IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

Lydia Sauls, Plaintiff, vs. Wyeth Pharmaceuticals, Inc., a division of former Wyeth, Inc.; Wyeth, LLC; and Pharmacia & Upjohn Company, LLC, Defendants.	)	C.A. No. 9:04-22297-HMH **OPINION & ORDER**

This matter is before the court on Defendants' motion for summary judgment pursuant to Federal Rule of Civil Procedure 56(a). Plaintiff Lydia Sauls ("Sauls") alleges that three prescription hormone replacement therapy medications manufactured by Defendants–Premarin, Prempro, and Provera (collectively hereinafter referred to as "hormone therapy medications")–caused her to develop breast cancer. She claims that the hormone therapy medications she ingested were defective because Defendants failed to adequately warn of the risks of developing breast cancer. However, because Sauls is unable to demonstrate that Defendants' failure to warn was the proximate cause of her injuries, the court grants summary judgment in favor of Defendants.

I. Factual and Procedural Background

For nearly seventy years, hormone therapy medications have been marketed to women for the treatment of menopausal symptoms that manifest when a woman's ovaries naturally stop ovulating, causing a dramatic reduction in the production of estrogen. (Am. Compl. ¶¶ 19, 21.)

Premarin is a hormone therapy medication containing estrogen, and since the mid-1980s, physicians have prescribed Premarin with a progestin, such as Provera, to protect against the risk of endometrial cancer associated with the taking of estrogen alone. (Id. ¶¶ 20, 44; Def. Statement Material Facts Supp. Dispositive & Daubert Mots. (hereinafter referred to as "Def. Statement of Material Facts") 2.) Both Premarin, which is manufactured by Defendant Wyeth, and Provera, which is manufactured by Defendant Upjohn, have been approved by the Food and Drug Administration ("FDA"). (Def. Statement of Material Facts 2.) Prempro is a single pill manufactured by Wyeth that contains both estrogen and progestin and is an alternative to the two-pill combination of Premarin and Provera. (Id.) It was approved by the FDA in December 2004. (Id.)

Sauls alleges that she "ingested the [D]efendants' hormone therapy products, Premarin, Prempro and Provera, from approximately 1998 to 2001." (Am. Compl. ¶ 4.) Dr. J.M. Bennett ("Dr. Bennett"), Sauls' primary care physician, was the only doctor to prescribe hormone therapy medications to Sauls. (Def. Statement of Material Facts 5.) In addition to being a medical doctor, Dr. Bennett was also a licensed pharmacist, and he maintained a pharmacy at the same location as his medical practice. (Id. Ex. 9 (Jones Dep. at 7-8).) Due to health reasons, however, he retired from the practice of medicine in 2006 and died in November 2008. (Id. Ex. 7 (Bennett Obituary at 1).) Most of Sauls' medical and pharmacy records prior to 2001 have been destroyed, and therefore, the precise extent and type of her hormone therapy regimen is unclear. (Id. at 5.) Sauls alleges that she was first prescribed hormone therapy medication by Dr. Bennett following her hysterectomy. (Id. Ex. 18 (Sauls Dep. at 95).) Pharmacy records indicate that Sauls filled prescriptions for Premarin and Provera from January 1998 to

September 1998. (Def. Statement of Material Facts Ex. 11 (Pharmacy Records, generally).) According to a document prepared by Linda Jones, who was employed by Dr. Bennett, Sauls received prescriptions for Prempro from October 1998 until September 2001, when she was diagnosed with invasive cancer of the left breast. (Id. Ex. 14 (Sauls' Medication List, generally).) Sauls' breast cancer was treated with a left breast lumpectomy on October 3, 2001. (Id. Ex. 6 (Sauls' Medical Records at 3).) After undergoing radiation and a five-year course of medication, Sauls has remained cancer free. (Id. at 5.)

On September 21, 2004, Sauls commenced this products liability action, alleging that the hormone therapy medications manufactured by Defendants caused her to develop breast cancer. On October 29, 2004, the United States Judicial Panel on Multidistrict Litigation ordered that this action be transferred to the United States District Court for the Eastern District of Arkansas for consolidated pretrial proceedings. This action was remanded to this court for further proceedings on January 21, 2011. Sauls subsequently filed an amended complaint on July 21, 2011, alleging claims of negligence and strict liability under theories of design defect and failure to warn. On January 3, 2012, Sauls stipulated to the dismissal with prejudice of her design defect claim. Defendants contend they are entitled to summary judgment on Sauls' remaining claims, arguing that she is unable to carry her burden in establishing proximate causation.[1] The parties have fully briefed the issues, and this matter is ripe for consideration.

[1] Proximate causation is an essential element to each of Sauls' theories of liability, Young v. Tide Craft, Inc., 242 S.E.2d 671, 675 (S.C. 1978), and she does not dispute that the issue of causation is dispositive for all of her claims.

II. DISCUSSION OF THE LAW

A. Summary Judgment Standard

Summary judgment is appropriate only "if the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In deciding whether a genuine issue of material fact exists, the evidence of the non-moving party is to be believed and all justifiable inferences must be drawn in his favor. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). However, "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." Id. at 248.

A litigant "cannot create a genuine issue of material fact through mere speculation or the building of one inference upon another." Beale v. Hardy, 769 F.2d 213, 214 (4th Cir. 1985). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, disposition by summary judgment is appropriate." Monahan v. County of Chesterfield, 95 F.3d 1263, 1265 (4th Cir. 1996).

B. Proximate Causation

Under South Carolina law, a "products liability case may be brought under several theories, including negligence, strict liability, and warranty." Rife v. Hitachi Constr. Mach. Co., 609 S.E.2d 565, 568 (S.C. Ct. App. 2005). Regardless of the particular theory under which the plaintiff proceeds, he must establish "(1) that he was injured by the product; (2) that the product, at the time of the accident, was in essentially the same condition as when it left the hands of the defendant; and (3) that the injury occurred because the product was in a defective condition

unreasonably dangerous to the user." Holst v. KCI Konecranes Int'l Corp., 699 S.E.2d 715, 719 (S.C. Ct. App. 2010). Because prescription drugs "often cause unwanted side effects despite the fact they have been carefully designed and properly manufactured," Brooks v. Medtronic, Inc., 750 F.2d 1227, 1230 (4th Cir. 1984), they generally are neither defective nor unreasonably dangerous as long as they are "accompanied by proper directions and warning." Restatement (Second) of Torts § 402A cmt. k (1965).[2] Failure to give an adequate warning, however, "constitutes a 'defect' in the product and renders the manufacturer liable for selling a product in an unreasonably dangerous manner." Brooks, 750 F.2d at 1231.

A prescription drug manufacturer's duty to warn is governed by the learned intermediary doctrine. Odom v. G.D. Searle & Co., 979 F.2d 1001, 1003 (4th Cir. 1992). Pursuant to the learned intermediary doctrine, a manufacturer has a duty to warn only a prescribing physician of the risks associated with a drug, and the physician then acts as a learned intermediary between the manufacturer and the physician's patient. Id. This rule is based upon the principle that a prescribing physician "is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment." Brooks, 750 F.2d at 1231. In addition to showing that the drug manufacturer's warning was inadequate, a plaintiff in a failure to warn case must also establish that the inadequacy of the warning was the proximate cause of the plaintiff's injury. Stanback v. Parke, Davis, & Co., 657 F.2d 642, 645 (4th Cir. 1981). To do

[2] Section 402A of the Restatement (Second) of Torts (1965) was expressly incorporated into the legislative intent of the South Carolina Defective Products Act, S.C. Code Ann. § 15-73-30, and South Carolina courts consistently have relied upon it and its commentary in the development of products liability case law. See, e.g., Madison v. Am. Home Prods. Corp., 595 S.E.2d 493, 496 & n.3 (S.C. 2004); Jackson v. Bermuda Sands, Inc., 677 S.E.2d 612, 615 (S.C. Ct. App. 2009); Wallace v. Owens-Illinois, Inc., 389 S.E.2d 155, 158 (S.C. Ct. App. 1989).

so, the plaintiff must "demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." Odom, 979 F.2d at 1003.

Defendants contend they are entitled to summary judgment because Plaintiff is unable to establish proximate causation. The court agrees. Dr. Bennett is the only physician to have prescribed hormone therapy medication to Sauls, and therefore, Sauls' failure to warn claim can succeed only if she can demonstrate that an adequate warning would have altered Dr. Bennett's prescription decision. Dr. Bennett, however, died four years after the commencement of this law suit, and neither his medical nor pharmaceutical records pertaining to Sauls could be located. Significantly, Sauls failed to preserve any testimony prior to Dr. Bennett's death regarding his knowledge of the risks associated with hormone therapy or whether a different warning would have affected his decision to prescribe hormone therapy medication to Sauls. See Nucor Corp. v. Bell, 251 F.R.D. 191, 194 (D.S.C. 2008) (recognizing that a "party has a duty to preserve evidence during litigation and at any time before the litigation when a party reasonably should know that the evidence may be relevant to anticipated litigation." (internal quotation marks omitted)). Sauls, therefore, is unable to proffer any admissible evidence showing what Dr. Bennett would have done if Defendants' hormone therapy medications were accompanied by a different, purportedly adequate, warning. Numerous courts have concluded that a plaintiff fails to carry her burden in establishing proximate cause in the absence of any evidence demonstrating how an adequate warning would have altered a physician's prescription decision. See, e.g., In re Zyprexa Prods. Liability Lit., Nos. 04-MD-1596 (JBW), 06-CV-2782 (JBW), 2009 WL 3596982, at *11 (E.D.N.Y. Oct. 20, 2009) (unpublished); Adams v. Wyeth,

No. 3452 JAN. TERM 2003, 2005 WL 1528656, at **5-6 (Pa. Ct. Com. Pl. June 13, 2005) (unpublished); Leffler v. Am. Home Prods., No. 3386 JUNE TERM 2003, 2005 WL 2999712, at **4-5 (Pa. Ct. Com. Pl. Oct. 20, 2005) (unpublished).

Sauls acknowledges the lack of any affirmative evidence suggesting that Dr. Bennett would have altered his prescription decision if the hormone therapy medications were accompanied by an adequate warning. Nevertheless, she urges the court to apply a heeding presumption which would shift the burden of proof on causation to Defendants if she were able to demonstrate that Defendants' warnings were deficient. (Pl. Resp. Opp'n Mot. Summ. J. 6-8.) This argument, however, is foreclosed by the Fourth Circuit's decision in Odom, in which the court concluded that South Carolina courts would not apply a causation presumption upon a showing that a prescription drug manufacturer's warning was inadequate. 979 F.2d at 1003. The Fourth Circuit held that "the burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." Id. Sauls suggests that the court should disregard Odom, claiming that it is "at best only a guess at the South Carolina Supreme Court's views on the heeding presumption in pharmaceutical cases." (Pl. Resp. Opp'n Summ. J. 6.) This court, however, is bound by the Fourth Circuit's interpretation of South Carolina law. Wankier v. Crown Equip. Corp., 353 F.3d 862, 866 (10th Cir. 2003) ("[W]hen a panel of this Court has rendered a decision interpreting state law, that interpretation is binding on district courts within this circuit . . . unless an intervening decision of the state's highest court has resolved the issue.") Sauls has not presented, and the court is unable to locate, any subsequent

South Carolina precedent that casts doubt upon the Fourth Circuit's conclusion in Odom. Bound by Odom, the court declines to apply a heeding presumption.

Sauls alternatively argues that she can establish proximate causation by relying exclusively upon expert testimony of how a reasonable physician would have responded if the hormone therapy medications were accompanied by an adequate warning. (Pl. Resp. Opp'n Summ. J. 1, 8-9.) In support of this contention, Sauls cites to a case from the United States Court of Appeals for the Fifth Circuit, in which the court interpreted Mississippi law and explained that a plaintiff may establish causation in a failure to warn case by producing "either objective evidence of how a reasonable physician would have responded to an adequate warning, or subjective evidence of how a treating physician would have responded." Thomas v. Hoffman-La-Roche, Inc., 949 F.2d 806, 812 (5th Cir. 1992) (internal footnote omitted). No other jurisdiction that adheres to the learned intermediary doctrine has followed the approach taken by the Fifth Circuit. See Schilf v. Eli Lilly & Co., No. CIV 07-4015, 2010 WL 4024922, at *4 n.3 (D.S.D. Oct. 13, 2010) (unpublished) ("It appears that only the Fifth Circuit has indicated that a plaintiff in some circumstances might be allowed to supplement the treating physician's testimony with objective evidence of how a reasonable physician would have responded to an adequate warning."). When interpreting South Carolina substantive law, the Fourth Circuit, moreover, has tailored its focus to the prescribing physician when applying the learned intermediary doctrine. Odom, 979 F.2d at 1003 ("The sole issue . . . is whether an adequate warning to [the plaintiff's] doctor about the risk of sterility would have deterred him from prescribing the IUD."); Brooks, 750 F.2d at 1232 ("It is the physician's duty to remain abreast of product characteristics and, exercising an informed professional judgment, decide

which facts should be told to the patient. Once adequate warnings are given to the physician, the choice of treatment and the duty to disclose properly fall on the doctor."). Absent any indication from a South Carolina court that it would permit a plaintiff to rely upon objective evidence to establish causation, the court declines to adopt the minority position here.

Sauls finally contends that proximate causation can be proven by relying upon her own testimony as well as the testimony of two of her oncologists who averred they no longer recommend hormone therapy medication to their patients because of its alleged carcinogenic effects.[3] (Pl. Resp. Opp'n Summ. J. 1-6.) Such evidence, however, cannot establish proximate causation. It is undisputed that only Dr. Bennett prescribed hormone therapy medication to Sauls. As explained above, to state a prima facie case for a failure to warn claim, the burden rests with Sauls to prove proximate causation by demonstrating that an adequate warning would have altered Dr. Bennett's prescription decision. Sauls has failed to proffer any evidence that could establish proximate causation.

[3] Sauls relatedly argues that this testimony raises a credibility issue sufficient to preclude summary judgment. (Pl. Resp. Opp'n Summ. J. 3-6.) The court rejects this argument. As one court has explained, "[w]ithout *some* evidence that [the prescribing doctor] would have changed his prescribing habits, there can be no issue to present to the jury." Adams, 2005 WL 1528656, at *5.

It is therefore

ORDERED that Defendants' motion for summary judgment, docket number 80, is granted. It is further

ORDERED that Defendants' pending motions in limine, docket numbers 81, 82, 83, 85, and 87, are denied as moot. It is further

ORDERED that the parties' joint motion for a trial date certain, docket number 115, is denied as moot.

IT IS SO ORDERED.

s/Henry M. Herlong, Jr.
Senior United States District Judge

Greenville, South Carolina
March 7, 2012