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; SCHWARZ PHARMA, INC.; PLIVA, INC.; and JOHN DOE DEFENDANTS #1-6

Defendants.

MEMORANDUM OPINION AND ORDER

Pending is defendant PLIVA, Inc.'s ("PLIVA") motion to dismiss based on federal preemption and its motion for summary judgment, both filed September 10, 2010.

I. Factual Background

This action arises out of PLIVA's alleged failure to warn plaintiff Shirlean Meade ("Mrs. Meade") of the potential adverse side-effects of the drug metoclopramide. PLIVA manufactures, labels, sells, and distributes metoclopramide, the generic equivalent of the brand name drug Reglan.[1] (Compl. ¶

[1] Plaintiffs and some deponents use the drug names "Reglan" and "metoclopramide" interchangeably. Inasmuch as this court previously determined that plaintiff has only ingested the generic form of the drug, the court will only refer to the drug as metoclopramide. See Meade v. Parsley, No. 2:09-cv-00388, slip

12). Since its approval by the Food and Drug Administration ("FDA") in 1980, metoclopramide has been widely used to treat gastroesophageal reflux disease ("GRD"), nausea, and gastroparesis. (Pl.'s Resp., Ex. 18).

On January 18, 2006, defendant Dr. Deidre Parsley prescribed metoclopramide to Mrs. Meade in order to treat her GRD, nausea, and loss of appetite. (Def.'s Mot. Summ. J., Ex. 2, Williamson Memorial Hospital Records, 5MEADE00031; Compl. ¶ 34). Mrs. Meade continued taking metoclopramide until February 2007. (Def.'s Mem. Supp. Mot. Summ. J. 5). The parties do not dispute that PLIVA manufactured the metoclopramide ingested by Mrs. Meade.

It is undisputed that, during the period when Mrs. Meade used the drug, PLIVA's metoclopramide packages included package inserts that contained the following warnings:

Under the heading "DOSAGE AND ADMINISTRATION"

> Therapy longer than 12 weeks has not been evaluated and cannot be recommended.

Under the heading "INDICATIONS AND USAGE" and the subheading "Symptomatic Gastroesophageal Reflux"

> Metoclopramide tablets are indicated as short-term (4 to 12 weeks) therapy for adults with symptomatic, documented gastroesophageal reflux who fail to respond to conventional therapy.

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op. (S.D. W. Va. Nov. 29, 2009).

Under the heading "WARNINGS" and the subheading "Tardive Dyskinesia":

> **Tardive Dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with metoclopramide. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients are likely to develop the syndrome. Both the risk of developing the syndrome and the likelihood that it will become irreversible are believed to increase with the duration of treatment and the total cumulative dose.**
>
> **Less commonly, the syndrome can develop after relatively brief treatment periods at low doses; in these cases, symptoms appear more likely to be reversible.**
>
> **There is no known treatment for established cases of tardive dyskinesia although the syndrome may remit, partially or completely, within several weeks-to-months after metoclopramide is withdrawn. Metoclopramide itself, however, may suppress (or partially suppress) the signs of tardive dyskinesia, thereby masking the underlying disease process. The effect of this symptomatic suppression upon the long term course of the syndrome is unknown. Therefore, the use of metoclopramide for the symptomatic control of tardive dyskinesia is not recommended.**

(See Pl.'s Resp., Ex. 5, metoclopramide tablets label, 2; Def.'s Mem. Supp. Mot. Summ. J. 14).

Mrs. Meade, who is 77 years of age, filled her metoclopramide prescriptions at the Sav-Rite Pharmacy in Kermit, West Virginia. (Id.). She never read any written materials accompanying her metoclopramide prescriptions. (Def.'s Mot.

Summ. J., Ex. 11, Meade Dep. 86-87). Dr. Parsley likewise did not read PLIVA's metoclopramide package insert or any other written materials produced by PLIVA before prescribing the drug to Mrs. Meade.[2] (Id., Ex. 16, Dr. Parsley Dep. 191-95). Dr. Parsley did, however, read the Physician's Desk Reference ("PDR") for Reglan, which contained the same warnings as the PLIVA metoclopramide package insert. (See id., Dr. Parsley Dep. 194; Pl.'s Resp. 12).

Between February 2007 and February 2008, Mrs. Meade began experiencing involuntary facial tremors. (Pl.'s Resp., Ex.

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[2] Specifically, Dr. Parsley testified as follows:

> Q. Okay. At any time prior to prescribing the metoclopramide to Mrs. Meade, did you ever review a product information that you knew was produced by Pliva?
>
> * * *
>
> A. Not that I recall.
>
> Q. Okay. Is it fair to say that throughout the entire time you were prescribing metoclopramide for Mrs. Meade, you never recall seeing any type of written information about metoclopramide that was published by Pliva?
>
> * * *
>
> A. Again, I don't recall seeing anything by Pliva.

(Def.'s Mot. Summ. J., Ex. 16, Dr. Parsley Dep. 192).

Although Dr. Parsley's testimony that she did not "recall" reading any PLIVA labeling could be characterized as equivocal, plaintiffs do not dispute that Dr. Parsley never read PLIVA's warning. (See Pl.'s Resp. 11-13 (addressing PLIVA's argument that Dr. Parsley never read the PLIVA labeling without disputing the underlying factual assertion)). In any event, the strong import of Dr. Parsley's testimony, taken as a whole, is that she read the PDR for Reglan but did not read the package insert for metoclopramide.

2, Dr. Patnaik Dep. 58). Although several physicians observed these tremors, the first doctor to diagnose Mrs. Meade with metoclopramide-induced tardive dyskinesia was Dr. Douglas Deitch, a neurologist. Based on his two examinations of Mrs. Meade -- one in December 2008 and another in March 2009 -- Dr. Deitch testified as follows:

> Q. Okay. Now, based on your two visits with Mrs. Meade, did you ever make any type of diagnosis of her involuntary movement disorder?
>
> A. Well, other than what I've stated as far as the tardive dyskinesia.
>
> Q. Did you determine a cause for her tardive dyskinesia?
>
> A. Well, I felt it was secondary to the Reglan [metoclopramide] she used in the past.

(Pl.'s Resp., Ex. 1, Dr. Deitch Dep. 17). Dr. Deitch also ruled out other potential causes of Mrs. Meade's symptoms:

> Q. Now, were there any things you were able to rule out in regard to Mrs. Meade's tardive dyskinesia?
>
> A. Well, yeah, I ruled out stroke, I ruled out aneurysm, I ruled out brain tumor, I ruled out Parkinson's disease, those things.

(Id. 19).

On February 26, 2009, the FDA required manufacturers of metoclopramide to insert a black box warning on the drug's labeling that would "alert physicians of the risk of tardive dyskinesia with chronic use of metoclopramide." (Pl.'s Resp., Ex. 7, Letter from Public Health Service, Food and Drug Administration, 2). PLIVA complied with this directive and

changed its metoclopramide package insert accordingly. (Def.'s Reply 10). The black box warning states as follows:

> **WARNING: TARDIVE DYSKINESIA**
>
> **Chronic treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with the duration of treatment and the total cumulative dose. The elderly, especially elderly women, are most likely to develop this condition.**
>
> **Metoclopramide therapy should routinely be discontinued in patients who develop signs or symptoms of tardive dyskinesia. There is no known treatment for tardive dyskinesia; however, in some patients symptoms may lessen or resolve after metoclopramide treatment is stopped.**
>
> **Prolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risks to the patient of developing tardive dyskinesia.**

(Id.).

By way of comparison, the PLIVA package insert noted that the risks of usage increased with the duration of treatment and total dosage, that metoclopramide is indicated as short term (4 to 12 weeks) therapy for GRD, and that usage beyond 12 weeks has not been evaluated and is not recommended. The 2009 FDA warning is somewhat more specific as to duration of use by directing that prolonged treatment greater than 12 weeks should be avoided in all but rare cases. It also directs that the warning be displayed in bold type in a box rimmed with a black border. Save for the placement of the warning in a black box,

the length of usage warning given by PLIVA largely approaches that of the 2009 FDA warning.[3]

II. Procedural History

Mrs. Meade and her husband Elmer Meade ("Mr. Meade") (collectively "plaintiffs") initiated this action in the Circuit Court of Mingo County, West Virginia on February 25, 2009. Defendants removed on April 20, 2009, invoking the court's diversity jurisdiction. Plaintiffs assert 13 counts (Nos. 2 through 14) against PLIVA in their complaint, all of which are based on the following material allegations: (1) defendants "fail[ed] to warn doctors and patients of information within its knowledge or possession or both, which indicated . . . [that metoclopramide], when taken for long periods of time, caused serious, permanent, and debilitating side effects, including Tardive Dyskinesia and Akathisia"; and (2) defendants "marketed, manufactured and distributed [metoclopramide] and encouraged the

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[3] **Plaintiffs also contend that PLIVA's warnings were inadequate in that they misleadingly invited long term use that has never been approved by the FDA, but the court notes that the PLIVA warning did state that therapy longer than 12 weeks has not been evaluated and cannot be recommended. In addition, plaintiffs claim that the warnings downplayed the seriousness and potential irreversibility of the risk of tardive dyskinesia in long term use, but the PLIVA warning did state that the risk is highest among the elderly, especially elderly women, and that the likelihood of irreversibility is believed to increase with the duration of treatment and the total cumulative dose. The court's ruling on PLIVA's summary judgment motion renders any further discussion of these contentions unnecessary, however.**

long term use of these drugs, misrepresented the effectiveness of the drugs and concealed the drugs's dangerous side effects." (Compl. ¶¶ 23-24) (emphasis in original).[4]

Counts 2 through 14 are asserted against the "manufacturing defendants," which includes PLIVA. Count 2 is a strict products liability claim; Count 3 is a manufacturing defect strict liability claim; Count 4 is a design defect strict liability claim; Count 5 is a breach of express warranty claim; Count 6 is a breach of implied warranty claim; Count 7 is a negligence claim; Count 8 is a negligent misrepresentation claim; Count 9 is a claim for breach of undertaking a special duty; Count 10 is a fraud and misrepresentation claim; Count 11 is a constructive fraud claim; Count 12 is a fraud by concealment claim; Count 13 is a claim for violation of the West Virginia Unfair Trade Practices Act; and Count 14 is an intentional infliction of emotional distress claim. (Id. ¶¶ 108-199).

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[4] The alleged connection between long-term use of metoclopramide and neurological disorders is not unique to this case. 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 v. Wyeth, 462 F.3d 364, 364 (5th Cir. 2006); In re Reglan/Metoclopramide Prod. Liab. Litig., 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); 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).

Plaintiffs seek recovery for actual damages, punitive damages, loss of consortium, and reasonable costs and attorneys fees. (Id. ¶¶ 200-208).

On September 10, 2010, PLIVA filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(c) and a motion for summary judgment pursuant to Rule 56. In its motion for summary judgment and supporting memorandum, PLIVA contends there are no genuine issues of material fact inasmuch as (1) plaintiffs cannot establish causation; (2) Dr. Parsley was aware of the risks of using metoclopramide when she prescribed the drug to Mrs. Meade; (3) PLIVA satisfied any alleged duty to warn by providing a package insert explaining potential side effects of metoclopramide; (4) PLIVA's product was reasonably safe for its intended use; (5) plaintiffs have not satisfied their burden of proof on their claims for breach of warranty, fraud, violation of West Virginia Unfair Trade Practices Act, and emotional distress; and (6) West Virginia law does not recognize any special duty by a pharmaceutical company to a consumer. (See generally Def.'s Mem. Supp. Mot. Summ. J.).

III. Motion for Summary Judgment

A. Governing Standard

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). Material facts are those necessary to establish the elements of a party's cause of action. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

A genuine issue of material fact exists if, in viewing the record and all reasonable inferences drawn therefrom in a light most favorable to the non-moving party, a reasonable fact-finder could return a verdict for the non-movant. Id. The moving party has the burden of showing -- "that is, pointing out to the district court -- that there is an absence of evidence to support the nonmoving party's case." Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). If the movant satisfies this burden, then the non-movant must set forth specific facts as would be admissible in evidence that demonstrate the existence of a genuine issue of fact for trial. Fed. R. Civ. P. 56(c); id. at 322-23. A party is entitled to summary judgment if the record as a whole could not

lead a rational trier of fact to find in favor of the non-movant. Williams v. Griffin, 952 F.2d 820, 823 (4th Cir. 1991).

Conversely, summary judgment is inappropriate if the evidence is sufficient for a reasonable fact-finder to return a verdict in favor of the non-moving party. Anderson, 477 U.S. at 248. Even if there is no dispute as to the evidentiary facts, summary judgment is also not appropriate where the ultimate factual conclusions to be drawn are in dispute. Overstreet v. Ky. Cent. Life Ins. Co., 950 F.2d 931, 937 (4th Cir. 1991).

A court must neither resolve disputed facts nor weigh the evidence, Russell v. Microdyne Corp., 65 F.3d 1229, 1239 (4th Cir. 1995), nor make determinations of credibility. Sosebee v. Murphy, 797 F.2d 179, 182 (4th Cir. 1986). Rather, the party opposing the motion is entitled to have his or her version of the facts accepted as true and, moreover, to have all internal conflicts resolved in his or her favor. Charbonnages de France v. Smith, 597 F.2d 406, 414 (4th Cir. 1979). Inferences that are "drawn from the underlying facts . . . must be viewed in the light most favorable to the party opposing the motion." United States v. Diebold, Inc., 369 U.S. 654, 655 (1962).

B. Causation

"Under West Virginia law, a claim for negligence, breach of warranty, and strict liability requires that the element of causation be satisfied." White v. Dow Chem. Co., 321 Fed. App'x 266, 273 (4th Cir. 2009) (citing Tolley v. Carboline Co., 617 S.E.2d 508, 511-12 (W. Va. 2005)). Since it appears the West Virginia Supreme Court of Appeals has never discussed the various types of causation in a pharmaceutical failure-to-warn action, the court finds it necessary to articulate the precise burden plaintiffs must satisfy to establish causation in this case.

In a pharmaceutical products liability action, a plaintiff must initially establish both general and specific causation for his injuries. Bourne ex rel. Bourne v. E.I. Dupont de Nemours & Co., 189 F. Supp. 2d 482, 485 (S.D. W. Va. 2002).[5] "General causation is whether a substance is capable of causing a

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[5] **Although the West Virginia Supreme Court of Appeals has not addressed the issue, it is well-settled that a plaintiff in a toxic tort case must prove both general and specific causation. See Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 351 (5th Cir. 2007); Norris v. Baxter Healthcare Corp., 397 F.3d 878, 881 (10th Cir. 2005); In re Hanford Nuclear Reservation Litig., 292 F.3d 1124, 1129 (9th Cir. 2002); Bonner v. ISP Techs., Inc., 259 F.3d 924, 928 (8th Cir. 2001); Raynor v. Merrell Pharms., Inc., 104 F.3d 1371, 1376 (D.C. Cir. 1997); Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1200 (6th Cir. 1988); Cavallo v. Star Enter., 892 F.Supp. 756, 771 (E.D. Va. 1995), aff'd in relevant part, rev'd in part, 100 F.3d 1150, 1159 (4th Cir. 1996); see also In re Bausch & Lomb Inc. Contacts Lens Solution Prods. Liab. Litig., 693 F. Supp. 2d 515, 518 (D.S.C. 2010) ("it appears that the concept of general causation as a necessary precursor to proving specific causation is the rule in all jurisdictions.").**

particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury." In re Rezulin Prods. Liab. Litig., 369 F. Supp. 2d 398, 402 (S.D.N.Y. 2005) (citing, among others, In re Hanford Nuclear Reservation Litig., 292 F.3d 1124, 1129 (9th Cir. 2002) and Bonner v. ISP Techs., Inc., 259 F.3d 924, 928 (8th Cir. 2001)). "General causation is established by demonstrating, often through a review of scientific and medical literature, that exposure to a substance can cause a particular disease." Id. (quoting Mary Sue Henifin, et al., Reference Guide on Medical Testimony, in Reference Manual on Scientific Evidence 439, 444 (Fed. Jud. Ctr., 2d ed. 2000)).

In addition to general and specific causation, plaintiffs must establish proximate causation. See Weilbrenner v. Teva Pharms., Inc., 696 F. Supp. 2d 1329, 1342 (M.D. Ga. 2010); Swicegood v. PLIVA, Inc., 2010 WL 1138455, at *3-*4 (N.D. Ga. Mar. 22, 2010) ("In products liability cases involving drug side effects, the plaintiff has the burden of showing general and specific causation . . . the plaintiff also must show that the defendant's actions were the proximate cause of her injury."). To show proximate causation in a failure-to-warn case based on an allegedly inadequate drug label, a plaintiff must show that a different label or warning would have avoided the plaintiff's injuries. Id.

Thus, a plaintiff seeking to establish causation in a pharmaceutical failure-to-warn case must show three things: (1) the drug is capable of causing the injury, (2) the drug did in fact cause the injury, and (3) a different warning would have avoided the injury.

1. General Causation

As an initial matter, the court must determine whether plaintiffs have offered evidence of general causation -- that is, whether plaintiffs have shown that metoclopramide is capable of causing tardive dyskinesia in the general population. PLIVA contends, and plaintiffs do not dispute, that none of plaintiffs' retained experts have offered any opinions regarding general causation. (Def.'s Mem. Supp. Mot. Summ. J. 10-11). But plaintiffs claim that several of Mrs. Meade's treating physicians (whom plaintiffs refer to as "non-retained experts") testified regarding the causal link between metoclopramide and tardive dyskinesia. (Pl.'s Resp. 10). In response, PLIVA maintains that since these non-retained experts have not provided written reports, they "may testify only as to their scope and treatment of Mrs. Meade" and therefore "may not offer any opinions regarding general causation." (Def.'s Mem. Supp. Mot. Summ. J. 10-11). Consequently, PLIVA asserts, "plaintiffs' claims necessarily must

fail because they do not have the requisite expert testimony." (Id.).

a. Treating Physicians' Testimony

The court need not reach the question of whether it is permissible for Mrs. Meade's treating physicians to opine as to general causation because, contrary to plaintiffs' assertions, it appears that none of these physicians have testified as to general causation. Plaintiffs first rely on the deposition testimony of Dr. Deitch, earlier quoted, citing the following passage:

> **Q. Did you determine a cause for her tardive dyskinesia?**
>
> **A. Well, I felt it was secondary to the Reglan [metoclopramide] she used in the past.**

(Pl.'s Resp., Ex. 1, Dr. Deitch Dep. 17). This testimony is relevant to specific, not general, causation. Indeed, rather than stating whether "a substance is capable of causing a particular injury or condition in the general population," Dr. Deitch's testimony concerned how a "substance caused a particular individual's injury." In re Rezulin, 369 F. Supp. 2d at 402 (citations ommitted). Of course, in opining on specific causation, Dr. Deitch necessarily assumed the existence of general causation (i.e., in testifying that metoclopramide did cause Mrs. Meade's tardive dyskinesia, Dr. Deitch assumed that

metoclopramide can cause tardive dyskinesia as a general matter). But this mere assumption does not establish general causation.

Plaintiffs next cite the following deposition testimony of Dr. Joby Joseph, a neurologist who treated Mrs. Meade:

> **Q. Okay. By definition, is tardive dyskinesia, given your understanding, a drug induced disorder?**
>
> **A. That's right.**
>
> *** * ***
>
> **Q. I know you mentioned earlier that you did not diagnose her with tardive dyskinesia?**
>
> **A. That's right.**
>
> *** * ***
>
> **Q. Do you have an opinion as to whether her taking Reglan [metoclopramide] contributed to her movement disorder?**
>
> **A. It is one of the drugs that can cause movement disorder. Did I say definitely it is? No, I didn't say that.**

(Pl.'s Resp., Ex. 3, Dr. Joseph Dep. 75, 82-83). Nowhere in this testimony did Dr. Joseph specifically comment on whether metoclopramide is capable of causing tardive dyskinesia in the general population. Although he stated that the drug "can cause movement disorder," he did not specify that this "movement disorder" was tardive dyskinesia. The fact that Dr. Joseph did not diagnose Mrs. Meade with tardive dyskinesia further bolsters the conclusion that his testimony did not concern any causal link between metoclopramide and tardive dyskinesia.

Finally, plaintiffs cite the following deposition testimony of Dr. Samrina Hanif, another neurologist who treated Mrs. Meade:

> **Q. Okay. But people do make diagnosis of tardive dyskinesia, correct?**
>
> **A. Yes.**
>
> **Q. And doctors do, from taking histories, talking to patients, looking at records, make a determination as to what caused tardive dyskinesia, don't they?**
>
> **A. They speculate, yes.**
>
> **Q. Can they make a diagnosis that a drug such as Reglan can cause tardive dyskinesia?**
>
> **A. They can speculate, yes.**
>
> **Q. But can they not make a diagnosis?**
>
> **A. 100 percent, they cannot. I don't think so. They can be -- they can state it with possibility.**
>
> **Q. Can they state whether that it's more likely than not that Reglan causes tardive dyskinesia?**
>
> **A. It's a possibility.**

(Pl.'s Resp., Ex. 4, 83). Dr. Hanif only testified that there is "a possibility" that a doctor could "state whether it's more likely than not that Reglan causes tardive dyskinesia." (Id.). To be sure, she did not testify about a general causal link between metoclopramide and tardive dyskinesia.

Even if Mrs. Meade's treating physicians did make some passing references to a general causal link between metoclopramide and tardive dyskinesia, this would not be

sufficient evidence of causation to survive summary judgment. As the West Virginia Supreme Court of Appeals has stated, "the law is clear that a mere possibility of causation" and, more specifically, "indeterminate expert testimony on causation that is based solely on possibility . . . is not sufficient to allow a reasonable juror to find causation." Tolley v. ACF Indus., Inc., 575 S.E.2d 158, 168 (W. Va. 2002). Rather, an expert's opinion as to causation must be stated in terms of "reasonable probability." Rohrbough v. Wyeth Labs., Inc., 916 F.2d 970, 972 (4th Cir. 1990) (citing Hovermale v. Berkeley Springs Moose Lodge No. 1483, 271 S.E.2d 335, 340 (W. Va. 1980)); see also Sakaria v. Transworld Airlines, 8 F.3d 164, 172-73 (4th Cir. 1993) ("In a long line of decisions in this circuit, we have emphasized that proof of causation must be such as to suggest 'probability' rather than mere 'possibility,' precisely to guard against raw speculation by the fact finder.").

Inasmuch as Mrs. Meade's treating physicians have offered no testimony -- let alone testimony stated in terms of reasonable probability -- regarding the general causal link between metoclopramide and tardive dyskinesia, plaintiffs have failed to provide any expert scientific testimony through her treating physicians as to general causation.

b. Other Possible Evidence of General Causation

As an additional basis for general causation, plaintiffs rely on PLIVA's admission "that its own package inserts and brand name warnings at least acknowledged the causal link" between metoclopramide and tardive dyskinesia. (Pl.'s Resp. 9-10). Plaintiffs cite no authority for the proposition that a plaintiff in a pharmaceutical products liability case can satisfy his burden of proving general causation by relying on the defendant manufacturer's drug label warnings. Moreover, this contention is undermined by the general principle that causation evidence in toxic tort cases must be in the form of expert scientific testimony. See Rider v. Sandoz Pharms. Corp., 295 F.3d 1194, 1197 (11th Cir. 2002) ("Toxic tort cases . . . are won or lost on the strength of the scientific evidence presented to prove causation."); Farris v. Intel Corp., 493 F. Supp. 2d 1174, 1186 (D.N.M. 2007) ("Expert testimony is necessary . . . since this is a toxic tort lawsuit") (citing Mitchell v. Gencorp. Inc., 165 F.3d 778, 784 (10th Cir. 1999)); Mancuso v. Consol. Edison Co. of New York, 967 F. Supp. 1437, 1445 (S.D.N.Y. 1997) (holding that expert testifying as to general causation must demonstrate that, "according to scientific literature, levels of the toxin comparable to those received by the plaintiff can cause the specific types of injuries he alleges."). PLIVA's drug label, which merely warns of metoclopramide's potential side-effects

without explaining the scientific basis for the warning, is no substitute for expert testimony that establishes causation in terms of reasonable probability.

Plaintiffs also cite, as evidence of general causation, the subsequent 2009 FDA directive requiring drug manufacturers to insert a black box warning on metoclopramide labels to convey a greater risk of tardive dyskinesia. (Pl.'s Resp. 10). Again, plaintiffs cite no authority supporting this contention. Several courts have, however, rejected reliance on agency determinations as a basis for general causation. See Allen v. Pennsylvania Eng'g Corp., 102 F.3d 194, 198 (5th Cir. 1996) ("Regulatory and advisory bodies . . . utilize a 'weight of the evidence' method to assess the carcinogenicity of various substances in human beings . . . The agencies' threshold of proof is reasonably lower than that appropriate in tort law"); Dunn v. Sandoz Pharms. Corp., 275 F. Supp. 2d 672, 684 (M.D.N.C. 2003) (holding that FDA determination was insufficient evidence of general causation; reasoning that "[t]he FDA is concerned with safety and risk benefit analysis . . . The FDA balanced Parlodel's possible harm against its limited beneficial use. The FDA's balancing does not demonstrate that Parlodel may cause stroke in postpartum women."). Inasmuch as the cost-benefit balancing employed by the FDA differs from the threshold standard for establishing causation in tort actions, this court likewise concludes that the FDA-mandated tardive dyskinesia warning cannot establish general

causation in this case. Plaintiffs have therefore failed to provide any evidence of general causation.[6]

2. Proximate Causation

Even assuming plaintiffs could establish both general and specific causation, the court determines that plaintiffs have nonetheless failed to provide evidence of proximate causation. Plaintiffs' claims for negligence, breach of warranty, and strict liability require proof of proximate causation.[7] Generally speaking, "'[p]roximate cause' must be understood to be that cause which in actual sequence, unbroken by any independent

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[6] The court acknowledges that the general causal link between metoclopramide and tardive dyskinesia has been established through expert testimony in other cases, see, e.g., Swicegood v. PLIVA, Inc., 2010 WL 1138455, at *3 (N.D. Ga. Mar. 22, 2010), though it is rarely challenged in the first place. As a consequence, the court would have considered granting plaintiffs leave to file an expert report regarding general causation before dismissing their claims.

The court also notes that Dr. Deitch's testimony appears to have raised a genuine issue of fact as to specific causation. However, the court's ruling on proximate causation grounds renders any further discussion of these issues unnecessary.

[7] See Aikens v. Debow, 208 W. Va. 486, 491, 541 S.E.2d 576, 581 (2000) (discussing requirement of proximate cause in negligence cause of action); City Nat'l. Bank of Charleston v. Wells, 181 W. Va. 763, 771, 384 S.E.2d 374, 382 (1989) (discussing requirement of proximate cause in breach of warranty cause of action); Ilosky v. Michelin Tire Corp., 172 W. Va. 435, 443, 307 S.E.2d 603, 611 (1983) (discussing requirement of proximate cause in failure to warn cause of action); Morningstar v. Black & Decker Mfg. Co., 162 W. Va. 857, 883, 253 S.E.2d 666, 680 (1979) (discussing requirement of proximate cause in strict liability cause of action).

cause, produced the wrong complained of, without which the wrong would not have occurred." Wilkinson v. Duff, 212 W. Va. 725, 731, 575 S.E.2d 335, 341 (2002) (citations omitted). The West Virginia Supreme Court of Appeals has held that the following jury instruction accurately states the proximate causation standard in failure-to-warn cases:

> In order to recover under a failure to warn theory, plaintiff must prove by a preponderance of the evidence that the lack or inadequacy of warnings in the 1988 Chevrolet Celebrity proximately caused Douglas Tracy's death. GM may only be liable to petitioner for failure to warn where there is evidence that a warning would have made a difference. Therefore, plaintiff must prove that the lack of a warning regarding the seat belts in the 1988 Chevrolet Celebrity proximately caused Douglas Tracy's death, and that the presence of a warning would have prevented his death. Plaintiff must establish that the warning suggested by plaintiff would have caused Douglas Tracy to act differently or otherwise change his behavior in a manner which would have avoided his death. If you find that a warning by GM would not have prevented Douglas Tracy's death, then you must find in favor of GM.

Tracy v. Cottrell, 206 W. Va. 363, 524 S.E.2d 879 n.9 (1999) (emphasis added). The court views this standard as particularly instructive because plaintiffs' negligence, breach of warranty, and strict liability claims are all premised on a failure-to-warn theory of liability.

The court must initially address whether PLIVA's duty to warn ran to Mrs. Meade or Dr. Parsley, as this affects the proximate causation analysis. The majority of states follow the learned intermediary doctrine, which provides that "the duty of the manufacturer to warn is owed to the prescribing physician not

the ultimate consumer -- the patient." Ashworth v. Albers Medical, Inc., 395 F. Supp. 2d 395, 407 (S.D. W. Va. 2005). But, as the parties acknowledge, the West Virginia Supreme Court of Appeals has rejected the learned intermediary doctrine and has instead held that "manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers." Syl. Pt. 3, State ex rel. Johnson & Johnson Corp. v. Karl, 220 W. Va. 463, 647 S.E.2d 899 (2007). Following Karl, the West Virginia Supreme Court has not had occasion to clarify whether a drug manufacturer must warn both the patient and the physician, or just the patient. The court need not resolve this issue in evaluating proximate causation, however, because the undisputed evidence shows that an adequate warning would not have changed either Mrs. Meade's or Dr. Parsley's behavior in a manner which would have avoided Mrs. Meade's injury.

Mrs. Meade testified that she never read PLIVA's package insert or any other documents accompanying her metoclopramide prescription. (See Def.'s Mot. Summ. J., Ex. 11, Meade Dep. 86-87). Dr. Parsley likewise testified that she did not read PLIVA's metoclopramide warning. (See id., Ex. 16, Dr. Parsley Dep. 191-95). And while Dr. Parsley did read the PDR for Reglan, it is undisputed that PLIVA did not create that PDR. (See id., Ex. 16, Dr. Parsley Dep. 191; Pl.'s Resp. 12). Many courts have declined to find proximate causation in

pharmaceutical failure-to-warn suits when the patient (or the prescribing physician if the learned intermediary doctrine is applicable) did not read the defendant manufacturer's allegedly inadequate warning.[8] These courts reasoned that if the patient or physician did not read the drug warning in the first instance, then there is no basis for finding that a stronger warning would have affected their behavior.

The parties acknowledge that in Tracey, the West Virginia Supreme Court recognized the need to show that "a warning would have made a difference." 524 S.E.2d at n.9. Plaintiffs add that "[w]here an individual testifies that her behavior would have changed if a different warning had been provided, this is sufficient to create a question of fact for the jury in a failure to warn case." (Pl.'s Resp. 11). Based on

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[8] See, e.g., Motus v. Pfizer Inc., 358 F.3d 659, 661 (9th Cir. 2004) (affirming summary judgment based on lack of causation; reasoning that stronger warnings would not have changed patient's treatment since prescribing physician "testified that he did not read the warning label"); Porterfield v. Ethicon, Inc., 183 F.3d 464, 468 (5th Cir. 1999) (same); In re Zyprexa Prods. Liab. Litig., 2009 WL 1514628, at *12 (E.D.N.Y. 2009) (applying West Virginia law and finding no proximate causation; reasoning that "[b]ecause there is no evidence that [plaintiff] ever read any of defendant's warnings of possible risks from Zyprexa, there is no evidence from which a jury could find that a different warning by [the drug manufacturer] would have prevented him from taking Zyprexa"); see also Shanklin v. Allis-Chalmers Mfg. Co., 254 F. Supp. 223 (S.D. W. Va. 1966) (holding that defendant's failure to supply proper operating manual for harvester did not proximately cause user's injury where user had not read manual supplied and would not have read proper manual if it had been supplied).

this standard, plaintiffs maintain they have established proximate causation through Dr. Parsley's deposition testimony, wherein she stated that the heightened metoclopramide warnings imposed by the FDA in February 2009 affected how she communicates with patients about metoclopramide. (Id.).

Rather than merely showing that "adequate warnings would have changed behavior," (Pl.'s Resp. 12), plaintiffs must establish that an adequate warning would have changed behavior "in a manner which would have avoided [the plaintiff's injury]," Tracy, 524 S.E.2d at n.9. Plaintiffs have not met this standard. As an initial matter, the court notes that the effect of the 2009 FDA black box warning on Dr. Parsley's behavior is irrelevant since neither Dr. Parsley nor Mrs. Meade read PLIVA's labeling and therefore would not have seen a heightened warning even if it had been implemented by PLIVA. Even assuming they had read PLIVA's labeling, Dr. Parsley's testimony does not show that a heightened warning like the one mandated by the FDA would have made a difference. While Dr. Parsley testified that she would have discussed the 2009 FDA black box warning with Mrs. Meade had that information been available when she prescribed the drug in 2006, she also indicated that she did discuss the risk of tardive dyskinesia when she originally prescribed metoclopramide to Mrs. Meade.[9] In addition, Dr. Parsley did not testify that the

[9] (See Pl.'s Resp., Ex. 8, Dr. Parsley Dep. 98 ("A. I would have discussed -- again, you know, the black box is

heightened FDA warning, if implemented in 2006, would have prevented her from prescribing the drug to Mrs. Meade. Thus, Dr. Parsley's testimony does not establish that a different warning from PLIVA would have affected her behavior in a manner that would have avoided Mrs. Meade's injury.[10]

In sum, plaintiff did not read the PLIVA labeling when she used metoclopramide in 2006 and 2007 and neither did Dr. Parsley. Even if PLIVA had set forth a heightened warning in its labeling, neither plaintiff nor Dr. Parsley would have seen it. And so, a stronger warning by PLIVA would not have affected the behavior of either plaintiff or Dr. Parsley. Plaintiffs have therefore failed to carry their burden of establishing proximate causation.

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basically stating what the risks are for Tardive Dyskinesia, and I certainly would have discussed that with her. But, again, you know, I believe we discussed -- I believe we would have discussed Tardive Dyskinesia when I prescribed it") (emphasis added)).

[10] Plaintiffs cite Salmon v. Parke, Davis & Co., 520 F.2d 1359 (4th Cir. 1975) for the proposition that "reliance on a faulty label is not required in order to establish proximate causation." (Pl.'s Resp. 11). While the Fourth Circuit noted in its recitation of facts that the patient did not read the allegedly inadequate drug warning, the court did find that the prescribing physician had read it. Since the plaintiffs' claims were based on the defendant's failure to warn physicians of the drug's hazards, and since the physician in Salmon had read the defendant's allegedly inadequate warning, there was no occasion for the court to find, as plaintiffs suggest, that reliance on a faulty label is not required in order to establish proximate causation. Here, neither Mrs. Meade nor Dr. Parsley read PLIVA's metoclopramide warning. Salmon is inapposite.

Inasmuch as plaintiffs have offered no evidence of proximate causation, PLIVA is entitled to summary judgment as to all of plaintiffs' claims that require proof of causation. As noted above, "[u]nder West Virginia law, a claim for negligence, breach of warranty, and strict liability requires that the element of causation be satisfied." White v. Dow Chem. Co., 321 Fed. App'x 266, 273 (4th Cir. 2009) (citing Tolley v. Carboline Co., 617 S.E.2d 508, 511-12 (W. Va. 2005)). Accordingly, the court grants summary judgment to PLIVA as to the following seven counts of plaintiffs' complaint: Count 2 (strict products liability), Count 3 (manufacturing defect strict liability), Count 4 (design defect strict liability), Count 5 (breach of express warranty claim), Count 6 (breach of implied warranty claim), Count 7 (negligence), and Count 9 (breach of undertaking a special duty).

C. Fraud, Misrepresentation, and West Virginia Unfair Trade Practices Act Claims

PLIVA contends that plaintiffs' remaining six claims for negligent misrepresentation (Count 8), fraud and misrepresentation (Count 10), constructive fraud, (Count 11), fraud by concealment (Count 12), and for violations of the West Virginia Unfair Trade Practices Act (Count 13) fail as a matter of law because all these claims "require proof of reliance on some representation by PLIVA," and "there is no evidence that

Mrs. Meade or Dr. Parsley relied on any statement made by PLIVA." (Def.'s Reply 18; Def.'s Mem. Supp. Mot. Summ. J. 25-26). In response, plaintiffs assert that PLIVA "represented to physicians and patients that the risk of developing [tardive dyskinesia] with use of its metoclopramide was 'rare' and occurred in 1 out of 500 patients," and that "Mrs. Meade and/or her physicians relied on this information in prescribing her metoclopramide." (Pl.'s Resp. 27).

PLIVA correctly observes that reliance is a necessary element of plaintiffs' fraud-based claims.[11] Yet, plaintiffs cite no evidence showing that Mrs. Meade or Dr. Parsley actually relied on PLIVA's alleged misrepresentations. (See Pl.'s Resp.

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[11] See Syl. Pt. 5, Kidd v. Mull, 595 S.E.2d 308 (W. Va. 2004) (recognizing reliance as element of fraud claim); Ochala v. Dyncorp Intern. LLC, No. 08-1027, 2009 WL 4152966, at *5 (S.D. W. Va. Nov. 23, 2009) (citing Folio v. City of Clarksburg, 655 S.E.2d 143, 151 (W. Va. 2007)) (recognizing "justifiable reliance" as element of negligent misrepresentation claim); Harless v. CSX Hotels, Inc., 265 F. Supp. 2d 620, 651 n.12 (S.D. W. Va. 2003) (citing Gum v. Dudley, 505 S.E.2d 391, 402 (W. Va. 1997)) (noting that plaintiff alleging constructive fraud must show he "acted on" [i.e., relied upon] misrepresentation); Livingston v. K-Mart Corp., 32 F. Supp. 2d 369, 374 (S.D. W. Va. 1998) (citing Kessel v. Leavitt, 511 S.E.2d 720, 763 (W. Va. 1998)) ("Fraudulent concealment requires some affirmative action, designed or intended to prevent, and which does prevent [i.e., induces reliance], the discovery of facts giving rise to the fraud claim.") (emphasis added); Knapp v. Americredit Fin. Servs., Inc., 245 F. Supp. 2d 841, 852 (S.D. W. Va. 2003) (citing Orlando v. Finance One of West Virginia, Inc., 369 S.E.2d 882, 888 (W. Va. 1988)) (noting that plaintiffs seeking damages under W. Va. Code § 46A-6-106(1) must prove they have suffered an "ascertainable loss . . . as a result of the use of the unfair act or practice of which they complain.") (emphasis added).

27-28). Indeed, as discussed above, the undisputed evidence shows that neither Mrs. Meade nor Dr. Parsley read or relied upon PLIVA's package insert or any other representations made by PLIVA. (See Def.'s Mot. Summ. J., Ex. 11, Meade Dep. 86-87; id., Ex. 16, Dr. Parsley Dep. 191-95). Although Dr. Parsley read the PDR for Reglan, it is undisputed that PLIVA did not create that PDR. (See id., Ex. 16, Dr. Parsley Dep. 191; Pl.'s Resp. 12). Because plaintiffs have offered no evidence showing that they relied on PLIVA's representations, the court grants summary judgment as to Count 8 (negligent misrepresentation), Count 10 (fraud and misrepresentation), Count 11 (constructive fraud), Count 12 (fraud by concealment), and Count 13 (violation of West Virginia Unfair Trade Practices Act).

D. Intentional Infliction of Emotional Distress Claim

PLIVA next asserts that plaintiffs' Count 14 claim for intentional infliction of emotional distress fails "because Mrs. Meade does not suffer from severe emotional distress." (Def.'s Mem. Supp. Mot. Summ. J. 27). Although plaintiffs maintain that they "have a viable claim for intentional infliction of emotional distress," they do not respond to PLIVA's assertion.

Under West Virginia law, a plaintiff must establish the following four elements to prevail on an intentional infliction of emotional distress claim:

> "(1) that the defendant's conduct was atrocious, intolerable, and so extreme and outrageous as to exceed the bounds of decency; (2) that the defendant acted with the intent to inflict emotional distress, or acted recklessly when it was certain or substantially certain emotional distress would result from his conduct; (3) that the actions of the defendant caused the plaintiff to suffer emotional distress; and (4) that the emotional distress suffered by the plaintiff was so severe that no reasonable person could be expected to endure it."

Syl. Pt. 2, Philyaw v. Eastern Assoc. Coal Co., 633 S.E.2d 8 (W. Va. 2006) (quoting Syl. Pt. 3, Travis v. Alcon Labs., 504 S.E.2d 419 (W. Va. 1998)). In their response, plaintiffs do not contend that Mrs. Meade suffers from severe emotional distress. (See Pl.'s Resp. 27-28). Nor does the record contain any evidence which shows that Mrs. Meade suffers from severe emotional distress. PLIVA is therefore entitled to summary judgment as to plaintiffs' intentional infliction of emotional distress claim (Count 14).

E. Loss of Consortium and Punitive Damages

Lastly, PLIVA asserts that plaintiffs' claims for loss of consortium and punitive damages should be dismissed. (Def.'s Mem. Supp. Mot. Summ. J. 28-30). Inasmuch as these "claims" are wholly dependent upon the success of plaintiffs' primary claims, which the court has determined fail as a matter of law, PLIVA is entitled to summary judgment as to plaintiffs' loss of consortium claim and their request for punitive damages.

IV. Conclusion

Based on the foregoing, the court ORDERS as follows:

1. That PLIVA's motion for summary judgment be, and it hereby is, granted, and PLIVA is dismissed from this action.
2. That PLIVA's motion to dismiss based on federal preemption be, and it hereby is, denied without prejudice as moot.

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

DATED: November 24, 2010

John T. Copenhaver, Jr.
United States District Judge