UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

MONROE DIVISION

PENNY MORRIS AND JOHN MORRIS	CIVIL ACTION NO. 09-00854
VERSUS	JUDGE JAMES
WYETH, INC., D/B/A WYETH; SCHWARZ PHARMA, INC.; PLIVA USA, INC.; TEVA PHARMACEUTICALS USA, INC.; ALAVEN PHARMACEUTICALS, LLC	MAGISTRATE JUDGE HAYES

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS WYETH, INC.'S AND SCHWARZ PHARMA, INC.'S MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Other

Defendants WYETH, INC. ("Wyeth") and SCHWARZ PHARMA, INC. ("Schwarz") (collectively, "Defendants") respectfully submit this Memorandum of Law in Support of their Motion for Summary Judgment.

INTRODUCTION

This is a product liability case in which Plaintiffs Penny and John Morris allege that Mrs. Morris suffered injuries arising from her use of the prescription drug metoclopramide. Compl. ¶¶ 3.02, 3.09. Plaintiffs have stipulated that Mrs. Morris did not ingest any metoclopramide, whether brand name or generic, manufactured or distributed by either Wyeth or Schwarz. Nevertheless, Plaintiffs assert that Wyeth and Schwarz, as previous manufacturers of brand name metoclopramide (known by the trade name Reglan®), are responsible for the warnings and information distributed by the generic metoclopramide manufacturers whose product Mrs. Morris ingested. Plaintiffs' claims fail as a matter of law.

In *Tarver v. Wyeth*, this Court rejected the exact theory of liability that Plaintiffs advance in this case – that Wyeth and Schwarz have a duty to warn about another manufacturer's product. No. Civ. A. 3-04-2036, 2005 WL 4052382, at *2 (W.D. La. June 7, 2005) (dismissing claims asserted against Schwarz) (cited hereafter as "Tarver I"); *see also Tarver v. Wyeth*, No. Civ. A. 3-04-2036, 2006 WL 1517546, at *2 (W.D. La. Jan. 26, 2006) (dismissing claims asserted against Wyeth) (cited hereafter as "Tarver II"); *see also Leblanc v. Wyeth*, No. Civ. A. 04-0611, 2006 WL 2883030, at *6 (W.D. La. Oct. 5, 2006) (citing *Tarver I*). Confirming the soundness of this Court's decisions in *Tarver I* and *Tarver II*, the Louisiana Court of Appeals has since held that, under Louisiana law, "a brand name drug manufacturer owes no legal duty to the

consumer of a generic equivalent of its drug." *Stanley v. Wyeth*, 991 So.2d 31, 34-35 (La. App. 1 Cir. 2008).

Louisiana is by no means alone on this issue. Almost every court in the nation to address the issue – thirty decisions in nineteen states (including Louisiana) – has rejected attempts to hold brand name drug manufacturers liable for injuries allegedly caused by a generic-equivalent drug. Indeed, twenty-one decisions in sixteen states have expressly rejected such claims against Wyeth and/or Schwarz in cases involving metoclopramide.

This Court should again follow this landslide of well-reasoned and persuasive authority and enter judgment as a matter of law on all of Plaintiffs' claims against Wyeth and Schwarz.

UNDISPUTED FACTS

Metoclopramide is a prescription drug approved by the FDA to treat, among other things, gastroesophageal reflux disease and diabetic gastroparesis. (*See* Compl. ¶ 3.70.) Metoclopramide is available in both brand (Reglan®) and generic formulation. (Minicozzi Aff. ¶ 6.)

At different times, Wyeth and Schwarz manufactured and distributed brand name Reglan®. From approximately 1989 through late December 2001, Wyeth manufactured and distributed Reglan® tablets. (*Id.* ¶¶ 2-3.) Schwarz acquired the rights to Reglan® tablets from Wyeth in late December 2001. Thereafter, Schwarz manufactured and distributed Reglan® tablets until February 2008.[1] (Siefert Aff. ¶ 2.) Since the mid-

[1] Contrary to Plaintiffs' allegation (see Compl. ¶¶ 3.66, 4.17), at no time did Schwarz publish a copy of its label for Reglan® tablets in the Physicians' Desk Reference. (Siefert Aff. ¶ 4.)

1980s, several companies – including defendants Pliva and Teva – have manufactured and distributed generic metoclopramide. (Minicozzi Aff. ¶ 6.)

Plaintiffs initiated this action on May 22, 2009. They allege that Mrs. Morris ingested metoclopramide tablets from early 2006 through July 2008 and, as a result, allegedly developed a neurological condition known as tardive dyskinesia. (Compl. ¶¶ 3.09, 3.16-3.17). The Complaint purports to assert five claims against Defendants: negligence (including gross negligence); strict liability; breach of warranty; misrepresentation and fraud; and violation of the Louisiana Unfair Trade Practices and Consumer Protection Law. (*see* Compl. ¶¶ 4.01-5.03.)

On August 7, 2009, Plaintiffs filed a Stipulation (Docket 43) conceding that "Penny Morris ingested only generic metoclopramide" and that "Penny Morris did not ingest any metoclopramide, whether generic or brand name (Reglan®), manufactured or distributed by" Wyeth or Schwarz. (*Id.* at ¶¶ 1-2). The Stipulation also confirms that "Plaintiff's causes of action against Wyeth, Schwarz, and Alaven are not based upon the claim that Wyeth, Schwarz, or Alaven manufactured or sold the Reglan®/ metoclopramide ingested by Penny Morris." (*Id.* at ¶ 3).

SUMMARY JUDGMENT STANDARD

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). When "a party . . . fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial . . . 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. v. Catrett*, 477 U.S. 317, 322-23 (1986); *New York Life Ins. Co. v. Travelers Ins. Co.*, 92 F.3d 336, 338 (5th Cir.1996); *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir.1994) (en banc). Under such circumstances, "[t]he moving party is 'entitled to a judgment as a matter of law' because the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Celotex Corp. v. Catrett,* 477 U.S. at 323. Applying these principles here, Wyeth and Schwarz are entitled to a judgment as a matter of law because Plaintiffs cannot establish a key element of their claims – namely, that Mrs. Morris ingested a product from Wyeth or Schwarz.

ARGUMENT

In Louisiana, the Louisiana Products Liability Act (LPLA) provides the exclusive grounds on which a manufacturer may be held liable for damage caused by its product. Plaintiffs' Complaint asserts five claims against Defendants: negligence; gross negligence; strict liability; breach of warranty; misrepresentation and fraud; and violation of the Louisiana Unfair Trade Practices and Consumer Protection Law. Compl. ¶¶ 4.01-5.03. Insofar as these claims are not recognized by, or brought independent of, the LPLA, they are not viable. Further, even if Plaintiffs' claims were recognized by the LPLA, they fail because Plaintiffs concede that Wyeth and Schwarz did not manufacture the product at issue. Finally, Louisiana law (like the law of eighteen other states) is clear – a manufacturer has no duty to warn about the dangers associated with another company's product. On that basis, this Court has repeatedly rejected claims against

Wyeth and Schwarz by plaintiffs who ingested only their competitors' generic drugs. It should again reject these claims here.

I. WYETH AND SCHWARZ CANNOT BE HELD LIABLE UNDER LOUISIANA LAW FOR INJURIES CAUSED BY ANOTHER MANUFACTURER'S PRODUCT.

A. Plaintiff's Claims Fail Under the LPLA, Because Wyeth and Schwarz Did Not Manufacture the Product Which Allegedly Injured Her.

As a threshold matter, each of Plaintiffs' claims fail because Plaintiffs cannot satisfy the requirements of the Louisiana Products Liability Act. The LPLA is the exclusive remedy for products liability claims in Louisiana; Plaintiffs "may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in" the LPLA. La.R.S. § 9.2800.52. The LPLA authorizes only four theories of recovery: (1) construction or composition defect; (2) design defect; (3) inadequate warning; or (4) breach of express warranty. La.R.S. §§ 9:2800.52-54; *accord Jefferson v. Lead Indus. Ass'n, Inc.*, 106 F.3d 1245, 1250-51 (5th Cir. 1997).

Plaintiffs' claims of negligence, strict liability, unfair trade practices, breach of implied warranty, misrepresentation and fraud, gross negligence and punitive damages all fall outside the scope of the LPLA. As Louisiana law prohibits Plaintiffs from asserting these claims as independent causes of action, they each fail as a matter of law. *Jefferson*, 106 F.3d at 1251 (affirming dismissal of negligence, fraud, market share liability, implied warranty, and civil conspiracy claims); *Grenier v. Medical Eng'g Corp.*, 99 F. Supp. 2d 759, 763-65 (W.D. La. 2000), *aff'd* 243 F.3d 200 (5th Cir. 2001) (claims for strict liability, negligence, breach of warranty of fitness, breach of implied warranty, fraud, misrepresentation, and false advertising are not recognizable); *Bladen v. C.B.*

Fleet Holding Co., 487 F. Supp. 2d 759 (W.D. La. 2007) (unfair trade practice claims are precluded by the LPLA).

Even if Plaintiffs had properly asserted their claims under the LPLA, these claims would still fail to meet the required elements of an LPLA action. Regardless of the particular theory of recovery, in order to bring *any* type of product liability action under the LPLA, a plaintiff must establish all of the following four elements: "(1) *that the defendant is a manufacturer of the product;* (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product 'unreasonably dangerous'; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else." *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 260-61 (5th Cir. 2002) (emphasis added); *see also* La.R.S. § 9:2800.54(A). In short, "[u]nder the LPLA the first element that must be proven by the claimant is that the defendant is the manufacturer of the product causing plaintiff's harm." *Stanley*, 991 So.2d at 33 n.2.

Here, it is undisputed that neither Wyeth nor Schwarz manufactured the metoclopramide that allegedly injured Mrs. Morris. Plaintiffs have conceded that Mrs. Morris did not use Wyeth and Schwarz's product. (Stipulation at ¶ 1-2). Further, they admit that their "causes of action are not based upon the claim that Wyeth [or] Schwarz ... manufactured or sold the Reglan®/metoclopramide ingested by Penny Morris." (*Id.* at ¶ 3). Thus, no question of material fact exists, and Wyeth and Schwarz are entitled to summary judgment on all of Plaintiffs' claims.

B. Louisiana State and Federal Courts Have Recognized that Wyeth and Schwarz Have No Duty to Warn About Another Manufacturer's Drug.

Even though the LPLA bars their claims against Wyeth and Schwarz, Plaintiffs seek to impose liability on these defendants for an injury allegedly caused by Mrs. Morris's use of the generic manufacturers' product. Plaintiffs argue that Wyeth and Schwarz may be held liable for a product they neither manufactured nor marketed, because the generic manufacturer used the brand name drug's warnings in marketing the generic version. (Plaintiff's Response to Defendant Alaven Pharmaceutical LLC's Motion to Dismiss, at 3). That theory has already been addressed – and rejected – by Louisiana courts, including this Court.

In *Stanley v. Wyeth*, plaintiffs sued Wyeth for injuries allegedly caused by a generic version of Wyeth's cardiac drug, Cordarone®. 991 So.2d at 32. As here, the plaintiffs conceded that Wyeth did not manufacture the drug ingested by Mrs. Stanley, but argued that they could still assert claims against Wyeth in "a negligent misrepresentation action and not an action under the LPLA." *Id.* at 33. The *Stanley* court disagreed, concluding that "a manufacturer 'cannot reasonably expect that consumers will rely on information they provide when actually ingesting another company's drug.'" *Id.* at 34 (quoting *Foster v. American Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994)). Therefore, the First Circuit Court of Appeal held as a matter of law that "a name brand drug manufacturer owes no legal duty to the consumer of a generic equivalent of its drug." *Id.* at 34-35.

This very Court previously came to the same conclusion regarding Wyeth and Schwarz in the Reglan®/metoclopramide context. In *Tarver I*, plaintiffs "attempt[ed] to hold liable a company even if it did not manufacture the product by asserting that it had

a duty to warn of the product's dangers." *Tarver I* at *2; *see also Tarver II* at *2. As in *Stanley*, plaintiffs argued that their claims against Wyeth and Schwarz were negligent misrepresentation claims that fell outside the scope of the LPLA. *Tarver I* at *3. This Court rejected that argument on two separate occasions and recognized that "the law is clear that Louisiana imposes on a manufacturer no duty to warn of the dangers of another company's product." *Id.* at *2-3.

Judge Melanson subsequently relied on this Court's rulings in *Tarver* when granting summary judgment in favor of Wyeth in *LeBlanc v. Wyeth*. 2006 WL 2883030 at *5-6. In *LeBlanc*, as in *Stanley* and *Tarver*, the court held plaintiff could not hold Wyeth, the brand name manufacturer of Cordarone®, liable under the LPLA when it was undisputed that the plaintiff ingested only a generic version of the drug manufactured by other companies. *Id.*

As these four rulings make clear, Louisiana courts have already rejected the theory of liability advanced by Plaintiffs in this case. Because Mrs. Morris ingested only generic metoclopramide manufactured by companies other than Wyeth and Schwarz, her claims cannot survive under Louisiana law and should once again be dismissed by this Court.

II. LOUISIANA LAW IS CONSISTENT WITH DECISIONS FROM ACROSS THE COUNTRY THAT HAVE REJECTED PLAINTIFFS' THEORY THAT BRAND NAME MANUFACTURERS ARE LIABLE FOR INJURIES CAUSED BY GENERIC PRODUCTS.

Louisiana law does not stand alone on this issue. *Thirty courts applying the laws of nineteen different states* (Alabama, Arkansas, Colorado, Florida, Georgia, Iowa, Kentucky, Louisiana, Oklahoma, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, North Carolina, Pennsylvania, Texas and Utah) have held that a

brand name manufacturer cannot be held liable for injuries caused by the ingestion of a generic manufacturer's product. *See Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994); *Stoddard v. Wyeth, Inc.*, --- F. Supp. 2d ---, No. 4:08-CV-173-H, 2009 WL 1883051, at *2-*3 (E.D.N.C. June 24, 2009); *Fields v. Wyeth, Inc.*, 613 F. Supp. 2d 1056 (W.D. Ark. 2009); *Moretti v. Wyeth, et al.*, No. 2:08-CV-00396, 2009 WL 749532, at *3-*4 (D. Nev. Mar. 20, 2009); *Schrock v. Wyeth, Inc., et al.*, 601 F. Supp. 2d 1262, 1266-67 (W.D. Okla. 2009); *Cousins v. Wyeth Pharma., Inc., et al.*, No. 3:08-CV-0310-N, 2009 WL 648703, at *2 (N.D. Tex. Mar. 10, 2009); *Mensing v. Wyeth, Inc., et al.*, Civil No. 07-3919 (DWF/SRN), 2008 WL 4724286, at *5 (D. Minn. Oct. 30, 2008); *Smith v. Wyeth, Inc.*, No. 5:07-CV-18-R, 2008 WL 2677051, at *4 (W.D. Ky. June 30, 2008); *Wilson v. Wyeth, Inc.*, No. 3:07-CV-378-R, 2008 WL 2677049, at *4 (W.D. Ky. June 30, 2008); *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R, 2008 WL 2677048, at *4 (W.D. Ky. June 30, 2008); *Pustejovsky v. Wyeth, Inc.*, No. 4:07-CV-103-Y, 2008 WL 1314902, at *2 (N.D. Tex. Apr. 3, 2008); *Swicegood v. Pliva, Inc.*, 543 F. Supp. 1351, 1358 (N.D.Ga. 2008); *Barnhill v. Teva Pharm. USA, Inc.*, No. Civ. A. 06-0282-CB M, Order at 4 (S.D. Ala. Apr. 24, 2007); *LeBlanc v. Wyeth, Inc.*, No. Civ. A 04-0611, 2006 WL 2883030, at *6 (W.D. La. Oct. 5, 2006); *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477, 2006 WL 2038436, at *6 (N.D.N.Y. July 19, 2006); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 540-41 (E.D. Pa. 2006), *aff'd in pertinent part and rev'd in other part*, 521 F.3d 253 (3d Cir. 2008), *vacated and remanded*, 129 S.Ct. 1578 (2009); *Tarver v. Wyeth*, No. Civ. A. 3-04-2036, 2005 WL 4052382, at *2 (W.D. La. June 7, 2005); *Block v. Wyeth, Inc.*, 02-CV-1077, 2003 WL 203067, at *2 (N.D. Tex. Jan. 28, 2003); *Stanley v. Wyeth, Inc.*, 991 So.2d 31, 34-35 (La. App. 1 Cir. 2008); *Flynn v. Am. Home Prods.*

Corp., 627 N.W. 2d 342, 350 (Minn. Ct. App. 2001); *Sharp v. Leichus*, 04-CA-643, 2006 WL 515532, at *4 (Fla. Cir. Ct. Feb. 17, 2006), *aff'd per curiam*, 952 So.2d 555 (Fla. 1st DCA 2007); *Huck v. Trimark Physicians Group, et al.*, No. LACV018947, Order at 1-2 (Iowa Dist. Ct. Feb. 27, 2009); *Buchanan v. Wyeth Pharm., Inc., et. al.*, CV-2007-900065, Order at 1 (Ala. Cir. Ct. Oct. 20, 2008); *Green v. Wyeth Pharm., Inc., et al.*, CV-06-3917 ER, Order at 1 (Ala. Cir. Ct. May 15, 2007); *Kelly v. Wyeth*, 03-CV-3314, 2005 WL 4056740, at *2 (Super. Ct. Mass. May 6, 2005); *Sheeks v. Am. Home Prods. Corp.*, No. 02CV337, 2004 WL 4056060, at *2 (Colo. Dist. Ct. Oct. 15, 2004); *Reynolds v. Anton*, No. 01A-76719-3, 2004 WL 5000272, at *9 (Ga. Super. Ct. Oct. 28, 2004); *Westerlund v. Wyeth, Inc.*, No. MID L02174-05, slip op. at 3 (N.J. Super. Ct. Oct. 20, 2008); *Sloan v. Wyeth*, No. MRS-L-1183-04, slip op. at 5 (N.J. Super. Ct. Oct. 13, 2004); *Beutella v. A.H. Robins Co., Inc.*, No. 05-CV-2372, 2001 WL 35669202, at *2 (Utah Dist. Ct. Dec. 10, 2001).[2]

Further, as explained below, *twenty-one decisions from sixteen states* have specifically held that Wyeth and/or Schwarz, as the manufacturers of brand name Reglan® may not be held liable for injuries allegedly caused by the ingestion of their competitors' generic metoclopramide.[3]

---

[2] Copies of the unreported opinions are attached in alphabetical order as Exhibit A.

[3] *See Stoddard*, 2009 WL 1883051, at *2-*3; *Fields*, 613 F. Supp. 2d 1056; *Moretti*, 2009 WL 749532, at *3 - *4; *Schrock*, 601 F. Supp. 2d at 1266-67; *Cousins*, 2009 WL 648703, at *2; *Mensing*, 2008 WL 4724286, at *5; *Smith*, 2008 WL 2677051, at *4; *Wilson*, 2008 WL 2677049, at *4; *Morris*, 2008 WL 2677048, at *4; *Pustejovsky*, 2008 WL 1314902, at *2; *Swicegood*, 543 F. Supp. 2d at 1358; *Tarver*, 2005 WL 4052382, at *2; *Block*, 2003 WL 203067, at *2; *Sharp*, 2006 WL 515532, at *4; *Huck*, Order at 1-2; *Buchanan*, Order at 1; *Green*, Order at 1; *Kelly*, 2005 WL 4056740, at *2; *Sheeks*, 2004 WL 4056060, at *2; *Sloan*, slip op. at 5; *Beutella*, 2001 WL 35669202, at *2. Only one decision, *Conte v. Wyethe*, A116707, A117353, 2008 WL 4823066 (Cal. Ct. App. Nov. 7, 2008), has ruled otherwise. All six courts that have considered the issue since *Conte* have declined to follow its reasoning and holding. *See Stoddard*, 2009 WL 1883051, at *2-*3; *Fields*, 613 F. Supp. 2d 1056; *Moretti*, 2009 WL 749532, at *3-*4; *Schrock*, 601 F. Supp. 2d at 1266-67; *Cousins*, 2009 WL 648703, at *2; *Huck*, Order at 1-2. Indeed, the *Moretti* court rejected *Conte* outright, describing the decision as "stand[ing] alone" and as "contrary to Nevada law and public policy." *Moretti*, 2009 WL 749532, at *4. Similarly, the rationale of *Conte* is

A. *Foster* is the Leading Authority.

The leading case on whether a brand name manufacturer can be held liable for injuries allegedly resulting from the use of a generic equivalent drug is *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994). The Fourth Circuit's *Foster* decision has been adopted by every court – but one – that has addressed the issue. *See Colacicco*, 432 F. Supp. 2d at 540 ("a review of caselaw [sic] reveals that every state and federal district court which has confronted the issue of innovator drug-manufacturer liability has either adopted the *Foster* reasoning or cited *Foster* with approval").

In *Foster*, the parents of a child who died after ingesting generic promethazine brought suit against Wyeth, the manufacturer of Phenergan®, the brand name version of the drug. *Foster*, 29 F.3d at 167. Even though the parents conceded that only the generic drug had been ingested, they argued (as Plaintiffs do here) that brand name manufacturers like Wyeth could be held liable because they knew that physicians rely on the brand name label and that "generic manufacturers rely on their studies and duplicate their labeling." *Id.* at 167-69. Thus, the parents argued, Wyeth was liable for the decedent's death to the extent that warning was defective. *Id.* The Fourth Circuit rejected these arguments for three separate and independent reasons.

First, the court reasoned that all of plaintiffs' claims – regardless of the theory of liability – failed as a matter of law because Wyeth did not manufacture or sell the specific product that caused the alleged injuries. *Id.* at 168. In so holding, the court found that plaintiffs were trying to disguise products liability claims as claims for misrepresentation and avoid the necessity of demonstrating that Wyeth manufactured

---

contrary to Louisiana law.

the allegedly defective drug: "the allegations of negligent misrepresentation are an effort to recover for injuries caused by a product without meeting the requirements the law imposes in products liability actions." *Id.* As the *Foster* court explained:

> The Fosters are attempting to hold Wyeth liable for injuries caused by another manufacturer's product, and we are persuaded that Maryland courts would reject this effort to circumvent the necessity that a defendant be shown to have manufactured the product that caused an injury prior to being held liable for such injury.

Id. In short, the Fourth Circuit held, "[r]egardless of the recovery theory," a products liability plaintiff must establish product identification. *Id.*

Second, the *Foster* court concluded that no legal precedent or FDA regulation imposes liability on the brand name manufacturer for injuries caused by the drug of its generic competitors. *Foster*, 29 F.3d at 170. The court recognized that "[n]ame brand manufacturers undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information." *Id.* After reviewing FDA statutes and regulations, common law and public policy implications, the court rejected plaintiffs' theory of liability:

> There is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control. This would be especially unfair when, as here, the generic reaps the benefits of the name brand manufacturer's statements by copying the labels and riding on the coattails of its advertising. The premarketing approval scheme Congress established for generic equivalents of previously approved drugs cannot be construed to create liability of a name brand manufacturer when another manufacturer's drug has been consumed.

Id. The court further commented that "[m]anufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products." *Id.*

Third, the court concluded that Wyeth did not owe a duty to plaintiffs to warn about the risks associated with the generic drug. Plaintiffs argued that it was "foreseeable to Wyeth that misrepresentations could . . . result in personal injury to users of . . . generic equivalents." *Foster*, 29 F.3d at 171. The court rejected these arguments, concluding that "Wyeth is under no duty of care" to consumers of other companies' generic drugs:

> We think to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far. The duty required . . . arises when there is such a relationship that one party has the right to rely for information upon the other, and the other giving the information owes a duty to give it with care. There is no such relationship between the parties to this case, as Brandy Foster was injured by a product that Wyeth did not manufacture.

Id. (internal quotations and citations omitted).

Each of the rationales underlying the *Foster* decision, (a) the requirement of product identification, (b) the absence of any legal or regulatory basis for liability, and (c) the absence of any duty, is consistent with Louisiana law and defeats Plaintiffs' claims.

B. Twenty-one Decisions in Sixteen Different States Have Rejected Identical Claims Against Wyeth and/or Schwarz in Cases Involving Metoclopramide Products.

Courts throughout the country have adopted the reasoning set forth in *Foster* and rejected claims brought by consumers of generic metoclopramide against Wyeth and/or Schwarz, as the manufacturers of brand name Reglan®. A combined twenty-one rulings in sixteen states have expressly held that Wyeth and/or Schwarz, as brand name Reglan® manufacturers, cannot be held liable for injuries allegedly caused by the ingestion of generic metoclopramide. *See* n.5, *supra*. These courts have systematically rejected attempts to assert strict liability, negligence, fraud, misrepresentation and other claims against Wyeth and Schwarz when their products have not been ingested. In

doing so, these courts have refused to impose liability or a duty on Wyeth and Schwarz because:

- Brand name manufacturers are only liable for injuries caused by their products, and not for the injuries caused by their competitors' generic products. *See, e.g., Stoddard*, 2009 WL 1883051, at *2-*3; *Mensing*, 2008 WL 4724286, at *5; *Smith*, 2008 WL 2677051, at *4; *Wilson*, 2008 WL 2677049, at *4; *Morris*, 2008 WL 2677048, at *4; *Pustejovsky*, 2008 WL 1314902, at *2; *Swicegood*, 543 F. Supp. 2d at 1358; *Moretti*, 2009 WL 749532, at *3-*4; *Kelly*, 2005 WL 4056740, at *2-*4; *Sharp*, 2006 WL 515532, at *2; *Sheeks*, 2004 WL 4056060, at *2; *Block*, 2003 WL 203067, at *1-*2.

- Foreseeability does not support liability of the brand name manufacturer who had no relationship with plaintiff. *See, e.g., Fields*, 613 F. Supp.2d 1056; *Sharp*, 2006 WL 515532, at *7; *Moretti*, 2009 WL 749532, at *3. In the absence of any relationship between the brand name manufacturer and the plaintiff, the imposition of liability on brand name manufacturers would extend the concept of duty "beyond reason and good sense." *Schrock*, 601 F. Supp. 2d at 1267.

- FDA statutes and regulations establish that a brand name manufacturer is responsible for only its drug; and not responsible for generic drugs. *E.g., Schrock*, 601 F. Supp. 2d at 1266; *Smith*, 2008 WL 2677051, at *4; *Wilson*, 2008 WL 2677049, at *4; *Morris*, 2008 WL 2677048, at *4; *Swicegood*, 543 F. Supp. 2d at 1358; *Mensing*, 2008 WL 4724286, at *5.

- Generic manufacturers are responsible for their own drug and label. *Foster*, 29 F.3d at 170; *Schrock*, 601 F. Supp. 2d at 1266; *Smith*, 2008 WL 2677051, at *4; *Wilson*, 2008 WL 2677049, at *4; *Morris*, 2008 WL 2677048, at *4; *Swicegood*, 543 F. Supp. 2d at 1358; *Mensing*, 2008 WL 4724286, at *5; *Sharp*, 2006 WL 515532, at *7.

- Wyeth's and Schwarz's respective warnings and labeling concerning Reglan® are representations about its product, and cannot form the basis for liability for injuries caused by their competitors' generic drug. *Smith*, 2008 WL 2677051, at *4; *Wilson*, 2008 WL 2677049, at *4; *Morris*, 2008 WL 2677048, at *4; *Sharp*, 2006 WL 515532 at *7.

- Holding brand name manufacturers liable is unfair and contrary to good public policy. *E.g., Fields*, 613 F. Supp.2d 1056; *Schrock*, 601 F. Supp. 2d at 1266-67; *Moretti*, 2009 WL 749532, at *4. Such liability is unduly burdensome and would deter the research and development of new drugs. *See, e.g., Kelly*, 2005 WL 4056740, at *4-*5; *Sloan*, slip op. at 9.

This Court should again follow this reasoning and "join[] with other courts nationwide in rejecting the claim that the manufacturer of the branded product is liable for misrepresentation in the labeling of the generic product." *Swicegood,* 543 F. Supp. 2d at 1358 (citing *Foster* with approval); *see also Schrock*, 601 F. Supp. 2d at 1267 (observing that, as of the date of that decision, "twenty four courts in fourteen different states have rejected the assertion that defendants have a duty to warn about products they did not manufacture").

To accept Plaintiffs' arguments would be contrary to Louisiana law and the near unanimous on-point authority from this and other jurisdictions. Such a holding would improperly make brand name manufacturers responsible for every injury caused by equivalent products made by every generic manufacturer in the United States. Indeed, such an inequitable, unprecedented, and illogical result would have a devastating impact on the entire pharmaceutical industry, deterring manufacturers from undertaking to research and develop new drugs, or from marketing existing drugs, *See, e.g.*, *Foster*, 29 F.3d at 170 (observing that such liability would be "especially unfair" because "the generic manufacturer reaps the benefits of the brand name manufacturer's statements by copying its labels and riding on the coattails of its advertising"); *Sloan*, slip. op. at 9 (stating that "manufacturers would be less likely to develop new products of generic manufacturers"). For these very reasons, courts have refused to extend tort law into such "new and uncharted territory." *Block*, 2003 WL 203067, at *3; *see also Colacicco*, 432 F. Supp. 2d at 543 (rejecting plaintiff's invitation "to drastically expand the boundaries of Pennsylvania tort law without precedent or policy to support his position" because "the Supreme Court of Pennsylvania would not accept this invitation").

CONCLUSION

Given the undisputed fact that Mrs. Morris did not ingest any metoclopramide that was manufactured or sold by Wyeth or Schwarz, and in the absence of any Louisiana law recognizing Plaintiffs' broad theories of recovery, this Court should grant summary judgment and enter judgment on all claims in favor of Wyeth and Schwarz.

Respectfully submitted,

COOK, YANCEY, KING & GALLOWAY
A Professional Law Corporation

By: s/John T. Kalmbach
Herschel E. Richard, Jr. #11229
John T. Kalmbach #24484

333 Texas Street, Suite 1700
P. O. Box 22260
Shreveport, LA 71120-2260
Telephone: (318) 221-6277
Telecopier: (318) 227-7850
herschel.richard@cookyancey.com
john.kalmbach@cookyancey.com

ATTORNEYS FOR WYETH, INC.
AND SCHWARZ PHARMA, INC.

Henninger S. Bullock
Andrew J. Calica
Mayer Brown LLP
1675 Broadway
New York, NY 10019

COUNSEL FOR SCHWARZ

Jeffrey R. Pilkington
Geoffrey C. Klingsporn
Davis Graham & Stubbs LLP
1550 Seventeenth Street, Ste. 500
Denver, CO 80202

COUNSEL FOR WYETH, INC.

CERTIFICATE

I HEREBY CERTIFY that the foregoing has been filed using the Court's electronic ECF/CM system and electronically served on all parties which have made an appearance herein and/or served via U.S. Mail.

Shreveport, Louisiana, this 19th day of August, 2009.

s/John T. Kalmbach
OF COUNSEL