UNITED STATES DISTRICT COURT **EASTERN DISTRICT OF TEXAS**

JUDITH FINNICUM,	§	
	§	
Plaintiff,	§	
	§	
versus	§	CIVIL ACTION NO. 1:09-CV-785
	§	
WYETH, INC., SCHWARZ PHARMA, INC., and ACTAVIS-ELIZABETH, L.L.C., Individually and as a Subsidiary of ACTAVIS, INC. and as Successor to PUREPAC PHARMACEUTICAL, INC.,	§	
	§	
Defendants.	§	

MEMORANDUM AND ORDER

Pending before the court is Defendants Wyeth, Inc. ("Wyeth") and Schwarz Parma, Inc.'s ("Schwarz") (collectively, "Defendants") Motion for Summary Judgment (#24). Defendants seek summary judgment on Plaintiff Judith Finnicum's ("Finnicum") claims related to her ingestion of the prescription drug metoclopramide. Having reviewed the pending motion, the submissions of the parties, the pleadings, and the applicable law, the court is of the opinion that summary judgment is warranted.

I. Background

Metoclopramide is a prescription medication that is used to treat gastric reflux symptoms. It is available in both brand-name and generic forms. Wyeth, a Delaware corporation with its principal place of business in New Jersey, manufactured and distributed the brand-name form of metoclopramide, also known as "Reglan," from approximately 1989 until 2001. In 2001, Schwarz, a Delaware corporation with its principal place of business in Wisconsin, acquired the rights to Reglan and manufactured and distributed the drug until approximately 2008. Other

companies, such as Defendant Actavis-Elizabeth, LLC ("Actavis") manufacture and distribute generic forms of metoclopramide.

Finnicum alleges that her doctor prescribed metoclopramide to treat her heartburn sometime in 2003 and that she regularly ingested a generic form of the drug until at least 2007. Finnicum stipulates, however, that she never ingested any form of metoclopramide manufactured or distributed by Wyeth or Schwarz. In mid-2007, Finnicum began exhibiting symptoms of tardive dyskinesia, a neurological disorder characterized by involuntary movements, especially of the lower face. Finnicum contends that her long-term ingestion of metoclopramide caused her to develop the disease. On August 14, 2009, Finnicum filed her original complaint in district court, followed by an amended complaint on August 31, 2009, asserting causes of action against Wyeth and Schwarz for negligence, strict products liability, breach of warranty, fraud, and violations of the Texas Deceptive Trade Practices Act. Finnicum seeks damages for past and future medical expenses, physical pain and suffering, physical disfigurement, and loss of earnings related to her development of tardive dyskinesia.

On November 20, 2009, Defendants filed the instant motion for summary judgment. Defendants contend that they cannot be held liable for Finnicum's condition under Texas law because Finnicum never ingested any form of metoclopramide that they manufactured or distributed. Finnicum responds that manufacturers of generic metoclopramide are required by federal law to use brand-name warnings when selling their products. Finnicum further contends that physicians rely on brand-name warnings when prescribing generic drugs. Finnicum maintains that Defendants, as manufacturers of brand-name Reglan, failed to provide adequate warnings of the long-term effects of metoclopramide use and, thus, may be held liable for her injuries.

II. Analysis

A. Summary Judgement Standard

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). The parties seeking summary judgment bear the initial burden of informing the court of the basis for their motion and identifying those portions of the pleadings, depositions, answers to interrogatories, admissions on file, and affidavits, if any, which they believe demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); *Warfield v. Byron*, 436 F.3d 551, 557 (5th Cir. 2006); *Lincoln Gen. Ins. Co. v. Reyna*, 401 F.3d 347, 349 (5th Cir. 2005).

"A fact is material only if its resolution would affect the outcome of the action . . . ." *Wiley v. State Farm Fire & Cas. Co.*, 585 F.3d 206, 210 (5th Cir. 2009); *accord Cooper Tire & Rubber Co. v. Farese*, 423 F.3d 446, 454 (5th Cir. 2005); *Harken Exploration Co. v. Sphere Drake Ins. PLC*, 261 F.3d 466, 471 (5th Cir. 2001). "Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "An issue is '*genuine*' if it is real and substantial, as opposed to merely formal, pretended, or a sham." *Bazan ex rel. Bazan v. Hidalgo County*, 246 F.3d 481, 489 (5th Cir. 2001) (emphasis in original). Thus, a genuine issue of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248; *accord Wiley*, 585 F.3d at 210; *EMCASCO Ins. Co. v. American Int'l Specialty Lines Ins. Co.*, 438 F.3d 519, 523 (5th Cir. 2006); *Cooper Tire & Rubber Co.*, 423 F.3d at 454. The moving parties, however,

need not negate the elements of the nonmovant's case. *See Boudreaux v. Swift Transp. Co.*, 402 F.3d 536, 540 (5th Cir. 2005) (citing *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994)); *Millennium Petrochemicals, Inc. v. Brown & Root Holdings, Inc.*, 390 F.3d 336, 339 (5th Cir. 2004).

Once a proper motion has been made, the nonmoving parties may not rest upon mere allegations or denials in the pleadings but must present affirmative evidence, setting forth specific facts, to show the existence of a genuine issue for trial. *Celotex Corp.*, 477 U.S. at 322 n.3 (quoting FED. R. CIV. P. 56(e)); *Anderson*, 477 U.S. at 256; *EMCASCO Ins. Co.*, 438 F.3d at 523; *Smith ex rel. Estate of Smith v. United States*, 391 F.3d 621, 625 (5th Cir. 2004). "[T]he court must review the record 'taken as a whole.'" *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986)); *see Riverwood Int'l Corp. v. Employers Ins. of Wausau*, 420 F.3d 378, 382 (5th Cir. 2005). All the evidence must be construed "in the light most favorable to the nonmoving party, and the court will not weigh the evidence or evaluate its credibility. *EEOC v. Chevron Phillips Chem. Co., LP*, 570 F.3d 606, 615 (5th Cir. 2009); *Reeves*, 530 U.S. at 150; *Lincoln Gen. Ins. Co.*, 401 F.3d at 350; *Smith*, 391 F.3d at 624; *Brown v. City of Houston*, 337 F.3d 539, 541 (5th Cir. 2003). The evidence of the nonmovant is to be believed, with all justifiable inferences drawn and all reasonable doubts resolved in her favor. *Groh v. Ramirez*, 540 U.S. 551, 562 (2004) (citing *Anderson*, 477 U.S. at 255); *Shields v. Twiss*, 389 F.3d 142, 150 (5th Cir. 2004); *Martin v. Alamo Cmty. Coll. Dist.*, 353 F.3d 409, 412 (5th Cir. 2003); *Martinez v. Schlumberger, Ltd.*, 338 F.3d 407, 411 (5th Cir. 2003); *Gowesky v. Singing River Hosp. Sys.*, 321 F.3d 503, 507 (5th Cir.), *cert. denied*, 540 U.S. 815 (2003).

Nevertheless, "only reasonable inferences in favor of the nonmoving party can be drawn from the evidence." *Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 779 (E.D. Tex. 2008) (citing *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 469 n.14 (1992)). "If the [nonmoving party's] theory is . . . senseless, no reasonable jury could find in its favor, and summary judgment should be granted." *Eastman Kodak Co.*, 504 U.S. at 468-69; *accord Shelter Mut. Ins. Co. v. Simmons*, 543 F. Supp. 2d 582, 584-85 (S.D. Miss.), *aff'd* , 293 F. App'x 273 (5th Cir. 2008). The nonmovant's burden is not satisfied by "'some metaphysical doubt as to the material facts,' by 'conclusory allegations,' by 'unsubstantiated assertions,'" by speculation, by the mere existence of some alleged factual dispute, or "by only a 'scintilla' of evidence." *Little*, 37 F.3d at 1075 (quoting *Lujan v. National Wildlife Fed'n*, 497 U.S. 871, 888 (1990); *Matsushita Elec. Indus. Co.*, 475 U.S. at 586; *Hopper v. Frank*, 16 F.3d 92, 97 (5th Cir. 1994); *Davis v. Chevron U.S.A., Inc.*, 14 F.3d 1082, 1086 (5th Cir. 1994)); *accord Thibodeaux v. Vamos Oil & Gas Co.*, 487 F.3d 288, 294-95 (5th Cir. 2007); *Warfield*, 436 F.3d at 557; *Boudreaux*, 402 F.3d at 540. "Unsubstantiated assertions, improbable inferences, and unsupported speculation are not sufficient to defeat a motion for summary judgment." *Brown*, 337 F.3d at 541; *accord Hugh Symons Group, plc v. Motorola, Inc.*, 292 F.3d 466, 468 (5th Cir.), *cert. denied*, 537 U.S. 950 (2002); *see Hockman v. Westward Commc'ns, LLC*, 407 F.3d 317, 332 (5th Cir. 2004); *Bridgmon v. Array Sys. Corp.*, 325 F.3d 572, 577 (5th Cir. 2003).

Summary judgment is mandated if the nonmovant fails to make a showing sufficient to establish the existence of an element essential to her case on which she bears the burden of proof at trial. *Nebraska v. Wyoming*, 507 U.S. 584, 590 (1993); *Celotex Corp.*, 477 U.S. at 322; *EMCASCO Ins. Co.*, 438 F.3d at 523; *Cutrera v. Board of Supervisors of La. State Univ.*, 429

F.3d 108, 110 (5th Cir. 2005); *Patrick v. Ridge*, 394 F.3d 311, 315 (5th Cir. 2004). "In such a situation, there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Celotex Corp.*, 477 U.S. at 322-23.

B. Finnicum's Claims

Finnicum stipulates that she never used any form of metoclopramide that Defendants manufactured. Nevertheless, Finnicum contends that, under federal law, manufacturers of brand-name Reglan are responsible for the warnings and information distributed by generic manufacturers. As such, Finnicum argues that Defendants' alleged failure to warn doctors and patients of the risks associated with metoclopramide gives rise to liability for her injuries even though she did not use their products. Therefore, the only issue to be resolved in this case is whether Defendants can be held liable on a failure-to-warn claim for injuries that Finnicum suffered after ingesting another manufacturer's drug.

Because federal jurisdiction in this case is based on diversity of citizenship, the court must apply Texas law when determining substantive issues. *See Foradori v. Harris*, 523 F.3d 477, 486 (5th Cir. 2008) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938)). If no state court decisions control, the court must make an "Erie guess" as to how the Texas Supreme Court would apply state law. *Beavers v. Metropolitan Life Ins. Co.*, 566 F.3d 436, 439 (5th Cir. 2009). Finnicum's claims against Defendants "aris[e] out of personal injury, death, or property damage allegedly caused by a defective product" and, as such, are properly characterized as products liability claims. TEX. CIV. PRAC. & REM. CODE ANN. § 82.001(2) (Vernon 2009); *see Burke v. Wyeth, Inc.*, No. G-09-82, 2009 WL 3698480, at *2 (S.D. Tex. Oct. 29, 2009). Although the

Texas Supreme Court has not addressed the specific issue involved in this case, it has recognized that imposition of products liability is precluded when the defendant did not supply the product that caused the plaintiff's injuries. *See Firestone Steel Prods. Co. v. Barajas*, 927 S.W.2d 608, 614 (Tex. 1996); *Gaulding v. Celotex Corp.*, 772 S.W.2d 66, 68 (Tex. 1989); *see also Sanchez v. Liggett & Myers, Inc.*, 187 F.3d 486, 491 (5th Cir. 1999). The Texas Supreme Court has further stated, "a manufacturer generally does not have a duty to warn or instruct about another manufacturer's products, even though a third party might use those products in connection with the manufacturer's own products." *Firestone Steel Prods. Co.*, 927 S.W.2d at 614. Guided by these authorities, this court and other federal district courts have held that Texas law does not permit a plaintiff who ingested another manufacturer's drug to maintain a failure-to-warn claim against a brand-name manufacturer. *See, e.g.*, *Hardy v. Wyeth, Inc.*, No. 9:09-CV-152, 2010 WL 1049588, at *4-5 (E.D. Tex. Mar. 8, 2010); *Burke*, 2009 WL 3698480, at *2; *Cousins v. Wyeth Pharm., Inc.*, No. 3:08-CV-0310-N, 2009 WL 648703, at *1 (N.D. Tex. Mar. 10, 2009); *Pustejovsky v. Wyeth, Inc.*, No. 4:07-CV-103-Y, 2008 WL 1314902, at *2 (N.D. Tex. Apr. 3, 2008); *Block v. Wyeth, Inc.*, No. 3:02-CV-1077, 2003 WL 203067, at *1-2 (N.D. Tex. Jan. 28, 2003).

These cases comport with federal appellate decisions in other jurisdictions. In *Foster v. American Home Prods. Corp.*, the Court of Appeals for the Fourth Circuit examined a similar situation under Maryland law. 29 F.3d 165 (4th Cir. 1994). In *Foster*, the plaintiffs brought suit after their daughter died upon ingesting a generic version of a drug used to treat colic. *Id.* at 167. The plaintiffs asserted a negligent misrepresentation claim against the brand-name manufacturer, arguing that federal law requires generic drug warnings to mimic their brand-name counterparts.

Id. at 169. The court rejected the plaintiffs argument, finding no legal precedent for holding a brand-name manufacturer liable for injuries caused by its competitors. *Id.* at 169-71. The court further reasoned that imposing a duty on the brand-name manufacturer under such circumstances "would be to stretch the concept of foreseeability too far." *Id.* at 171.

The Eighth Circuit followed the *Foster* decision in *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009). In *Mensing*, the plaintiff developed tardive dyskinesia after long-term use of generic metoclopramide. *Id.* at 614. The plaintiff asserted causes of action for fraud and negligent misrepresentation against manufacturers of brand-name Reglan, contending that her doctor relied on Reglan's label when assessing the risk and proper use of the generic brand. *Id.* at 605. According to the court, "regardless of whether her doctor relied upon the Reglan label, [the plaintiff] must show that the name brand manufacturers owed *her* a duty of care." *Id.* at 613. As in *Foster*, the court concluded that the relationship between the plaintiff and the brand-name manufacturer, whose product the plaintiff never ingested, was too attenuated to trigger a duty of care. *Id.* The court also recognized that "the overwhelming majority of courts considering this issue has reached the same conclusion." *Id.* at 613 & n.8.

Although the Fifth Circuit has not directly confronted this issue, dictum in the recent decision *Demahy v. Actavis, Inc.* is consistent with the holdings of the Fourth and Eighth Circuits that no liability can be imposed upon the brand-name manufacturer for the effects of a generic drug manufactured by another company. 593 F.3d 428, 449 (5th Cir. 2010). In *Demahy*, the Fifth Circuit expressly rejected the defendant's argument that the plaintiff's failure-to-warn claim against a generic drug manufacturer under Louisiana law was preempted by federal law requiring that generic drugs "be the 'same as' a name brand drug . . . as to active ingredients, route of

administration, dosage form, strength, and conditions of use recommended in the labeling." *Id.* at 432 (quoting 21 U.S.C. § 355(j)(2)(A)(iii)) . In addressing the liability of a generic drug manufacturer, the court stated:

> In this case, unless the law would somehow harness liability onto name brand manufacturers for all failure-to-warn claims, preemption in this case would leave Demahy without a remedy. Yet "[i]f Congress had intended to deprive [Demahy] of a long available form of compensation, it surely would have expressed that intent more clearly." To hold otherwise would leave us with the bizarre conclusion that Congress intended to implicitly deprive a plaintiff whose doctor prescribes a generic drug of *any* remedy, while . . . that same plaintiff would have a state-law claim had she only demanded a name brand drug instead.

Id. (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)). Although the *Demahy* court was not faced with the issue involved here, the implication is that a plaintiff who ingested only a generic drug would have no avenue for relief if he was foreclosed from suing a generic manufacturer for failure to warn of the effects of its product due to the labeling laws.

Finnicum argues that this court should apply the foreseeability standard set forth in a California decision, *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008). In *Conte*, the court extended a brand-name drug manufacturer's duty of care regarding product information to patients who were injured by generic brands. *Id.* at 312-13. The court reasoned that it is "eminently foreseeable" that a physician might prescribe generic medication based on a brand-name manufacturer's representations about its drug. *Id.* at 313. This argument, however, was raised and rejected in *Burke*, in which the court opined that a Texas court would follow the reasoning in *Foster* and conclude that "'to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far.'" *Burke*, 2009 WL 3698480, at *3 (quoting *Foster*, 29 F.3d at 171).

Likewise, Finnicum's reliance on *Easter v. Aventis Pasteur, Inc.*, No. 5:03-CV-141(TJW), 2004 WL 3104610 (E.D. Tex. Feb. 11, 2004), is not persuasive. In *Easter*, the district court denied a motion to dismiss a claim against the designer of a pediatric vaccine that was manufactured by another company, holding that the designer of a product has a duty to develop a safe design and to inform users of hazards associated with its product. *Id.* at 9 (citing *Alm v. Aluminum Co.*, 717 S.W.2d 588, 591 (Tex. 1986)). In a subsequent order on a motion for reconsideration, however, the court clarified that the pleadings alleged that the defendant designed the vaccine that was injected into the plaintiff and purportedly caused the plaintiff's injuries. *Easter v. Adventis Pasteur, Inc.*, No. 5:03-CV-141 (document #98 filed on May 18, 2004). In contrast, in the instant case, Finnicum has stipulated that she never ingested Defendants' products. Furthermore, in *Blackmon v. American Home Prods. Corp.*, a case against the same defendant as in *Easter*, the court refused to extend liability and granted summary judgment, finding that the defendant did not manufacture the vaccines taken by the plaintiffs or intend for the manufacturer to use its design. 346 F. Supp. 2d 907, 919 (S.D. Tex. 2004). The *Blackmon* court noted the *Block* decision, in which the court refused to "'extend Texas tort law into new and uncharted territory' in order to hold the original designer of a drug liable for alleged defects in a generic version of the drug." *Id.* at 919 n.5 (quoting *Block*, 2003 WL 203067, at *3). The court finds the *Blackmon* decision more analogous to the case at bar.

For the reasons discussed above, the court finds that the Texas Supreme Court would conclude that a brand-name manufacturer does not owe a duty to warn users of the risks related to another manufacturer's product. In the instant case, Finnicum did not ingest any form of

metoclopramide manufactured by either Wyeth or Schwarz. Therefore, the court is of the opinion that Defendants owed no duty to Finnicum and, thus, no basis for liability exists against them.

III. Conclusion

Under Texas law, a brand-name drug manufacturer may not be held liable on a failure-to-warn claim asserted by a plaintiff who ingested a generic drug that was manufactured by another company. Because Finnicum has stipulated that she ingested metoclopramide manufactured by other companies, Defendants may not be held liable for her injuries. Accordingly, Defendants are entitled to summary judgment on Finnicum's claims.

SIGNED at Beaumont, Texas, this 28th day of April, 2010.

Marcia A. Crone

MARCIA A. CRONE
UNITED STATES DISTRICT JUDGE