UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

CHERIE LEDET RHODES, ET AL.	CIVIL ACTION NO. 10-1695
VERSUS	JUDGE S. MAURICE HICKS, JR.
BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL.	MAGISTRATE JUDGE HORNSBY

MEMORANDUM RULING

Before the Court is Bayer Healthcare Pharmaceuticals Inc.'s ("Bayer") Motion for Summary Judgment. See Record Document 31. Bayer filed the motion pursuant to Federal Rule of Civil Procedure 56, seeking dismissal of all of Plaintiffs' claims. Plaintiffs Cherie Ledet Rhodes and Keith Rhodes[1] opposed the motion. See Record Document 36. For the reasons set forth below, Bayer's motion is **GRANTED** and all of Plaintiffs' claims against Bayer are **DISMISSED WITH PREJUDICE**.

I. BACKGROUND[2]

This is a products liability/failure to warn case. Plaintiffs allege that they have suffered damages as a result of Ms. Rhodes' ingestion of the prescription medication Avelox. They contend that Bayer manufactured the Avelox Ms. Rhodes ingested. They further allege that "Avelox was defective and unreasonably dangerous when it left the control of [Bayer] pursuant to the Louisiana Products Liability Act" ("LPLA"). Record Document 1 at ¶ 9. Under the LPLA, Plaintiffs assert that Bayer failed to provide

[1]Cherie Ledet Rhodes and Keith Rhodes are plaintiffs individually and one behalf of their minor child, Amanda Rhodes.

[2]The facts are drawn from the complaint (Record Document 1), Bayer's Statement of Uncontested Material Facts (Record Document 31-3), and Plaintiffs' Statement of Contested Material Facts (Record Document 36-1). Many of the facts set forth in Bayer's Statement of Uncontested Material Facts went undisputed by Plaintiffs. Those facts have, therefore, been incorporated into the instant ruling.

adequate warnings regarding the hazards associated with the use of Avelox and that Avelox was defective and unreasonably dangerous in design and composition. See id. Plaintiffs have also alleged a breach of warranty claim. See id. at ¶¶ 19-22.[3]

In October 2009, Ms. Rhodes saw her treating physician, Dr. John M. Chandler, for problems with her ears. Dr. Chandler concluded that she had sinusitis and prescribed her Omnicef, an oral antibiotic. In early November 2009, Ms. Rhodes returned to Dr. Chandler because her sinus issues had not resolved. Dr. Chandler then prescribed Avelox, a fluoroquinolone antibiotic, to Ms. Rhodes. Ms. Rhodes ingested two Avelox pills over the course of a two-day span on or about November 10, 2009. Plaintiffs allege that, as a result of ingesting these two pills, Ms. Rhodes suffered peripheral neuropathy.

Prior to prescribing Avelox to Ms. Rhodes, Dr. Chandler had prescribed Avelox to other patients. He has been prescribing Avelox since 1999. He believes that all prescription medications have some type of risks associated with them. He does not believe, however, that a medication is unsafe simply because it has a serious side effect listed in the warnings or precautions of the medication's labeling. Since finding out about Ms. Rhodes' alleged reaction to Avelox, Dr. Chandler has continued to prescribe Avelox to his patients. He continues to prescribe Avelox to date.

II. RULE 56 STANDARD

Summary judgment is proper pursuant to Rule 56 of the Federal Rules of Civil

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[3]The statutory mechanisms for establishing that a product is unreasonably dangerous under the LPLA are predicated on principles of strict liability, negligence, or warranty. Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254, 261 (5th Cir. 2002). However, for causes of action arising after the effective date of the LPLA, negligence, strict liability, and breach of express warranty are not available as theories of recovery against a manufacturer, independent from the LPLA. See id.

Procedure when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[4] Quality Infusion Care. Inc. v. Health Care Serv. Corp., 628 F.3d 725, 728 (5th Cir.2010). "Rule 56[(a)] mandates the entry of summary judgment, after adequate time for discovery and upon motion, 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." Patrick v. Ridge, 394 F.3d 311, 315 (5th Cir.2004). If the movant demonstrates the absence of a genuine dispute of material fact, "the nonmovant must go beyond the pleadings and designate specific facts showing that there is a genuine [dispute] for trial." Gen. Universal Sys., Inc. v. Lee, 379 F.3d 131, 141 (5th Cir.2004). Where critical evidence is so weak or tenuous on an essential fact that it could not support a judgment in favor of the nonmovant, then summary judgment should be granted. See Boudreaux v. Swift Transp. Co., 402 F.3d 536, 540 (5th Cir.2005). The Fifth Circuit has cautioned that "conclusory allegations, speculation, and unsubstantiated assertions are inadequate to satisfy" the nonmovant's burden in a motion for summary judgment. Ramsey v. Henderson, 286 F.3d 264, 269 (5th Cir.2002).

The Fifth Circuit has upheld summary judgment in products liability cases, holding that the record evidence was insufficient to create a genuine issue of material fact. See Hebert v. Miles Pharmaceuticals, No. 92-4290, 1994 WL 10184, *3 (E.D.La. Jan. 13, 1994) "Indeed in a products liability case if the claimant fails to come forward with sufficient evidence of either a product defect within the meaning of the law or that such defect

[4] The court notes that amended Rule 56 requires that there be "no genuine **dispute** as to any material fact," but this change does not alter the court's analysis. F.R.C.P. 56(a) and advisory committee's note (emphasis added).

probably caused the damages, then the trial court should enter judgment as a matter of law in favor of the defendants." Id.

III. ANALYSIS

A. Causation Evidence.

Bayer moved for summary judgment on the ground that Plaintiffs have no evidence of causation to present to the jury. This Court previously excluded the causation opinions of Dr. Stephen Hamilton. See Record Documents 41 & 42. Plaintiffs have not proffered any additional expert medical testimony.

In opposing the Motion for Summary Judgment, Plaintiffs point to Dr. Suresh Kumar, a neurologist and a witness listed by Plaintiffs. See Record Document 36-1 at ¶ 16. Plaintiffs contend that Dr. Kumar diagnosed Plaintiff with peripheral neuropathy. See id. First, Plaintiffs do not connect how Dr. Kumar's "diagnosis" establishes causation, that is, how Ms. Rhodes' alleged peripheral neuropathy was caused by Avelox. Additionally, there is nothing in the record to indicate that Plaintiffs designated Dr. Kumar, a treating physician, as a medical expert under Federal Rule of Civil Procedure 26. Rather, it appears he is simply a fact witness. Finally, Dr. Kumar's neurodiagnostic report lists "mild demylinating diffuse peripheral neuropathy in motor and sensory nerves" under the "Impression" heading and further states that such impression "should be correlated clinically." Record Document 36, Exhibit E at 2. At best, Dr. Kumar's medical impression is inconclusive and is subject to clinical corroboration. Plaintiffs have pointed to nothing in the record that provides such corroboration. Therefore, Dr. Kumar's "impression" is not expert evidence on the issue of causation.

The lack of an expert to establish causation is fatal to Plaintiffs' claims. "When a

conclusion regarding medical causation is not one within common knowledge, expert medical testimony is required in a tort action." Johnson v. E.I. DuPont deNemours & Co., Inc., No. 08-628 (La.App. 5 Cir. 1/13/09), 7 So.3d 734, 740. The Johnson court explained that "whether or not plaintiffs suffered injuries as a result of chemical exposure from the Dupont incident is not a determination based on common knowledge, so the plaintiffs were required to present expert medical testimony in order to meet their burden of proving medical causation." Id.

The medical causation issues presented in this case, i.e., whether the ingestion of Avelox caused peripheral neuropathy, is a matter beyond the common knowledge of a lay person; thus, expert evidence is required in order for Plaintiffs' case to survive. See Hebert, 1994 WL 10184 at *2 (E.D.La. Jan. 13, 1994) ("The product at issue . . . is the drug DES that was available by prescription only. The product at issue can hardly be characterized as uncomplicated. Moreover a finding of medical causation is not something a layman can readily grasp or divine without some expert guidance."). Because Dr. Stephen Hamilton's opinion testimony regarding causation has been excluded, Plaintiffs have no expert evidence to establish (1) the conditions from which Ms. Rhodes suffers and (2) the causative link between Avelox and these alleged conditions. "The essential elements of proof in a products liability claim are that: (1) the product was unreasonably dangerous; ***(2) the resulting injury was caused by the defendant manufacturer's product;*** and (3) the condition rendering the product unreasonably dangerous existed at the time the product left the manufacturer's control." Id. (emphasis added). While the method of proof will vary under each distinct theory of liability (i.e., unreasonably dangerous per se; unreasonably dangerous in construction; unreasonably dangerous for failure to

warn; and unreasonably dangerous in design), "recovery under all theories is predicated on proof of the same three essential elements set forth above." Id. As stated above, Plaintiffs have no expert evidence to establish an essential element of their claims, that is, Ms. Rhodes' resulting injury was caused by Bayer's product, Avelox. Plaintiffs' claims must fail and summary judgment in favor of Bayer is appropriate.[5]

B. Failure-to-Warn Claim and the Learned Intermediary Doctrine.

"To successfully maintain a failure-to-warn claim under the LPLA, a plaintiff must demonstrate that the product in question has a potentially damage-causing characteristic and that the manufacturer failed to use reasonable care to provide an adequate warning about this characteristic." Stahl, 283 F.3d at 264. Louisiana uses the "learned intermediary doctrine" in conjunction with products liability claims involving prescription drugs. See id. at 265. "Under this doctrine, a drug manufacturer discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm from a drug." Id. When the learned intermediary doctrine is applicable, courts are to employ a two-part test:

> First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician. Second, the plaintiff must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury.

Id. at 265-266.

Bayer contends that Plaintiffs' failure to warning claim under the LPLA is barred by the learned intermediary doctrine. See Record Document 31-1 at 4. Conversely, Plaintiffs

[5]Upon reviewing the entirety of the summary record, this Court finds that there is a complete absence of proof of medical causation, an essential element of all of Plaintiffs' claims. The absence of any such proof essentially renders any and all factual disputes immaterial.

argue that summary judgment is not appropriate her because the reasonableness of a party's conduct is at issue. See Record Document 36 at 2. Plaintiffs further maintain that Bayer cannot satisfy the Stahl requirements for summary judgment because "Dr. Chandler, the prescribing physician, testified that he had no opinion about whether the warning was adequate." Id.

Here, Bayer has come forward with competent summary judgment evidence that as early as April 2004, Avelox's product label contained the following under its "warnings" section:

> **Peripheral neuropathy:** Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones.

Record Document 31, Exhibit 5 (emphasis in original). Ms. Rhodes allegedly took two Avelox pills in November 2009. Thus, this warning came well before Dr. Chandler prescribed Avelox to Ms. Rhodes.

Bayer also noted that the record contains no affirmative evidence that Ms. Rhodes' treating physician would have changed his decision to prescribe Avelox to Ms. Rhodes had a different warning been given. See Zachary v. Dow Corning Corp., 884 F.Supp. 1061, 1065 (E.D.La. 1995). ("Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician; but for the inadequate warning, the treating physician would not have used or prescribed the product."). Plaintiffs' counsel never asked Dr. Chandler during his deposition whether he would have changed his decision to prescribe Avelox to Ms. Rhodes if an allegedly different warning had been given. In fact, when asked if he had an opinion about whether the current Avelox warning was adequate, Dr. Chandler simply responded

that he could not "answer one way or the other." Record Document 31, Exhibit 2 at 29.

Plaintiffs bear the burden to show that a proper warning would have changed the decision of Dr. Chandler, i.e., that but for the inadequate warning, he would not have used or prescribed Avelox. See Willett v. Baxter, Int'l, Inc., 929 F.2d 1094, 1099 (5th Cir. 1991). As noted by Bayer, "there is an utter lack of evidence with regard to" this issue. Hebert, 1994 WL 10184, *4. Plaintiffs' warning claim is barred by the learned intermediary doctrine and summary judgment in favor of Bayer is appropriate.[6]

IV. CONCLUSION

For the all of the above and foregoing reasons, Bayer's Motion for Summary Judgment is **GRANTED**. All of Plaintiffs' claims are **DISMISSED WITH PREJUDICE**. A judgment consistent with the terms of the instant Memorandum Ruling shall issue herewith.

THUS DONE AND SIGNED, in Shreveport, Louisiana, this 28th day of March, 2013.

S. MAURICE HICKS, JR.
UNITED STATES DISTRICT JUDGE

[6]Having found on the basis of a complete failure of proof regarding essential elements of Plaintiffs' claims that Bayer is entitled to summary judgment, the Court does not address the preemption issue.