UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

ANDREA FRISCHHERTZ, wife of/and BRAD FRISCHERTZ, individually and on behalf of the minor child, E.F.	**CIVIL ACTION**
VERSUS	**NO. 10-2125**
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE	**SECTION "C" (1)**

ORDER AND REASONS[1]

Before the Court are a Motion for Summary Judgment and a Motion to Strike the Affidavit of Dr. Rama Kongara ("Dr. Kongara") filed by Defendant. Rec. Doc. 122; Rec. Doc. 150. Plaintiffs oppose the Motions. Rec. Doc. 139; Rec. Doc. 154. Having considered the memoranda of counsel, the record, and the applicable law, the Court finds that the Motion for Summary Judgment and the Motion to Strike are DENIED for the following reasons.

I. BACKGROUND

The relevant facts in this case are largely undisputed. Plaintiff Andrea Frischhertz (Mrs. Frischhertz) began using Paxil CR on June 27, 2002. Rec. Doc. 122-7 at 3. Paxil CR was then

[1]Jason A. Danowsky, a second-year student at the University of Texas School of Law, assisted in the preparation of this Order & Reasons.

classified a Pregnancy Category "C" drug. Rec. Doc. 122-12 at 3. A drug is labeled Pregnancy Category "C" if "animal reproduction studies have shown an adverse effect on the fetus, if there are no adequate and well-controlled studies in humans, and if the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks." 73 FR 30831-01. She continued to use Paxil CR and other anxiety-reducing medications, such as Xanax and Klonopin, for almost two more years. Rec. Doc. 122-7 at 2; Rec. Doc. 122-6 at 14-15. Xanax and Klonopin were then classified as Pregnancy Category "D" drugs. Rec. Doc 122-6 at 15. A drug is labeled Pregnancy Category "D" if "there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks." 73 FR 30831-01.

On August 13, 2004, Mrs. Frischhertz saw her prescribing doctor, Dr. Kongara, and reported that she was pregnant and had stopped taking her medication. Rec. Doc. 122-6 at 13. There is disagreement as to whether Mrs. Frischhertz continued taking Paxil at this time: Mrs. Frischhertz testified that she received instructions from Dr. Kongara that she could continue taking Paxil and did so. Rec. Doc. 148-1 at 2. Conversely, Dr. Kongara testified that Mrs. Frishhertz had quit her medications at this time. Rec. Doc. 122-6 at 13. It is clear that, at least by December 2, 2004, Mrs. Frischhertz was again taking Paxil. Rec. Doc. 122-10 at 2.

On March 30, 2005, Mrs. Frishhertz gave birth to her son, E.F., who suffered several birth defects. Rec. Doc. 64 at 1. In December 2005, following the request of the FDA, Defendant changed Paxil's pregnancy category to "D." Rec. Doc. 148-7 at 2. Plaintiffs allege that

Defendant withheld data related to Paxil's pregnancy risks. Rec. Doc. 148-7. Plaintiffs allege that Paxil during pregnancy caused birth defects in E.F. and that Mrs. Frischhertz would have not taken Paxil had she been aware of the risks associated with Pregnancy Category "D" drugs. Rec. Doc. 64.

In his deposition, Dr. Kongara was asked "Did you ever discuss fetal risk with [Mrs. Frischhertz] when Paxil was classified as a Schedule C?" Rec. Doc. 122-6 at 19. Dr. Kongara responded "I don't recall exactly. But, in general, I can tell you that we always discuss with the patient the potential risks and benefits." Rec. Doc. 122-6 at 19. In a later affidavit introduced to oppose Defendant's Motion for Summary Judgment, Dr. Kongara made the following statements: "I never discussed fetal risk of Paxil with [Mrs. Frischhertz] because Paxil was Pregnancy Category 'C' when I prescribed it to [Mrs. Frischhertz]," "Now that Paxil is Pregnancy Category 'D', I always discuss fetal risk with a patient when prescribing Paxil," and "Now that Paxil is Pregnancy Category 'D', I spend way more attention to warning the patient when prescribing Paxil." Rec. Doc. 148-5 at 2.

II. SUMMARY JUDGMENT STANDARD

Summary judgment is proper only when the record indicates that there is not a "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. A genuine issue of fact exists if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1996). When considering a motion for summary judgment, this Court "will review the

facts drawing all inferences most favorable to the party opposing the motion." *Reid v. State Farm Mut. Auto Ins. Co .*, 784 F.2d 577, 578 (5th Cir. 1986).

The party moving for summary judgment bears the initial burden of "informing the district court of the basis for its motion, and identifying those portions [of the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. V. Catrett*, 477 U.S. 317, 323 (1986). Once the moving party has met its initial burden, however, "the burden shifts to the non-moving party to produce evidence or designate specific facts showing the existence of a genuine issue for trial." *Engstrom v. First Nat'l Bank of Eagle Lake*, 47 F.3d 1459, 1462 (5th Cir. 1995). In order to satisfy its burden, the non-moving party must put forth competent evidence and cannot rely on unsubstantiated assertions and conclusory allegations. *See Hopper v. Frank*, 16 F.3d 92 (5th Cir. 1994).

Additionally, "[a] nonmovant cannot defeat a summary judgment motion by submitting an affidavit which contradicts, without explanation, the nonmovant's previous testimony in an attempt to manufacture a disputed material fact issue." *Thurman v. Sears, Roebuck & Co.*, 952 F.2d 128 (5th Cir. 1992).

III. LAW AND ANALYSIS

Plaintiffs conceded all their claims are void except for the failure to warn claims under the Louisiana Products Liability Act. Rec. Doc. 148 at 1. This leaves only the questions of whether Dr. Kongara's affidavit should be struck and whether Plaintiff can survive summary judgment with or without Dr. Kongara's affidavit.

A. Motion to Strike

Defendant moves to strike Dr. Kongara's affidavit under *Thurman*. While Dr. Kongara's use of contradictory absolute qualifiers ("always" discussing risks and "never" discussing risks) in his deposition and affidavit may indicate that he did not carefully consider his use of adverbs, he nonetheless provides an explanation as to the apparent contradiction between his deposition and affidavit. In his deposition, he described his discussions with patients "in general," while the subsequent affidavit describes how Dr. Kongara discusses drugs in different pregnancy categories: he explicitly states that he spends "way more attention" when discussing Paxil now that it is category "D" than he would if it were category "C." Thus, the latter will not be struck and will be considered in the Motion for Summary Judgment.

B. Summary Judgment

Plaintiffs may claim damages under the LPLA when an adequate warning about the product has not been provided. La. Rev. Stat. §2800.54. Louisiana applies the "learned intermediary doctrine" to products liability claims involving prescription drugs. *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254, 265 (5th Cir. 2002) . Under the learned intermediary doctrine, a drug manufacturer discharges its duty to consumers by providing an adequate warning to prescribing physicians. *Id*. The two-prong test governing inadequate warning claims under the LPLA requires first that the plaintiff 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. *Id*. at 265-266. 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 266. That is, "the plaintiff must show that but for the inadequate warning, the treating physician

would not have used or prescribed the product." *Ferguson v. Proctor and Gamble Pharmaceuticals*, 353 F.Supp.2d 674, 679 (E.D.La. 2004) (citing *Willet v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1099 (5th Cir. 1991) (pre-LPLA but adopted by LPLA case law).

Plaintiffs argue proximate cause by alleging that Defendant withheld data related to pregnancy risks. Plaintiffs support this allegation with an expert report noting that an internal document, predating Mrs. Frischhertz's pregnancy by over decade, stated that a study in rats "could contraindicate the use of [Paxil] in pregnancy." Rec. Doc. 148-7 at 5. The expert report also notes that "only at the request of the FDA was a secondary study conducted" to investigate the pregnancy risk of Paxil and other drugs. Rec. Doc. 148-7 at 5. The expert concludes that these internal documents indicate that Defendant's "limited release of information [...] might raise . . . concern by regulatory agencies and prescribers." Rec. Doc. 148-7 at 7. A reasonable jury could conclude that Defendant's limited release of information prevented an earlier pregnancy category change in Paxil, which may have then changed Dr. Kongara's prescribing policies. Defendant's memoranda does not contradict the allegation that it suppressed data that may have led to a pregnancy category change; thus, Defendant has not demonstrated "the absence of a genuine issue of material fact" with regard to whether Defendant suppressed such data.

Instead, Defendant argues that, even if the pregnancy category of Paxil was "D," Dr. Kongara still would have prescribed the medication. Defendant notes that, even if Paxil were a Pregnancy Category "D" drug, Dr. Kongara admitted he "could still prescribe the Paxil because it is helping the patient in spite of the side effects." Rec. Doc. 122-6 at 17. However, Dr.

Kongara also stated, "[a]lthough it is my job to counsel the patient on the medication, it is ultimately the patient's decision as to whether or not to take the medication." Rec. Doc. 139-5 at 2. Because Dr. Kongara defers to the patient's assessment of the benefits and risks of the medication, the warnings Dr. Kongara gave and the decision Mrs. Frischhertz made based upon those warnings are pertinent to this Motion.

Regarding Paxil, Dr. Kongara stated, "I never discussed fetal risk of Paxil with [Mrs. Frischhertz] because Paxil was Pregnancy Category "C" when I prescribed it to [Mrs. Frischhertz]," "[n]ow that Paxil is Pregnancy Category 'D', I always discuss fetal risk with a patient when prescribing Paxil," and "[n]ow that Paxil is Pregnancy Category 'D', I spend way more attention to warning the patient when prescribing Paxil." In her own affidavit, Mrs. Frischhertz states, "had Dr. Kongara explained to me that Paxil was in any way associated with increased risks of birth defects, that I would not have chosen to take the medication, even if Dr. Kongara was still willing to prescribe the medication to me." Rec. Doc. 139-1 at 2. Thus, questions of fact remain on at least three issues: 1) whether Defendant suppressed information that would have led to a pregnancy category change in Paxil, 2) whether that pregnancy category change would have led to Dr. Kongara giving different advice to Mrs. Frischhertz, and 3) whether Mrs. Frischhertz would have decided not to take Paxil based upon such different advice by Dr. Kongara. Because questions of fact remain, summary judgment is inappropriate.

IV. CONCLUSION

Accordingly,

IT IS ORDERED that Defendant's Motion for Summary Judgment is DENIED. Rec.

Doc. 122.

IT IS ORDERED that Defendant's Motion to Strike is DENIED. Rec. Doc. 150.

New Orleans, Louisiana, this 19th day of July, 2012.

HELEN G. BERRIGAN
UNITED STATES DISTRICT JUDGE