s Opp. at 8). Upjohn does not dispute this point. The court is not inclined, in any event, to endorse the broad proposition apparently urged by Upjohn that a plaintiff in a pharmaceutical products liability action must offer pharmacy records to prove that she ingested the

defendant's drugs. Nor does the court consider plaintiff's failure to include the National Drug Codes for Provera in her sworn fact sheet as a reason to grant summary judgment for Upjohn. In the court's view, plaintiff's medical records and deposition testimony are sufficient to raise genuine issues of material fact.

Second, Upjohn attacks the reliability of plaintiff's deposition testimony by pointing out that she thought Provera was the estrogen component of her HRT regimen, when Provera is, in fact, the progestin component. Plaintiff also testified that her Provera prescription strength never changed, that she took the pill every day of the month, and that it was always a "small white pill." Attempting to discredit this testimony, Upjohn notes that plaintiff's medical records show that her progestin prescription strength did change, that she was prescribed the drug only 9 days out of the month, and that the particular pill she claimed to have ingested was peach colored, not white. These arguments are unavailing at the summary judgment stage, however, where the court is not at liberty to make credibility determinations concerning plaintiff's testimony and must resolve internal conflicts in the plaintiff's favor.

Third, Upjohn's invocation of West Virginia's generic substitution statute is not persuasive. That statute generally

requires, subject to certain exceptions, that prescriptions for brand name drugs be substituted for less expensive generic equivalents when economically advantageous to the buyer. See W. Va. Code § 30-5-12b. If, however, the prescribing physician writes "Brand Medically Necessary" on the prescription form, the pharmacist is required to dispense the brand name drug and may not make a generic substitution. Id. § 30-5-12b(b)-(c). Upjohn contends that since plaintiff has offered no evidence showing that her physician wrote "Brand Medically Necessary" on her prescriptions, plaintiff's pharmacists must have filled her prescriptions with generic MPA rather than brand name Provera.

Upjohn essentially reads § 30-5-12b to create a presumption that a pharmacist, who fills a prescription, substituted generic drugs, which a plaintiff may rebut by showing that the physician wrote "Brand Medically Necessary" on the prescription form. However, the statute creates no such presumption and the court declines to recognize one. Upjohn also incorrectly reads § 30-5-12b as allowing a pharmacist to dispense a brand name drug if and only if the physician writes "Brand Medically Necessary" on the prescription. But the statute also grants the pharmacist discretion to dispense a brand name drug instead of a generic substitution if "in the exercise of his or her professional judgment the pharmacist believes that the less

expensive drug is not suitable for the particular patient." W. Va. Code § 30-5-12b(b). Thus, the absence of a notation from plaintiff's physician that brand name Provera was medically necessary does not presumptively establish, as Upjohn suggests, that the pharmacist dispensed generic drugs to plaintiff. Even if it did, plaintiff's deposition testimony still creates an issue of fact as to whether she received Provera from her pharmacist.

The court's conclusion is not affected by the unpublished Minnesota state court decision relied upon by Upjohn, Zandhi v. Wyeth, No. A08-1455, 2009 WL 2151141 (Minn. Ct. App. July 21, 2009). There, in a case applying New York's generic substitution statute, the Minnesota Court of Appeals upheld the trial court's decision to grant summary judgment to three defendants (who were HRT drug manufacturers) on the grounds that the plaintiff failed to show that she had ingested their drugs. In so holding, the court noted the following relevant factors: (1) generic versions of MPA were available on the market during the time she took HRT drugs; (2) the physicians who made "Provera" notations in the plaintiff's medical records testified that this word was intended to refer to the generic drug, MPA; (3) New York's generic substitution law generally required pharmacies to fill prescriptions with the generic drug unless the

prescription slip was marked "d.a.w." ("dispense as written"), and plaintiff's prescription slips did not say "d.a.w."; and (4) although the New York law had an exception allowing the pharmacist to dispense a brand name drug (even without a "d.a.w." notation) if the generic drug was unavailable and the pharmacist sold it at the generic drug's price, the mere existence of this exception only allowed for "speculation" that the plaintiff "might have sometimes received Provera." Id. at *4. The court ultimately concluded that the plaintiff failed to present admissible evidence showing that she had received and ingested drugs manufactured by the defendants. Id.

This case is distinguishable from Zandi. Unlike the plaintiff in Zandi, the plaintiff here explicitly testified that she received "Provera" only and that she never received generic drugs. (Pl.'s Opp., Ex. 13, Keffer Dep. at 288). There is also no testimony from the prescribing physician in this case that the "Provera" notations in plaintiff's medical records actually referred to the generic form of the drug. And the West Virginia generic substitution statute is, apart from its overall objectives, not entirely comparable to the New York statute. Among other differences, the West Virginia statute grants the pharmacist some discretion in making generic substitution decisions, whereas the New York statute appears to place greater

restrictions on a pharmacist's ability to dispense brand name drugs. Compare W. Va. Code § 30-5-12b(b) (generally requiring that prescriptions be filled generically but permitting pharmacist to dispense brand name drugs if he believes the generic version is unsuitable for the patient); with N.Y. Educ. Law § 6810(6)(a) (generally requiring that prescriptions be filled generically and only allowing pharmacist to unilaterally decide to dispense brand name drugs when the generic drug is unavailable and other conditions are met).

III. Conclusion

In sum, viewing the record in the light most favorable to the plaintiff, genuine issues of material fact persist as to whether plaintiff ingested Provera. The court accordingly ORDERS that Upjohn's motion for summary judgment be, and it hereby is, denied.

The Clerk is directed to forward copies of this written opinion and order to all counsel of record.

DATED: May 13, 2011

John T. Copenhaver, Jr.
United States District Judge