UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

SHIRLEAN MEADE and ELMER MEADE,

Plaintiffs,

v. Civil Action No. 2:09-cv-00388

DEIDRE E. PARSLEY, D.O.; WYETH, INC., doing business as Wyeth; SCHWARTZ PHARMA, INC.; PLIVA, INC.; and JOHN DOE DEFENDANTS #1-6

Defendants.

MEMORANDUM OPINION AND ORDER

Pending is the Joint Motion for Summary Judgment of defendants Wyeth, Inc., and Schwarz Pharma, Inc., filed July 31, 2009.[1]

I.

Plaintiffs initiated this action against defendants Wyeth, Schwarz, Pliva and six fictional defendants, all alleged to be manufacturers of the pharmaceutical metoclopramide. Wyeth manufactured and distributed metoclopramide under the brand name

[1] "Schwarz Pharma, Inc." is the correct spelling of the defendant named in the case style as "Schwartz Pharma, Inc." The clerk is directed to amend the style accordingly.

Reglan from approximately 1989 through late December 2001. (Mot. Summ. Jgt. 3). Schwarz acquired the rights to Reglan in late December 2001, and manufactured and distributed it until 2008. (Mot. Summ. Jgt. 3). Plaintiffs refer to the drug throughout their complaint as "Reglan/metoclopramide," but they concede that Mrs. Meade never purchased nor ingested Reglan. (Resp. to Mot. Summ. Jgt. 1).

Since the mid-eighties, other drug companies have manufactured and distributed generic versions of Reglan. (Mot. Summ. Jgt. 3). Plaintiffs allege that defendants Pliva and the six fictitious parties, or the "generic defendants" as they are referred to in the complaint, are such generic manufacturers. Plaintiffs bring suit against not only the generic manufacturers but also the brand name manufacturers, Wyeth and Schwarz, based on the following facts.

From January 2006 to February 2007, Mrs. Meade's physician prescribed to her Reglan to treat her reflux disease. (Compl. ¶¶ 34, 40). Mrs. Meade's pharmacist filled her Reglan prescription with one of the generic versions of metoclopramide, presumably manufactured by one of the "generic defendants," "as required by the generic laws in the State of West Virginia." (Resp. to Mot. Summ. Jgt. 19-20).

While taking metoclopramide, Mrs. Meade developed symptoms of the neurological disorders tardive dyskinesia and akathisia.[2] (Compl. ¶¶ 31, 38, 39). The symptoms of these disorders include "involuntary and uncontrollable movements of the head, neck, face, arms, legs and trunk in addition to grotesque facial grimacing and open-mouthed, uncontrollable tongue movements, tongue thrusting, tongue chewing, and other involuntary movements." (Compl. ¶ 31). Mrs. Meade's symptoms were diagnosed on or about April 2, 2007. (Compl. ¶ 41).

In their complaint, plaintiffs allege 13 counts of

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[2] **The alleged connection between long-term use of metoclopramide and neurological disorders is not unique to this case. Metoclopramide affects the nervous system by blocking receptors of dopamine, the chemical that sends signals between nerves, in the brain. See McNeil v. Wyeth, 462 F.3d 364, 366 (5th Cir. 2006). Many patients who have been prescribed a form of metoclopramide developed neurological disorders and subsequently brought suit against the manufacturers of the drug. See, e.g., McNeil, 462 F.3d 364; In re Reglan/Metoclopramida Product Liability Litigation, 622 F.Supp.2d 1380 (U.S.J.P.M.L 2009); Stoddard v. Wyeth, Inc., 630 F.Supp.2d 631 (E.D. N.C. 2009); Fields v. Wyeth, Inc., 613 F.Supp.2d 1056 (W.D. Ark. 2009); Schrock v. Wyeth, Inc., 601 F.Supp.2d 1262 (W.D. Okla. 2009); Morris v. Wyeth, Inc., --- F.Supp.2d ---, 2009 WL 424590 (W.D. Ky. 2009); Wilson v. PLIVA, Inc., 640 F.Supp.2d 879 (W.D. Ky. 2009); Kellogg v. Wyeth, 612 F.Supp.2d 421 (D. Vt. 2008); Demahy v. Wyeth Inc., 586 F.Supp.2d 642 (E.D. La. 2008); Morris v. Wyeth, 582 F.Supp.2d 861 (W.D. Ky. 2008); Mensing v. Wyeth, Inc., 562 F.Supp.2d 1056 (D. Minn. 2008); Swicegood v. Pliva, Inc., 543 F.Supp.2d 1351 (N.D. Ga. 2008). Indeed, Wyeth has been a party to nearly all of these cases.**

wrongdoing against defendants under theories of strict product liability, breach of express and implied warranties, negligence, misrepresentation, fraud, the West Virginia Unfair Trade Practices Act and intentional infliction of emotional distress.

Plaintiffs initiated this action in the Circuit Court of Mingo County on February 25, 2009. Defendants timely removed on April 20, 2009, on the grounds of diversity jurisdiction. (Not. of Removal 2). On July 31, 2009, defendants Wyeth and Schwarz moved for summary judgment on the grounds that they are not liable for damages caused by another manufacturer's product. A party is entitled to summary judgment "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). There is no genuine issue as to any material fact here.

II.

In their motion for summary judgment, Wyeth and Schwarz note that Reglan, their product, was never ingested by Mrs. Meade and they argue that they are thus not liable to plaintiffs for

the claims alleged. (Mot. Summ. Jgt. 1). Plaintiffs, on the other hand, describe this action as a "failure to warn case," rather than a product liability action, and argue that Wyeth and Schwarz, as the original manufacturers, had a duty to "ensure their warnings to the medical community [were] accurate and adequate . . .." (Compl. ¶¶ 57-60; Resp. to Mot. Summ. Jgt. 1).

Plaintiffs' claims against Wyeth and Schwarz are based on underlying Federal Drug Administration ("FDA") regulations regarding innovator and generic drug manufacturers. (Resp. to Mot. Summ. Jgt. 3). In short, plaintiffs assert that if generic manufacturers affirm that their product is identical to the corresponding brand name drug, they can get FDA approval without submitting independent evidence of safety and efficacy, and the generic manufacturers essentially adopt the brand name manufacturers' label, including their warnings. (Resp. to Mot. Summ. Jgt. 4). See Foster v. American Home Products Corp., 29 F.3d 165, 168 (4th Cir. 1994) (citing 21 U.S.C.A. § 355(j)(2)(A)(v)). Plaintiffs further assert that inasmuch as generic manufacturers are permitted to rely on brand name manufacturers' warnings, the brand name manufacturers are ultimately liable for inaccuracies and deficiencies in their safety information, regardless of whether the brand name or

generic drug was ingested. (Resp. to Mot. Summ. Jgt. 9).

III.

Despite the plaintiffs' alleged reliance, or vicarious reliance through Mrs. Meade's physician, on Wyeth and Schwarz's representations with respect to Reglan, and despite the many theories of liability plaintiffs set forth, Wyeth and Schwarz are not responsible for the damage resulting from a product that they did not manufacture, distribute or sell. This is directly in line with our court of appeals's decision in Foster v. American Home Products. Foster is the leading authority for the line of cases rejecting the claim that a manufacturer of a brand name drug is responsible for misrepresentations when a generic manufacturer's product caused the plaintiff's injury. See Stoddard v. Wyeth, Inc., 630 F.Supp.2d 631, 634 (E.D.N.C. 2009) (adopting Foster's reasoning with respect to Wyeth and generic metoclopramide); Fields v. Wyeth, 613 F.Supp.2d 1056, 1061 (W.D. Ark. 2009) (following Foster and concluding that "the party that actually controls the manufacturing and labeling of the product in question, and enjoys the profit of its sale, should bear legal liability for any resulting injury"); Swicegood v. Pliva, Inc., 543 F.Supp.2d 1351, 1358 (N.D. Ga. 2008) (concluding that a

manufacturer of a brand name product is not liable for misrepresentations in the generic product's label); Colacicco v. Apotex, Inc., 432 F.Supp.2d 514, 540 (E.D. Pa. 2006) (noting Foster's "widespread acceptance" and citing other cases that adopt its reasoning), aff'd on other grounds, (3d Cir.2008), vacated on other grounds, cert. granted, 77 U.S.L.W. 3499 (U.S. Mar. 9, 2009) (No. 08-437).

In Foster, the plaintiffs appealed the district court's judgment concerning their negligent misrepresentation claim against the brand name manufacturer of a drug, the generic version of which, plaintiffs alleged, caused the death of their daughter. Id. at 166, 167-68. Earlier in the proceedings, the district court granted the brand name defendant summary judgment on the plaintiffs' negligence, strict liability and breach of warranty counts inasmuch as the defendant was not the manufacturer of the drug that was actually taken. Id. at 167.

The Fourth Circuit concluded that a brand name manufacturer's representations about its own product cannot serve as a basis of liability for damages caused by a generic manufacturer's product. Id. at 170. The Foster court noted that the brand name defendant was under no duty of care to the plaintiffs when the brand name drug was never used, and that

"When a generic manufacturer adopts a brand name manufacturer's warnings and representations without independent investigation, it does so at the risk that such warnings and representations may be flawed." Id. at 169.

Foster was based in Maryland product liability law, but West Virginia law does not yield a different result. Product liability law in West Virginia allows for recovery when the plaintiff can prove that "a product was defective when it left the manufacturer and the defective product was the proximate cause of the plaintiff's injuries." Dunn v. Kanawha County Bd. of Educ., 194 W.Va. 40, 459 S.E.2d 151, 157 (1995) (citing Morningstar v. Black & Decker Mfg. Co., 162 W.Va. 857, 253 S.E.2d2d 666, 677 (1979). Because neither Wyeth nor Schwarz manufactured the product that injured plaintiffs, there is no proximate cause.

Plaintiffs nevertheless rely on Conte v. Wyeth, Inc., 168 Cal.App.4th 89, 85 Cal.Rptr.3d 288 (Cal. Ct. App. 2008). The facts of Conte are identical to those of this case. The plaintiff developed tardive dyskinesia after taking a generic form of metoclopramide and brought suit against Wyeth for its representations of Reglan. Id. at 305. The court in Conte allowed the plaintiff to go forward, not on a product liability

theory, but on a negligent misrepresentation theory so that she might establish Wyeth's liability by proving that her treating physician relied on Wyeth's warnings when prescribing Reglan to the plaintiff. Id. at 310-11.

So far, Conte, which recognized but declined to follow Foster, is the only decision in several like actions that has allowed the plaintiff to proceed against Wyeth when only the generic version of the drug was ingested. Our court of appeals in Foster has addressed this issue, making the negligent misrepresentation theory of liability unavailable to plaintiffs seeking damages against brand name defendants when their injuries resulted from another manufacturer's product. Inasmuch as the remaining claims against Wyeth and Schwarz require a duty of care to the plaintiffs or proximate cause, summary judgment is proper as to Wyeth and Schwarz.

IV.

It is, accordingly, ORDERED that Wyeth's and Schwarz's motion for summary judgment be, and it hereby is, granted. It is further ORDERED that Wyeth and Schwarz be, and they hereby are, dismissed from this action.

The Clerk is directed to forward copies of this written opinion and order to all counsel of record and any unrepresented parties.

DATED: November 13, 2009

John T. Copenhaver, Jr.
United States District Judge