# IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF MISSISSIPPI EASTERN DIVISION

## ELLA MAY CROSS, et al.

## PLAINTIFFS

VS.

# CASE NO. 1:05-cv-00170-MPM-SAA

# FOREST LABORATORIES

#### DEFENDANT

#### MEMORANDUM OPINION

# BACKGROUND

This cause comes before the court on the defendant's motions for summary judgment based on federal preemption [81] and on state law grounds [83]. The court has reviewed the briefs, exhibits, and relevant law and is prepared to rule.

This is a failure to warn products liability case. The plaintiffs are the family of Leon Cross. The defendant is Forest Laboratories.

Leon Cross was an 81 year-old resident of Kosciusko, Mississippi. Mr. Cross had a history of medical problems including prostate cancer, Type II diabetes, hypertension, chronic anemia, arthritis, and degenerative joint disease of the lumbar spine. Mr. Cross also suffered from chronic abdominal pain with diverticulitis and chronic constipation. In November 2003, Mr. Cross had a colonoscopy, which revealed gastritis and diverticula coli, a possible sign of colon cancer. Between November 2003 and May 2004, after repeated complaints of constipation and abdominal pain, several doctors recommended that Mr. Cross undergo colectomy surgery, but Mr. Cross declined.

In addition to his medical problems, Mr. Cross was also the primary care giver for his late wife Ella Mae, who recently passed away after suffering from Alzheimer's for several years. By 2004, Mrs. Cross was in an advanced stage of Alzheimer's, which rendered her unable to care for or assess Mr. Cross's medical problems. Mrs. Cross was dependent on Mr. Cross for her basic care including administering medications, preparing her food, and other basic needs. Mr. Cross also took care of all the household chores.

Ultimately, on May 20, 2004, Mr. Cross scheduled a colectomy to deal with abdominal pain he had been suffering. The surgery was scheduled for June 4, 2004. In the weeks preceding the surgery, Mr. Cross experienced pre-surgery anxiety and extreme abdominal pain. On May 22, 2004, Mr. Cross's son, Theodore, took Mr. Cross to the emergency room. Mr. Cross saw Dr. Ked Eccles-James, an emergency room physician. Dr. Eccles-James examined and diagnosed him with "anxiety/depression, mood disorder." Dr. Eccles James prescribed him Lexapro, a selective serotonin re-uptake inhibitor (SSRI) manufactured by Forest, to help manage the anxiety. Dr. Ked Eccles-James discharged Mr. Cross with instructions to follow up with his primary care physician the next clinic day and to return to the emergency room should Mr. Cross's symptoms worsen.

On the morning of May 24, Mr. Cross told his wife that he intended to kill himself. Mr. Cross left his home and fatally shot himself in the stomach. A toxicology report revealed the presence of an SSRI in Mr. Cross's blood sample.

In the years before Mr. Cross's suicide, there was discussion in the medical and scientific community about whether SSRIs might be linked to increased violence in patients, and especially an increased risk of suicidality. On March 19, 2004, the Food and Drug Administration advised Forest Laboratories that labeling changes for Forest's SSRIs were warranted, and asked them to submit these changes as changes-being-effected (CBE). On March 22, 2004, the FDA issued a Public Health Advisory asking SSRI manufacturers to include warnings and instructions for "close observation of adult and pediatric patients treated with those

drugs for worsening depression or the emergence of suicidality," especially when beginning drug therapy. On April 19, 2004, Dr. David Paul of the FDA sent an email to Forest approving updated labeling and encouraging Forest to update the labeling "immediately," and authorized it to use the CBE regulation to do so. On April 30, 2004, Forest submitted its proposed label changes but stated it only intended to include the new warning on packages distributed from their facilities around May 31, 2004. These changes were approved on May 20, 2004, two days before Mr. Cross was prescribed Lexapro. The changes were not actually implemented until after Mr. Cross's death.

The Cross family filed suit alleging that Forest had failed to include an adequate warning about the increase of suicidality at the beginning of treatment and the need to monitor the patient during the first few months of drug therapy. Forest has filed a motion for summary judgment based on federal preemption [81] and several state law grounds [83].

#### **STANDARD OF REVIEW**

Summary judgment is appropriate when there is "no genuine issue of material fact and the movant is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(a). The facts and evidence are taken in a light most favorable to the non-moving party. *LeMaire v. La. Dep't of Transp. & Dev.*, 480 F.3d 383, 386 (5th Cir.2007).

A dispute regarding a material fact is "genuine" if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 2510, 91 L. Ed. 2d 202 (1986). Summary judgment is appropriate if "critical evidence is so weak or tenuous on an essential fact that it could not support a judgment in favor of the non-movant." *Armstrong v. City of Dallas*, 997 F.2d 62 (5th Cir.1993). A party opposing a properly supported motion for summary judgment "may not rest upon the mere allegations or denials of his pleading, but ... must set forth specific facts showing that there is a genuine issue for trial." *Anderson*, at 248. If the nonmoving party fails to meet this burden, the motion for summary judgment must be granted.

# I. FEDERAL PREEMPTION

A state law may be federally preempted under the Supremacy Clause, U.S. Const., Art. VI, cl. 2, in three ways. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78, 110 S. Ct. 2270, 2275, 110 L. Ed. 2d 65 (U.S. 1990). The first is express preemption, where Congress explicitly defines to what extent the federal law preempts state law. *Id.* The second is field preemption, where the state law is preempted because it attempts to regulate "conduct in a field that Congress intended the Federal Government to occupy exclusively." *Id.* at 79, 110 S. Ct. at 2275. Last is conflict preemption, where the state law actually conflicts with the federal law. *Id.* This includes cases where it is impossible for a party to comply with both state and federal requirements. *See, e.g., Flordia Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143, 83 S.Ct. 1210, 1217-1218, 10 L.Ed.2d 248 (1963).

The FDA approves a new drug application (NDA) only when it meets certain standards for safety and effectiveness, including proper labeling. 21 C.F.R. § 314.105(c). Generally any changes to the label require the manufacturer to submit a supplemental submission and obtain approval. 21 C.F.R. § 314.70(b). However, manufacturers may make some changes without prior FDA approval under the changes-being-effected (CBE) provision. In 2004 the CBE provision read:

(iii) Changes in the labeling, except for changes to the information required in § 201.57(a) of this chapter (which must be made pursuant to paragraph (b)(2)(v)(C) of this section), to accomplish any of the following:

(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction;

(B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage;
(C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product;
(D) To delete false, misleading, or unsupported indications for use or claims for effectiveness; or
(E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision.

## 21 C.F.R § 314.70(c)(6)(iii)(2004).

In *Wyeth v. Levine*, the Supreme Court directly addressed "whether the FDA's drug labeling judgments preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." 555 U.S. 555, 563, 129 S. Ct. 1187, 1193, 173 L. Ed. 2d 51 (2009) (quotations omitted). The plaintiff in *Levine* had her right forearm amputated as a result of an IV-push injection of Phenergan. *Id.* at 559, S. Ct. at 1191. Wyeth, the drug's manufacture, argued that it was impossible to comply with both a state-law warning cautioning against IV-push injections of the drug and FDA labeling requirements. *Id.* at 568, S. Ct. at 1196.

The Supreme Court, however, held that "when the risk of gangrene from IV-push injection of Phenergan became apparent, Wyeth had a duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval." *Id.* at 571, S. Ct. at 1198. The CBE regulation shows that it is "the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to FDA approval." *Id.* Preemption would apply only if the defendant showed "clear evidence that the FDA would not have approved a change." *Id.* What constitutes clear evidence is not defined, and "lower courts are left to determine what satisfies

this . . . standard in each case." *Dobbs v. Wyeth Pharm.*, 797 F.Supp.2d 1264, 1270 (W.D. Okla. 2011) (quoting *Schilf v. Eli Lilly & Co.*, No. CIV 07–4015, 2010 WL 3909909, at \*4 (D.S.D. Sept. 30, 2010)).

Forest argues that FDA regulations prevented it from implementing a "black box warning" or distributing a Medical Guide. It is correct in that regard. *See* 21 C.F.R. § 201.80(e) (only FDA may require addition of boxed warning to labeling); 21 C.F.R. §208.24 (manufacturer must "obtain FDA approval of the Medication Guide before [it] may be distributed"). Forest also argues that the FDA would have rejected a proposed warning about the link between SSRIs and suicidality in adults because the FDA has not found a clear causal link between the two. But the Crosses do not ask for such a warning. Instead, the Crosses argue that a warning was required to caution physicians and patients about the need for close observation and certain symptoms that were a precursor to suicidality.

Actions by both Forest and the FDA cast serious doubt that the FDA would have denied a change. Indeed, prior to Mr. Cross's suicide, the FDA asked that such a change be made.<sup>1</sup> On March 19, 2004, the FDA requested that Lexapro's label be updated to include the following:

Nevertheless, patients being treated with antidepressants should be observed closely for clinical worsening and sociality, especially at the beginning of a course of drug therapy . . . Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications should be alerted about the need to monitor patients for emergence of agitation, irritability, and other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers.

Dkt. 90, Ex. Y, Correspondence from FDA, at 2. This language was substantially similar to the suggested warning given by the plaintiff's expert. Dkt. 87, Ex. 1, Hamrell Report, at 17. Forest agreed to implement these changes only on packages distributed from the company's facilities on

<sup>&</sup>lt;sup>1</sup> Prior to 2007, the FDA lacked authority to order drug manufacturers to revise their labels based on safety information made available after the drug's initial approval. *See* 121 Stat. 924-926.

or before May 31. Dkt. 90, Ex. AA., Correspondence from Forest to FDA, at 2. Forest forwarded the proposed changes to the FDA, which were approved on May 20, 2004, the same day Mr. Cross was prescribed Lexapro. Dkt. 90, Ex. BB, Correspondence from FDA.

This court cannot say the FDA would have clearly rejected a change they asked to be implemented. There is no clear evidence that the FDA would have requested changes be made on March 19, approved said changes on May 20, but ultimately rejected a CBE implementation of the changes on the dates in between. Nor was the FDA likely to deny a change before March 19 when they were about to request the revision be made. Several other courts have also found these expanded warnings on SSRI labels were not preempted even before the FDA asked the labels be changed. *See Mason v. SmithKline Beecham Corp.*, 596 F.3d 387 (7<sup>th</sup> Cir. 2010); *Koho v. Forest Laboratories, Inc.*, 17 F.Supp.3d 1109 (W.D. Wash. 2014); *Baumgardner v. Wyeth Pharm.*, 2010 WL 3431671 (E.D. Pa. Aug. 31, 2010); *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142 (C.D. Cal. 2010); *Aaron v. Wyeth*, 2010 WL 653984 (W.D. Pa. Feb. 19, 2010). In each of these cases, fellow courts have held that manufacturers did not provide clear evidence the FDA would have rejected the updated labels as early as 2000. *See, e.g., Baumgardner*, 2010 WL 3431671 at \* 1.

"Impossibility pre-emption is a demanding defense." *Wyeth v. Levine*, 555 U.S. at 573, 129 S. Ct. at 1199. The defendant has not shown "clear evidence that the FDA would not have approved a change." *Id.* at 571, S. Ct. at 1198. For the foregoing reasons, the court finds that the Cross's state law claims are not preempted by federal law and as such Forest Laboratories' Motion for Summary Judgment Based on Federal Preemption [81] is DENIED.

## II. STATE LAW CLAIMS

## A. Adequacy of Warning

Under Mississippi law, pharmaceutical manufacturers, like all manufacturers, have a duty to provide products that are defect free. *See* Miss. Code. Ann. § 11-1-63. Because some products

have dangers inherent in their use, manufacturers must provide warnings that are adequate to communicate those dangers and how to safely use the product. *See id.* Miss. Code. Ann. § 11-1-63(a)(1)(2) states that a seller may not be liable unless the claimant proves by preponderance of the evidence that the product contained inadequate warnings and instructions. In prescription drug and medical device cases, an adequate warning is one that "[takes] into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product." Miss. Code. Ann. §11-1-63(c)(ii).

This was a codification of the "learned-intermediary" doctrine that was adopted by the Mississippi Supreme Court in *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688 (Miss. 1988). *Fortenberry* involved a patient who became seriously ill after receiving an influenza vaccination. *Id.* at 689. On appeal, the defendant pharmaceutical company alleged that the plaintiff had failed to prove proximate causation. *Id.* At 690. The Supreme Court agreed. They established that the manufacturer has duty to warn the physician, not the patient. *Id.* at 691. They held where a warning was adequate, no liability would flow to the manufacturer. *Id.* at 692. The Supreme Court viewed this as a break in the "proximate cause" relationship. *Id.* at 691.

The test was two-part: (1) was the warning adequate; and (2) if not, would an adequate warning have changed the prescribing physician's conduct? *Id.* The Supreme Court did not reach the second question, holding that the warning at issue was adequate. *Id.* They noted that "the issue of a warning's adequacy is factual and usually will be resolved by the trier of fact," *Id.* at 692, and that "the adequacy of a warning addressed to the medical community may fall into the category of issues requiring expert testimony." *Id.* 

Even if the warning was inadequate, though, the Supreme Court indicated there was insufficient evidence to find the physician would not have prescribed the medicine. "The record contains no testimony showing that Dr. Moore would not have administered the flu shot if adequate warning had been given." *Id.* at 691. Further, the physician had testified that he stayed up to date on the relevant medical literature and did not think there was a causal connection between the drug and the adverse reaction. *Id.* at 693.

The next major case to deal with Mississippi's doctrine was *Thomas v. Hoffman-LaRoche Inc.*, 949 F.2d 806 (5th Cir. 1992). Thomas began the acne treatment Accutane, and thereafter began suffering disorientation, headaches, and eventually seizures. *Id.* at 808. At trial, she presented evidence that the warning given to prescribing physicians about Accutane was inadequate. *Id.* at 809-10. The district court set aside a verdict in her favor, and on appeal Thomas argued that Mississippi law did not require the plaintiff show that an adequate warning would have changed the prescribing physician's action. *Id.* at 811-13.

The Fifth Circuit rejected the argument, holding that under Mississippi law, "the plaintiff must establish that an adequate warning would have convinced the treating physician not to prescribe the product for the plaintiff." *Id.* at 812. The plaintiff had one of two avenues to present this evidence:

[A] plaintiff may introduce either objective evidence of how a reasonable physician would have responded to an adequate warning, or subjective evidence of how the treating physician would have responded. But, to create a jury question, the evidence introduced must be of sufficient weight to establish, by the preponderance of the evidence, at least some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug.

Id. (citations omitted).

Janssen Pharmaceutical, Inc. v. Bailey, 878 So. 2d 31 (Miss. 2004), concerned multiple

plaintiffs who suffered adverse effects after taking medicine prescribed for gastroesophageal

reflux disease. *Id* at 35. After losing at trial, the pharmaceutical company appealed, challenging the sufficiency of the plaintiffs' causation evidence.

The Mississippi Supreme Court reiterated not only their holding in *Fortenberry* but also the 5th Circuit's holding in *Thomas* that the plaintiff bears the burden of establishing that "an adequate warning would have convinced the treating physician not to prescribe the product for the plaintiff" *Id.* at 58 (citing *Thomas*, 949 F.2d at 811). Additionally, the Court noted the adequacy of the warning was an issue for the jury. *Id.*<sup>2</sup>

In applying these cases, courts have held that ordinarily a drug manufacturer owes a duty to the prescribing physician and not the patient. A plaintiff can overcome this doctrine by showing: (1) the warning was inadequate; and (2) the physician would have altered his conduct if the warning was adequate. For purposes of summary judgment, then, there must be a dispute of material fact as to both the adequacy of the warning and the knowledge and action of the physician. The following analysis begins with the second prong of that test. Taking the evidence in the light most favorable to the non-moving party, there still must be sufficient evidence to show "at least some reasonable likelihood" the warning would have affected the doctor's conduct.

At this point, the court clarifies what is meant by "alter the doctor's conduct." In *Fortenberry, Thomas,* and *Jansseen,* altering the doctor's conduct meant altering the doctor's decision to prescribe the drug. Plaintiffs urge this court to distinguish between preventable and unavoidable risks, and to determine that the risk in this case was preventable. In other words, according to the plaintiffs, an adequate warning would have instructed how to safely use the

<sup>&</sup>lt;sup>2</sup> The plaintiffs' downfall was sufficient evidence of causation – they had presented insufficient evidence such that the jury could find for the plaintiffs, in light the numerous preexisting conditions that were much more likely the cause of the plaintiffs' injuries. *Id.* at 57-61. Ultimately, the Mississippi Supreme Court found that the joinder of the plaintiffs in the action was improper because their claims each had a "unique set of facts and circumstances," and remanded the case to be severed. *Id.* at 63.

product, or avoid a preventable risk. In contrast, in the aforementioned cases, the inadequacy of the warning dealt with unavoidable risks inherent in using the product. Plaintiffs have not provided, and this court has been unable to find, any authority that would extend the meaning of "altering the doctor's conduct" beyond the decision to prescribe or not to prescribe and into the realm of what instructions the doctor gives the patient when prescribing the drug. This court is unable to make an *Erie* prediction that the Mississippi Supreme Court would extend failure-to-warn jurisprudence to the instructions a doctor gives the patient. This court is bound by 5th Circuit precedent on this issue and will follow *Thomas*'s explicit holding that "in a prescription drug failure to warn case, the plaintiff must establish that an adequate warning would have convinced the treating physician not to prescribe the product for the plaintiff." *Thomas*, 949 F.2d at 812 Therefore, plaintiffs must point to specific evidence that creates a genuine issue as to whether an adequate warning would have changed Dr. Eccles-James' decision to prescribe Lexapro to Mr. Cross.

Plaintiffs argue that several pieces of testimony from Dr. Eccles-James, the prescribing physician, create a genuine dispute as to whether an adequate warning would have altered his conduct. First, plaintiffs point out that Dr. Eccles-James testified he generally heeds warnings given by manufacturers. Dkt. 102, Ex. G, Deposition of Dr. Ked Eccles-James, at 70. By itself, this does not prove or disprove that Dr. Eccles-James would have altered his conduct at the time he prescribed Lexapro to Mr. Cross. In fact, Dr. Eccles-James was aware of the debate within the medical community about SSRI-induced suicidality and the need to monitor patients. *Id.* at 23-25, 34-37. Second, Cross notes that Dr. Eccles-James testified if he had been shown data concerning the suicide risk of Lexapro, he would have done further research. *Id.* at 116. The testimony is as follows (questions by plaintiffs' counsel):

Q: Read that –

A: "A third case-control study (Juurlink and others) looked at suicides in elderly depressed patients and the comparison was with SSRI use was over..." – "versus use of other antidepressants. They found nearly five-fold greater risk of suicide in SSRI-treated patients compared to patients receiving other antidepressants but only in the first month of treatment."

Q: Okay. And then you see the odds ratio given to you as 4.8?

A: Mm-hmm.

Q: And then the confidence interval?

A: 1.9 to 12.2

•••

Q: Is that information that you would have liked to have known prior to treating Mr. Cross?

A: If available, yes.

Q: Well, you told me that if you had known about this, you would have done further research.

A: What I'm saying, yes, if available. If I research – I would – it look on to it (sic).

*Id.* at 116. It is important to note that Dr. Eccles-James testified that he would have done further research *if the data were available*, which seems to suggest that these data were not available to Dr. Eccles-James at the time he prescribed Mr. Cross Lexapro. The study that presumably served as the basis for plaintiffs' questions was published in the American Journal of Psychiatry in May 2006, authored by David N. Juurlink and others.<sup>3</sup> This study claimed an odds ratio of 4.8 and a confidence interval of 1.9-12.2. This data was published in 2006 and was not available to Dr. Eccles-James at the time he made the prescription, so the court fails to see how data published in

<sup>&</sup>lt;sup>3</sup> Am. J. Psychiatry, 2006 May; 163(5):813-21; Juurlink DN, Mamdani MM, Kopp A, and Redelmeier DA.; *See* Dkt. #87, Ex. 62.

2006 could have affected Dr. Eccles-James in 2004. Further, even if, in 2004, Dr. Eccles-James had had the data and had done further research, he might have still prescribed Lexapro. There is no affirmative and specific evidence provided by plaintiffs that suggest an adequate warning would have changed Dr. Eccles-James' conduct in a way to prevent Mr. Cross's suicide.

Also of concern to the court, plaintiffs, in their response memorandum, state that Dr. Eccles-James "has, in fact, 'altered' his prescribing practices by heeding the warnings of SSRIinduced suicidality and following the instructions in the FDA-mandated labeling to avoid these risks." Dkt. 101, Plaintiffs' Memo, at 15. Plaintiffs state this without citing the record and this court cannot find where that statement is substantiated. A similar statement is made at page 6 of the response memorandum, but plaintiffs only cite to page 88 of the Dr. Eccles-James deposition transcript. Dkt. 101, Plaintiffs' Memo, at 6. A reading of the transcript at that page provides no support for plaintiffs' interpretation. Because the plaintiffs have failed to support the statement, by affidavit or testimony, that Dr. Eccles-James has in fact altered his prescribing practices, the court will disregard this statement and not consider it as evidence bearing on the summary judgment motion.

Other testimony by Dr. Eccles-James in response to Forest's questions tends to support Forest's position that Dr. Eccles-James would not have changed his conduct had the warning been adequate. At pages 108-109 of the deposition transcript (questions by defense counsel):

Q: Now, Doctor, my question is: If you had that information in your hands in 2004 when you saw Mr. Cross, that placebo studies – clinical studies demonstrated an increased risk for children and adolescents, would that in any way have affected your decision to prescribe Lexapro for Mr. Cross?

## A: I wouldn't think so.

*Id.* at 108-09 (emphasis added). Additionally, near the end of the deposition at page 113 (questions by defense counsel):

Q: Have you seen any information, any documentation, today – do you have any knowledge about this medicine today as we sit here that would have changed your decision to prescribe Lexapro to Mr. Cross when you saw him on May 22nd, 2004?

A: I don't think so.

Q: You do still prescribe Lexapro, correct?

A: Yes. Yes, I do.

Id. at 113 (emphasis added).

Finally, as mentioned earlier, Plaintiffs also argue that an adequate warning, including the need to closely monitor patients, would have changed the instructions Dr. Eccles-James gave Mr. Cross. Even assuming this court adopted plaintiffs' theory of failure to warn, Plaintiffs have failed to point to specific facts that would support their assertion. Plaintiffs have failed to show an adequate warning would have altered Dr. Eccles-James' conduct in any way. Plaintiffs point out that Dr. Eccles-James generally heeds warnings. That he would do so in this case, and that heeding the warning would have changed his behavior, is mere speculation. In fact, the record seems to contradict this assertion.

Dr. Eccles-James testified that he was aware and understood that patients being treated with antidepressants should be observed closely. *Id.* at 34-37. Reading from the updated Lexapro label, Forrest's counsel asked:

Q: ... "Nevertheless, patients being treated with antidepressants should be observed closely for clinical worsening and suicidality, especially when they first begin treatment with a medicine." Was that your understanding or is that your practice in 2004 as well?

A: Yes.

*Id.* at 34. Because Dr. Eccles-James saw Mr. Cross in the emergency department at Monfort Jones Hospital and was not his primary care physician, Dr. Eccles-James did not have an

ongoing relationship with Mr. Cross. So, Dr. Eccles-James instructed Mr. Cross to follow up with his primary care physician the next clinic day, especially if his symptoms got worse. Dr. Eccles-James also gave Mr. Cross an instruction to follow up with his surgeon for pre-surgery counseling. And finally, Mr. Cross signed discharge instructions from the emergency department that stated: "Discharge instructions have been provided and I understand these as explained. If my condition becomes worse, I will come to the emergency room. If my symptoms continue, I will see my family doctor within two days." It is unclear to this court what more Dr. Eccles-James could have done or how his behavior would have changed with an adequate warning.

In sum, plaintiffs have not borne their burden of pointing to specific facts, beyond mere speculation, to support a genuine issue of material fact as to whether an adequate warning would have altered Dr. Eccles-James' decision to prescribe Lexapro, as required by the learned intermediary doctrine. Viewing the facts in the light most favorable to the plaintiff, this court finds a reasonable jury could not find an essential element of plaintiffs' case, that an adequate warning would have altered Dr. Eccles-James' conduct. Therefore, Forest's motion for summary judgment will be GRANTED.

### CONCLUSION

ACCORDINGLY, while the court denies Forest's motion for summary judgment based on federal preemption [81], the court also finds that the plaintiffs have not given sufficient evidence to defeat summary judgment on state law grounds. Therefore, Forest Laboratories' Motion for Summary Judgment Based on State Law Grounds [83] is GRANTED.

A separate judgment will be entered this date, pursuant to Fed. R. Civ. P. 58.

So ordered this the 6<sup>th</sup> day of April, 2015.

# <u>/s/ MICHAEL P. MILLS</u> UNITED STATES DISTRICT JUDGE NORTHERN DISTRICT OF MISSISSIPPI