UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

CAROLYN MICHAEL,

Plaintiff,

v. Civil Action No. 2:04-0435

WYETH, LLC, and
PHARMACIA & UPJOHN COMPANY
(n/k/a PHARMACIA & UPJOHN
COMPANY LLC),

Defendants.

MEMORANDUM OPINION AND ORDER

Pending is the motion for summary judgment of defendant Pharmacia & Upjohn Company ("Upjohn"),[1] filed March 28, 2011.

I. Background

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

[1] Although the motion was originally filed by former defendant Pfizer Inc., the parties have since agreed that Upjohn should be substituted in this action in place of Pfizer. Pfizer was accordingly dismissed by agreed order dated May 12, 2011, and Upjohn was added as a defendant by way of plaintiff's fourth amended complaint, filed May 18, 2011.

Provera, a progestin drug. The chemical name for Provera is medroxyprogesterone acetate ("MPA").

In 1994, 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 1994 to 1996.

After being diagnosed with breast cancer in November 2001, plaintiff stopped taking HRT drugs. She thereafter instituted this action on May 6, 2004, invoking the court's diversity jurisdiction.[2] Her complaint asserts claims against defendants for negligence, strict liability (design defect and failure to warn), and breach of warranty (express and implied).

Defendant Upjohn has moved for summary judgment, asserting that plaintiff has failed to carry her burden of showing that she ingested Provera or any other Upjohn product.

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[2] The case was transferred to multidistrict litigation in the United States District Court for the Eastern District of Arkansas on July 26, 2004. Over five years later, on April 13, 2010, it was remanded to this court for the completion of discovery, pretrial activity, and trial.

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) (applying Maryland law and holding that "a plaintiff seeking to recover for an injury by a product [must] demonstrate that the defendant manufactured the product at issue"); 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 1994 to 1996, plaintiff relies primarily on her prescribing doctors' medical records. Those records document three doctor visits -- occurring from January 17, 1995 to July 11, 1996 -- that all note prescriptions to plaintiff for "Provera" in varying doses. (See Pl.'s Opp., Ex. 12, Michael Medical Records). There is also deposition testimony in the evidentiary record from plaintiff's physicians, Dr. Alexander Wanger and Dr. Jane Park, confirming prescriptions to plaintiff for "Provera." (Doc. No. 134, Ex. 4, Dr. Wanger Dep. at 94; Ex. 5, Dr. Park Dep. at 40).

Upjohn argues that plaintiff has not carried her burden of establishing product identification based upon the following grounds: (1) the "Provera" notations in plaintiff's medical records do not constitute evidence that her pharmacist filled prescriptions with brand name Provera; (2) plaintiff's deposition testimony shows both that she received a generic form of Provera and 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 shown in this case. (Def.'s Mem. at 19-20; Def.'s Reply at 3-5). For the reasons that follow, the court finds none of these grounds persuasive at this stage.

First, Upjohn cites no authority in support of its contention that plaintiff cannot rely on notations of "Provera" in her medical records as circumstantial evidence that she ingested the drug. Rather, it maintains that a notation for "Provera" should be looked at no differently than a reference to "Kleenex" or "Xerox," inasmuch as it is merely a shorthand reference for a product that comes both in generic and brand name forms, but that is often identified by a more popular brand name. While that generally may be the case, there is no evidence in the record showing that the particular "Provera" notations at issue referred to the generic form of the drug. On the contrary, plaintiff's physicians confirmed that they prescribed Provera in their depositions. They were not asked and did not go on to explain whether they actually meant for the pharmacist to dispense a generic form of the drug. In the court's view, plaintiff's medical records and her physicians' testimony give rise to a genuine issue of fact as to whether plaintiff ingested

Provera.

Second, Upjohn argues that plaintiff's testimony shows both that she received a generic form of Provera and that she could not sufficiently recall her HRT regimen. To show that plaintiff received generic drugs, Upjohn cites the following exchange from plaintiff's deposition:

> Q Okay. From 1994 to '98 where did you have your prescriptions filled?
>
> A Probably at Rite Aid.
>
> Q Okay. During that time period do you know if you would receive a generic equivalent of a brand named product? And, for instance, what I'm saying is Provera is the brand-name. Would you receive a generic?
>
> A Yes.
>
> Q You would have -- if the pharmacy filled it for a generic you would have received it and taken the generic form?
>
> A Yes.
>
> Q Okay. Is that still your practice today?
>
> A Yes.

(Pl.'s Opp., Ex. 13, Michael Dep. at 321-22). Upjohn also cites passages suggesting that plaintiff has little recollection of the specific HRT drugs she ingested:

> Q . . . your records indicate that you took Provera and Premarin. Do you have any recollection, independent recollection of that other than by your medical records?

A Yes, it's coming back to me little by little --

*** * * ***

Q Okay. There was actually two pills . . . you took; is that correct?

A I'm not sure.

Q Do you remember taking Provera? Do you remember what the pill looked like?

A No.

Q The color?

A No.

Q The shape?

A No.

Q The size.

A No.

(Def.'s Mot. Summ. J., Ex. 11, Michael Dep. 318-19). Plaintiff further testified that, other than Prempro, she could not recall the names of the HRT medications she ingested. (Pl.'s Opp., Ex. 13, Michael Dep. at 28).

Viewing this testimony in the light most favorable to the plaintiff, the court finds that genuine issues of fact persist. Plaintiff's answer of "Yes" in response to counsel's inartfully phrased double question ("During that time period do you know if you would receive a generic equivalent of a brand named product? And, for instance, what I'm saying is Provera is

the brand-name. Would you receive a generic?") does not appear to be conclusive testimony from plaintiff that she ingested only generic rather than brand name Provera. And the other deposition passages cited above indicate that plaintiff's recollection of her HRT regimen from the 1990s is incomplete at best. Meanwhile, there is sufficient evidence in the form of plaintiff's medical records and her doctors' testimony to create an issue of fact as to her ingestion of Provera.

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 inasmuch as 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. The court notes that none of the prescriptions are in evidence.

Upjohn essentially reads § 30-5-12b to create a presumption that any pharmacist who fills a prescription did so with 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. 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 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, even if it were established that there was no notation on the prescription from plaintiff's physician that brand name Provera was medically necessary, a presumption does not arise, as Upjohn suggests, that the pharmacist dispensed generic drugs to plaintiff.

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.

In contrast to Zandhi, there is no testimony from the prescribing physicians here that the "Provera" notations in plaintiff's medical records actually referred to the generic form

of the drug. Furthermore, 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 23, 2011

John T. Copenhaver, Jr.
United States District Judge