UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

MICHELLE E. HOWE and RICHARD F. HOWE, Jr.,

Plaintiffs,

v. CASE NO. 8:09-CV-610-T-17AEP

WYETH INC., D/B/A WYETH, Individually and as successor-in-interest to A.H. Robbins, Inc., American Home Products Corporation and ESI, Lederle, Inc., WYETH PHARMACEUTICALS, INC., SCHWARZ PHARMA, INC., MCKESSON CORPORATION, ACTAVIS ELIZABETH, LLC, AND ACTAVIS, INC., and INNOVEX, INC.,

Defendants.

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ORDER ON DEFENDANTS WYETH, WYETH PHARMACEUTICALS INC., AND SCHWARTZ PHARMA, INC.'S MOTION FOR SUMMARY JUDGMENT

THIS CAUSE is before the Court on Defendants', Wyeth, Wyeth Pharmaceuticals Inc., and Schwarz Pharma, inc. ("Defendants") Motion for Summary Judgment (Dkt. No. 94) and response thereto (Dkt. No 108) filed by the Plaintiffs, Michelle Howe and Richard F. Howe, Jr. ("Plaintiffs"). For the reasons set forth below, Defendants' motion is **GRANTED**.

Background and Procedural History

Metoclopramide is a prescription drug approved by the FDA to treat, among other things, gastroesophadeal reflux disease and diabetic gastroparesis. (Dkt. 94.) Metoclopramide is available in both brand (Reglan) and generic formulation (*Id*.)

At different times, Wyeth and Schwartz manufactured and distributed name brand Reglan, from approximately 1989 through late December 2001, (*Id*.) Wyeth manufactured and distributed Reglan tablets. (*Id*.) Schwartz acquired the rights to Reglan tablets from Wyeth in late December 2001. (*Id*.) Thereafter, Schwartz manufactured and distributed Reglan tablets until 2008. (*Id*.) Since the mid-1980s, several companies, including the generic manufacturers sued here as co-defendants, have manufactured and distributed generic metoclopramide. (*Id*.)

On March 31, 2009, Plaintiffs filed this action alleging that Mrs. Howe ingested metoclopramide from early 2002 until April 2005 and as a result developed a neurological condition known as tardive dyskinesia. (Dkt. 1.) Plaintiffs allege that Defendants acted as the Reference Listed Drug ("RLD") Holder from Reglan, which was the Referenced Listed Drug for the generic metoclopramide. (Dkt. 108.) Plaintiffs stipulate that Mrs. Howe ingested only generic metoclopramide and did not ingest any metoclopramide, whether generic or name brand (Reglan), manufactured or distributed by Wyeth or Schwartz. (Dkt. 94.) However, Plaintiffs argue that despite evidence that long term metocopramide use carried a risk of tardive dyskinesia greater than indicated on the label, Defendants failed to take any steps to change the label warnings. (Dkt. 108.) Plaintiff cites to a study suggesting that the prevalence and severity of metoclopramide induced tardive dyskinesia were underestimated and occurred approximately 100 times more often than previously reported when metoclopramide was used beyond a twelve week period. (*Id*. at Exs. C) According to Plaintiffs, Defendants either negligently or

intentionally distributed false and misleading information into the stream of commerce regarding the risks of using metoclopramide. (Dkt. 108.) Additionally, Plaintiffs claim that although Mrs. Howe never ingested Reglan or generic metoclopramide made by Defendants, her physician(s) may have relied on information provided by Defendants (such as information found in labels, promotional materials, package inserts, etc). (*Id*.)

Plaintiffs' causes of action are set forth generally against each of the named defendants in this action, accordingly, the Court considers each cause of action as they pertain to the instant Motion and Defendants. With respect to Count 1 alleging negligence, Plaintiffs assert that Defendants owed a duty to the general public to exercise reasonable care in the marketing of metoclopramide and breached that duty because they failed to warn that, as designed, metoclopramide was capable of causing serious personal injuries such as those suffered by Plaintiff. (Dkt. 9) Additionally, Plaintiffs allege, *inter alia*, that Defendants failed to provide adequate training or information to medical care providers for appropriate use of Reglan and that Defendants failed to warn the public that Reglan should not be prescribed for more than twelve weeks. (*Id*.)

As to Count II, Plaintiffs allege that Defendants are strictly liable under a products liability theory for placing into the stream of commerce a defective and unreasonably dangerous product. (*Id*.) Although Plaintiffs concede that the wife did not ingest Defendants' drug, Plaintiffs argue that the package insert/labeling information formed part of an overall product. (Dkt. 108) Plaintiffs assert that Defendants are the equivalent of a component part manufacturer because they provided the information in the insert/label which was allegedly defective. (*Id*.) Additionally, Plaintiffs allege under Count III that Defendants breached their express and

implied warranties of merchantability because the metoclopramide was unfit for its intended purposes. (Dkt. 9)

Under Count IV, Plaintiffs allege that Defendants materially misrepresented or fraudulently concealed adverse information regarding the safety and effectiveness of metoclopramide. (*Id*.) Specifically, Plaintiffs allege Defendants concealed from Plaintiffs and the public that metoclopramide use significantly increased the probability of neuromuscular side effects, that metoclopramide should not be used for more than twelve weeks, and that it was not fully and adequately tested. (*Id*.)

In Count V, Plaintiffs allege that Defendants committed negligence *per se* because the product label and package insert for metoclopramide was misbranded within the meaning of 21 U.S.C. §§ 352(a) and (f), since it was false and misleading and failed to give adequate warnings and directions for use by physicians who prescribe it. (*Id*.)

Finally, Plaintiffs, allege that Defendants actions resulted in a loss of consortium. (*Id*.) More specifically, Plaintiffs allege that as a result of Michelle Howe's inability to perform work, services and duties as a spouse, both now and in the future, Richard Howe is deprived and will continue to be deprived of the work, services, duties, companionship and consortium of his spouse. (*Id*)

Standard for Summary Judgment

Summary judgment is appropriate where "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)(2). A dispute about a material fact is genuine if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). In reviewing the motion, the Court must view the evidence and all factual inferences in the light

most favorable to the non-moving party, and all reasonable doubts about the facts are resolved in favor of the non-movant. *Dadeland Depot, Inc. v. St. Paul Fire and Marine Ins. Co.*, 483 F.3d 1265, 1268 (11th Cir. 2007) (citations omitted).

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 the other facts immaterial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). "The moving party is 'entitled to a judgment as a matter of law' because the nonmoving party has failed the make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Id*. at 323.

Discussion and Analysis

In evaluating Defendants' motion for summary judgment, the Court is left with a question of law- whether a brand name manufacturer, as a RLD holder, owes a duty to generic manufacturers' consumers, and , therefore, be held liable under Florida law. Thus far, Florida courts and the overwhelming majority of courts in the United States have held that brand manufacturers are not liable for injuries caused by generic drugs produced by generic manufacturers, including the generic drug at issue in this case. *See, e.g*., *Sharp v. Leichus*, No. 2004-CA-0642, 2006 WL 515532 (Fla. Cir. Ct. Feb 17, 2006), *aff'd per curiam*, 952 So. 2d 555 (Fla. Dist Ct. App. 2007); *Mensing v. Wyeth*, No. 08-3850, 2009 WL 4111209 (8th Cir. Nov. 27, 2009); *Foster v. Am. Home Prods. Corp*., 29 F.3d 165 (4th Cir. 1994). *But see Conte v. Wyeth*, 2008 WL 4823066 (Cal. Ct. App. Nov. 7, 2008) (holding brand manufacture may be liable). Defendants also cite to *Engle v. Liggett Group, Inc*., 945 So. 2d 1246, 1276 (Fla. 2006) for the

proposition that a defendant cannot be held liable if they do not manufacture or sell any of the products that allegedly caused the plaintiff's injuries. *See also Liggett Group Inc. v. Engle*, 853 So. 2d 434, 466 n. 44 (Fla. Dist. Ct. App. 2003) ("[i]t is aphoristic that a plaintiff cannot prevail on claims for negligence, breach of warranty or strict liability, unless the plaintiff establishes that the product which allegedly caused the plaintiff's injury was manufactured or sold by the defendant"), *aff'd on this ground, rev'd on other grounds*, 945 So. 2d 1246.

This Court recently issued an order on an identical case to that at issue here with the exception of the loss of consortium claim. *Levine v. Wyeth Inc*., No. 8:09-cv-854-T-33AEP, slip op. at 2-3 (M.D. Fla. Feb. 10, 2010). In this order, the Court adopted the Report and Recommendation of the Magistrate Judge in its entirety and granted summary judgment for the Defendants. *Id*.

The Court found, as a matter of law, that there was no duty owed to the Plaintiff since he, like the Plaintiff in the case at issue here, did not ingest the product made by Defendants. *Levine v. Wyeth Inc*., Report and Recommendation at 8 (M.D. Fla. Jan. 13, 2010). Accordingly, the Report and Recommendation suggested granting summary judgment in favor of Defendants as to the Plaintiff's claims alleging negligence by Defendants. *Id*. Here, since the facts of this case are identical to those in *Levine*, the Court should also grant summary judgment in favor of Defendants as to the Plaintiff's claims alleging negligence by Defendants (causes of action one and five of the complaint).

In addressing the strict liability and breach of warranty claims asserted in *Levine*, the Court determined that because the product ingested by Plaintiff was not manufactured by Defendants, Plaintiff could not hold Defendants strictly liable for injuries caused by the product. (R & R at 10.) The Court went on the explain that because the product was not manufactured by

Defendants and there was no privity between Plaintiff and Defendants or Defendants and the manufacturer who made the drug that was ingested, Defendants cannot be held liable for breach of warranty. *Id*. Here, again since the facts are identical to those in *Levine*, the court should also grant summary judgment in favor of Defendants as to the Plaintiffs' claims alleging strict liability and breach of warranties (causes of action two and three of the Complaint).

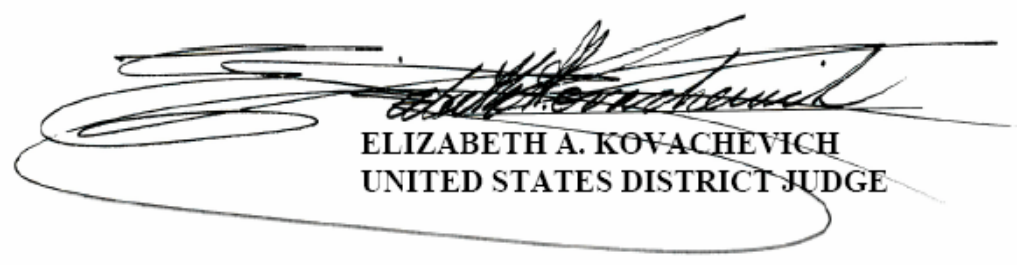
Lastly, the Court addressed Levine's negligent misrepresentation and fraud claims. First, the court determined that there was no duty of care owed to Plaintiff, a requirement to succeed in a claim for negligent misrepresentation, and accordingly recommended that summary judgment be granted in favor of Defendants on the negligent misrepresentation claims. (R & R at 13.) Second, the Court determined that because there was no confidential, contractual, or fiduciary relationship alleged between Defendants and Plaintiff, or between Defendants and the manufacturer of the drug used by Plaintiff and because Defendants had no duty to disclose to Plaintiff, since they did not sell or manufacture the drugs ingested, Plaintiffs could not maintain a claim for fraudulent misrepresentation or fraudulent concealment. (R & R at 14.) As a result, in the Report and Recommendation, the Court suggested granting summary judgment in favor of Defendants as to Plaintiff's claims alleging fraud. *Id*. Here, as a result of the facts identical to those in *Levine*, this Court should again grant summary judgment as to Plaintiffs' claims alleging fraud by Defendants under the fourth cause of action of the complaint.

In order to establish a claim for loss of consortium, the Plaintiffs must prove a loss of companionship and fellowship of husband and wife and the right of each to the company, cooperation, and aid of the other in every conjugal relation. *Gates v. Foley*, 247 So. 2d 40 (Fla. 1971). However, this Court has already determined that the Defendants had no duty to the Plaintiffs since they did not manufacture the product that caused the injuries and accordingly

cannot be held responsible for the loss of consortium suffered by the Plaintiff. Thus, this Court should grant summary judgment as to Plaintiff's claims alleging loss of consortium caused by Defendants under the seventh cause of action of the complaint. Accordingly, it is

ORDERED that the motion for summary judgment be GRANTED and the Defendants, Wyeth, Wyeth Pharmaceuticals Inc., and Schwarz Pharma, inc. be dismissed from the cause of action. The Clerk of Court is directed to enter judgment for these defendants.

DONE AND ORDERED in Chambers, in Tampa Florida, this 26th day of April, 2010.



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