UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: VIOXX **PRODUCTS LIABILITY LITIGATION**	MDL NO. 1657 SECTION L JUDGE FALLON MAG. JUDGE KNOWLES

THIS DOCUMENT RELATES TO: ***Jo Levitt v. Merck Sharp & Dohme Corp.*****, 06-9757**

ORDER & REASONS

The Court has before it Defendant Merck's Motion for Summary Judgment for Failure to Satisfy Specific Causation on Ms. Levitt's Claims of Heart Attacks (Rec. Doc. 64878) and Merck's Motion for Summary Judgment Regarding Proximate Causation (Rec. Doc. 65087). The Court has reviewed the parties' briefs and applicable law, and having heard oral argument on the motions, now issues this Order & Reasons.

I. BACKGROUND

To put this matter in perspective, a brief review of this multidistrict litigation ("MDL") is appropriate. This litigation involves products liability claims pertaining to the prescription drug Vioxx, known generically as Rofecoxib. Merck, a New Jersey corporation, researched, designed, manufactured, marketed and distributed Vioxx to relieve pain and inflammation resulting from osteoarthritis, rheumatoid arthritis, menstrual pain, and migraine headaches. On May 20, 1999, the Food and Drug Administration ("FDA") approved Vioxx for sale in the United States. Vioxx remained publicly available until September 30, 2004, when Merck withdrew it from the market after data from a clinical trial known as APPROVe indicated that the use of Vioxx increased the risk of cardiovascular thrombotic events such as myocardial infarction (that is, heart attack) and ischemic stroke. Thereafter, thousands of individual suits and numerous class actions were filed

against Merck in state and federal courts throughout the country alleging various products liability, tort, fraud, and warranty claims.

Following six "bellwether" trials in this proceeding—as well as trials in other proceedings in Alabama, California, Illinois, Florida, New Jersey, and Texas—the negotiating plaintiffs' counsel ("NPC") and Merck's counsel engaged in protracted settlement discussions over the course of a year, conducting hundreds of in-person and telephone meetings. On November 9, 2007, the parties announced a $4.85 billion master settlement agreement ("MSA") that intended to—and actually did—resolve most Vioxx-related claims through a resolution program. In its recitals, the MSA expressly states that its purpose was to "establish a pre-funded, structured private settlement program . . . to resolve . . . claims against Merck involving heart attacks, ischemic strokes and sudden cardiac deaths." This was an "opt-in" program, meaning an interested claimant had to take affirmative steps to enroll in it. Jo Levitt chose not to enroll, and instead proceeded in this Court.

II. FACTS

Plaintiff Jo Levitt began taking Vioxx when Dr. Hartman prescribed the drug for her in the summer of 1999. Ms. Levitt claims that she requested this prescription, and Dr. Hartman's medical records corroborate Plaintiff's position. Hartman Med. Recs., July 16 & 20, 1999, (Rec. Doc. 65168 at 2) ([Ms. Levitt] wants to see dermatologist re: rosacea. Want to try Vioxx 25 mg for….”). *See also* Levitt Dep. 69:18-70:13, July 12, 2012; Aff. Jo Levitt, Feb. 24, 2015 (“I specifically requested that my treating physician, Dr. Hartman, prescribe me Vioxx after I saw advertisements for Vioxx.). Ms. Levitt went to see Dr. Arthur Katz, a rheumatologist, in October 1999, and Dr. Katz ultimately diagnosed Ms. Levitt with fibromyalgia, for which he prescribed Vioxx. In Dr. Katz's deposition, he noted that Ms. Levitt had already been prescribed Vioxx but

was taking Vioxx on an "as-needed" basis. Katz Dep. 28:6-24, Jan. 30, 2013. Dr. Katz testified that after evaluating Ms. Levitt, he determined that it was appropriate for her to start taking Vioxx daily and arrived at that conclusion independent of the fact that Dr. Hartman had previously prescribed her Vioxx. Katz. Dep. 44:7-44:21, Jan. 30, 2013. Dr. Katz directed Ms. Levitt to take the Vioxx already in her possession and wrote her a new prescription on December 27, 1999. Katz. Dep. 44:21-45:6, Jan. 30, 2013.

Ms. Levitt disputes Merck's position that Dr. Katz independently prescribed her Vioxx and emphasizes that she asked Dr. Hartman for the prescription after she saw advertisements for the drug. Plaintiff's counsel asserted during oral argument that both Dr. Hartman and Dr. Katz continued to prescribe Vioxx for Ms. Levitt; the two doctors issued parallel prescriptions and she continued to seek treatment from Dr. Hartman. This contention is supported by Dr. Katz's medical record from February 7, 2000, which indicates that Dr. Hartman switched Ms. Levitt's Vioxx prescription to Relafen. Katz Med. Rec., Feb. 7, 2000, (Rec. Doc. 65182-2 at 7). Dr. Katz also testified to this end, stating that "from the February 7, 2000 note we should mention, I don't think we have, that Dr. Hartman had changed her from Vioxx to Relafen." Katz Dep., 52:1-4, Jan. 30, 2013; (Rec. Doc. 65167-5 at 15).

Ms. Levitt suffered two cardiac events in 2000. On March 9, 2000, after experiencing severe heart burn and chest pressure, Ms. Levitt saw Dr. Hartman. During that visit, Dr. Hartman observed abnormal patterns in her EKG and immediately sent her to the hospital. Mid-America Records at 1 (Mar. 10, 2000 Hosp. History & Physical), (Rec. Doc. 65087-2 at 62). Once admitted, she was ultimately diagnosed with unstable angina and coronary artery disease. Mid-America Records at 1 (Mar. 11, 2000 Discharge Diagnosis), (Rec. Doc. 65087-2 at 65). While in the hospital, she received an angioplasty and two stents. *Id.* On May 26, 2000,

approximately two months later, Ms. Levitt went to the emergency room with chest pains. Mid-America Records at 1 (May 29, 2000), (Rec. Doc. 65087-2 at 68). After finding that her stents had severely re-narrowed, she underwent double bypass surgery. *Id*

For two years following these episodes, Ms. Levitt continued to take Vioxx without incident until April 29, 2002, when Dr. Katz changed her prescription to Bextra. *See* Levitt Dep. 130:8-22. Dr. Katz testified that he discontinued Ms. Levitt's Vioxx prescription in April 2002 because her insurance ceased coverage for the medication. Katz Dep. 65:7-9, Jan. 30, 2013. His medical records corroborate this testimony. Ms. Levitt avers that Dr. Katz discontinued her prescription after Merck changed the Vioxx label warning, as it occurred around the same time that Dr. Katz changed her prescription.

On September 29, 2006, Jo Levitt brought this action against Merck in the United States District Court for the Western District of Missouri. In her complaint, she alleges that she suffered two heart attacks in 2001 as a result of taking Vioxx and brings the following causes of action: strict liability; negligence; negligence per se; breach of express warranty; and breach of implied warranty. She seeks compensatory and punitive damages, as well as interest, costs, attorneys' fees and any other available relief. On November 8, 2006, the matter was transferred to this Court for inclusion in the *Vioxx* MDL. As mentioned above, Ms. Levitt chose not to enroll in the settlement program and exercised her right to proceed with her claim. For a time, Ms. Levitt was *pro se*, but she eventually secured counsel. Discovery lingered in the case.

On November 14, 2013, some seven years later, this Court ordered that Ms. Levitt designate expert witnesses and provide their reports on or before December 13, 2013. (Rec. Doc. 64688). Ms. Levitt timely designated five expert witnesses. Of those, Dr. Jay Schapira addressed specific causation with regard to her two heart attacks, and according to Ms. Levitt, Dr. David

Egilman addressed specific causation with regard to her other injuries (the remaining expert witnesses addressed only general causation and damages). However, Ms. Levitt also disclosed Dr. Thomas Rosamond, her cardiologist, and reserved the right to call any and all treating physicians and other providers as fact or expert witnesses regarding the nature and extent of her injuries and resulting damages. Of her treating physicians, Merck only deposed Dr. Arnold Katz, her rheumatologist. On March 20, 2014, Ms. Levitt informed Merck that she was withdrawing Dr. Schapira as an expert witness. The Defendant now moves for summary judgment on specific causation (Rec. Doc. 64878) and on proximate causation (Rec. Doc. 65087).

III. PRESENT MOTIONS

A. The Standard

Summary judgment is appropriate if the moving party can show "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[1] FED. R. CIV. P. 56(a). Under Federal Rule of Civil Procedure 56(c), the moving party 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, 322 (1986). When the moving party has met its Rule 56(c) burden, the non-movant cannot survive a motion for summary judgment by resting on the mere allegations of its pleadings. *See Prejean v. Foster*, 227 F.3d 504, 508 (5th Cir. 2000). "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 253 (1986). Furthermore, "[t]he non-movant cannot avoid summary judgment . . . by merely making 'conclusory allegations' or 'unsubstantiated

[1] Ms. Levitt mistakenly relies on the Missouri standard for summary judgment. (Rec. Doc. 64966 at 6).As noted, this matter was filed in federal court and is subject to the procedural law of this forum.

assertions.'" *Calbillo v. Cavender Oldsmobile, Inc.*, 288 F.3d 721, 725 (5th Cir. 2002) (quoting *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994)). In deciding a summary judgment motion, a court reviews the facts drawing all reasonable inferences in the light most favorable to the non-movant. *Id.* at 255.

As a preliminary matter, it is necessary to determine what substantive and procedural law applies to Ms. Levitt's action. In an MDL, a transferee court applies the choice-of-law provisions of the state in which the transferor court is located. Missouri has adopted the *Restatment (Second) on Conflict of Laws*, which generally provides that, "[i]n an action for a personal injury, the local [substantive] law of the state where the injury occurred determines the rights and liabilities of the parties." RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 146 (1971); *see Kennedy v. Dixon*, 439 S.W.2d 173, 184, 713 (Mo. 1969). Ms. Levitt's injury occurred in Missouri and she filed this action in federal court in that state, therefore Missouri substantive law applies. Further, federal procedural law applies because the forum is a federal court.

B. Motion for Summary Judgment for Failure to Satisfy Specific Causation on Ms. Levitt's Claims of Heart Attacks (Rec. Doc. 64878)

1.The Parties' Arguments

Merck moves for summary judgment on the basis that Ms. Levitt has not designated an expert witness who can establish specific causation for the injuries alleged in her complaint. (Rec. Doc. 64878). In response, Ms. Levitt admits that she needs an expert witness to prove her claims, but disagrees with Merck's formulation of her injuries as being limited to the heart attacks. (Rec. Doc. 64966).[2] Instead, she contends that she has provided the requisite expert witness designation and report for other injuries, even if she has not provided such a designation and report for the heart attacks. Specifically, she concedes that the only injuries alleged in her

[2] Ms. Levitt filed two responses, which appear identical. (*See* Rec. Docs. 64965, 64966). Accordingly, the Court will only reference the latter of these.

complaint were the heart attacks, but explains that "the nature of [her] alleged cardiac injuries is more complicated than merely summarizing them as 'heart attacks.'" (*Id*. at 1). Ms. Levitt suggests that she has given Merck notice of these other injuries previously. For instance, she notes that her plaintiff profile form ("PPF") and amended and supplemental plaintiff profile form ("ASPPF") describe non-heart attack injuries, including arterial plaque, stenosis, and aggressive heart disease. She also references the *Lone Pine* report by Dr. Rosamond, her cardiologist, which indicates that her heart disease was likely exacerbated by Vioxx.[3] Ms. Levitt then argues that Dr. Rosamond and Dr. Egilman will speak to specific causation as it pertains to these other injuries.

Merck then replies. (Rec. Doc. 64931). It states that, until now, the only injuries Ms. Levitt has alleged were the two heart attacks. It observes that she has never sought to amend her complaint to add the amorphous injuries that she now claims. Further, Merck argues that even if Ms. Levitt is permitted to allege other injuries, she has not produced the requisite expert witness designation and report substantiating them. Specifically, Merck explains that Dr. Rosamond is unable to act as an expert witness because he formed his opinions regarding specific causation after he had ceased to be Ms. Levitt's treating physician. It also suggests that Dr. Egilman's expert witness report is unreliable because it is devoid of any methodology on the issue of specific causation. Merck further argues that it had no affirmative obligation to depose any of her expert witnesses, and that its burden is limited to demonstrating there is no evidence or testimony to support Ms. Levitt's claims.

On June 30, 2014, Ms. Levitt filed a sur-reply. (Rec. Doc. 64994). Ms. Levitt emphasizes the fact that she provided Merck with an amended PPF, which provided a great deal of detail and context regarding her injuries. Ms. Levitt argues that the fact that this amended PF

[3] This letter was entered into the record on April 28, 2010, as an exhibit to Ms. Levitt's motion to vacate this Court's order of dismissal.

was not signed should not matter, as it still put Merck on notice of her injuries and provided Merck with information that it was later able to use at Ms. Levitt's deposition. Ms. Levitt argues that Merck has been on notice for years that she is claiming heart disease. Ms. Levitt argues that her complaint satisfies the federal "notice pleading" requirements. According to Ms. Levitt, *Cutrer v. Bd. Of Supervisors of La. State* Univ, which is cited by Merck, is inapplicable. Ms. Levitt argues that unlike the plaintiff in that case, she is not trying to assert an entirely new claim. Rather, she is merely providing a more descriptive explanation of her injuries. (Rec. Doc. 64994 at 4). Similarly, Ms. Levitt claims that Merck's reliance on this court's opinion in *Offshore Marine Contractors, Inc. v. Palm Energy Offshore LLC*, is misplaced. 2012 WL 6161937 (E.D. La. Dec. 11, 2012). Ms. Levitt claims that the plaintiff in that case was trying to discuss events that occurred at completely separate oil wells, once the plaintiff realized that the defendant had no connection to the oil wells that formed the basis of the case. Ms. Levitt argues that she is not trying to allege a completely new set of facts or injuries.

In the alternative, Ms. Levitt seeks leave to amend her complaint under Federal Rule of Civil Procedure 16(b).

Ms. Levitt argues that pursuant to Federal Rule of Civil Procedure 26, she is not required to obtain an expert report from Dr. Rosamond because he was her treating physician. Ms. Levitt argues that this is the case even if Dr. Rosamond testifies about information he obtained after his treatment of Ms. Levitt. Ms. Levitt further argues that Dr. Rosamond provided a written letter that set forth the subject matter on which he is expected to testify, which satisfies the Federal Rule of Civil Procedure requirement. (Rec. Doc. 64994 at 10). Similarly, Ms. Levitt argues that Dr. Egilmann's report satisfies the requirements of Rule 26. Ms. Levitt asks the Court to grant her leave to re-designate Dr. Schapira as an expert.

On July 21, 2014, Merck filed a response to Ms. Levitt's sur-reply. Merck claims that Ms. Levitt's counsel is essentially trying to start over after more than nine years of litigation before this Court. Merck claims that before it filed the present motion for summary judgment, at no point did Ms. Levitt indicate that she had abandoned her claimed injury of heart attacks and was instead proceeding with a claim of exacerbated cardiovascular disease. Merck argues that Fifth Circuit precedent mandates that this Court must disregard claims and theories of liability that were not presented in Ms. Levitt's complaint. Merck emphasizes that the only injury alleged in Ms. Levitt's complaint is heart attacks. Merck claims that it would be severely prejudiced if Ms. Levitt is allowed to now substitute her original claim. Merck claims that if the focus of this case is on Ms. Levitt's general cardiac health, rather than the two alleged acute events, then a lot more discovery will be necessary. Merck argues that Ms. Levitt's late attempt to amend her complaint is inappropriate. Merck further argues that Ms. Levitt's "astonishing request" to re-designate Dr. Schapira as an expert "makes a mockery out of the entire discovery process . . . ." (Rec. Doc. 65003-1 at 7).

During oral argument, Plaintiff's counsel indicated that Ms. Levitt had not abandoned a claim of heart attacks and may still pursue this claim.

2. Law and Analysis

Under Missouri law, "causation may be shown by direct or circumstantial evidence." *Harris v. Washington*, 654 S.W.2d 303, 306 (Mo. Ct. App. 1983). Ordinarily, an expert witness is necessary to establish causation in a product liability personal injury claim.[4] *Id*. In "a product liability action of a highly technical and scientific nature, expert testimony is essential to establish causation" *Eppler v. Ciba-Geigy Corp.*, 860 F. Supp. 1391, 1395 (W.D. Mo. 1994).

[4] An exception to this requirement exists in instances of "sudden onset, visible injury, or an injury that as a matter of common knowledge follows the [alleged] act [or omission]." *Id.*

Here, the parties do not dispute that Ms. Levitt must prove causation through an expert witness. Without such an expert witness, "all claims based on those injuries must fail." *Id*. at 1394.

That said, a plaintiff is not required to "produce evidence in a form that would be admissible at trial in order to avoid summary judgment." *Celotex Corp.*, 477 U.S. at 324. Nor is a plaintiff required to "depose her own witnesses." *Id*. A plaintiff is permitted to oppose summary judgment using "any of the kinds of evidentiary materials listed in Rule 56(c), except the mere pleadings themselves." *Id.* In sum, "Rule 56 must be construed with due regard not only for the rights of persons asserting claims and defenses that are adequately based in fact to have those claims and defenses tried to a jury, but also for the rights of persons opposing such claims and defenses to demonstrate . . . that the claims and defenses have no factual basis." *Id.* at 327.

Generally, "a claim which is not raised in the complaint but, rather, is raised only in response to a motion for summary judgment is not properly before the court." *Cutrera v. Bd. of Sup'rs of La. State Univ.*, 429 F.3d 108, 113 (5th Cir. 2005). Here, Ms. Levitt has not asserted a new legal claim, but has merely sought to redefine her alleged injuries. In so doing, she alleges injuries that are very closely related to—if not a component part of—the initially alleged injury. The term "heart attack" is defined as "an acute episode of heart disease . . . ." *Heart Attack*, MERRIAM-WEBSTER. Although that term may not encompass the other injuries she alleges, it is very much intertwined with those other injuries—heart disease is itself a cause of a heart attack. Merck reasonably should have anticipated that Ms. Levitt would not only present evidence of her two heart attacks, but also evidence any related cardiovascular conditions. Moreover, Merck has been on notice of her claimed heart disease since 2009, when she submitted her amended PPF. *See* (Rec. Doc. 641996-1 at 11). It is therefore difficult to conjure what prejudice Merck will incur by allowing Ms. Levitt to proceed with these claimed injuries. For these reasons, the

Court will deny Merck's Motion for Summary Judgment on Specific Causation (Rec. Doc. 64878).

C. Motion for Summary Regarding Proximate Causation (Rec. Doc. 65087)

1. The Parties' Arguments

Merck also moves for summary judgment on all claims and argues that Ms. Levitt is unable to establish proximate causation because her claims invoke the learned intermediary doctrine, and Dr. Katz testified that he would have prescribed Vioxx for Ms. Levitt even if it had a black box warning. In a footnote, Merck states that although the Complaint alleges causes of action other than "failure to warn," the facts indicate that all of the facts pleaded show that Plaintiffs' theory of liability rest on Merck's alleged failure to warn. Defendant cites *In re Norplant Contraceptive Prod. Liab. Litig.* as support for this proposition. In that case, the Court found that application of the learned intermediary doctrine was dispositive of all of Plaintiffs' claims, including strict liability, negligence, misrepresentation, implied warranty, and claims under the Texas Deceptive Practices Act, because each claim was based upon a failure to warn. (Rec. Doc. 65087 at 11, n. 11) (citing *In re Norplant Contrcepttive Prod. Liab. Litig.* 955 F. Supp. 700, 709 (E.D. Tex. 1997)). Merck also argues that Ms. Levitt's claims based on a design defect claim fail under any other theory besides a failure to warn, as FDA regulations prohibit changes to a medication's formula without FDA approval. (Rec. Doc. 65087 at 11, n. 11) (citing *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475 (2013); *Booker v. Johnson & Johnson*, 2014 WL 5113305, at *5 (N.D. Ohio Oct. 10, 2014)).

Merck argues that Ms. Levitt fails to establish proximate causation because Dr. Katz testified that he would have still prescribed Vioxx for Ms. Levitt, even if it carried a black box warning as to its cardiovascular risks. (Rec. Doc. 65087 at 13). As further support, Merck

points to the fact that Dr. Katz continues to prescribe Celebrex to his fibromyalgia patients, and Celebrex has a similar safety profile as Vioxx. (Rec. Doc. 65087 at 13-14) (citing Katz Dept. 83:9-16, 20:21-21:17). Based on these facts, Merck argues that Ms. Levitt is unable to establish that any allegedly deficient warnings were the proximate cause of her injuries under Missouri Law.

Ms. Levitt opposes the motion. Ms. Levitt contends that the learned intermediary doctrine does not apply to all of her causes of actions. In response to Merck's reliance on *In re Norplant Contraceptive Products Liability Litigation*, Ms. Levitt cites *Hill v. Wyeth*, a Missouri case, where the court refused to apply *Norplant's* reasoning to find that all of the plaintiff's claims were based on an alleged failure to warn. (Rec. Doc. 65166 at 7)(citing 2007 WL 674251 (E.D. Mo. 2007)). Like *Hill*, Ms. Levitt contends that she pled several causes of action, including defective design; breach of duty to adequately and properly test Vioxx; and breach of express and implied warranties that Vioxx was safe, effective, and proper of its intended use. (Rec. Doc. 65166 at 8). Ms. Levitt also argues that her claims based on actions other than a failure to warn are not preempted by federal law. Ms. Levitt cites *Wyeth v. Levine*, a Supreme Court case where the Court held that state tort claims alleging a failure to warn against a brand-name drug manufacturer are not preempted by federal law. (Rec. Doc. 65166 at 9) (citing 555 U.S. 555, 570-71 (2009)).

Ms. Levitt argues that the learned intermediary doctrine does not apply to her failure to warn claim. First, Ms. Levitt avers that as a paid speaker and investigator for Merck, Dr. Katz does not qualify for the learned intermediary doctrine. (Rec. Doc. 65166 at 11). Second, Ms. Levitt argues that Merck's direct-to-consumer marketing campaign qualifies for the "direct-to-consumer exception" ("DTC") to the learned intermediary doctrine, and Missouri Courts have

"embraced" this exception. (Rec. Doc. 65166 at 13) (citing *Plubell v. Merck and Co. Inc.*, 2008 WL 4771525; *Doe v. Miles, Inc.*, No. ED75100, 2000 WL 667383, at *17 (Mo. Ct. App. May 23, 2000)). Here, Ms. Levitt argues, the learned intermediary does not apply because she first learned of Vioxx through its advertising campaign. (Rec. Doc. 65166 at 14).

Furthermore, Ms. Levitt highlights several disputed material facts that she contends renders the learned intermediary inapplicable or summary judgment inappropriate. Ms. Levitt states that contrary to Merck's representations, Dr. Katz was not Ms. Levitt's only prescribing physician, and that "Dr. Katz merely continued her current meds but was not making independent decisions about these prescriptions." (Rec. Doc. 65166 at 15) (citing Katz Med. Recs., Rec. Doc. 651618-2). Ms. Levitt avers that contrary to Dr. Katz's testimony that he terminated her Vioxx prescription due to a change in insurance coverage, the change was due to the fact that Merck changed the Vioxx warning label. (Rec. Doc. 65166 at 16).

Merck replies and concedes that Ms. Levitt had previously obtained Vioxx from her primary physician, Dr. Hartman, but states "the record clearly shows that she was no longer taking Vioxx when she sought treatment from Dr. Katz." (Rec. Doc. 65183 at 4). In response to Ms. Levitt's contention that Dr. Katz stopped prescribing her Vioxx due to an insurance change, Merck recounts Ms. Levitt's July 2012 deposition testimony where she stated, "I must be mistaken…I guess I was given something else because my insurance wouldn't cover [Vioxx]." (Rec. Doc. 65183 at 5). Ms. Levitt produced this response after she was shown Dr. Katz's record indicating that she had been switched to Refalen because her insurance no longer covered Vioxx, and Merck also notes that she conceded this point in her opposition to Merck's first motion for summary judgment. (Rec. Doc. 65183 at 5-6).

Merck argues that Ms. Levitt's pontifications about what she would have done if Dr. Katz had relayed adequate warnings are irrelevant to the learned intermediary doctrine. (Rec. Doc. 65173 at 7). The only relevant inquiry, Merck argues, is whether Dr. Katz would have changed his decision to prescribe the drug with the proper warning. (Rec. Doc. 65183 at 7) (citing *Brinkley*, 772 F.3d at 1138). Merck vehemently opposes Ms. Levitt's contention that the learned intermediary does not apply because of Dr. Katz's alleged biases, noting that Ms. Levitt fails to submit evidence of actual bias. (Rec. Doc. 65183 at 8). Merck posits "absent evidence of actual bias the learned intermediary still applies." (Rec. Doc. 65183 at 8)(citing *In re Trysylol Prods. Liab. Litig.*, No. 08-MD-01928, 2011 WL 2117257, at *4 (S.D. Fla. May 23, 2001); *In re Vioxx Cases*, 2006 WL 6305292 (California); *Murphy v. Abbot Laboratories*, 847 F. Supp. 2d 958 (S.D. Tex. 2010)). Merck also argues that Ms. Levitt's argument that the learned intermediary does not apply because of Vioxx's advertising campaign lacks merit, as Missouri does not have a direct-to-consumer exception. (Rec. Doc. 65183) (citing *Centocor*, 372 S.W.3d at 161).

Finally, Merck reasserts the argument that summary judgment based on the learned intermediary theory ends her case because the facts in her complaint only support a failure-to-warn theory. Merck also reasserts that "any claim that would require Merck to have reformulated Vioxx or withdrawn it from the market is preempted by federal law." In response to Ms. Levitt's argument that *Bartlett* is distinguishable from the instant case because Vioxx did not qualify as a generic drug, Merck avers "*Bartlett* cannot be limited to the general drug context because, like drug manufacturers, brand manufacturers cannot reformulate drugs without first obtaining FDA approval." (Rec. Doc. 65183 at 10) (citing *Booker v. Johnson & Johnson*, 2014 WL 5113305 (N.D. Ohio Oct. 10, 2014)).

2. Law and Analysis

Under Missouri law, "it is incumbent upon the manufacturer to bring the warning home to the doctor." *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 146 (Mo.1967) (internal quotations omitted). The physician thus acts as a "learned intermediary" between the manufacturer and the patient. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir.1966). A warning to the doctor is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of prescription drugs. *See Johnston v. Upjohn Co.*, 442 S.W.2d 93, 95 (Mo.Ct.App.1969).

A plaintiff seeking to overcome the learned intermediary doctrine must prove that: (1) the warnings given by the drug manufacturer to the healthcare provider were inadequate; and (2) the inadequate warnings were the proximate cause of plaintiff's injuries. *Madsen v. Am. Home Prods. Corp.*, 477 F.Supp.2d 1025, 1035 (E.D.Mo.2007) (citing *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F.Supp.2d 795, 821 (E.D.Tex.2002)). *See also Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014) (outlining what a plaintiff must show to recover under a failure to warn doctrine pursuant to Missouri law). "'[E]ven assuming the warnings are inadequate, plaintiffs must show that a proper warning would have changed the decision of the treating physician, *i.e.* that but for the inadequate warning, the treating physician would not have used or prescribed the product.'" *Madsen*, 477 F. Supp. 2d at 1035 (quoting *In re Norplant*, 215 F.Supp.2d at 821). *See Brinkley*, 772 F.3d at 1138 (averring that plaintiff must show that the inadequate warning "caused her doctor to prescribe the drug for her") (internal quotations omitted). Here, Merck concedes that the warning was inadequate, so the crux of this Court's analysis is whether there is a disputed material fact regarding causation.

The Court finds that there are disputed material facts as to whether Dr. Katz is the only relevant prescribing physician. Merck concedes that Dr. Hartman initially prescribed Vioxx for Ms. Levitt but argues that Dr. Katz placed her on a daily regimen and controlled her Vioxx prescription after October 1999. Since Ms. Levitt was not taking Vioxx daily prior to this time, and Dr. Katz was her sole conduit for the Vioxx prescription, Merck avers that Dr. Katz is the only relevant physician for the Court's analysis of the learned intermediary doctrine. The underlying evidence, however, compels this Court to find that this remains a disputed material fact. Specifically, Dr. Katz's own records indicate that Dr. Hartman continued to prescribe Ms. Levitt Vioxx as of February 7, 2000. *See* Katz Med. Rec., Feb. 7, 2000, (Rec. Doc. 65182-2 at 7) (noting that Dr. Hartman had changed Ms. Levitt's Vioxx prescription to Relafen). Dr. Katz also testified to this end, stating that "from the February 7, 2000 note we should mention, I don't think we have, that Dr. Hartman had changed her from Vioxx to Relafen." Katz Dep., 52:1-4, Jan. 30, 2013; (Rec. Doc. 65167-5 at 15). This evidence undercuts Merck's theory that Dr. Katz exercised sole control over Ms. Levitt's Vioxx prescription, and the Court thus finds that there are disputed material facts, namely: (1) whether Dr. Hartman continued to prescribe Vioxx for Ms. Levitt, and (2) if so, whether Dr. Hartman would have prescribed Vioxx with an adequate warning. These questions render summary judgment on Ms. Levitt's failure to warn theory inappropriate at this time.

Ms. Levitt also raises a genuine question of Dr. Katz's credibility, and a reasonable juror could question his testimony that he would prescribe Vioxx to Ms. Levitt with a black box warning. Further fact investigation into these alleged biases could ultimately thwart application of the learned intermediary doctrine and thus bolsters support for denial of summary judgment. The Court issues a cautionary note, as the case law indicates that mere evidence of a consulting

relationship between a doctor and a drug manufacturer is not sufficient to prove that the doctor failed to exercise independent judgment when prescribing the drug in question. *See generally Talley v. Danek Medical Inc.*, 179 F.3d 154, 163-64 (4th Cir. 1999) (holding that evidence of consulting relationship between doctor and drug manufacturer is not enough to prove that doctor was biased and did not prescribe drug based on independent medical judgment); *In re Trayslo Prods. Liab. Lit.*, MDL 1928, 2011 WL 2117257, at *4 (S.D. Fla. May 23, 2011) (granting summary judgment and finding that the fact that doctor entered paid consulting agreement with drug manufacturer did not inform his decision to prescribe that drug).

Based on these remaining questions of fact, and notably that no party has taken the deposition of Dr. Hartman, the Court will reopen discovery. The Court urges the parties to resolve these fact issues in an expeditious manner, as this litigation has already spanned nine years and should be put to rest.

While the Court agrees with Ms. Levitt that there is a disputed material fact as to whether Dr. Katz informed Ms. Levitt of Vioxx's associated risks, that fact does not disturb Merck's invocation of the learned intermediary doctrine. The doctrine is premised on the idea that a patient can only obtain prescription drugs when a doctor exercises his discretion and prescribes that drug; the physician is the sole avenue for a patient to secure prescription drugs. Missouri law recognizes that "the drug patient is expected to and, it can be presumed, [ ] place primary reliance upon [the doctor's] judgment ." *Terhune v. A.H. Robins Co.*, 90 Wash. 2d 9, 14 (1978). When determining the drug manufacturer's liability, it is therefore of no consequence whether the doctor relayed these warnings to the patient, as the physician constitutes the only relevant character in a causation analysis vis à vis the drug manufacturer. Indeed, Dr. Katz's failure to relay any warnings to Ms. Levitt is only relevant to an analysis of Dr. Katz's liability, as such a

finding could support an argument that Dr. Katz breached his duty to Ms. Levitt and caused her injuries. This failure, however, bears no effect on Merck's liability.

Since the Court denies summary judgment on the crux of Merck's argument, the Court will reserve judgment as to (1) whether the failure to warn claim encompasses all of Ms. Levitt's claims besides defective design; (2) whether federal law preempts Ms. Levitt's defective design claim; and (3) whether the Court should apply the DTC exception. Looking to the preemption argument, the Court notes that the scope of the *Bartlett* holding has been the subject of much debate among lower courts. Some courts read *Bartlett* narrowly to apply only to generic drugs. *See, e.g., Estate of Cassel v. Alza Corp.*, No. 12–771, 2014 WL 856023 (W.D.Wis. Mar. 5, 2014); *Dopson–Troutt v. Novartis Pharm. Corp.*, No. 06–1708, 975 F.Supp.2d 1209, 2013 WL 5330463 (M.D.Fla. Sept. 23, 2013). Others disagree, finding that *Bartlett* preempts design-defect claims against brand-name manufacturers as well. *See, e.g., Thompson v. Allergan USA, Inc.*, No. 4:13CV00030 AGF, 993 F.Supp.2d 1007, 2014 WL 308794 (E.D.Mo. Jan. 28, 2014). It is therefore not settled law as to whether federal law preempts Ms. Levitt's claims, and certainly not an undisputed point as to warrant placing the legal argument in a footnote.

Looking to Ms. Levitt's argument that the Court should apply the DTC exception, Missouri courts have not affirmatively accepted nor rejected the DTC exception. As this Court recognized in oral argument, this Court is a Federal Court applying Missouri law, so the Court remains reluctant to apply the DTC when Missouri has been silent on the issue. The Court reminds the parties that the MDL panel transferred this case, and other related actions, to this Court for "coordinated or consolidated pretrial proceedings." 28 U.S.C. § 1407(a). Once the parties have completed discovery, the Court must remand this case to the transferor court. *See Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

IV. CONCLUSION

For the foregoing reasons, **IT IS ORDERED** Merck's Motions for Summary Judgment (Rec. Docs. 64878 and 65087) are hereby **DENIED**. **IT IS FURTHER ORDERED** that discovery in this case is re-opened, and any discovery stay, including the deadlines set forth in this Court's Minute Entry (Rec. Doc. 64688), is lifted.

New Orleans, Louisiana, this 20th day of April, 2015.

UNITED STATES DISTRICT JUDGE