UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Gladys Mensing,

Plaintiff,

v.

WYETH, INC. (d/b/a WYETH); SCHWARZ PHARMA, INC.; TEVA PHARMACEUTICALS, USA, INC.; UDL LABORATORIES, INC.; and the following fictitious party defendants (whether singular or plural, individual or corporate): No. 1, that entity which originally obtained permission from the U.S. Food and Drug Administration to market the drug branded Reglan; No. 2, that entity which obtained permission from the FDA to market the Reglan, metoclopramide and/or metoclopramide HCI ingested by Gladys Mensing; No. 3, that entity which originally manufactured and sold any Reglan which was ultimately ingested by Gladys Mensing: No. 4, that entity which originally manufactured and sold any Reglan, metoclopramide and/or metoclopramide HCI which was ultimately ingested by Gladys Mensing: No. 5, that entity which marketed Reglan or generic metoclopramide and/or metoclopramide HCI, jointly and individually,

Defendants.

Civil No. 07-3919 (DWF/SRN)

AMENDED MEMORANDUM OPINION AND ORDER

Daniel J. McGlynn, Esq., and Patty F. Trantham, Esq., McGlynn, Glisson & Koch, APLC; and Lucia J. W. McLaren, Esq., and Michael K. Johnson, Esq., Goldenberg & Johnson, PLLC, counsel for Plaintiffs.

Bridget M. Ahmann, Esq., and Erin M. Verneris, Esq., Faegre & Benson LLP; and Jeffrey R. Pilkington, Esq., and Tom Wagner, Esq., Davis, Graham & Stubbs, LLP, counsel for Defendant Wyeth, Inc.

Andrew J. Calica, Esq., and Henninger S. Bullock, Esq., Mayer Brown, LLP; and Erin M. Verneris, Esq., and Bridget M. Ahmann, Esq., Faegre & Benson LLP, counsel for Defendant Schwartz Pharma, Inc.

David L. Hashmall, Esq., and Donald G. Heeman, Esq., Felhaber Larson Fenlon & Vogt, PA, counsel for Defendants Teva Pharmaceuticals USA, Inc. and UDL Laboratories, Inc.

The Court amends the Memorandum, Opinion and Order dated October 24, 2008, so as to make a correction in footnote 8. The footnote is amended to indicate that Schwarz, not Wyeth, cited to the cases listed in footnote 8.

INTRODUCTION

This matter is before the Court on a Motion for Summary Judgment brought by Schwarz Pharma, Inc. ("Schwarz"); a Motion for Summary Judgment brought by Teva Pharmaceuticals USA, Inc. ("Teva") and UDL Laboratories, Inc. ("UDL"); and a Motion for Summary Judgment brought by Wyeth, Inc. ("Wyeth"). For the reasons stated below, the Court grants the pending motions.

BACKGROUND

In her Amended Complaint, Plaintiff[1] alleges that her physician prescribed the drug Reglan to her to treat diabetic gastroparesis. The active ingredient in Reglan is metoclopramide ("MCP"). MCP, which is available in name-brand form (Reglan) or generic form ("generic MCP"), is used to treat certain gastrointestinal disorders. Plaintiff alleges that the long-term ingestion of MCP caused her to develop tardive dyskinesia, a neurological movement disorder.

[1] The Court notes and respects that Plaintiff personally attended the recent hearings in this matter.

Plaintiff asserts state-law tort claims against Defendants as the manufacturers and distributors of Reglan and generic MCP. At the core of all of Plaintiff's claims is the basic assertion that Defendants failed to adequately warn about the association between long-term ingestion of MCP and movement disorders. In an Order dated June 17, 2008 (the "June 2008 Order"), the Court held that Plaintiff's claims against manufacturers of generic MCP, Actavis Elizabeth, LLC ("Actavis") and Pliva, Inc. ("Pliva"), were preempted by federal law. In the June 2008 Order, the Court concluded that under the federal statutory scheme, the labeling for generic drugs must always remain the same as that of the name brand drug (in this case Reglan), and that a generic drug manufacturer cannot unilaterally change its label without prior approval from the Food and Drug Administration ("FDA"). The Court held that because Plaintiff's failure to warn claims relied on state law imposing a duty on the generic drug manufacturers, these claims directly conflicted with, and stood as an obstacle to the execution of, federal law.

Wyeth manufactured and distributed name-brand Reglan from approximately 1989 through 2001. (Aff. of Paul Minicozzi, Ph.D. ("Minicozzi Aff.") ¶ 3.) From approximately 1995 through 2001, Wyeth also manufactured and sold generic MCP through its subsidiaries. (Minicozzi Aff. ¶ 4.) In December 2001, Wyeth sold to Schwarz the rights to manufacture and distribute name-brand Reglan tablets. (Decl. of Jeff. Siefert ("Siefert Decl.") ¶¶ 1-2; Minicozzi Aff. ¶ 3.) Schwarz thereafter manufactured and distributed name-brand Reglan through 2005. At no time did Schwarz manufacture or distribute generic MCP. (Siefert Decl. ¶ 3.) Teva has manufactured and sold only generic MCP. (Aff. of Philip Erickson in Supp. of Mot. for Summ. J.

("Erickson Aff.") ¶ 2.) At times relevant to this matter, Teva and UDL were parties to a Supply and Distribution Agreement under which UDL distributed generic MCP manufactured by Teva. (Erickson Aff. ¶ 4; Affidavit of Timothy G. Wait in Supp. of Mot. for Summ. J. ("Wait Aff.") ¶ 2.)

Plaintiff's counsel provided pharmacy records reflecting Plaintiff's MCP purchases from November 15, 2001, through the present. (Decl. of Erin Verneris ("Verneris Decl.") ¶ 2, Ex. A.) Those records demonstrate that from November 2001 until the time Plaintiff stopped taking MCP, Plaintiff was dispensed only generic MCP products; none of the generic MCP was manufactured or distributed by Schwarz; and Plaintiff never purchased or used any name-brand Reglan manufactured by Wyeth.[2]

Here, in three separate motions, Teva, UDL, Wyeth, and Schwarz have moved for summary judgment on Plaintiff's claims against them.

DISCUSSION

I. Standard of Review

Summary judgment is proper if there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The

[2] The record reflects that the pharmacy records prior to November 2001 are not available due to the pharmacy's record-keeping policy. On July 10, 2008, Plaintiff sought and was granted leave to seek specific discovery to identify the manufacturers of MCP that supplied Plaintiff's pharmacy prior to 2001. (Doc. No. 94.) The additional discovery sought by Plaintiff would not affect the outcome of Schwarz's current motion, as Schwarz did not acquire the rights associated with name-brand Reglan until December 2001. In addition, even though the discovery sought could show that Wyeth supplied the pharmacy with name-brand Reglan, the discovery would be unable to provide evidence of what drugs were actually dispensed to Plaintiff.

Court must view the evidence, and the inferences that may be reasonably drawn from the evidence, in the light most favorable to the nonmoving party. *Enter. Bank v. Magna Bank of Mo.*, 92 F.3d 743, 747 (8th Cir. 1996). However, as the Supreme Court has stated, "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy, and inexpensive determination of every action.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (quoting Fed. R. Civ. P. 1).

The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. *Enter. Bank*, 92 F.3d at 747. The nonmoving party must demonstrate the existence of specific facts in the record that create a genuine issue for trial. *Krenik v. County of Le Sueur*, 47 F.3d 953, 957 (8th Cir. 1995). A party opposing a properly supported motion for summary judgment may not rest upon mere allegations or denials but must set forth specific facts showing that there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986).

II. Generic Manufacturer Liability

Teva, UDL, and Wyeth (collectively, the "Generic MCP Defendants")[3] move to dismiss Plaintiff's claims against them. The Generic MCP Defendants assert that

[3] Despite the fact that there is no evidence that Plaintiff ingested any name-brand Reglan manufactured by Wyeth, Plaintiff claims that because Wyeth manufactures the name-brand drug, it, along with Schwarz, is liable for allegedly misstating the true risks associated with ingesting generic MCP. The Court discusses this assertion of "name-brand manufacturer liability" in Section III below.

because they are manufacturers of generic MCP, Plaintiff's claims are preempted by federal law for the reasons set forth in the Court's June 2008 Order. Specifically, the Generic MCP Defendants contend that Plaintiff's claims against them are identical to the claims asserted against Actavis and Pliva that were determined to be preempted by federal law in the June 2008 Order. Plaintiff does not dispute that only generic MCP was dispensed to her. Further, Plaintiff does not attempt to distinguish between Actavis and Pliva and the Generic MCP Defendants with respect to the issue of federal preemption. At the time of the hearing, Plaintiff's only arguments in opposition to the Generic MCP Defendants' motions were those previously made in opposition to Actavis and Pliva's prior motions to dismiss. The Court has already heard, considered, and rejected these arguments. (Doc. No. 86.)

Moreover, because the issue of federal preemption as it relates to generic manufacturers of MCP has already been decided in this case, Plaintiff's opposition to the Generic MCP Defendants' present motions is akin to a request to file a motion to reconsider the June 2008 Order. Pursuant to Local Rule 7.1(g), a request for leave to file a motion for reconsideration will only be granted upon a showing of "compelling circumstances." A motion to reconsider should not be employed to relitigate old issues but to "afford an opportunity for relief in extraordinary circumstances." *Dale & Selby Superette & Deli v. U.S. Dept. of Agric.*, 838 F. Supp. 1346, 1348 (D. Minn. 1993).

After the hearing on this motion, Plaintiff submitted supplemental authority to the Court, in particular a recently filed opinion in *McKenney v. Purepac Pharmaceutical Co*., F052606 Super. Ct. No. 343927 (Cal. 5th Dist. Ct. App. Sept. 25, 2008) (Aff. of

Michael K. Johnson ("Johnson Aff.") ¶ 2, Ex. 1). In *McKenney*, a California Court of Appeal reversed the decision of a California Superior Court, wherein the lower court sustained the demurrer of a generic MCP manufacturer on preemption grounds. The California Court of Appeal held "that the federal requirement that a generic drug have the same labeling as a reference listed drug does not necessarily result in federal preemption of a state tort action against the generic manufacturer for failure to adequately warn of the dangers of the drug." (*Id*. at 2.) The Court has reviewed the *McKenney* opinion and determines that it would not alter the Court's analysis and conclusions set forth in the June 2008 Order. First, the decision is not binding on the Court. Second, the Court disagrees with the *McKenney* court's brief discussion of the FDA's regulatory scheme and its bearing on the preemption analysis. This Court previously considered and discussed the same regulatory scheme and came to the opposite conclusion on the issue of preemption. Because the issue of preemption was already considered and the *McKenney* case does not alter this Court's conclusions, the Court finds that no compelling circumstances exist to warrant a motion to reconsider the June 2008 Order.

Accordingly, Teva's and UDL's motion is granted; Wyeth's motion is granted on the issue of Wyeth's liability as a manufacturer of generic MCP.

III. Name-Brand Manufacturer Liability[4]

In December 2001, Schwarz acquired from Wyeth the rights to manufacture and distribute name-brand Reglan. (Siefert Decl. ¶¶ 1-3.) At no time did Schwarz manufacture or distribute generic MCP. (Siefert Decl. ¶ 3.) Plaintiff concedes that "it appears" that she never ingested name-brand Reglan manufactured by Schwarz or Wyeth. (Pl.'s Mem. in Opp. to Def. Schwarz Pharma Inc.'s Mot. for Summ. J. at 3.) Even so, Plaintiff maintains that Schwarz and Wyeth are liable for negligent misrepresentation, misrepresentation by omission, fraud by concealment, and constructive fraud for misstating the true risks associated with ingesting MCP.[5] Plaintiff asserts that she is pursuing only the above-mentioned claims and states that all of those claims are essentially contained within the elements of negligent misrepresentation.

The elements of negligent misrepresentation are: (1) a duty of reasonable care in conveying information; (2) breach of that duty by negligently giving false information; (3) reasonable reliance on the misrepresentations, which reliance is the proximate cause of physical injury; and (4) damages.[6] *See Smith v. Brutger Cos.*, 569 N.W.2d 408, 414

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[4] Wyeth did not move separately on the issue of "name-brand liability," but joined Schwarz's motion at the hearing.

[5] In Count Ten of her Amended Complaint, Plaintiff asserts a claim for intentional infliction of emotional distress. Schwarz argues that this claim was time-barred. Plaintiff does not object to the entry of summary judgment based on the statute of limitations. Accordingly, Count Ten is dismissed.

[6] The tort of negligent misrepresentation involving the risk of physical harm has not been specifically adopted or rejected in Minnesota. *Smith*, 569 N.W.2d at 414.

(Minn. 1997). Here, the Court's focus is on whether Wyeth and Schwarz, as name-brand manufacturers, have a legal duty to warn so as to give rise to a claim by a consumer for injuries caused by the ingestion of another manufacturer's generic product.

Schwarz and Wyeth argue that they are entitled to summary judgment on Plaintiff's claims against them because they cannot be liable for injuries allegedly caused by another manufacturer's generic product. Plaintiff, on the other hand, asserts that Schwarz and Wyeth were under a legal duty to be truthful in their representations to the public about its name-brand products even if the aggrieved member of the public is not injured by those products.

The leading case on whether a name-brand manufacturer can be held liable for injuries caused by a generic equivalent is *Foster v. American Home Products Corp.*, 29 F.3d 165, 171 (4th Cir. 1994). In *Foster*, the parents of a child who died after being given the generic equivalent of one of Wyeth's brand name prescription drugs sued Wyeth for negligent misrepresentation.[7] 29 F.3d 165, 166-67. The plaintiffs in the *Foster* case argued that the fact that Wyeth did not manufacture the drug their child ingested did not shield Wyeth from a negligent misrepresentation claim. *Id*. at 169. With respect to the plaintiffs' negligent misrepresentation claim, the United States Court of Appeals for the Fourth Circuit held that a name-brand manufacturer was under no duty to

[7] The *Foster* plaintiffs also sued Wyeth for negligence, strict liability, and breach of warranty. These causes of action were dismissed on summary judgment because Wyeth did not manufacture the drug ingested by the plaintiffs' child. *Foster*, 165 F.3d at 167. At that time, the district court allowed plaintiffs' negligent misrepresentation claim to stand. *Id*.

the consumers of another company's product and could not be held liable for injuries stemming from the ingestion of another generic manufacturer's product. *Id.* at 171. In so holding, the Fourth Circuit noted that "[t]here 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." *Id*. at 170. The Fourth Circuit also rejected the plaintiffs' arguments that it was foreseeable to Wyeth that misrepresentations as to its product could result in the injury to users of generic equivalents. *Id*. at 171. The Fourth Circuit explained that to impose such a duty in that case "would be to stretch the concept of foreseeability too far." *Id*. *Foster* has been adopted or cited with approval by numerous federal and state courts. *See, e.g., Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 538-39, 540 (E.D. Pa. 2006), *aff'd* 521 F.3d 253 (3d Cir. 2008) (holding that "a name brand drug manufacturer does not owe a legal duty to consumers of a generic equivalent of its drug"; noting that *Foster* has wide-spread acceptance).[8] The Court finds *Foster* persuasive.

More importantly, the law in Minnesota similarly provides that a party does not have a duty to warn about another manufacturer's product. *See Flynn v. Am. Home*

[8] Indeed, Schwarz has cited to numerous cases involving generic MCP wherein the *Foster* case has been accepted and applied. *See, e.g., Sharp v. Leichus*, Case No. 2004-CA-0643, 2006 WL 515532, at *4 (Fla. Cir. Ct. Feb. 17, 2006), *aff'd* 925 So.2d 555 (Fla. App. 1 Dist. Jan. 22, 2007); *Smith v. Wyeth, Inc.*, No. 5:07-CV-18-R, 2008 WL 2677051, 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. April 3, 2008); *Block v. Wyeth*, No. Civ. A 3-02-CV-1077, 2003 WL 203067, at *2 (N.D. Tex. Jan. 28, 2003).

Prods. Corp., 627 N.W.2d 342, 350 (Minn. Ct. App. 2001). In *Flynn*, plaintiff brought an action against American Home Products Corporation ("AHPC"), the manufacturer of the name-brand version of "fen-phen," alleging that misrepresentations made by AHPC to the FDA caused her to ingest the generic equivalent of fen-phen, which then injured her.[9] *Id*. The plaintiff asserted claims for fraud, negligent misrepresentation, and violation of Minnesota consumer fraud statutes. *Id*. at 346. The Minnesota Court of Appeals affirmed the district court's grant of summary judgment in favor of AHPC, rejecting the plaintiff's theory of recovery.[10] As to whether AHPC had a duty to warn about the generic manufacturer's drug, the court explained that "[a]lthough federal regulations required respondents to disclose product safety information to the FDA, respondents did not owe appellant, who did not purchase their product and with whom they had no relationship, the same obligation." *Id*. at 350 (citing *In re Minn. Breast Implant Litig.*, 36 F. Supp. 2d 863, 880 (D. Minn. 1998)).

While *Flynn*, *Foster*, and numerous other cases have answered "no" to the question of duty under these circumstances, Plaintiff nonetheless asserts that the question deserves examination and that alleged inaccuracies in Wyeth's and Schwarz's warnings can form the basis of a claim for negligent misrepresentation to the extent that a generic drug manufacturer must or will foreseeably rely on those disclosures in formulating their

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[9] The court in *Flynn* analyzed plaintiff's claims under a "fraud-on-the-FDA" theory and under Minnesota common law. *Id*. at 350-51.

[10] The court in *Flynn* also held alternatively that the plaintiff's claims were preempted by federal law. *Id*. at 349.

own warnings. Plaintiff asserts that there are sound justifications for imposing such a duty—namely because the issuance of a name-brand manufacturer's label is analogous to a product endorsement and the Restatement (Second) Torts forms a basis for exacting such a duty. The Court disagrees. As a federal court sitting in diversity, the Court must apply Minnesota state law. *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). Under Minnesota law, as set forth in *Flynn*, Schwarz and Wyeth did not have a legal duty to warn Plaintiff so as to give rise to Plaintiff's claim for injuries caused by the ingestion of another manufacturer's generic MCP. *See Flynn*, 627 N.W.2d 342 at 350. The Court discerns no support under Minnesota law for the recognition of a cause of action against a manufacturer for representations concerning its own product based on an injury caused by another manufacturer's product. Accordingly, Plaintiff's negligent misrepresentation claim is dismissed.

The Court is sympathetic to the fact that Plaintiff may lack a legal remedy due to the fact that she did not ingest name-brand Reglan and that her claims against the generic manufacturers are preempted by federal law. However, such sympathy does not warrant a departure from clear Minnesota law. That Plaintiff is left without a remedy is an issue for the legislature, not this Court.

CONCLUSION

Accordingly, **IT IS HEREBY ORDERED** that:

1. Wyeth's Motion for Summary Judgment (Doc. No. 110) is **GRANTED**.

2. Teva and UDL's Motion for Summary Judgment (Doc. No. 87) is **GRANTED**.

3. Schwarz's Motion for Summary Judgment (Doc. No. 96) is **GRANTED**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: October 30, 2008

s/Donovan W. Frank
DONOVAN W. FRANK
Judge of United States District Court