833 F.Supp.2d 775
United States District Court,
N.D. Ohio,
Western Division.

Ashante LEGARD, et al., Plaintiffs,
v.
ORTHO–McNEIL PHARMACEUTICAL, INC., et al., Defendant.

Case No. 1:08 oe 40197.
|
June 24, 2011.

Synopsis
Background: Patient who had been prescribed birth control patch brought state-court products liability action against manufacturer of patch and others, asserting failure to warn claims arising out of development of deep vein thrombosis (DVT) in her left calf vein. Following removal, defendants moved for summary judgment.

Holdings: The District Court, Katz, J., held that:

[1] manufacturer adequately warned prescribing physician of increased risk of blood clots associated with use of hormonal contraceptives, as required to discharge its duty to consumer under learned intermediary doctrine, and

[2] patient failed to demonstrate that manufacturer's alleged failure to warn prescribing physician of increased risk of blood clots associated with use of hormonal contraceptives was cause-in-fact and proximate cause of her development of DVT.

Motion granted.

Attorneys and Law Firms

***776** Heidi M. Vessel, Zachary, LA, for Plaintiffs.

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MEMORANDUM OPINION

KATZ, District Judge.

I. BACKGROUND

In May 2002, Ashante Legard, a Louisiana resident, was prescribed the Ortho Evra® birth control patch by Dr. Kirk Rousset. Ms. Legard used the patch until May 10, 2006, when she contacted Dr. Rousset's office to complain of pain in her left leg for approximately three months. Upon Dr. Rousset's advice, Ms. Legard immediately discontinued use of the patch

The next day, Ms. Legard, a nursing student, went to the Southern University Student Health Services Clinic complaining of pain in her left calf and reported she had been using the patch. The Clinic's medical records confirm Ms. Legard advised the clinic's doctor she "was informed of causing clots and concerned," had been "told to remove the patch," but she still had it on when she presented at the clinic. Def's Exh. B. The clinic referred her for a vascular study of her left calf with the results showing no evidence of a deep vein thrombosis ("DVT"). Ms. Legard did not follow up with her doctor following the vascular study.

In July 2006, Ms. Legard attempted to refill her prescription for the Ortho Evra® patch but Dr. Rousset's office required a follow-up appointment before authorizing a refill. At her appointment the following month, Ms. Legard informed Dr. Rousset of the vascular study and the results but indicated she wanted to continue use of the patch. Dr. Rousset prescribed the patch based upon her negative vascular study but advised her of the risk of clots and the warning signs thereof.

Ms. Legard continued her use of the patch until February 12, 2007, when she presented at the Capital City Family Health Center complaining of pain in her left calf for two days. She was directed to the Earl K. Long Hospital for testing and another vascular study showed a DVT in her

left calf vein. That same day, Ms. Legard was discharged with directions to discontinue use of the patch, take 325 mg aspirin daily, wear a compression hose on her left leg and to keep her leg elevated.

***777** On March 26, 2008, Ms. Legard, joined by her two minor children ("Plaintiffs"), instituted a products liability suit against Ortho–McNeil Pharmaceutical, Inc., Johnson & Johnson Pharmaceutical Research & Development Corporation, LLC, and Johnson & Johnson (collectively referred to as "Defendants") in Louisiana state court. Following removal by the Defendants, the matter was transferred to the undersigned as related to the Ortho Evra litigation by the Judicial Panel on Multidistrict Litigation. *In re Ortho Evra Products Liability Litigation* 1:06 cv 40000, MDL 1742 (N.D.Ohio).

This matter is before the Court on Defendants' unopposed motion for summary judgment filed on December 21, 2010. On February 9, 2011, counsel for Defendants filed a notice of service indicating they served their dispositive motion on Plaintiffs' counsel of record via overnight mail. Under Local Rule 7.1(d), a response was due no later than March 10, 2011. As no response to the motion is forthcoming, the matter is ripe for adjudication. This Court has jurisdiction pursuant to 28 U.S.C. § 1332.

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). The moving party bears the initial responsibility of "informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett,* 477 U.S. 317, 323, 106 S.Ct. 2548, 2553, 91 L.Ed.2d 265 (1986). The movant may meet this burden by demonstrating the absence of evidence supporting one or more essential elements of the non-movant's claim. *Id.* at 323–25, 106 S.Ct. 2548. Once the movant meets this burden, the opposing party "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 250, 106 S.Ct. 2505, 2511, 91 L.Ed.2d 202 (1986) (*quoting* FED. R. CIV. P. 56(e)).

Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient "simply [to] show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 586, 106 S.Ct. 1348, 1356, 89 L.Ed.2d 538 (1986). Rather, Rule 56(e) "requires the nonmoving party to go beyond the pleadings" and present some type of evidentiary material in support of its position. *Celotex,* 477 U.S. at 324, 106 S.Ct. at 2553; *see also Harris v. General Motors Corp.,* 201 F.3d 800, 802 (6th Cir.2000). Summary judgment must be entered "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex,* 477 U.S. at 322, 106 S.Ct. at 2552.

"In considering a motion for summary judgment, the Court must view the facts and draw all reasonable inferences therefrom in a light most favorable to the nonmoving party." *Williams v. Belknap,* 154 F.Supp.2d 1069, 1071 (E.D.Mich.2001) (citing *60 Ivy Street Corp. v. Alexander,* 822 F.2d 1432, 1435 (6th Cir.1987)). However, " 'at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the ***778** matter,' " *Wiley v. U.S.,* 20 F.3d 222, 227 (6th Cir.1994) (quoting *Anderson,* 477 U.S. at 249, 106 S.Ct. 2505); therefore, "[t]he Court is not required or permitted ... to judge the evidence or make findings of fact." *Williams,* 154 F.Supp.2d at 1071. The purpose of summary judgment "is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried." *Abercrombie & Fitch Stores, Inc. v. Am. Eagle Outfitters, Inc.,* 130 F.Supp.2d 928, 930 (S.D.Ohio 1999). Ultimately, this Court must determine "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson,* 477 U.S. at 251–52, 106 S.Ct. 2505; *see also Atchley v. RK Co.,* 224 F.3d 537, 539 (6th Cir.2000).

III. DISCUSSION

Defendants move for summary judgment on Plaintiffs'

failure-to-warn claims based upon application of the learned intermediary doctrine.

[1] Under this doctrine, a manufacturer of a prescription drug discharges their duty to the consumer by providing precautionary information to the prescriber. The rationale for this doctrine was explained as follows:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

[2] *Reyes v. Wyeth Labs.,* 498 F.2d 1264, 1276 (5th Cir.), *cert. denied,* 419 U.S. 1096, 95 S.Ct. 687, 42 L.Ed.2d 688 (1974). Louisiana has adopted the learned intermediary doctrine noting that where "[t]he doctor acts as an informed intermediary, [ ] the decision to use the drug in a particular circumstance rests with the doctor and the patient, not the manufacturer." *Mikell v. Hoffman–LaRoche, Inc.,* 649 So.2d 75, 80 (La.App.1994) (citations omitted).

[3] Where the doctrine is applicable, a plaintiff must demonstrate the following:

> First, the plaintiff must show that the defendant failed to warn (or adequately warned) the physician of a risk associated with the product that was not otherwise known to the physician. *Willett v. Baxter Int'l Inc.,* 929 F.2d 1094, 1098 (5th Cir.1991). Second, the plaintiff must show that this failure to warn was both a cause in fact and the proximate cause of the plaintiff's injury.

Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254, 265–66 (5th Cir.2002), *cert. denied,* 537 U.S. 824, 123 S.Ct. 111, 154 L.Ed.2d 34 (2002).

[4] To establish a failure-to-warn claim under Louisiana law[1] a plaintiff must demonstrate ***779** (1) that the defendant failed to warn the physician of a risk associated with the use of the product, not otherwise known to the physician; and (2) that the failure to warn the physician was both a cause-in-fact and the proximate cause of her injury. *Zachary v. Dow Corning Corp.,* 884 F.Supp. 1061, 1065 (M.D.La.1995), citing *Willett v. Baxter Int'l, Inc.,* 929 F.2d 1094, 1098 (5th Cir.1991).

[1] La.Rev.Stat. Ann. § 9:2800.57 UNREASONABLY DANGEROUS BECAUSE OF INADEQUATE WARNING

A. A product is unreasonably dangerous because an inadequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

B. A manufacturer is not required to provide an adequate warning about his product when:

(1) The product is not dangerous to an extent beyond that which would be contemplated by the ordinary user or handler of the product, with the ordinary knowledge common to the community as to the product's characteristics; or

(2) The user or handler of the product already knows or reasonably should be expected to know of the characteristic of the product that may cause damage and the danger of such characteristic.

C. A manufacturer of a product who, after the product has left his control, acquires knowledge of a characteristic of the product that may cause damage and the danger of such characteristic, or who would have acquired such knowledge had he acted as a reasonably prudent manufacturer, is liable for damages caused by his subsequent failure to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.

[5] In support of their motion, Defendants submit deposition testimony of Dr. Rousset and the Ms. Legard. During his deposition, Dr. Rousset acknowledged that he was aware of the potential risks associated with hormonal contraceptives including the 2001 Ortho Evra® insert which warned of "[a]n increased risk of thromboembollic

and thrombotic disease associated with the use of hormonal contraceptives is well established." Def's Exh. F. In considering Ms. Legard's request to be placed on Ortho Evra®, Dr. Rousset stated he took into account the information provided by the manufacturer, the patient's medical history, her physical condition, her health as well as the risks and benefits for the particular patient. Based upon this information, Dr. Rousset agreed to place Ms. Legard on the Ortho Evra® patch in May 2002.

At her deposition, Ms. Legard acknowledged the risks of blood clots based upon her reading of the package insert. At each subsequent visit after prescribing the patch, Dr. Rousset noted Ms. Legard had no complaints and she continued on the patch.

Dr. Rousset acknowledged having received and reading the information regarding the November 2005 and February 2006 Dear Health Care Provider letters which advised physicians that Ortho Evra® exposed women to 60% more estrogen than a 35 mcg birth control pill. After being contacted by Ms. Legard in May 2006 regarding leg pain, Dr. Rousset directed her to discontinue use of the patch until he determined her pain was not the result of a blood clot. In a follow-up visit, in August 2006, which was prompted by Ms. Legard seeking to refill her prescription for the patch, Dr. Rousset agreed to renew her prescription because her vascular study was negative but emphasized the risks:

> So when [the vascular study] became negative, I'm sure we had the discussion about this was negative, that's a good thing, it's probably not a clot but you still have to be aware that you can have that and you need to watch for any signs or symptoms of that. I probably would have been more emphatic with it after having a symptom which turned out to be negative according to the workup.

Rousset Dep., p. 93.

Despite being aware of the risks, Ms. Legard chose to continue using the Ortho Evra® patch. Legard Dep., pp. 180–181.

The evidence presented by Defendants establishes Dr. Rousset's knowledge of the risks associated with use of the patch at the time he prescribed it for Plaintiff in ***780** 2002 and when he renewed her prescription after her 2006 leg pain event. The undisputed evidence also demonstrates Dr. Rousset reminded Ms. Legard of the risks associated with the patch after her May 2006 leg pain event. Therefore, the first prong of the learned intermediary doctrine is satisfied as Ms. Legard has not demonstrated the Defendants failed to warn (or adequately warn) Dr. Rousset of a risk associated with the patch that was not otherwise known to the physician.

[6] Ms. Legard has also failed to demonstrate that the failure to warn was cause-in-fact and proximate cause of her injury. Dr. Rousset's testimony supports the Defendants' position that no additional information regarding the patch would have changed the prescriber's decision to continue use by the Plaintiff after the November 2005 warning. As Ms. Legard was aware of the risks attendant with use of the patch prior to her initial use, in 2002, and after her 2006 leg event, it is undisputed she was aware of the risks associated with the Ortho Evra® patch. As the Plaintiff has failed to establish the second prong under the doctrine, the Defendants are entitled to summary judgment under the learned intermediary doctrine.

IV. CONCLUSION

Plaintiffs have failed to establish their failure-to-warn claims. Based on the undisputed evidence, the Defendants are entitled to summary judgment as a matter of law and the Court will grant Defendants' motion for summary judgment (Doc. No. 19) based upon the learned intermediary doctrine. Plaintiffs' claims are dismissed with prejudice.

IT IS SO ORDERED.

All Citations

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