IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

DANA FIELDS, individually and as Natural Parent of D.F., a minor,	)	
Plaintiff,	)	
v.	)	CASE NO. 2:13-CV-35-WKW
	)	[WO]
ELI LILLY AND COMPANY,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

In this pharmaceutical products liability action, Plaintiff Dana Fields alleges that her use of Prozac® during her pregnancy in the mid-1990s caused her son, D.F., to be born with a congenital heart defect. She brings this action both individually and as the natural parent of D.F., seeking monetary recovery on various state-law claims from the drug's manufacturer, Eli Lilly and Company ("Lilly"). Before the court is Lilly's motion for summary judgment. (Doc. # 90.) Lilly argues that Mrs. Fields cannot establish a genuine dispute of material fact that she took Prozac® during her pregnancy with D.F. or that, under the learned-intermediary doctrine, Lilly's warnings about Prozac®, even if inadequate, were the factual causation of Mrs. Fields's ingesting Prozac®.[1] The parties have fully

[1] There are other pending motions for summary judgment and to exclude expert testimony that are not addressed in this opinion.

briefed the motion and have submitted evidence in support of their opposing positions. (Docs. # 91–92, 99, 100, 102.) After careful consideration of the arguments of counsel, the relevant law, and the submissions of the parties, the court finds that Lilly's motion is due to be denied.

I. JURISDICTION AND VENUE

Subject-matter jurisdiction is proper pursuant to 28 U.S.C. § 1332. Personal jurisdiction and venue are uncontested.

II. STANDARD OF REVIEW

To succeed on summary judgment, the movant must demonstrate "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The court must view the evidence and the inferences from that evidence in the light most favorable to the nonmovant. *Jean-Baptiste v. Gutierrez*, 627 F.3d 816, 820 (11th Cir. 2010).

The party moving for summary judgment "always bears the initial responsibility of informing the district court of the basis for its motion." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). This responsibility includes identifying the portions of the record illustrating the absence of a genuine dispute of material fact. *Id*. Or a movant who does not have a trial burden of production can assert, without citing the record, that the nonmoving party "cannot produce admissible evidence to support" a material fact. Fed. R. Civ. P. 56(c)(1)(B); *see*

also Fed. R. Civ. P. 56 advisory committee's note ("Subdivision (c)(1)(B) recognizes that a party need not always point to specific record materials. . . . [A] party who does not have the trial burden of production may rely on a showing that a party who does have the trial burden cannot produce admissible evidence to carry its burden as to the fact."). If the movant meets its burden, the burden shifts to the nonmoving party to establish – with evidence beyond the pleadings – that a genuine dispute material to each of its claims for relief exists. *Celotex*, 477 U.S. at 324. A genuine dispute of material fact exists when the nonmoving party produces evidence allowing a reasonable fact finder to return a verdict in its favor. *Waddell v. Valley Forge Dental Assocs.*, 276 F.3d 1275, 1279 (11th Cir. 2001). On the other hand, "[i]f the evidence is merely colorable or is not significantly probative, summary judgment may be granted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249–50 (1986).

III. BACKGROUND

On January 29, 1997, Mrs. Fields gave birth to a son, D.F. The birth of a child is generally a time of immense joy, but there was little time for celebration for Mrs. Fields and her husband. Their son, D.F., was born with tetralogy of Fallot and moderate pulmonary valve insufficiency. Mrs. Fields contends that her son's congenital heart defect was caused by her ingestion of the prescription drug Prozac® during the first eight months of her pregnancy. Mrs. Fields brings an

assortment of state-law claims against Lilly for its alleged tortious conduct in connection with its manufacturing and marketing of Prozac®. The facts, viewed in the light most favorable to Mrs. Fields, are as follows.

A. Prozac® and Its Warning Label

This action focuses on Lilly's alleged failure to provide adequate warnings in 1996 about the risks of Prozac® to cause birth defects if used during pregnancy. Prozac® is a well-known, widely prescribed antidepressant medication manufactured by Lilly. Also known by its generic name, fluoxetine, Prozac® is in the class of drugs referred to as selective serotonin reuptake inhibitors, or "SSRIs." The U.S. Food and Drug Administration ("FDA") approved Lilly's marketing of the drug in 1987.

During the time frame that Mrs. Fields took Prozac®, the warning label read:

> Pregnancy – Teratogenic Effects – Pregnancy Category B; Reproduction studies have been performed in rats and rabbits at doses 9 and 11 times the maximum daily human dose (80 mg) respectively and have revealed no evidence of harm to the fetus due to Prozac. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

(Doc. # 100-6, at 11; *see also* Doc. # 99-1, at 24; Doc. # 102, at 5 n.2.)

B. Mrs. Fields's Prozac® Use During Her Pregnancy with D.F.

Beginning in 1987, Mrs. Fields's primary care physician was Jimmy D. Durden, M.D., who practiced in her hometown of Tallassee, Alabama. Dr. Durden served as Mrs. Fields's primary care physician until his death in 2009.

On May 23, 1996, when she was twenty-two years old, Mrs. Fields had an appointment with Dr. Durden. The medical records document that she complained of malaise, fatigue, tiredness, and generally of not "feeling good." Dr. Durden rendered diagnoses of "anemia and malaise."[2] In the plan section of the record, he wrote: "I'm going to go ahead and put her on some Chromagen but I'm going to wait to see her thyroid and chemistry. If they are normal[,] I'm going to start her on some Prozac, one daily." (Doc. # 100-2.) This is the only mention of Prozac® in the medical records produced during discovery. Dr. Durden's records do not include the laboratory test results on Ms. Fields's "thyroid and chemistry" or any notation by Dr. Durden that he prescribed Prozac® to Mrs. Fields at any time after the May 23 appointment.

When deposed, however, Mrs. Fields provided additional information about her May 23 appointment and Prozac® use. She testified that, during this appointment, Dr. Durden recommended Prozac® and gave her a starter blister pack

[2] Mrs. Fields testified that, around this time frame, Dr. Durden knew that she was trying to get pregnant and knew that she had had a miscarriage in 1995, although Mrs. Fields's testimony does not indicate whether she discussed her pregnancy plans with Dr. Durden during the May 23, 1996 appointment. (Pl.'s Dep., at 134, 305–06.)

of Prozac®, as well as a prescription with three refills. (Pl.'s Dep., at 160–64, 220, 225–29 (Doc. # 92-3).) Dr. Durden knew that she was trying to conceive a child but did not inform her that ingestion of Prozac® during pregnancy posed an increased risk of birth defects. (Pl.'s Dep. at 306–07.) Mrs. Fields completed her laboratory tests the same day, but she does not recall learning the results of those tests. She "just assumed" that the tests were normal – in other words that no news was good news – and started taking Prozac® shortly after the May 23 appointment. (Pl.'s Dep., at 220.)

Eleven days later, on June 3, 1996, Mrs. Fields had another appointment with Dr. Durden and reported a positive pregnancy test. (Doc. # 100-2, at 2; Pl.'s Dep., at 222–24.) During that appointment, Dr. Durden did not discuss with her any medications, including her use of Prozac®. (Pl.'s Dep. at 224–25.) Rather, in accordance with his general practice, that same day, Dr. Durden referred Mrs. Fields to Ralph Garrard, M.D., an obstetrician and gynecologist in Montgomery, Alabama, for treatment during her pregnancy with D.F. (Doc. # 100-2, at 2.) Beginning on June 10, 1996, and throughout her pregnancy, Mrs. Fields remained under the care of Dr. Garrard.

Mrs. Fields does not recall whether she told Dr. Garrard that she was taking Prozac®, but she confirms that Dr. Garrard did not prescribe it for her. (Pl.'s Dep., at 210–11, 229, 242–43, 248, 252.) Dr. Garrard likewise has no independent

recollection of Ms. Fields's having informed him that Dr. Durden had prescribed her Prozac®, and the medical records covering Dr. Garrard's treatment of her contain no indication – one way or the other – of Prozac® use by Mrs. Fields.

Additionally, Mrs. Fields had no consultations with Dr. Durden about her Prozac® use during the time that she was under Dr. Garrard's care. (Pl.'s Dep., at 209–111, 226–27, 229.) Nonetheless, although some of the testimony about the dosages and number of prescription refills Dr. Durden prescribed is difficult to follow, Mrs. Fields testified that the starter pack, prescriptions, and refills provided ample Prozac® to last throughout her pregnancy with D.F., and that she continued to use Prozac® until approximately her eighth month of pregnancy. She ceased using Prozac® at that time, not on a physician's advice, but based on her own decision because of nausea she experienced during her third trimester. (*See* Pl.'s Dep., at 165, 201–07, 210, 226–34.)

Mrs. Fields's husband, Scott Fields, also has submitted a declaration. He verifies Mrs. Fields's use of Prozac® from approximately May 1996 to December 1996 and confirms that, during this time frame, he saw the prescription bottles labeled "Prozac®." (Scott Fields's Decl., at 1 (Doc. # 92-13).)

C. <u>The Birth of D.F.</u>

Mrs. Fields delivered her son, D.F., on January 29, 1997. (Pl.'s Dep., at 247.) A congenital heart defect was suspected, and D.F. was airlifted to

Children's Hospital in Birmingham, Alabama. (Pl.'s Dep., at 266.) On January 30, 1997, D.F. was diagnosed with tetralogy of Fallot with moderate pulmonary valve deficiency. D.F. had his first open-heart surgery when he was six weeks old and a second open-heart surgery to repair damaged valves when he was around five years old. He remains under specialized cardiac care and has undergone multiple heart catheterizations and other procedures to monitor and correct his congenital heart defect. (Pl.'s Dep., at 267–69, 280; Pl.'s Suppl. Resp. to Interrog. No. 10 (Doc. # 92-2, at 10).)

It is undisputed that cardiac development occurs during the first trimester of pregnancy. Mrs. Fields's first trimester of pregnancy with D.F. occurred from approximately May 1996 to August 1996, a time period during which Mrs. Fields says she took Prozac®.

D. The Absence of Documentary or Other Physical Evidence of Mrs. Fields's Prozac® Use

As mentioned, there is a stark absence of documentary or other physical evidence of Mrs. Fields's Prozac® use. There are no medical or pharmaceutical records that indicate that Mrs. Fields ever was prescribed Prozac® or provided samples of Prozac® at any time before, during, or after her pregnancy with D.F. There is only a single notation in Dr. Durden's medical chart on May 23, 1996, that indicated he would "start [Ms. Fields] on some Prozac, one daily," if he was

satisfied with the pending laboratory tests as to "her thyroid and chemistry." (Doc. # 100-2.) There also are no pharmaceutical records because, according to Mrs. Fields, the pharmacy in Tallassee where she filled the prescriptions no longer has those records. (Pl.'s Dep., at 15–16, 209.) Furthermore, Mrs. Fields is unable to produce "a written doctor's order or pharmacy record reflecting a prescription for Prozac." (Pl.'s Resp. to Req. for Admis., No. 5 (Doc. # 92-11, at 3).) She also has not produced any bank statement, receipts, or other financial documents reflecting a purchase of Prozac®.

E. <u>This Lawsuit</u>

Mrs. Fields filed this diversity action against Lilly on January 16, 2013, contending that her use of Prozac® during her pregnancy caused her son's congenital heart defect. The dominant theme underlying Mrs. Fields's state-law claims is that, during the time frame that she was pregnant with D.F., Lilly failed to warn adequately of the risks of birth defects associated with the use of Prozac® during pregnancy. The Complaint alleges multiple claims, some of which Mrs. Fields now has decided not to "further pursue." (Doc. # 163-4, at 25 n.65.) The following claims remain: (1) failure to warn under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") (2) negligence; (3) negligent failure to warn; (4) breach of express warranty; (5) fraud; (6) negligent

misrepresentation; (7) negligence *per se*; and (8) unfair and deceptive trade practices. Lilly has filed this summary judgment motion as to these claims.

IV. DISCUSSION

Lilly's summary judgment motion is predicated on two grounds. First, Lilly contends that Mrs. Fields fails to establish a genuine dispute of material fact that she took Prozac® during her pregnancy with D.F. Second, Lilly argues that, under Alabama's learned-intermediary doctrine, Mrs. Fields cannot establish factual causation on her failure-to-warn claims because there is no testimony from the prescribing physician – who died four years prior to the commencement of this suit – that he would not have prescribed Mrs. Fields Prozac® had Lilly warned about an increased risk of birth defects associated with the use of Prozac® during pregnancy.

A. Whether There Is a Genuine Dispute of Material Fact that Mrs. Fields Took Prozac® During Her Pregnancy

Lilly insists that Mrs. Fields's claims cannot survive summary judgment based upon her own self-serving testimony, supported only by the equally self-serving testimony of her husband, that Dr. Durden prescribed her Prozac® and that she took it during her pregnancy with D.F. Lilly argues that Mrs. Fields has no "hard evidence" to support her and her husband's testimony that she took Prozac® during her pregnancy with D.F. (Doc. # 91-1, at 11 (citation and internal quotation

marks omitted).) Lilly highlights the absence of any medical or pharmaceutical records documenting a prescription for Prozac® or of any physical evidence, such as even a leftover pill bottle. Lilly sums up the state of the summary judgment record by emphasizing that, "in all of [Mrs. Fields's] medical records from the last twenty-four years, the only reference to Prozac is Dr. Durden's statement from May 23, 1996[,] that he was 'going to wait' for some test results before he determined whether or not to prescribe Prozac." (Doc. # 91-1, at 13.) Based upon the lack of physical evidence, Lilly argues that the self-serving testimony offered by Mrs. Fields and her husband is insufficient to raise a genuine dispute of material fact on an essential element of her causes of action, namely, "proof of use of the product at issue." (Doc. # 91-1, at 14.) Mrs. Fields contends, on the other hand, that the fact that her and her husband's testimony is self-serving does not disqualify its consideration on summary judgment. The law supports Mrs. Fields's position.

The summary judgment process is not about judging credibility or weighing the evidence, or even about the certainty of the evidence. The inquiry on summary judgment is "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. Evidence is not so one-sided merely because it is self-serving. As the Eleventh Circuit has recognized, "[c]ourts

routinely and properly deny summary judgment on the basis of a party's sworn testimony even though it is self-serving." *Price v. Time, Inc.*, 416 F.3d 1327, 1345 (11th Cir.) (collecting cases), *as modified on denial of reh'g*, 425 F.3d 1292 (11th Cir. 2005); *see also United States v. Davis*, 809 F.2d 1509, 1512–13 (11th Cir. 1987) (explaining that "self-serving testimony, by itself" can create a genuine dispute of material fact). The self-serving nature of testimony is not a bar to its consideration on summary judgment where the testimony comes from personal knowledge and sets forth facts that would be admissible in evidence. *See Berry v. Chi. Transit Auth.*, 618 F.3d 688, 691 (7th Cir. 2010) ("[W]e long ago buried – or at least tried to bury – the misconception that uncorroborated testimony from the non-movant cannot prevent summary judgment because it is 'self-serving.' If based on personal knowledge or firsthand experience, such testimony can be evidence of disputed material facts." (internal citation and quotation marks omitted); *Santiago-Ramos v. Centennial P.R. Wireless Corp.*, 217 F.3d 46, 53 (1st Cir. 2000) (A "party's own affidavit, containing relevant information of which he has first-hand knowledge, may be self-serving, but it is nonetheless competent to support or defeat summary judgment." (citation and internal quotation marks omitted)).

Not surprisingly, the Federal Rules of Civil Procedure are in harmony with the case law. With respect to summary judgment affidavits or declarations, the

federal rules require that they "be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." Fed. R. Civ. P. 56(c)(1)(4). There is no prohibition against self-serving testimony. The Rule 56(c)(1)(4) criteria also are appropriate for gauging whether deposition testimony is admissible on summary judgment. *See Macuba v. Deboer*, 193 F.3d 1316, 1323 (11th Cir. 1999) (holding that Rule 56(e), now Rule 56(c)(1)(4), "also applies to testimony given on deposition"). Admissibility is not foolproof, however. If the deposition testimony is "so fantastic, so internally inconsistent, or so speculative that it ha[s] no probative value," then the summary judgment standard does not permit its consideration. *Davis*, 809 F.2d at 1513.

There is no question that Mr. and Mrs. Fields's deposition and declaration testimony is self-serving. But based upon the foregoing principles, the testimony's self-serving nature will not bar its consideration at the summary-judgment stage so long as the deponent (Mrs. Fields) and the declarant (Mr. Fields) are competent, the testimony is based on personal knowledge, and the testimony contains facts that would be admissible at trial. These three prerequisites are met.

1. *A Competent Witness*

The court need not tarry long on the requirement of a competent witness. The summary judgment record contains no evidence and no argument has been made that Mr. and Mrs. Fields are not competent to testify.

2. *Personal Knowledge*

Mr. and Mrs. Fields's testimony is based upon their personal knowledge of Mrs. Fields's Prozac® use. Mrs. Fields provides specific, non-conclusory testimony about the time frame during which she took Prozac®, who prescribed her Prozac®, how the pills were packaged, what the pills looked like, the number of refills permitted for each prescription, the dosage prescribed, and the pharmacy where she filled the prescriptions. Also, Mr. Fields provides particularized insight as to the time frame during which Mrs. Fields took Prozac® and gives personal observations from that time frame, including that he saw the Prozac® pill bottles in their home and saw Mrs. Fields take the pills.

3. *Admissibility of Testimony*

Lilly argues that, even if the self-serving nature of the testimony is not an impediment to its consideration, the testimony of the Fields contains three other flaws that preclude its admissibility.

First, Lilly points out that there are internal inconsistencies in Mrs. Fields's own testimony (whether she used Prozac® just during her pregnancy with D.F. or

for a longer overlapping time period), as well as inconsistencies between Mrs. Fields's testimony and that of her husband's (including, for example, where in their home Mrs. Fields stored her prescription medication bottles, what time of day Mrs. Fields took her Prozac® pills, and how many pills were in the starter blister pack). Based upon careful review, there lies ample fodder in the summary judgment record for attacking the credibility of the testimony that Mrs. Fields took Prozac® during her pregnancy with D.F. These inconsistencies are not so contradicting, however, that no reasonable jury could believe the core of the testimony that Mrs. Fields, in fact, took Prozac® during her pregnancy with D.F. The inconsistencies in the testimony go to its weight but do not undermine it sufficiently to preclude a reasonable jury from believing and finding in favor of Mrs. Fields. The court would be required to reach this conclusion even if it were inclined to find the testimony suspect. *See Miller v. Harget*, 458 F.3d 1251, 1256 (11th Cir. 2006) ("Even if the district court believes that the evidence presented by one side is of doubtful veracity, it is not proper to grant summary judgment on the basis of credibility choices.").

Second, Lilly argues that the testimony of Mr. and Mrs. Fields contradicts the medical and pharmaceutical records such that the testimony is wholly discredited and fantastical. Lilly relies upon the Supreme Court's holding in *Scott v. Harris*, 550 U.S. 372 (2007), that, "[w]hen opposing parties tell two different

stories, one of which is blatantly contradicted by the record, such that no reasonable jury could believe it, a court should not adopt that version of the facts for purposes of ruling on a motion for summary judgment." *Id.* at 380. In *Scott*, a video recording of law enforcement officers' pursuit of a fleeing suspect, whose aggressive maneuvering of his vehicle posed a great danger to other motorists and pedestrians, "clearly contradict[ed]" the testimony of the criminal suspect (turned civil plaintiff) that he was abiding by all rules of the road and driving in a controlled and careful manner. *See id.* at 378–79. Because the objective video recording of the police chase so "utterly discredited" the plaintiff's story to the degree that "no reasonable jury could have believed him," the summary judgment facts were those shown in the video recording, and not those insisted upon by the plaintiff. *Id.* at 380–81.

This case is not like *Scott*. Here, there is an absence of any documentation in the medical and pharmaceutical records that Dr. Durden prescribed Prozac® to Mrs. Fields, either during or after the May 23, 1996 appointment. However, the *absence of physical evidence* to support a fact is not the same thing as the *presence of physical evidence* that directly contradicts a fact. There is no *direct* contradiction in the medical and pharmaceutical records to justify rejecting the

testimony of Mr. and Mrs. Fields.[3] The testimony, taken together with Dr. Durden's notation in the May 23, 1996 medical record that he would prescribe Prozac® to Mrs. Fields if the pending laboratory tests for her "thyroid and chemistry" returned normal results (Doc. # 110-2), supports an inference from which a reasonable jury could find that Mrs. Fields took Prozac® during her pregnancy with D.F. The general rule on summary judgment is that "facts must be viewed in the light most favorable to the nonmoving party." *Scott*, 550 U.S. at 380. Ms. Fields's version of the facts is not "blatantly contradicted by the record" so as to warrant an exception to the general rule. *Id.*

Third, Lilly suggests that a different rule should apply in pharmaceutical cases where the plaintiff cannot produce medical or prescription records to substantiate a self-serving affidavit or declaration that he or she actually used the drug at issue. But the court is unfamiliar with any binding precedent, and none is cited that sets forth the rule Lilly urges. The few out-of-circuit unpublished district court cases upon which Lilly relies stand in a different posture from this case, and none concluded that a plaintiff's declaration or sworn testimony about his or her product use was insufficient evidence to defeat summary judgment. In sum, Lilly

[3] There is then no need to decide whether an affirmative notation in a medical or pharmaceutical record of a physician's refusal to prescribe Prozac® to the patient would be analogous to the objective video recording in *Scott*.

advances no persuasive argument that the testimony of Mr. and Mrs. Fields would not be admissible at trial.[4]

4. *Summary*

Mr. and Mrs. Fields's testimony, even though self-serving, satisfies the criteria for consideration on summary judgment. That testimony creates a genuine dispute of material fact on the issue of product use. Accordingly, Lilly's motion for summary judgment on this ground is due to be denied.

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

Lilly next argues that Mrs. Fields's failure-to-warn claims fail under Alabama's learned-intermediary doctrine. Where a plaintiff asserts a claim based upon a manufacturer's failure to warn adequately of a drug's side effects, Alabama has adopted the learned-intermediary doctrine.[5] *See Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313–14 (11th Cir. 2000) (observing that Alabama courts apply the learned-intermediary doctrine "[i]n cases involving complex products, such as those in which pharmaceutical companies are selling prescription drugs");

[4] Based upon these findings, it is not necessary to address the opposing arguments concerning whether the testimony from Mrs. Fields's sister, concerning a conversation she had with Mrs. Fields about her (Mrs. Fields's) Prozac® use, constitutes hearsay or falls within an exception to the hearsay rule.

[5] The parties do not dispute that Alabama law controls. This court, which sits in diversity, must adhere to the substantive law of the forum state. *See Towne Realty, Inc. v. Safeco Ins. Co. of Am.*, 854 F.2d 1264, 1269 n.5 (11th Cir. 1988) ("[W]hen considering a diversity case under state law, we are bound to decide the case the way it appears the state's highest court would . . . .").

Stone v. Smith, Kline & French Labs., 447 So. 2d 1301, 1304–05 (Ala. 1984) (adopting the learned-intermediary doctrine in pharmaceutical products liability cases). Under the learned-intermediary doctrine, "[a] prescription-drug manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug." *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 673 (Ala. 2014). A drug manufacturer has no duty to ensure, therefore, that the adequate warning reaches the patients to whom the physician prescribes the drug. "The principle behind the learned-intermediary doctrine is that prescribing physicians act as learned intermediaries between a manufacturer and the consumer/patient and, therefore, the physician stands in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment." *Nail v. Publix Super Markets, Inc.*, 72 So. 3d 608, 614 (Ala. 2011).

For purposes of its summary judgment motion only, Lilly assumes that its warning on the Prozac® label in May 1996 was inadequate and should "have warned of an increased risk of birth defects" from ingestion of Prozac® during pregnancy.[6] (Doc. # 102-1, at 5 n.2.) The same assumption as to the inadequacy of the warning will be made for purposes of this opinion.[7]

[6] Lilly denies that a warning stronger than the one it provided in 1996 was required. If Lilly ultimately proves that the warning was adequate, then it will prevail under the learned-intermediary doctrine. *See Wyeth*, 159 So. 3d at 673 ("A prescription-drug manufacturer fulfills

An inadequate warning does not end the inquiry, however. Even when the warning to the prescribing physician is "inadequate or misrepresents the risk," the patient still must prove that the inadequacy of the warning "was the actual and proximate cause of the patient's injury." *Wyeth*, 159 So. 3d at 673. The focus here is on factual causation. The court refers to the causation inquiry as "factual causation" to distinguish the inquiry from "legal causation."[8] "Factual causation, or 'but for' causation, is that part of causation analysis that asks if the complained-of injury or damage would have occurred but for the act or omission of the defendant." *Springer v. Jefferson Cnty.*, 595 So. 2d 1381, 1383 (Ala. 1992). On the other hand, "[p]roximate or legal causation is that part of causation analysis that asks if 'the act for which the [defendant] is responsible [is] of such a nature that courts of law will recognize it as the [cause] of the injury.'" *Id.* (citation and internal quotation marks omitted).

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its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug."). This Memorandum Opinion and Order expresses no opinion on the adequacy of the warning.

[7] Other courts applying Alabama law have made the same assumption and focused on causation. *See, e.g.*, *Bodie v. Purdue Pharma Co.*, 236 F. App'x at 511, 519 (11th Cir. 2007) ("Even were we to assume that Purdue's warnings and accompanying literature about OxyContin were, in fact, inadequate and deceptive, . . . Bodie has failed to satisfy his burden of providing proximate causation between these allegedly flawed warnings and his injury of addiction."); *Trasylol Prod. Liab. Litig. MDL-1928*, No. 08-MD1928, 2011 WL 2117257, at *4 (S.D. Fla. May 23, 2011) ("[a]ssuming, only for the sake of argument, that Bayer's warning was inadequate . . . ." (applying Alabama law)).

[8] Lilly uses the terminology "warning causation." (Doc. # 136-1.)

While there is a dispute whether Mrs. Fields ever was prescribed Prozac®, it is undisputed that, if she was, it was Dr. Durden who did so. Thus, under the learned-intermediary doctrine, the success of Mrs. Fields's failure-to-warn claims is contingent upon whether she can show that an adequate warning would have altered Dr. Durden's prescribing practices. Lilly contends that, under Alabama's learned-intermediary doctrine, Mrs. Fields cannot make that showing. It argues that the effect of the warnings on Mrs. Fields's decision of whether to refuse to take Prozac® is not relevant to the causation equation because, under the learned-intermediary doctrine, the focus is on the warning's effect on the physician, not on the patient. (Doc. # 102-1, at 9 n.6.) Lilly says, therefore, that Mrs. Fields fails to demonstrate that the allegedly inadequate warning caused her to ingest Prozac®. The culmination of Lilly's argument is that Dr. Durden is "[t]he only witness capable of providing testimony necessary to help [Mrs. Fields] meet her burden" of proving that a different warning would have prevented her ingestion of Prozac®, but that, prior to his death, "his testimony was never preserved." (Doc. # 91-1, at 19.)

To be sure, Alabama law underscores the importance of the prescribing physician's perspective in a failure-to-warn case where the learned-intermediary doctrine is in play, and persuasive federal court authority confirms it. *See Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 522 n.12 (11th Cir. 2007) ("The question,

for purposes of [the plaintiff's] negligent failure to warn action, is whether [the doctor's] decision to prescribe OxyContin to [the plaintiff] ultimately hinged on the information (accurate or inaccurate) that he obtained from Purdue."); *Tatum v. Schering Corp.*, 795 F.2d 925, 927 (11th Cir. 1986) (applying Alabama law in a failure-to-warn action and observing that "[i]t all returns . . . to the critical inquiry of what Dr. Karst knew" for purposes of causation). Mrs. Fields does not dispute the law and admits she lacks evidence – either testimonial or documentary – directly from her prescribing physician who died four years prior to the commencement of this suit. Recognizing these evidentiary shortcomings, as well as the dearth of Alabama case law addressing causation on a failure-to-warn claim where the prescribing physician has died prior to suit, Mrs. Fields argues that the Alabama Supreme Court, if asked to rule, would align with the Fifth Circuit's pronouncements in *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992).

Thomas, which involved an interpretation of Mississippi law, is factually distinct in that the prescribing physician testified at trial. *See id.* at 811. Nonetheless, Mrs. Fields relies upon *Thomas* because it offered an alternative method for proving causation, apart from the treating physician's testimony. The Fifth Circuit held that a plaintiff can demonstrate causation by introducing "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." *Id.* at 812. First, Mrs. Fields points to the testimony of other doctors concerning the standard of medical practice in the locality during the relevant time frame as objective evidence "of how a reasonable physician would have responded to an adequate warning." *Id.* Second, she relies upon the deposition testimony of Dr. Durden's nurse of twelve years, concerning Dr. Durden's customs and practices, as subjective evidence of how Dr. Durden would have responded to an adequate warning. She argues that this subjective evidence proves that had Lilly warned Dr. Durden of an increased risk of birth defects posed by Prozac® use during pregnancy, he would have passed along those warnings to Mrs. Fields, who he knew was trying to conceive a child, and she would have declined to take Prozac®. Hence, under either method of proof, Mrs. Fields argues that the allegedly inadequate warnings are the factual cause of her ingestion of Prozac®.

Alabama courts have not had the occasion to sanction or reject the objective-evidence standard, and Lilly cites persuasive authority that the objective-evidence standard in *Thomas* represents the minority position among courts. *See Sauls v. Wyeth Pharm., Inc.*, 846 F. Supp. 2d 499, 503 (D.S.C. 2012) (observing that "[n]o other jurisdiction that adheres to the learned intermediary doctrine has followed the approach taken by the Fifth Circuit" in *Thomas*) (citing, among other cases, *Schilf v. Eli Lilly & Co.*, No. CIV 07–4015, 2010 WL 4024922, at *4 n.3 (D.S.D. Oct. 13,

2010) ("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.")). Ultimately, the court need not decide whether Alabama's highest court would adopt *Thomas*'s objective-evidence standard in a prescription drug case involving the learned-intermediary doctrine because the court finds that Mrs. Fields can proceed under the subjective-evidence standard. But the path to that finding is a rocky one.

The subjective-evidence standard of how the treating physician would have responded to an adequate warning finds ample support in Alabama law because, under Alabama's "'learned intermediary doctrine,' the adequacy of [the drug manufacturer's] warning is measured by its effect on the *physician* . . . to whom it owed a duty to warn, and not by its effect on [the patient]." *Toole v. McClintock*, 999 F.2d 1430, 1433 (11th Cir. 1993) (citing *Stone*, 447 So. 2d at 1304–05). Nonetheless, the subjective-evidence path that Mrs. Fields trudges brings to the forefront two other issues under Alabama law. The first is whether Alabama courts would recognize the theory that Mrs. Fields advances, namely, that had Dr. Durden received a stronger warning from Lilly about the increased risk of birth defects from the ingestion of Prozac® during pregnancy, he would have passed along that warning to Mrs. Fields and, in turn, Mrs. Fields would have declined to

take Prozac®, even if Dr. Durden still had recommended it. The second issue is whether subjective evidence of how the treating physician would have responded to an adequate warning can be established with evidence other than the prescribing physician's testimony. Lilly says both issues must be answered in the negative. It contends, first, that, under Alabama law for purposes of the learned-intermediary doctrine, Plaintiff must show that Dr. Durden *would not have prescribed* Prozac® had he been warned adequately and, second, that the evidence to prove this theory must come from the Dr. Durden himself.

1. *Mrs. Fields's Theory*

Mrs. Fields does not rely upon the Eleventh Circuit's interpretation of Alabama's learned-intermediary doctrine in *Toole v. McClintock* to argue that she has a viable theory for proving her failure-to-warn claims. Nor does Lilly mention *Toole* in the present briefing.[9] The court does not have the benefit, therefore, of vigorous exchange between adversaries as to *Toole*'s principles and its applicability here. Nonetheless, although *Toole* is not on all fours, the court finds that there is sufficient reasoning in *Toole* to permit Mrs. Fields to go forward on her failure-to warn claims.

In *Toole*, the plaintiff developed scar tissue around her silicone breast implants and underwent a closed capsulotomy, a procedure where a surgeon

[9] In a subsequently filed summary-judgment motion in this case, Lilly cites *Toole* favorably. (Doc. # 136-1, at 16–17.)

manually compresses the affected breast to rupture the scar tissue. This procedure ruptured her breast implants, causing serious injuries. The plaintiff sued the manufacturer of her breast implants, alleging that it had failed to warn her doctor of the risk of ruptures during a closed capsulotomy. 999 F.2d at 1431. The jury returned a verdict in the plaintiff's favor, and the Eleventh Circuit affirmed the district court's denial of the manufacturer's motion for a directed verdict, rejecting the manufacturer's argument that there was "no evidence that a different warning from [the manufacturer] would have caused [the plaintiff's physician] to behave differently." *Id.* at 1433.

Applying Alabama's learned-intermediary doctrine, the Eleventh Circuit held that a reasonable jury could have found that the manufacturer's warning "understated the risks of implant rupture from closed capsulotomies" and that the jury heard evidence that "*a different warning would have caused [the physician] to warn [the plaintiff] before her augmentation surgery*." *Id.* (emphasis added). Hence, the physician would have behaved differently had the manufacturer issued a stronger warning because he testified that he would have warned the plaintiff of the risk of implant rupture prior to performing the augmentation surgery. *See id.* at 1433 n.6. The further implication in *Toole* was that had the plaintiff received a stronger warning from the physician, she would not have consented to breast-augmentation surgery. *See id.* at 1432–33; *see also Barnhill v. Teva Pharm. USA,*

Inc., 819 F. Supp. 2d 1254, 1261 (S.D. Ala. 2011) (recognizing that, under Alabama law, "[t]heoretically," proof of proximate cause could take the form of evidence that, "although [the physician] still would have prescribed [the drug], [the physician] would have changed her behavior or treatment in some way that would have resulted in a different outcome for the [p]laintiff"); *cf. McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2006) ("Where the physician would have adequately informed a plaintiff of the risks of a disease, had the label been sufficient, but fails to do so on that account, and where the plaintiff would have rejected the drug if informed, the inadequate labeling could be a 'producing' cause of the injury, because it effectively sabotages the function of the intermediary." (applying Texas law)).

Although *Toole* involved a failure-to-warn claim in the context of a physician-provided product, rather than a physician-provided prescription drug, both *Toole* and this case involve complex products to which Alabama's learned-intermediary doctrine applies. This court is bound by *Toole*, *see United States v. Chubbuck*, 252 F.3d 1300, 1305 n.7 (11th Cir. 2001) (noting that the prior precedent rule applies to the circuit's interpretation of state law), unless Alabama's highest court or an intermediate appellate court has "specifically contradict[ed]" its holding. *Roboserve, Ltd. v. Tom's Foods, Inc.*, 940 F.2d 1441, 1451 (11th Cir. 1991); *see also Provau v. State Farm Mut. Auto. Ins. Co.*, 772 F.2d 817, 820 (11th

Cir. 1985) (In a diversity case, where "the state supreme court has not addressed the issue, a federal court applying state law is bound to adhere to decisions of the state's intermediate appellate courts absent some persuasive indication that the state's highest court would decide the issue otherwise." (alterations, citation, and internal quotation marks omitted)). Lilly does not cite an Alabama appellate decision that undermines *Toole*'s holding with respect to its interpretation of Alabama's learned-intermediary doctrine.

Lilly does rely on *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014), elsewhere in its briefing. In *Wyeth*, the Alabama Supreme Court summed up the learned-intermediary doctrine by stating, "[i]n short, the patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient." *Id.* at 673–74. But *Wyeth* addressed an issue very different from the present one. It tackled as a matter of first impression on a certified question the sustainability of a fraudulent suppression claim against a brand-name-drug company for injuries suffered by a generic drug consumer. *Wyeth* did not address whether, in a pharmaceutical failure-to-warn case, evidence that, had the warnings been adequate, the prescribing physician would have altered his risks discussion with the patient and, resultantly, the patient would not have taken the drug. That issue simply was not before the court in *Wyeth*, and *Wyeth* does not undermine *Toole*.

The court finds that, in accordance with *Toole*, under Alabama's learned-intermediary doctrine, Mrs. Fields can demonstrate factual causation by proving that had Lilly given Dr. Durden a stronger warning about the association between the ingestion of Prozac® during pregnancy and an increased risk of birth defects, Dr. Durden would have informed Mrs. Fields of the risk and his warning would have resulted in a different outcome for Mrs. Fields in that she would not have taken Prozac®. This theory is not predicated on the effect an adequate warning would have had on Mrs. Fields, but rather upon the effect an adequate warning would have had on Dr. Durden's prescribing practices.[10] *Toole* is contrary, therefore, to Lilly's argument that the sole method by which to measure a

[10] Florida law also applies the learned-intermediary doctrine for failure-to-warn claims brought against a drug manufacturer. It is notable that, in cases applying Florida law where there is evidence that the physician would have conveyed drug warnings to the plaintiff if the drug manufacturer had provided them, courts have denied summary judgment based upon the plaintiff's testimony that he would not have taken the drug if he had been adequately warned. *See Kirchman v. Novartis Pharm. Corp.*, No. 8:06cv1787-T-24-TBM, 2014 WL 2158519, at *19 (M.D. Fla. May 23, 2014) (collecting cases). In *Kirchman*, the drug manufacturer argued that the plaintiff could not establish proximate cause on a failure-to-warn claim because the physician testified that he still would have prescribed Aredia or Zometa, even if the warnings had been adequate. The court agreed with the plaintiff's counterargument that the physician's decision of whether to prescribe the drugs "does not control the proximate cause issue." *Id.* at *5. It denied summary judgment on the issue of proximate cause because there was evidence from which "a reasonable juror could find that [the prescribing physician], had he been adequately warned, would have changed his prescribing practices by giving different warnings or instructions to [the plaintiff]" and that the plaintiff, "had he been given different warnings or instructions, would have declined Aredia and/or Zometa." *Id.* Notably, *Kirchman* cited *Toole* as persuasive authority for its holding. *See id.* at *5 (citing *Toole*, 999 F.2d at 1433); *see also Levine v. Wyeth, Inc.*, No. 8:09-cv-854-T-33AEP, 2010 WL 5137424, at *6 n.2 (M.D. Fla. Dec. 10, 2010) (finding *Toole* instructive for interpreting Florida law because "both Florida and Alabama apply the learned intermediary doctrine when analyzing a failure to warn claim against a manufacturer of a prescription drug or device").

warning's effect on the physician is through evidence that the prescribing physician would not have prescribed the drug had the warnings been adequate.

Moreover, this legal conclusion finds some support in the Alabama Supreme Court's treatment of evidence in medical malpractice, informed-consent cases, an analogy that at least one circuit has found fitting in the pharmaceutical products-liability context.[11] In informed-consent cases brought under Alabama law, the plaintiff's testimony as to whether he or she would have consented to a procedure upon full disclosure of the risks is a factor that "may prove helpful to the factfinder." *Phelps v. Dempsey*, 656 So. 2d 377, 381 (Ala. 1995). The rationale of

[11] In *Payne v. Novartis Pharmaceuticals Corp.*, 767 F.3d 526, 532 (6th Cir. 2014), the Sixth Circuit, applying Tennessee law, addressed whether, in a failure-to-warn case where the learned-intermediary doctrine applies, the Tennessee Supreme Court would forestall summary judgment based upon evidence that the plaintiff would have refused to take a drug, where there was evidence that had the physician known of the drug's risks, he would have warned the plaintiff about those risks prior to prescribing the drug. The Sixth Circuit found germane to the causation analysis that the Tennessee Supreme Court had permitted similar testimony from plaintiffs in medical malpractice actions where it was alleged that a physician had failed to obtain the patient's informed consent prior to performing a procedure.

In informed-consent cases, the Tennessee Supreme Court permits the "'finder of fact [to] consider and give weight to the patient's testimony as to whether the patient would have consented to the procedure upon full disclosure of the risks.'" *Payne*, 767 F.3d at 532 (quoting *Ashe v. Radiation Oncology Assocs.*, 9 S.W. 3d 119, 123–24 (Tenn. 1999)). The *Payne* court observed that under Tennessee law, "[c]ausation in both types of cases – informed consent and failure to warn – ultimately rests with the patient's decision to take or reject the medication." *Id.* Because "[b]oth types of cases address the same issue," the Sixth Circuit found "no indication that the Tennessee Supreme Court would adopt a different standard of proof for essentially the same link in the causal chain." *Id.* Accordingly, the *Payne* court held that the evidence was sufficient to send the causation issue to the jury and, as a result, the district court erred by granting summary judgment in favor of the drug manufacturer.

Phelps fits here as well, and Lilly offers no reason why Alabama's highest court would apply a different rationale in pharmaceutical failure-to-warn cases.

2. *The Source of the Evidence to Prove the Theory*

The issue turns to whether evidence that the physician would have informed the patient of the adequate warning, had the manufacturer provided it, must come directly from the prescribing physician. Mrs. Fields has no testimony from Dr. Durden, as he is deceased, but instead relies upon the deposition testimony of Ms. Ledbetter. Ms. Ledbetter worked as a licensed practical nurse for Dr. Durden from 1988 to 2000, participated in the "on-hand care of the patient" in the exam room, and was familiar with Dr. Durden's prescribing practices. (Ledbetter's Dep., at 9–12 (Doc. # 92-7).) She testified that it was Dr. Durden's standard practice to discuss with all of his patients the risks and benefits disclosed on a drug's package insert.[12] (Ledbetter's Dep., at 11, 27–28, 34, 86.) Mrs. Fields contends that it is reasonable to infer from this testimony that had the package insert disclosed that ingestion of Prozac® during pregnancy increased the risks for birth defects, Dr. Durden would have disclosed those risks to Mrs. Fields in the course of prescribing Prozac® to her.

Whether Ms. Ledbetter's testimony is sufficient to create a jury question on the theory advanced by Mrs. Fields necessitates a discussion of Federal Rule of

[12] Lilly does not dispute, as a general matter, that Ms. Ledbetter is a "disinterested" and "unbiased" witness. (Doc. # 91-1, at 15.)

Evidence 406. The Rule 406 issue is whether Ms. Ledbetter's testimony establishes that Dr. Durden had a habit of conveying to his patients all of the risks of a prescription drug so as to prove that Dr. Durden would have acted in accordance with that habit in his course of treating Mrs. Fields in May 1996. *See* Fed. R. Evid. 406. "Habit . . . describes one's regular response to a repeated specific situation." *United States v. Aguirre*, 368 F. App'x 979, 990 (11th Cir. 2010) (citation and internal quotation marks omitted). Mrs. Ledbetter's testimony is that, based upon her twelve years of professional employment with Dr. Durden, she observed that he diligently read the package inserts accompanying prescription drugs and that he discussed with his patients the risks and benefits of all medications he prescribed. Lilly has not refuted this evidence as insufficient to raise a genuine dispute of material fact concerning Dr. Durden's prescribing habits for purposes of Rule 406. On this record and in the absence of persuasive legal arguments by Defendant, the court declines to enter summary judgment.

3. *Summary*

Mrs. Fields has established a genuine dispute of material fact on factual causation under Alabama's learned-intermediary doctrine. There is sufficient evidence demonstrating that, if Lilly had provided adequate warnings (and even if Dr. Durden still would have recommended Prozac® to Mrs. Fields), Dr. Durden would have changed his treatment practices by passing along adequate warnings of

the drug's risks to Mrs. Fields and she would have not taken the drug. Accordingly, Lilly is not entitled to summary judgment.

V. CONCLUSION

For the foregoing reasons, Mrs. Fields has raised a genuine dispute of material fact as to whether she took Prozac® during her pregnancy with D.F. and as to factual causation under Alabama's learned-intermediary doctrine. Accordingly, it is ORDERED that Lilly's motion for summary judgment (Doc. # 90) is DENIED.

DONE this 20th day of July, 2015.

/s/ W. Keith Watkins
CHIEF UNITED STATES DISTRICT JUDGE