IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FflorENCE DIVISION

William R. Fisher and Silbray N. Fisher, Plaintiffs, vs. Mark F. Pelstring, M.D., Wyeth, Inc., Schwarz Pharma, Inc., and PLIVA USA, Inc., Defendants.	)	Civil Action No.: 4:09-cv-00252-TLW

ORDER

This action was removed to this Court from the Court of Common Pleas for Horry County, South Carolina on January 30, 2009. (Doc. #1). The plaintiffs, William R. Fisher and Silbray N. Fisher ("plaintiffs"), who are husband and wife, allege William Fisher ("Mr. Fisher") suffers from Tardive Dyskinesia caused by his long-term use of the prescription drug metoclopramide. They assert causes of action against his treating physician, Dr. Mark F. Pelstring, who prescribed metoclopramide to him. They also assert causes of action against Wyeth, Inc. and Schwarz, Inc., who they allege manufactured metoclopramide under the brand-name Reglan and in its generic form. On July 28, 2010, this Court granted summary judgment to Wyeth and Schwarz and they were dismissed from this action. (Doc. # 89). In addition to Wyeth and Schwarz, the plaintiffs bring causes of action against PLIVA USA, Inc. ("PLIVA"), who they allege manufactured the generic metoclopramide ingested by Mr. Fisher.

Before the Court are several motions filed by the plaintiffs and PLIVA. On December 10, 2010, PLIVA filed a motion to dismiss based on federal preemption (Doc. # 104) and a motion for summary judgment (Doc. # 112). The plaintiffs filed responses to these motions

(Docs. 130, 134), to which PLIVA submitted replies (Docs. 146, 147). On April 19, 2011, the plaintiffs filed a motion for partial summary judgment. (Doc. # 160). PLIVA filed a response to this motion (Doc. # 174), to which the plaintiffs submitted a reply (Doc. # 176). PLIVA also filed a surreply to the plaintiffs' reply (Doc. # 187), and the plaintiffs submitted a response to PLIVA's surreply (Doc. # 193). In light of the Supreme Court's decision in PLIVA, Inc. v. Mensing, -- U.S. --, 131 S. Ct. 2567 (2011), where it considered the issue of federal preemption of state-law failure to warn claims involving generic drug manufacturers, this Court, on July 5, 2011, directed the plaintiffs and PLIVA to file supplemental briefing. (Doc. # 180). The parties submitted their supplemental briefs on July 25, 2011. (Docs. 182, 183).

Also before the Court are PLIVA's motions to exclude testimony of the following expert witnesses: Suzanne Parisian (Doc. # 106), Philip Seeman (Doc. # 108), and David Ross (Doc. # 110). Additionally, the plaintiffs have filed a motion to preclude Dr. Pelstring from offering any expert testimony or opinion (Doc. # 103) and motions to exclude testimony of the following expert witnesses: Raymond D. Harbison (Doc. # 157), Steven Lamm (Doc. # 158), and James Morrison (Doc. # 159).

The Court has considered the applicable law, arguments of counsel, and memoranda submitted. These motions are now ripe for disposition.

FACTS

The plaintiffs allege that Dr. Pelstring began prescribing metoclopramide to Mr. Fisher on about January 15, 2003 to treat symptoms of acid reflux disease. (Compl. ¶ 41). Dr. Pelstring allegedly continued to prescribe metoclopramide to Mr. Fisher until January 31, 2005. Id. The plaintiffs assert that Mr. Fisher's long-term use of metoclopramide caused him to develop Tardive Dyskinesia, which is an incurable neurological disorder that can cause 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. ¶¶ 32-33). In 2005, Dr. Pelstring referred Mr. Fisher to a neurologist, Dr. Michael McCaffrey, who examined Mr. Fisher on May 25, 2005. Id. ¶¶ 42-43. Although the plaintiffs assert in the complaint that during this examination Mr. Fisher was diagnosed with drug-induced Tardive Dyskinesia, id. ¶ 43, the plaintiffs now argue that this date is incorrect. Instead, they allege in their response to PLIVA's motion for summary judgment that Dr. McCaffrey diagnosed Tardive Dyskinesia on July 13, 2005, but later retracted this diagnosis and there was considerable confusion regarding Dr. McCaffrey's diagnosis. They assert that Mr. Fisher was first definitively diagnosed with Tardive Dyskinesia by Dr. David Ross on May 15, 2008.

Because the plaintiffs are asserting a medical malpractice claim against Dr. Pelstring and in accordance with South Carolina Code Annotated § 15-79-125, the plaintiffs filed a Notice of Intent to File Suit on May 22, 2008, in the Court of Common Pleas for Horry County, South Carolina before initiating this lawsuit. They initiated this lawsuit by filing their complaint in the same court on January 16, 2009. The lawsuit was then removed to this Court on January 30, 2009. (Doc. #1). In addition to their medical malpractice claim against Dr. Pelstring, the plaintiffs assert causes of action for strict products liability based on warning defects, manufacturing defects, and design defects; breach of express warranty; breach of implied warranties; negligence; negligent misrepresentation; breach of undertaking a special duty; fraud and misrepresentation; constructive fraud; fraud by concealment; violation of the South Carolina Unfair Trade Practices Act; intentional infliction of emotional distress; and loss of consortium.

DISCUSSION

I. Motion to Dismiss Based on Federal Preemption

PLIVA argues in its motion to dismiss that federal law preempts the plaintiffs' state law claims. Federal law imposes complex drug labeling requirements, which involve proof by a manufacturer seeking federal approval to market a new drug that the drug is safe and effective and that the proposed label is accurate and adequate, a process which involves costly and lengthy clinical testing. PLIVA, Inc. v. Mensing, -- U.S. --, 131 S. Ct. 2567, 2574 (2011) ("Mensing"). In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585, commonly called the Hatch-Waxman Amendments. Id. This law allowed "generic drugs" to "gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA," thereby allowing inexpensive development of generic drugs. Id. "A generic drug application must also 'show that the [safety and efficacy] labeling proposed . . . is the same as the labeling approved for the [brand-name] drug.'" Id. (quoting 21 U.S.C. § 355(j)(2)(A)(v)) (alterations and omission in original). Thus, "brand-name and generic drug manufacturers have different federal drug labeling duties." Id. "A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label." Id. On the other hand, a generic drug manufacturer "is responsible for ensuring that its warning label is the same as the brand name's." Id. At issue in the Supreme Court's decision in PLIVA, Inc. v. Mensing and also at issue in this case is "whether, and to what extent, generic drug manufacturers may change their labels after initial FDA approval." Id.

The plaintiffs "contend that PLIVA failed to adequately warn consumers and physicians of a far greater risk of developing tardive dyskinesia than suggested by its product label, and that PLIVA breached its obligation to assess the risks associated with metoclopramide exposure."

Pl.'s Resp. to PLIVA's Mot. to Dismiss, p. 3 (Doc. # 134). PLIVA argues in its motion to dismiss that the plaintiffs' state law claims are preempted by federal law because they "place generic drug manufacturers in the untenable position of choosing between state and federal law. If a manufacturer complies with federal law governing generic drugs it can be held liable under state law for not using warnings different from the branded drug counterpart. If, to avoid liability under state law, a generic drug manufacturer changes the warnings, it will violate federal law, rendering its product misbranded." Mem. in Support of PLIVA's Mot. to Dismiss, p. 2 (Doc. # 104, attach. 1). In response, the plaintiffs state they "do not contend that PLIVA should have unilaterally issued a new and different warning. Rather, [they] maintain that PLIVA should have notified the FDA of the risks associated with metoclopramide and requested that all manufacturers of metoclopramide/Reglan be required to update its labels to properly reflect current medical knowledge." Pl.'s Resp. to PLIVA's Mot. to Dismiss, p. 5 (Doc. # 134).

In Mensing, the Supreme Court ruled on this issue and held that impossibility preemption applies to state tort law claims based on generic drug manufacturers' failure to provide adequate warning labels for generic metoclopramide. Mensing, 131 S. Ct. at 2572. The Court largely accepted the reasoning advanced by PLIVA, namely that if manufacturers of metoclopramide independently seek to satisfy their state law duties by changing their labels, they violate federal law. Id. at 2577-78. Even assuming federal law imposes a duty on a generic drug manufacturer that becomes aware of safety problems to request a strengthened warning, the Court concluded preemption still applies, reasoning that "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." Id. at 2576-77, 2579. The Court held that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment

by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." Id. at 2580-81.

After the Supreme Court issued its opinion in Mensing, this Court directed the parties to submit supplemental briefing. PLIVA asserts that the Mensing decision controls the disposition of this case and means that all of the plaintiffs' causes of action should be dismissed. However, the plaintiffs argue, based on certain documents they recently learned existed that had been requested in discovery but never produced, that Mensing is not dispositive of this case.[1] They allege these documents show PLIVA did not incorporate into its generic metoclopramide labeling certain FDA-approved warnings added to the labeling for Reglan in 2003 and July 2004. The 2003 addition to the Reglan label includes a warning specific to use of the drug in geriatric patients, which states that persons age 65 and over "may be at greater risk for tardive dyskinesia."[2] (2004 Reglan Label) (Doc. # 176, attach. 2). The July 2004 changes include the following bolded language under both the "Indications and Usage" and "Dosage and Administration" sections: "**Therapy should not exceed 12 weeks in duration.**"[3] Id. PLIVA argues in its brief that it brought to the Supreme Court's attention before oral arguments were held in Mensing that it may not have made the changes that were approved for the Reglan label in July 2004.[4] Because the issue was not raised at oral argument or in the Supreme Court's

[1] Attached to the plaintiffs' brief is a March 11, 2011, letter from PLIVA's national counsel in the metoclopramide litigation to other attorneys involved in the litigation notifying them that the 2004 revisions to Reglan's label "were not included in certain post-2004 PLIVA metoclopramide package inserts." (Doc. # 183, attach. 5).

[2] Based on medical records submitted to the Court, it appears Mr. Fisher was over the age of 65 during the time period he took metoclopramide.

[3] PLIVA's label did include the following language: "Therapy longer than 12 weeks has not been evaluated and cannot be recommended." PLIVA's 2002 Metoclopramide Package Insert (Doc. # 130, attach. 7).

[4] The plaintiffs also attached to their brief discussing the impact of the Mensing decision a letter from PLIVA's counsel, dated March 11, 2011, addressed to the Clerk of the United

decision, PLIVA argues this possible deviation between its labeling for generic metoclopramide and the labeling for Reglan has no impact on the effect of the Mensing decision on this case.

Contrary to PLIVA's assertion, this possible deviation impacts the Court's analysis of its motion to dismiss. Once the FDA approved the addition of these warnings to the Reglan label, PLIVA has not indicated that any federal law prevented PLIVA from also adding these warnings to its generic metoclopramide products.[5] Indeed, the parties agree that federal law requires a generic drug label to be the same as its brand-name counterpart. Moreover, Mr. Fisher was prescribed metoclopramide during the time period that PLIVA's labeling for generic metoclopramide may not have included the warnings added to the Reglan labeling in 2003 and 2004. The Court finds that this possible deviation in PLIVA's label for generic metoclopramide, which both parties indicate exists, is sufficient to conclude the plaintiffs' claims are not entirely preempted. Therefore, PLIVA's motion to dismiss (Doc. # 104) is **DENIED**. While the Court does not conclude that the plaintiff's claims are preempted in their entirety, the Court does reach this finding with respect to some of the plaintiffs' causes of action. These findings with respect

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States Supreme Court. (Doc. # 183, attach. 4). The letter states its purpose is to inform the Court that it appears at least some of PLIVA's post-2004 labels did not include the change made to the Reglan label in 2004. The letter also discusses PLIVA's opinion of the impact of this information. In doing so, the letter indicates a possible explanation for why the Supreme Court did not address the issue in its decision. More specifically, the letter states that Ms. Mensing last received PLIVA's metoclopramide product before the FDA approved the 2004 change to the Reglan label. Here, Mr. Fisher was prescribed metoclopramide during the time period PLIVA's label may not have included the 2003 and 2004 changes to the Reglan label.

[5] See also Brief for the United States as Amicus Curiae Supporting Respondents at p. 16 n.8, PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011) ("FDA Amicus Brief") (Doc. # 174, attach. 14) (stating that a "changes being effected" supplement is the appropriate process for a generic drug manufacturer to conform its labeling to updated approved labeling for the brand-name drug "because, under those circumstances, the change would be consistent with the substantive requirements for generic labeling").

to individual claims are discussed in the Court's analysis of PLIVA's motion for summary judgment.[6] See infra pp. 30-33, 36-38.

II. PLIVA's Motion for Summary Judgment

a. Summary Judgment Standard

Pursuant to Federal Rule of Civil Procedure 56(a), the moving party is entitled to summary judgment if the pleadings, responses to discovery, and the record reveal that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." A genuine dispute of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). As the party seeking summary judgment, the moving party bears the initial responsibility of informing this Court of the basis for its motion. See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). This requires that the moving party identify those portions of the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," which it believes demonstrate the absence of a genuine dispute of material fact. Celotex, 477 U.S. at 323; see also Anderson, 477 U.S. at 249.

Though the moving party bears this initial responsibility, the nonmoving party, must then produce "specific facts showing that there is a genuine issue for trial." Fed R. Civ. P. 56(e); see Celotex, 477 U.S. at 324. In satisfying this burden, the nonmoving party must offer more than a mere "scintilla of evidence" that a genuine dispute of material fact exists, Anderson, 477 U.S. at 252, or that there is "some metaphysical doubt" as to material facts. Matsushita Elec. Indus. Co.

[6] On September 23, 2011, PLIVA filed a notice of supplemental authority (Doc. # 201) referring to a decision by the Sixth Circuit on September 22, 2011, which held that three lawsuits asserting failure-to-warn claims against generic metoclopramide manufacturers were preempted under Mensing. See Smith v. Wyeth, Inc., No. 09-5460 (6th Cir. Sept. 22, 2011). This Court has reviewed that decision and finds that it does not affect the analysis set forth in this Order.

v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Rather, the nonmoving party must produce evidence on which a jury could reasonably find in their favor. See Matsushita, 475 U.S. at 587.

In considering a motion for summary judgment, this Court construes all facts and reasonable inferences in the light most favorable to the nonmoving party. See Miltier v. Beorn, 896 F.2d 848, 852 (4th Cir. 1990). Summary judgment is proper "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there [being] no genuine issue for trial." Matsushita, 475 U.S. at 587 (1986) (internal quotations omitted).

b. Statute of Limitations

PLIVA asserts that the plaintiffs' claims are barred by the applicable statute of limitations, which the parties agree is three years. See S.C. Code Ann. § 15-3-530. The parties also agree that a personal injury action accrues on the date that a "person knew or by the exercise of reasonable diligence should have known that he had a cause of action." S.C. Code Ann. § 15-3-535. "The exercise of reasonable diligence means simply that an injured party must act with some promptness where the facts and circumstances of an injury would put a person of common knowledge and experience on notice that some right of his has been invaded or that some claim against another party might exist." Snell v. Columbia Gun Exchange, Inc., 278 S.E.2d 333, 334 (S.C. 1981). The "standard as to when the limitations period begins to run is objective rather than subjective." Burgess v. Am. Cancer Soc'y, S.C. Div., Inc., 386 S.E.2d 798, 800 (S.C. 1989). "The burden of establishing the bar of the statute of limitations rests upon the one interposing it." Brown v. Finger, 124 S.E.2d 781, 786 (S.C. 1962). If the materials facts as to whether the statute of limitations is a bar are in dispute, "the issue becomes one for the jury." Columbia Venture, LLC v. Dewberry & Davis, LLC, 604 F.3d 824, 829 (4th Cir. 2010) (citing Brown, 124 S.E.2d at 786) (applying South Carolina law); see also Garner v. Houck, 435 S.E.2d

847, 849 (S.C. 1993) ("If there is conflicting evidence as to whether a claimant knew or should have known he or she had a cause of action, the question is one for the jury.").

For all medical malpractice claims arising after July 1, 2005, South Carolina law requires a plaintiff to file a Notice of Intent to File Suit prior to initiating a civil action. See S.C. Code Ann. § 15-79-125.[7] "Filing the Notice of Intent to File Suit tolls all applicable statutes of limitations." Id. After the Notice of Intent to File Suit is filed, the parties are directed to participate in mediation. Id. If the matter cannot be resolved through mediation and the plaintiff chooses to initiate a civil action, "[t]he action must be filed: (1) within sixty days after the mediator determines that the mediation is not viable, that an impasse exists, or that the mediation should end; or (2) prior to expiration of the statute of limitations, whichever is later." Id.

The plaintiffs filed their complaint on January 16, 2009. Included in the lawsuit is a medical malpractice claim against Dr. Pelstring, which means South Carolina Code Annotated § 15-79-125 applies if the plaintiffs' claims arose after July 1, 2005.[8] The plaintiffs filed a Notice of Intent to File Suit on May 22, 2008, meaning all applicable statutes of limitations were tolled at that point if the plaintiffs' claims arose after July 1, 2005. See S.C. Code Ann. § 15-79-125.

[7] See also 2005 S.C. Acts 32 (S.B. 83).

[8] PLIVA asserts in a footnote to its reply to the plaintiffs' response in opposition to its motion for summary judgment (Doc. # 147) that South Carolina Code Annotated § 15-79-125 does not apply to the plaintiffs' claims against PLIVA because § 15-79-125 is only applicable to medical malpractice claims. However, the plaintiffs' complaint includes a cause of action against Dr. Pelstring for medical malpractice, and § 15-79-125 states that a party must file of Notice of Intent to File Suit "[p]rior to filing or initiating a civil action alleging . . . medical malpractice." (Emphasis added). Section 15-79-125 also states that filing the Notice of Intent "tolls all applicable statutes of limitation." (Emphasis added). PLIVA provides no authority indicating that § 15-79-125 does not toll the statute of limitations applicable to a defendant against whom no medical malpractice claim is asserted when that defendant is joined in a civil action with a defendant against whom a medical malpractice claim is asserted. Section 15-79-125 also does not include any language indicating that the case number under which a Notice of Intent is served on a defendant must be the same as the case number assigned to the complaint served on that defendant if a civil action is ultimately initiated.

If the plaintiffs' claims accrued before July 1, 2005, the plaintiffs do not receive the benefit of the tolling provision outlined in § 15-79-125, and their claims are time-barred under South Carolina Code Annotated § 15-3-530. Regardless of whether § 15-79-125 applies, the plaintiffs' claims are also time-barred if the limitations period ran before they filed the Notice of Intent to File Suit.

In support of its position, PLIVA refers to deposition testimony by various doctors and to Mr. Fisher's medical records. On April 11, 2005, Dr. Pelstring indicated in his notes that Mr. Fisher was taken off Reglan nine days ago and after five days began to feel more alert and steadier on his feet. (Southern Medical Associates' medical records ("SMA R."), FISHER CO00020-21) (Doc. # 112, attach. 6). At his deposition, Dr. Pelstring testified that he observed a tremor during this visit also. (Pelstring Dep. pp. 116-17) (Doc. # 112, attach. 8). According to the complaint, Dr. Pelstring referred Mr. Fisher to a neurologist, Dr. Michael McCaffrey. (Compl. ¶ 42) (Doc. # 1, attach. 3). Dr. McCaffrey examined Mr. Fisher on May 25, 2005. Id. ¶ 43. Prior to Mr. Fisher's evaluation by Dr. McCaffrey, the Fishers completed a "Patient Data Base" form, dated May 25, 2005, on which Mr. Fisher reported that "after taking Reglan 10 mg since 1-03," he had uncontrolled shaking and jerking, bad nerves, weakness, weak spells, wobbliness when walking, and depression. (Fisher Dep., Ex. 1) (Doc. # 112, attach. 11). Mr. Fisher also indicated on this form that "taking more Reglan 10 mg" made his problems worse. Id. Relying on Dr. McCaffrey's deposition testimony and the "Patient Data Base" form, PLIVA argues that the Fishers were on notice at this visit on May 25, 2005, that they had a potential claim against PLIVA. Finally, PLIVA asserts that the plaintiffs judicially admitted their claims accrued at the latest on May 25, 2005, by alleging in their complaint that Dr. McCaffrey

diagnosed Mr. Fisher as suffering from drug-induced Tardive Dyskinesia on May 25, 2005. (Compl. ¶ 43) (Doc. # 1, attach. 3).

In response, the plaintiffs assert their claims accrued on May 15, 2008, when Dr. David Ross definitively diagnosed Mr. Fisher with Tardive Dyskinesia. Earlier the record reflects that, as the plaintiffs assert, Dr. McCaffrey wrote Tardive Dyskinesia under the heading "Impression" in his notes for his July 13, 2005, exam of Mr. Fisher, which was an indication that his impression was Tardive Dyskinesia had developed. Later, however, Dr. McCaffrey retracted this diagnosis on September 21, 2005.

In support of their argument, the plaintiffs refer to the medical records from Mr. Fisher's visits with Dr. McCaffrey. In his notes for his examination of Mr. Fisher on May 25, 2005, Dr. McCaffrey wrote under the heading "History of Present Illness" that Mr. Fisher started developing abnormal movements and was taken off Reglan, that Mr. Fisher "can develop spontaneous whole body dystonias suggestive of tardive dyskinesia," and that he "did not see any of these movements while in the office today." (Strand Regional Specialty Associates medical records ("SRSA R."), p. 1) (Doc. # 131, attach. 2). Dr. McCaffrey also indicated under the heading "Impression" that Mr. Fisher "may have problems with tardive dyskinesia secondary to Reglan." Id., p. 2. In his notes for Mr. Fisher's examination on June 8, 2005, Dr. McCaffrey stated that Mr. Fisher was being seen for follow-up of "ataxia/jerking thought to be secondary to tardive dyskinesia" and that this ataxia/jerking "is more than likely secondary to a mild/moderate case of tardive dyskinesia secondary to Reglan." Id., p. 3-4. For Mr. Fisher's examination on July 13, 2005, Dr. McCaffrey noted that Mr. Fisher was being seen in follow-up "for tardive dyskinesia" and that his impression was "tardive dyskinesia." Id., p. 5-6. However, for Mr. Fisher's next visit on September 21, 2005, Dr. McCaffrey noted that he had not seen, in his

office, "any movements whatsoever to call [Mr. Fisher's] disorder tardive dyskinesia," that "it is unclear at this time whether any of [Mr. Fisher's] symptoms are secondary to Reglan," and that "all of [Mr. Fisher's] symptoms at present may be secondary to depression." Id., p. 7-8.

The plaintiffs also cite to deposition testimony by Dr. Pelstring and Ms. Fisher. During his deposition, Dr. Pelstring stated that he did not believe Mr. Fisher had Tardive Dyskinesia or Akathisia at the time he referred Mr. Fisher to a neurologist and that he believed Mr. Fisher's tremor was related to his anxiety disorder. Pelstring Dep. p. 119-20 (Doc. # 130, attach. 2). Ms. Fisher testified that Dr. McCaffrey did not appear to know what was causing Mr. Fisher's problems during the May 25, 2005, visit and that he indicated he would run some tests. (Fisher Dep. p. 33) (Doc. # 130, attach. 3). In addition, Ms. Fisher testified that she did not recall Dr. McCaffrey saying during the May 25th visit that Mr. Fisher may have Tardive Dyskinesia but that at a later visit he indicated that Mr. Fisher had Tardive Dyskinesia. Id. p. 33-34. Ms. Fisher also stated there was a lot of confusion with Dr. McCaffrey regarding Mr. Fisher's diagnosis. Id. p. 52-53.

The evidence of record at this stage is similar to that in Garner v. Houck where the South Carolina Supreme Court held there was a jury question as to when a claim was or should have been discovered because there was "no evidence conclusively showing" the plaintiff knew or should have known outside of the limitations period that he had a cause of action. Garner, 435 S.E.2d at 848-50. PLIVA argues the plaintiffs' claims accrued on April 11, 2005, when Dr. Pelstring noted Mr. Fisher began to feel better after being taken off metoclopramide and, according to Dr. Pelstring's deposition testimony, he observed a tremor. However, no conclusive evidence has been presented showing that Dr. Pelstring diagnosed Mr. Fisher as suffering a side effect of metoclopramide. Alternatively, PLIVA asserts, at the latest, that the

plaintiffs' claims accrued on May 25, 2005, when Dr. McCaffrey first examined Mr. Fisher. The "Patient Data Base" form filled out by the Fishers before this examination suggests that the plaintiffs suspected Mr. Fisher was suffering a side effect of metoclopramide. In addition, Dr. McCaffrey's notes from the May 25, 2005, and the June 8, 2005, visits indicate that Mr. McCaffrey suspected Mr. Fisher may have had Tardive Dyskinesia. Again, however, no conclusive evidence has been presented showing that the Fishers knew Mr. Fisher was suffering a side effect of Reglan, that they suspected the severity of the potential side effect they described on the Patient Data Base form, or that Dr. McCaffrey indicated to them during the May 25th or June 8th visits that Mr. Fisher's health problems were caused by metoclopramide. As well, notably, on September 21, 2005, Dr. McCaffrey indicated in his notes he saw "no movements whatsoever to call [Mr. Fisher's] disorder tardive dyskinesia" and that it is "unclear . . . whether any of [Mr. Fisher's] symptoms are secondary to Reglan" or "may be secondary to depression." Dr. McCaffrey is essentially concluding it is unclear that Reglan caused the plaintiffs' medical problems. In sum, this Court does not find that the Fishers having only unconfirmed suspicions that Mr. Fisher may be experiencing a side effect of metoclopramide is enough to conclusively start the running of the limitations period on their claims prior to the diagnosis by Dr. Ross on May 15, 2008. Cf. Graniteville Co. v. IH Serv., Inc., 447 S.E.2d 226, 228 (S.C. Ct. App. 1994) ("It would be paradoxical to hold that a person suffering an injury is required to determine the causation of the injury without benefit of expert opinion and then require causation testimony at trial to be limited to expert opinion. When the injury requires an expert to make a determination of the cause of the injury and an expert is retained, this, in and of itself, is evidence of reasonable diligence in determining whether or not the injury is attributable to a wrong inflicted by someone else.").

Therefore, after careful consideration of the arguments of the parties and evidence in the record, the Court concludes there is an issue of fact at this stage of the litigation as to whether the plaintiffs' claims are timely. If their claims accrued before July 1, 2005, the plaintiffs do not receive the benefit of the tolling provision in South Carolina Code Annotated § 15-79-125, and their claims are time-barred. Viewed in a light most favorable to the plaintiffs and similar to the facts in Garner, no evidence has been presented to the Court "conclusively showing" that the Fishers knew or by the exercise of reasonable diligence should have known that they had a cause of action against PLIVA prior to July 1, 2005. Garner, 435 S.E.2d at 850. Moreover, much of the case law cited by the parties in their briefs supports the conclusion there is an issue of fact at this stage of the litigation. See Collins v. R.J. Reynolds Tobacco Co., 901 F. Supp. 1038, 1046 (D.S.C. 1995) (concluding personal injury action accrued at least by date that decedent was aware of diagnosis of emphysema and that his injury might be related to smoking); Quattlebaum v. Carey Canada, Inc., 685 F. Supp. 939, 940 (D.S.C. 1988) (finding statute of limitations began to run on decedent's personal injury claim on date he received diagnosis of asbestosis or an asbestos-related disease); Hinson v. Owens-Illinois, Inc., 677 F. Supp. 406, 411 (D.S.C. 1987) (concluding the statute of limitations began to run, at the very latest, on the date a cat scan positively showed asbestosis).[9] For the reasons stated, PLIVA's motion for summary judgment based on the statute of limitations is denied.

[9] Furthermore, the Court does not conclude that the other three cases cited by PLIVA lead to a conclusion that the plaintiffs' claims are time-barred. Wilson v. Shannon is distinguishable because it involved a lawsuit against a physician for negligently prescribing Valium to treat the plaintiff's anxiety and depression. 386 S.E.2d 257, 258 (S.C. Ct. App. 1989). In Wilson, the court held the plaintiff's claims accrued by the date another physician told him he should be on an antidepressant rather than Valium, which is a depressant. Id. at 258-59. In the case before the Court, Mr. Fisher's alleged injury is a side effect of metoclopramide, and there is no conclusive evidence at this stage that a physician told him prior to July 1, 2005, that he should not have been taking metoclopramide or that the health problems he was experiencing were caused by it.

The plaintiffs have requested an opportunity to amend the allegations in the complaint regarding the date of Mr. Fisher's diagnosis of Tardive Dyskinesia. The plaintiffs' request is granted. They shall have twenty (20) days from the filing date of this Order to file an amended complaint.

c. Causation

1. Proximate Cause/Learned Intermediary Doctrine

PLIVA asserts summary judgment should be granted because the plaintiffs cannot establish proximate cause. The plaintiffs do not dispute that proximate cause is an element of at least some of their claims. See Bray v. Marathon Corp., 588 S.E.2d 93, 95 (S.C. 2003) ("A products liability plaintiff must prove the product defect was the proximate cause of the injury sustained."); Young v. Tide Craft, Inc., 242 S.E.2d 671, 675 (S.C. 1978) (holding proximate cause is an "essential element" of negligence, breach of implied warranty, and strict liability theories of recovery); Small v. Pioneer Mach., Inc., 494 S.E.2d 835, 842 (S.C. Ct. App. 1997)

Strong v. University of South Carolina School of Medicine is also distinguishable because in Strong a physician wrote in his notes that the plaintiff's condition was due to poor follow-up care whereas here Dr. McCaffrey's notes prior to the July 1, 2005, visit do not show a definitive diagnosis of Tardive Dyskinesia or of metoclopramide causing Mr. Fisher's health problems. 447 S.E.2d 850, 851-52 (S.C. 1994). Finally, Barnes v. Schering Corp. is distinguishable because, in Barnes, there was clear evidence of the physician to whom the plaintiff was referred having a discussion with the plaintiff about the physical abnormalities she was experiencing and the association between these problems and the drug that ultimately served as the basis of her products liability action. No. 93-1638, 1994 WL 20110, at *1-2 (4th Cir. Jan. 26, 1994). Additionally, in Barnes, the doctor to whom the plaintiff was referred sent a letter to the plaintiff's treating physician, relating that he discussed with the plaintiff the nature of the problems associated with the drug and opining that the drug accounted for the physical abnormality the plaintiff was experiencing. Id. at *2. Moreover, Barnes is an unpublished decision. See 4th Cir. R. 32.1 ("Citation of this Court's unpublished dispositions issued prior to January 1, 2007, in briefs and oral arguments in this Court and in the district courts within this Circuit is disfavored, except for the purpose of establishing res judicata, estoppel, or the law of the case.").

(holding proximate cause is an element of strict liability, warranty, and negligence theories of recovery).

PLIVA also argues it is entitled to summary judgment based on the learned intermediary doctrine. Under the learned intermediary doctrine, "the manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device." Odom v. G.D. Searle & Co., 979 F.2d 1001, 1003 (4th Cir. 1992); see also Tarallo v. Searle Pharm., Inc., 704 F. Supp. 653, 659 n.2 (D.S.C. 1988) ("The learned intermediary defense rests on the sufficiency and clarity of warnings given to the trained, licensed physician. If the doctor receives a warning which fully comports with the FDA legal standards, the doctrine prevents recovery by a treated patient against the manufacturer."). "[T]he physician is called on to act as a 'learned intermediary' between the manufacturer and the consumer because he is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment." Brooks v. Medtronic, Inc., 750 F.2d 1227, 1231 (4th Cir. 1984). As a result, under this doctrine, "the manufacturer cannot be said to have caused the injury if the doctor already knew of the medical risk." Odom, 979 F.2d at 1003 (citing Stanback v. Parke, Davis & Co. 657 F.2d 642, 645-46 (4th Cir. 1981)). Moreover, the Fourth Circuit has declined to create a presumption of causation under South Carolina law where a warning is proven inadequate. Id. Rather the Fourth Circuit has held "'[t]he burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the

product for the plaintiff.'" Id. (quoting Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 814 (5th Cir. 1992)).[10]

PLIVA asserts summary judgment should be granted because Dr. Pelstring never read or relied on PLIVA's metoclopramide warnings and because the plaintiffs cannot show that Dr. Pelstring did not appreciate the risks of metoclopramide or would have acted differently if the package insert contained a different warning. PLIVA relies heavily on Odom v. G.D. Searle & Co. where the Fourth Circuit applied South Carolina law in affirming a grant of summary judgment to a manufacturer of an intrauterine device ("IUD"). Odom, 979 F.2d at 1001-04. In Odom, the plaintiff's treating physician "testified at length about his independent knowledge of the risk" of pelvic inflammatory disease from the use of an IUD, and "his own estimate of the risk actually exceeded that of" the plaintiff's expert. Id. at 1003. PLIVA also cites to Dr. Pelstring's deposition testimony in which he indicates the following: (1) he was aware Tardive Dyskinesia was a possible side effect of metoclopramide and is familiar with its symptoms, Pelstring Dep., pp. 141-43, 15-17 (Doc. # 112, attachs. 7, 8); (2) he read the Physician's Desk Reference insert for Reglan when it came on the market and was aware of the product and its risks, id. at 139; (3) he issued new prescriptions for Reglan a couple times a month in 2003 or 2004 for different conditions, id. at 22; (4) at the time of his deposition on August 19, 2010, he still issued new prescriptions for Reglan approximately twice a month, id. at 25; (5) he at all times felt he had enough information from the manufacturers about metoclopramide to make

[10] Notably, in Thomas v. Hoffman-LaRoche, Inc., although unwilling to presume causation, the Fifth Circuit was "willing to assume that the failure to give an adequate warning of a known risk entitles the plaintiff to a rebuttable presumption that the learned intermediary would have read and heeded a proper warning." 949 F.2d 806, 814 (5th Cir. 1992). However, the Fifth Circuit reasoned that "'heed' in this context means only that the learned intermediary would have incorporated the 'additional' risk into his decisional calculus. The burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." Id.

decisions about prescribing it, id. at 164; (6) he had never heard of PLIVA before this lawsuit, had never met with a representative of PLIVA, and had never received any literature of any kind from PLIVA, id. at 136; and (7) to the best of his knowledge, he had never seen a PLIVA package insert for metoclopramide or relied on information from PLIVA in making his treatment decisions for Mr. Fisher, id. at 149.[11]

In response, the plaintiffs argue it is axiomatic to conclude proximate cause requires proof that either the plaintiffs or Dr. Pelstring read PLIVA's specific metoclopramide label and that reading the brand-name Reglan label is not enough when PLIVA repeatedly asserts its label has to be the same as the brand-name label. The plaintiffs also argue they can prove proximate cause by demonstrating the chain of events resulting in Mr. Fisher's injuries would have been interrupted if a proper warning had been provided. They cite to Dr. Pelstring's deposition testimony that his understanding was that the risk of developing Tardive Dyskinesia as a side effect of metoclopramide was not significant enough to warrant a specific discussion with a patient in all circumstances. Pelstring Dep., pp. 68-70 (Doc. # 130, attach. 2). When questioned about the impact on his decision-making of a statement in the Physician's Desk Reference in 2003 or 2004 that the risk of a side effect such as Tardive Dyskinesia might be as high as 20

[11] In addition, PLIVA cites to Andrews v. Buckman Lab., Inc., where the Fourth Circuit, applying South Carolina law, held that the plaintiff could not succeed on his claim that the defendant negligently failed to warn him of the dangers of a product because he never read the Material Safety Data Sheet for the product even though it was posted near his workstation. No. 98-1189, 1999 WL 321526, at *3 (4th Cir. May 21, 1999) (per curiam). Buckman is distinguishable because it did not involve a prescription drug or the learned intermediary doctrine. Moreover, it is an unpublished decision. See 4th Cir. R. 32.1 ("Citation of this Court's unpublished dispositions issued prior to January 1, 2007, in briefs and oral arguments in this Court and in the district courts within this Circuit is disfavored, except for the purpose of establishing res judicata, estoppel, or the law of the case."). PLIVA also refers to two recent grants of summary judgment in favor of PLIVA in cases involving metoclopramide. See Pustjejovsky v. PLIVA, Inc., 623 F.3d 271 (5th Cir. 2010); Meade v. Parsley, No. 2:09-cv-00388, 2010 WL 4909435 (S.D.W. Va. Nov. 24, 2010).

percent, Dr. Pelstring responded that if he was prescribing a medication for the first time and the risk was 20 percent, he would certainly mention the side effect to a patient.[12] Id. at 74. However, if his experience in prescribing the drug over a period of time indicates the risk is much lower than what is stated in the Physician's Desk Reference, he would balance the 20 percent risk against his own observations. Pelstring Dep., pp. 74-75 (Doc. # 112, attach. 7). Dr. Pelstring testified that he was aware when the FDA issued the Black Box Warning for

[12] In 2009, the FDA required manufacturers of metoclopramide to add a black box warning to their products, which stated:

> WARNING
> TARDIVE DYSKINESIA
>
> Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with duration of treatment and total cumulative dose.
>
> Metoclopramide therapy should be discontinued in patients who develop signs or symptoms of tardive dyskinesia. There is no known treatment for tardive dyskinesia. In some patients, symptoms may lessen or resolve after metoclopramide treatment is stopped.
>
> Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia.

2009 Reglan/Metoclopramide Label (Doc. # 130, attach. 8).
Additionally, some language was added to the "Warnings" section of the 2009 label, which provided that "[a]lthough the risk of [Tardive Dyskinesia] with metoclopramide has not been extensively studied, one published study reported a [Tardive Dyskinesia] prevalence of 20% among patients treated for at least 12 weeks. Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing [Tardive Dyskinesia]." Id. In 2010, this language that was added to the "Warnings" section in 2009 was removed and the following language was added: "The risk of developing tardive dyskinesia increases with the duration of treatment and the total cumulative dose. An analysis of utilization patterns showed that about 20% of patients who used metoclopramide took it for longer than 12 weeks. Treatment with metoclopramide for longer than the recommended 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing [Tardive Dyskinesia]." Letter from FDA to Alaven Pharm. (July 20, 2010) (Doc. # 174, attach. 12); 2010 Reglan label (Doc. # 174, attach. 13).

Reglan/metoclopramide in 2009 because he receives email notices about black box warnings. Pelstring Dep., p. 24 (Doc. # 130, attach. 2).

There is not an abundance of case law in South Carolina on proximate cause in prescription drug cases and the learned intermediary doctrine, but Odom is most directly on point. However, Odom is distinguishable from this case because there was lengthy testimony from the treating physician in Odom that he understood the risks associated with using an IUD and his own estimate of the risk of developing pelvic inflammatory disease actually exceeded that of the plaintiff's expert. PLIVA has not cited any deposition testimony by Dr. Pelstring where his estimate of the risk of developing Tardive Dyskinesia exceeded that of the plaintiffs' experts in this case. To the contrary, Dr. Pelstring's testimony was that his understanding of the risk of developing Tardive Dysknesia as a side effect was too small to warrant a specific discussion with a patient in all circumstances before prescribing the drug. Furthermore, Dr. Pelstring testified he read the Physician's Desk Reference insert for Reglan when it came on the market, which indicates he relied to some extent on the labeling for the drug when making treatment decisions.[13] Additionally, in their brief filed in response to this Court's Order directing supplemental briefing in light of the Mensing decision, the plaintiffs argue that PLIVA did not take sufficient steps to notify prescribing physicians about the changes made to the labeling in 2003 and 2004. Pl. Supplemental Br., pp. 2-3 (Doc. # 183). Dr. Pelstring indicates in his deposition testimony that he never received any literature from PLIVA and that he was not aware of a label change in 2004. Pelstring Dep., pp. 68, 136 (Doc. # 112, attachs. 7, 8). Conversely, Dr. Pelstring testified that he was aware when the FDA issued the Black Box Warning for

[13] The Physician's Desk Reference is a compilation of information supplied by manufacturers about their products. FDA Amicus Brief, p. 8 n.4 (Doc. # 174, attach. 14). The FDA views these submissions as labeling. Id.

Reglan/metoclopramide in 2009 because he receives email notices regarding black box warnings. Id. at 24. Further, PLIVA may have had avenues available to it to communicate with physicians about the 2003 and 2004 label changes without seeking FDA approval first. In Mensing, the Supreme Court accepted the FDA's interpretation that generic drug manufacturers may not use "Dear Doctor" letters to send additional warnings to prescribing physicians because such letters are labeling and "must be 'consistent with and not contrary to [the drug's] approved . . . labeling.'" Mensing, 131 S. Ct. at 2576 (quoting 21 C.F.R. § 201.100(d)(1)) (alteration and omission in original); FDA Amicus Brief, pp. 18-19. If PLIVA had made changes to its labeling consistent with the 2003 and 2004 changes to the Reglan labeling, a letter alerting physicians to this change would arguably not be inconsistent with the drug's approved labeling. Therefore, an issue of fact exists at this time regarding whether PLIVA should have done more when the labeling changes occurred in 2003 and 2004 and if it had done more, whether it would have impacted Dr. Pelstring's decision about prescribing metoclopramide to Mr. Fisher or his decision about discussing the risk of developing Tardive Dyskinesia with Mr. Fisher. Summary judgment is denied on this basis.

2. General Causation and Specific Causation

"Where a medical causal relation issue is not one within the common knowledge of the layman, proximate cause cannot be determined without expert medical testimony." In re Bausch & Lomb Inc. Contacts Lens Solution Prod. Liab. Litig, 693 F. Supp. 2d 515, 518 (D.S.C. 2010) (internal quotation marks and citation omitted). "To establish medical causation in a product liability case, a plaintiff must show both general causation and specific causation." Id. "General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular

individual's injury." Id. (internal quotation marks and citation omitted). "If a plaintiff is not able to establish general causation, it is unnecessary to consider whether the plaintiff can establish specific causation." Id. (internal quotation marks and citation omitted).

PLIVA argues that the testimony of the plaintiffs' proffered experts on the issues of general and specific causation should be excluded. Federal Rule of Evidence 702 provides that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Thus, expert testimony is admissible if (1) the expert is qualified; (2) the evidence is relevant in that it relates to an issue in the case; and (3) the evidence is reliable. See Fed R. Evid. 702; Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589-91 (1993). The Supreme Court has set forth the following list of non-exclusive, flexible factors to be used in assessing whether the reasoning or methodology underlying expert testimony is scientifically valid and whether the reasoning or methodology properly can be applied to the facts in issue: (1) whether a theory or technique can and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) a consideration of the known or potential rate of error and the existence and maintenance of standards controlling the technique's operation; and (4) whether there is "general acceptance" of the theory or technique within the relevant scientific community. Daubert, 509 U.S. at 592-95. The focus of the Rule 702 analysis is on the "principles and methodology" applied by the expert, not on the conclusions reached. Id. at 595. The objective of the Court's gatekeeping role "is to make certain that an expert,

whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999).

i. General Causation

PLIVA asserts in its motion for summary judgment that the testimony of the plaintiffs' proffered expert on the issue of general causation, Dr. Philip Seeman, should be excluded. PLIVA also filed a separate motion to exclude Dr. Seeman's testimony. (Doc. # 108). After careful consideration of the arguments submitted by the parties, the Court does not find at this stage of the proceedings that Dr. Seeman should be excluded from offering expert testimony on the issue of general causation. "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 (e.g., that smoking cigarettes can cause lung cancer)." Mary Sue Henifen et al., Reference Manual on Scientific Evidence 439, 444 (Fed. Jud. Ctr., 2d ed.). The plaintiffs argue and Dr. Seeman's report indicates that his opinions are based on medical literature relating to the issues in this case. Pl.'s Resp. to PLIVA's Mot. to Exclude Seeman's Test., pp. 3, 20 (Doc. # 132); Seeman's Expert Report, pp. 4-7 (Doc. # 132, attach. 3). Additionally, the Court does not conclude at this time that Dr. Seeman's opinions are inadmissible to the extent they are based on in vitro testing and animal testing. See McClellan v. I-Flow Corp., 710 F. Supp. 2d 1092, 1110-11 (D. Or. 2010) ("[D]efendants cannot credibly argue that the reliance on in vitro and animals studies is scientifically invalid in this case. Whatever inadequacies arise from extrapolation will no doubt be addressed through vigorous cross-examination by defense counsel."); In re Neurontin Marketing, Sales Practices, & Prod. Liab. Litig., 612 F. Supp. 2d 116, 159 (D. Mass. 2009) (allowing expert witness that relied primarily on in vitro animal studies where expert's

testimony was also supported by a long trail of literature and where the expert was "an exceptionally well-qualified individual who has applied methods generally accepted in his field").[14]

PLIVA also argues that even if Dr. Seeman's testimony is admissible, it is entitled to summary judgment because his testimony does not establish that metoclopramide is capable of causing Tardive Dyskinesia in the general sub-population of which Mr. Fisher is a member. However, PLIVA provides no case law to support a finding that general causation requires such a showing. In addition, the case law cited by the parties to set forth the legal standard for general causation provides that it "'is whether a substance is capable of causing a particular injury . . . in the general population.'" In re Bausch & Lomb, 693 F. Supp. 2d at 518 (quoting Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 351 (5th Cir. 2007)) (emphasis added). As a result, the Court finds no basis to conclude that general causation requires a showing that metoclopramide is capable of causing Tardive Dyskinesia in the general sub-population of which Mr. Fisher is a member. Therefore, PLIVA's motion to exclude the testimony of the plaintiffs' proffered expert on the issue of general causation, Dr. Seeman, (Doc. # 108) is **DENIED** at this stage of the litigation. The Court also concludes that PLIVA is not entitled to summary judgment on the issue of general causation.

Finally, PLIVA asserts that Dr. Seeman's expert report which was served on October 20, 2010, should be excluded because the report was filed after the deadline set forth in the scheduling order for serving expert statements. The plaintiffs argue that Dr. Seeman merely updated his report to clarify portions of his testimony in his first deposition on August 24, 2010,

[14] The Court limits its discussion in this Order to the issue of whether Dr. Seeman should be excluded from offering expert testimony on general causation because that is what is at issue in PLIVA's motion for summary judgment.

by further explaining statements made in his original report, which was submitted on September 8, 2010. Federal Rule of Civil Procedure 26(e) provides that a party which plans to use an expert witness at trial has a duty to supplement information contained in the expert's Rule 26(a)(2) report and given during the expert's deposition if the party learns in some material respect the report or testimony is incomplete or incorrect. See also Solaia Tech., LLC v. ArvinMeritor, Inc., 361 F. Supp. 2d 797, 805-06 (N.D. Ill. 2005) (discussing Rule 26(e) in the context of information given in an expert's report and deposition). Such supplementations must be disclosed by the time the parties' pretrial disclosures under Rule 26(a)(3) are due. Fed. R. Civ. P. 26(e)(2). Based on the language in Rule 26(e), this Court does not find that Dr. Seeman's October report should be excluded because it is untimely. The plaintiffs had an ongoing duty to supplement Dr. Seeman's report if it learned that in some material respect the report was incomplete or inaccurate. Moreover, PLIVA was not prejudiced by the supplementation because it had an opportunity to question Dr. Seeman about his October report at his second deposition on October 28, 2010. Therefore, PLIVA's motion to exclude Dr. Seeman's October expert report is denied.

ii. Specific Causation

PLIVA asserts it is entitled to summary judgment on the issue of specific causation because the testimony of the plaintiffs' proffered expert on the subject, Dr. David Ross, should be excluded. PLIVA has filed a separate motion to exclude Dr. Ross's testimony. (Doc. # 110). "Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) (emphasis added). "A reliable differential diagnosis typically, though not invariably, is performed after physical examinations, the taking of medical histories, and the review of clinical tests, including

laboratory tests, and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely." Id. (emphasis added) (internal quotation marks and citation omitted). "A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation." Id. at 265. "However, a medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness." Id. (internal quotation marks and citation omitted). Rather "[t]he alternative causes suggested by a defendant 'affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony,' unless the expert can offer 'no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause.'" Id. (second alteration in original) (quoting Heller v. Shaw Indus., 167 F.3d 146, 156-57 (3d Cir. 1999)).

In his expert report, Dr. Ross states that Mr. Fisher has two movement disorders caused by metoclopramide—Tardive Dyskinesia and Tardive Akathisia. Ross Report, p. 15 (Doc. # 110, attach. 18). He also states that Mr. Fisher suffered from metoclopramide-induced Parkinsonism but that the condition has resolved. Id. Additionally, he acknowledges that Mr. Fisher has numerous other medical conditions. Id. at pp. 15-16. After careful consideration of the arguments presented by the parties, this Court does not find at this stage of the proceedings that because Dr. Ross is a neuropsychiatrist and not a neurologist, he is unqualified to give an expert opinion regarding whether Mr. Fisher suffers from Tardive Dyskinesia and Tardive Akathisia. PLIVA also argues that Dr. Ross did not conduct a proper differential diagnosis because he failed to eliminate other possible causes of Mr. Fisher's conditions documented by

Mr. Fisher's treating physicians. The Court does not find that Dr. Ross's opinion fails to take into account other possible causes of Mr. Fisher's medical problems to such an extent that his testimony is inadmissible. PLIVA indicates in its motion that Dr. Ross examined Mr. Fisher and reviewed at least some of his medical records, which is part of the differential diagnosis process. Further, the extent to which Dr. Ross's conclusions differ from those of Mr. Fisher's treating physicians is an issue for the jury to consider in weighing the testimony. Thus, the Court does not conclude that Dr. Ross's opinions should be excluded because they are not the result of an accepted scientific methodology. Therefore, (1) PLIVA's motion to exclude Dr. Ross's testimony (Doc. # 110) is **DENIED** at this stage of the proceedings, and (2) PLIVA is not entitled to summary judgment on the issue of specific causation.

d. Design Defect and Manufacturing Defect Claims

"In a products liability action, regardless of the theory on which the plaintiff seeks recovery, he must establish three elements: (1) he was injured by the product; (2) the injury occurred because the product was in a defective condition, unreasonably dangerous to the user; and (3) that the product at the time of the accident was in essentially the same condition as when it left the hands of the defendant." Small, 494 S.E.2d at 842; see S.C. Code Ann § 15-73-10. "There are three defects a plaintiff in a products liability lawsuit can allege: 1) a manufacturing defect, 2) a warning defect, and 3) a design defect." Watson v. Ford Motor Co., 699 S.E.2d 169, 174 (S.C. 2010). "When a manufacturing defect claim is made, a plaintiff alleges that a particular product was defectively manufactured." Id. "When a warning defect claim is made, a plaintiff alleges that he was not adequately warned of dangers inherent to a product." Id. Finally, "[w]hen a design defect claim is made, a plaintiff alleges that the product at issue was defectively designed, thus causing an entire line of products to be unreasonably dangerous." Id.

In addition to their warning defect claim, the plaintiffs assert claims based on design and manufacturing defects.

1. Design Defect Claim

The South Carolina Supreme Court has adopted the risk-utility test for a design defect claim under which a plaintiff must prove an alternative feasible design. Watson, 699 S.E.2d at 178 n.4; see also Branham v. Ford Motor Co., 701 S.E.2d 5, 16 (S.C. 2010) ("In sum, in a product liability design defect action, the plaintiff must present evidence of a reasonable alternative design."). The plaintiffs have offered no evidence of a feasible alternative design for metoclopramide. Instead, they argue they should not have to offer a feasible alternative design for metoclopramide but rather should only be required to offer an alternative design for PLIVA's label and that the FDA has already implemented one in the form of the 2009 Black Box Warning. The plaintiffs provide no authority in support of this argument. The law in South Carolina is that a plaintiff must demonstrate an alternative feasible design in a product liability action based on a design defect. The plaintiffs have not met their burden of producing such proof. Therefore, PLIVA's motion for summary judgment is **GRANTED** as to the plaintiffs' design defect claim. See also Gerber v. Hoffman-La Roche, Inc., 392 F. Supp. 2d 907, 922 (S.D. Tex. 2005) (granting summary judgment to manufacturer on plaintiff's design defect claim in products liability action involving prescription drug Accutane where plaintiff provided no evidence of a safer alternative design).

2. Manufacturing Defect Claim

A manufacturing defect claim is an allegation "that a particular product was defectively manufactured." Watson, 699 S.E.2d at 174. There is not an abundance of case law in South Carolina about how a manufacturing defect differs from other defects. Other courts have defined

a manufacturing defect as existing "when a product does not conform to the design standards and blueprints of the manufacturer and the flaw makes the product more dangerous and therefore unfit for its intended or foreseeable uses." See Gerber, 392 F. Supp. at 922 (internal quotation marks and citation omitted) (applying Texas law) (granting summary judgment to a manufacturer on a plaintiff's manufacturing defect claim in a products liability action involving prescription drug Accutane); see also Wheeler v. HO Sports, Inc., 232 F.3d 754, 757 (10th Cir. 2000) (applying Oklahoma law) ("A product is defective in manufacture if it deviates in some material way from its design or performance standards. The issue is whether the product was rendered unsafe by an error in the manufacturing process," which is "often established by showing that a product, as produced, failed to conform with the manufacturer's specifications." (internal quotation marks and citations omitted)); Wankier v. Crown Equip. Corp., 353 F.3d 862, 867 (10th Cir. 2003) (applying Utah law) (holding that "a manufacturing defect claim, by its nature, involves a deviation from the product's design specifications, to the injury or potential injury of a user" and that "[t]he gravamen of the tort is not defective design but defective execution of the design"). At this stage of the litigation, the evidence supports a finding that there is an issue of fact as to whether some error in the manufacturing process caused the 2003 or 2004 changes to the Reglan labeling to not be included on some of PLIVA's metoclopramide labels. Therefore, PLIVA is not entitled to summary judgment on the plaintiffs' manufacturing defect claim.

e. Breach of Express Warranty Claim

A seller may create an express warranty in a number of ways, including "[a]ny affirmation of fact or promise, including those on containers or labels, made by the seller to the buyer, whether directly or indirectly, which relates to the goods and becomes part of the basis of the bargain." S.C. Code Ann. § 36-2-313(1). In addition, "[a]ny description of the goods which

is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description." Id. In order to establish a breach of an express warranty, a plaintiff must show "the existence of the warranty, its breach by the failure of the goods to conform to the warranted description, and damages proximately caused by the breach." First State Sav. & Loan v. Phelps, 385 S.E.2d 821, 825 (S.C. 1989). The plaintiffs contend that PLIVA breached the following express warranty appearing on its label for metoclopramide: "Extrapyramidal symptoms, manifested primarily as acute dystonic reactions, occur in approximately 1 in 500 patients treated with the usual adult dosages of 30 to 40 mg/day of metoclopramide." See Pl.'s Resp. to PLIVA's Mot. for Summ. J., p. 22 (Doc. # 130); PLIVA's 2002 Metoclopramide Package Insert (Doc. # 130, attach. 7). Tardive Dyskinesia is considered an extrapyramidal symptom. Additionally, another section of PLIVA's label states: "Extrapyramidal Reactions (EPS): Acute dystonic reactions, the most common type of EPS associated with metoclopramide, occur in approximately 0.2% of patients (1 in 500) treated with 30 to 40 mg of metoclopramide per day." PLIVA's 2002 Metoclopramide Package Insert (Doc. # 130, attach. 7). In light of the 2009 change to metoclopramide label indicating that one published study reported a Tardive Dyskinesia prevalence of 20 percent among patients treated for at least 12 weeks, the plaintiffs assert that PLIVA's label at the time Mr. Fisher took the drug either misstated the risk of developing Tardive Dyskinesia or misled the reader with regard thereto. The defendants present three arguments as to why the plaintiffs' claims should be dismissed: (1) their claim is preempted by federal law; (2) they have not identified any express warranty PLIVA made; and (3) they cannot show their damages were proximately caused by a breach of an express warranty because neither PLIVA nor the Fishers ever saw or read PLIVA's labeling for metoclopramide. As for PLIVA's second argument, the plaintiffs have identified an affirmation of fact or promise

relating to the goods. PLIVA has not presented any argument or authority as to why the statements identified above should not be treated as an express warranty.

The next question before the Court is whether the plaintiffs' claim is preempted by federal law or, in other words, whether federal law directly conflicts with state law. See Mensing, 131 S. Ct. at 2577. "[S]tate and federal law conflict where it is 'impossible for a private party to comply with both state and federal requirements.'" Id. (quoting Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)). In Mensing, the Supreme Court held that federal law preempts "state tort-law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic metoclopramide." Id. at 2572. Further, the Court reached this conclusion assuming that federal law requires generic drug manufacturers to seek the FDA's assistance in convincing the brand-name manufacturer to change its label so that generic drug manufacturers can do so as well. Id. at 2577. In reaching its decision, the Court reasoned "it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." Id. at 2580-81.

This Court finds that the same reasoning applies to the plaintiffs' breach of express warranty claim. State law imposes an obligation on sellers not to sell goods that fail to conform with affirmations of fact or promise made by the sellers with respect to the goods sold. Assuming the express warranty identified by the plaintiffs in this case is inaccurate, PLIVA would have to alter or omit the language at issue to avoid breaching its obligation under state law. However, the plaintiffs have not identified any mechanism by which PLIVA could have independently changed the express warranty they allege was breached without first seeking the

federal government's special permission and assistance. See id. at 2575-76 (accepting the FDA's interpretation of its regulations that a generic drug manufacturers may neither make use of the "changes-being-effected" process to change their labels in a manner that is inconsistent with the brand-name label nor issue additional warnings through "Dear Doctor" letters sent to prescribing physicians). If PLIVA unilaterally changed its label to satisfy its state law obligations without a corresponding change in the brand-name label, it would violate federal law under the Mensing analysis. Without a mechanism by which PLIVA could independently change the language that allegedly created an express warranty, the plaintiffs' breach of express warranty claim is preempted. Therefore, PLIVA's motion for summary judgment is **GRANTED** as to the plaintiffs' breach of express warranty claim.

f. Breach of Implied Warranty of Merchantability

PLIVA seeks summary judgment on the plaintiffs' claim that PLIVA breached the implied warranty of merchantability. "Unless excluded or modified . . . , a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." S.C. Code Ann. § 36-2-314(1). South Carolina law sets forth several requirements that must be met for goods to be merchantable. See S.C. Code Ann. § 36-2-314(2) For purposes of the plaintiffs' claim, the only two which are relevant are that the goods, to be merchantable, "must be at least such as . . . pass without objections in the trade under the contract description" and "are fit for the ordinary purposes for which such goods are used." Id.

PLIVA argues that merchantable goods conform in all respects to applicable state and federal regulations establishing standards of quality and safety of goods and that its product satisfied this standard. PLIVA also asserts that liability for breach of an implied warranty of

merchantability cannot rest on the mere fact that a prescription drug may cause certain side effects. Along these lines, PLIVA states that it is generally understood prescription drugs may react differently in different people, and "as there can be no assumed or 'ordinary' benefit or risk by any individual prescription drug user, logic dictates that prescription drugs cannot be impliedly warranted as being fit for an 'ordinary purpose.'" Mem. in Support of PLIVA's Mot. for Summ. J., p. 28 (Doc. # 112, attach. 1). Finally, PLIVA argues that the plaintiffs cannot show their damages were proximately caused by a breach of the implied warranty of merchantability because neither they nor Dr. Pelstring saw or relied on any warnings by PLIVA.

Although the FDA has never approved metoclopramide for use longer than twelve weeks, the plaintiffs argue that, in spite of this, PLIVA's label during the time Mr. Fisher took metoclopramide contained language encouraging long-term use. Specifically, the plaintiffs reference the following language under the "Indications and Usage" section of the label: "Metoclopramide is indicated for the relief of symptoms associated with acute and recurrent diabetic gastric stasis." PLIVA's 2002 Metoclopramide Package Insert (Doc. # 130, attach. 7) (emphasis added). The plaintiffs also refer to language under the "Dosage and Administration" section:

> For the Relief of Symptoms Associated with Diabetic Gastroparesis (Diabetic Gastric Stasis): Administer 10 mg of metoclopramide 30 minutes before each meal and at bedtime for two to eight weeks, depending upon response and the likelihood of continued well-being upon drug discontinuation.
>
> Id. (emphasis added).

This section of the label also provides that "[s]ince diabetic Gastric Stasis is frequently recurrent, metoclopramide therapy should be reinstituted at the earliest manifestation" and that "[e]xperience with esophageal erosions and ulcerations is limited, but healing has thus far been documented in one controlled trial using q.i.d. therapy at 15 mg per dose, and this regimen

should be used when lesions are present, so long as it is tolerated." Id. (emphasis added). Based on this language, the plaintiffs argue that long-term use is an ordinary purpose for which metoclopramide is used even though the FDA has only approved the drug for short-term use.

After careful consideration, PLIVA's motion for summary judgment with respect to the plaintiffs' claim for breach of the implied warranty of merchantability is denied. PLIVA provides no authority in support of the argument that prescription drugs cannot be impliedly warranted as being fit for an ordinary purpose. Additionally, in light of the parties' indication that PLIVA's label omitted the 2004 warning that therapy should not exceed 12 weeks, the Court does not find as a matter of law that long-term use was not an ordinary purpose for which metoclopramide was used during the time period Mr. Fisher took the drug. Finally, the warranty of merchantability is implied in a contract for the sale of goods, "unless excluded or modified." See S.C. Code Ann. § 36-2-314(1). Thus, even if the plaintiffs or Dr. Pelstring read PLIVA's label and did not see a warranty of merchantability mentioned, the warranty would still apply unless the label excluded it. As a result, the Court does not reach the conclusion that the plaintiffs can only establish proximate cause if they or Dr. Pelstring read PLIVA's label. Again, PLIVA's motion for summary judgment on this claim is denied.

g. Breach of Implied Warranty of Fitness for a Particular Purpose

South Carolina law also provides for an implied warranty of fitness for a particular purpose under which "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified . . . an implied warranty that the goods shall be fit for such purpose." S.C. Code Ann. § 36-2-315. If "the particular purpose for which a product is purchased is also the ordinary or intended purpose

of the product, the warranties of merchantability and of fitness for a particular purpose merge and are cumulative, such that a plaintiff may proceed upon either theory." Soaper v. Hope Indus., 424 S.E.2d 493, 495 (S.C. 1992) (holding that plaintiff, who purchased film processing machine, "impliedly made known to [defendant] that his particular purpose for the machine was fast film processing" and that "[w]hen the machine failed in that purpose, it was both unmerchantable and unfit for its particular purpose").

At this time, there is an issue of fact as to whether PLIVA knew the metoclopramide it manufactured was being used for long-term treatment of gastrointestinal issues. Additionally, in light of the fact that its label may have been missing the 2004 warning that treatment should not exceed 12 weeks, this Court does not reach the conclusion that long-term treatment of gastrointestinal issues should not be considered a particular purpose for which metoclopramide is purchased. Finally, there is an issue of fact at this stage of the litigation as to whether PLIVA's metoclopramide was fit for the particular purpose for which Mr. Fisher used it.

h. Misrepresentation and Fraud Claims

PLIVA seeks summary judgment as to the plaintiffs' eighth cause of action for negligent misrepresentation. The elements of a cause of action for the common law tort of negligent misrepresentation under South Carolina law are: "(1) the defendant made a false representation to the plaintiff; (2) the defendant had a pecuniary interest in making the statement; (3) the defendant owed a duty of care to see that he communicated truthful information to the plaintiff; (4) the defendant breached that duty by failing to exercise due care; (5) the plaintiff justifiably relied on the representation; and (6) the plaintiff suffered a pecuniary loss as the proximate result of his reliance on the representation." Quail Hill, LLC v. Cnty. of Richland, SC, 692 S.E.2d 499, 508 (S.C. 2010) (citation omitted).

PLIVA also seeks summary judgment as to the plaintiffs' tenth cause of action for fraud and misrepresentation, their eleventh cause of action for constructive fraud, and their twelfth cause of action for fraud by concealment. Under South Carolina law, the elements of a cause of action for "fraud and deceit, based upon misrepresentation" include "(1) a representation; (2) its falsity; (3) its materiality; (4) either knowledge of its falsity or a reckless disregard of its truth or falsity; (5) intent that the representation be acted upon; (6) the hearer's ignorance of its falsity; (7) the hearer's reliance on its truth; (8) the hearer's right to rely thereon; (9) the hearer's consequent and proximate injury." M.B. Kahn Constr. Co. v. S.C. Nat'l Bank of Charleston, 271 S.E.2d 414, 415 (S.C. 1980). "Failure to prove any one of the foregoing elements is fatal to recovery." Id. (citation omitted). "The key difference between fraud and negligent misrepresentation is that 'fraud requires the conveyance of a known falsity, while negligent misrepresentation is predicated upon transmission of a negligently made false statement.'" Armstrong v. Collins, 621 S.E.2d 368, 375-76 (S.C. Ct. App. 2005) (quoting Brown v. Stewart, 557 S.E.2d 676, 681 (S.C. Ct. App. 2001)). "To establish constructive fraud all elements of actual fraud except the element of intent must be established."[15] O'Quinn v. Beach Assoc., 249 S.E.2d 734, 738 (S.C. 1978).

PLIVA argues it is entitled to summary judgment on the plaintiffs' negligent misrepresentation, fraud, and constructive fraud claims because the plaintiffs have not identified any false representation PLIVA made in its label during the time Mr. Fisher took metoclopramide. It is not entirely clear from the plaintiffs' response to PLIVA's summary judgment motion what representation they assert is false, but there is some indication it is the

[15] The plaintiffs agree that PLIVA accurately outlines in its motion for summary judgment the elements of causes of action for negligent misrepresentation, fraud, constructive fraud, and fraud by concealment. Pl.'s Resp. to PLIVA's Mot. for Summ. J., p. 25 (Doc. # 130).

statements on PLIVA's label which allegedly understate the risk of developing Tardive Dyskinesia while taking metoclopramide. Pl.'s Resp. to PLIVA's Mot. for Summ. J., p. 26 (Doc. # 130). Thus, the Court concludes the statements on the label regarding the risk of developing extrapyramidal symptoms which the plaintiffs argue create an express warranty are also the allegedly false representations that serve as the basis for its negligent misrepresentation, fraud, and constructive fraud claims. Assuming these statements are indeed false, state law would impose a duty upon PLIVA to omit or alter them. However, similar to the plaintiffs' breach of express warranty claim, the plaintiffs have not identified any mechanism by which PLIVA could have independently changed or omitted the allegedly false representations on its label without first seeking the federal government's special permission and assistance. See Mensing at 2575-76, 2580-81. If PLIVA attempted to do so without the federal government's permission and assistance, it would violate federal law. Id. at 2580-81. Without such a mechanism, the plaintiffs' negligent misrepresentation and fraud claims are preempted. Therefore, PLIVA's motion for summary judgment as to the plaintiffs' causes of action for negligent misrepresentation, fraud, and constructive fraud is **GRANTED**.[16]

With respect to the plaintiffs' fraud by concealment claim, an action for fraud based on concealment of truth lies when there is a duty to speak, which generally exists when there is a

[16] "[I]n a constructive fraud case, where there is no confidential or fiduciary relationship, and an arm's length transaction between mature, educated people is involved, there is no right to rely." Ardis v. Cox, 431 S.E.2d 267, 270 (S.C. Ct. App. 1993) (citing Poco-Grande Inv. v. C&S Family Credit, Inc., 391 S.E.2d 735, 735 (S.C. Ct. App. 1990)). The plaintiffs agree in their response to PLIVA's motion for summary judgment that constructive fraud is reserved for cases where a fiduciary relationship exists between the parties. Pl.'s Resp. to PLIVA's Mot. for Summ. J., p. 25 (Doc. # 130). However, the plaintiffs have not argued a basis for concluding there was a fiduciary relationship between the plaintiffs and PLIVA. Therefore, summary judgment is also appropriate with respect to the plaintiffs' constructive fraud claim because the plaintiffs have not argued or presented evidence that a fiduciary relationship existed here.

fiduciary relationship between the parties.[17] Regions Bank v. Schmauch, 582 S.E.2d 432, 445 (S.C. Ct. App. 2003) (citing Manning v. Dial, 245 S.E.2d 120, 122 (S.C. 1978)). However, a fiduciary relationship is not always required for a duty to disclose to exist. See, e.g., Lawson v. Citizens & S. Nat'l Bank of S.C., 193 S.E.2d 124, 127-28 (S.C. 1972) (holding a duty to disclose arises in the context of a sale of real property). In light of the relationship between drug manufacturers and purchasers of their products and the statutory obligations placed on manufacturers with respect to their labeling, this Court does not conclude at this stage of the proceedings that PLIVA did not have a duty to disclose to purchasers of its products the 2003 and 2004 changes to the labeling for Reglan. Therefore, PLIVA's motion for summary judgment with respect to the plaintiffs' cause of action for fraud by concealment is denied.

i. Breach of Undertaking a Special Duty

PLIVA seeks summary judgment on the plaintiffs' cause of action for breach of undertaking a special duty. The plaintiffs argue their claim is "viable because PLIVA had an active duty under FDA regulations to communicate adequate safety information regarding its

[17] See Regions Bank v. Schmauch, 582 S.E.2d 432, 445-46 (S.C. Ct. App. 2003) ("'The duty to disclose may be reduced to three distinct classes: (1) where it arises from a preexisting definite fiduciary relation between the parties; (2) where one party expressly reposes a trust and confidence in the other with reference to the particular transaction in question, or else from the circumstances of the case, the nature of their dealings, or their position towards each other, such a trust and confidence in the particular case is necessarily implied; (3) where the very contract or transaction itself, in its essential nature, is intrinsically fiduciary and necessarily calls for perfect good faith and full disclosure without regard to any particular intention of the parties.'" (quoting Jacobson v. Yaschik, 155 S.E.2d 601, 605 (S.C. 1967)).

"A confidential or fiduciary relationship exists when one imposes a special confidence in another, so that the latter, in equity and good conscience, is bound to act in good faith and with due regard to the interests of the one imposing the confidence." Hendricks v. Clemson Univ., 578 S.E.2d 711, 715 (S.C. 2003) (internal quotation marks and citation omitted). "A relationship must be more than casual to equal a fiduciary relationship." Armstrong, 621 S.E.2d at 376 (citation omitted). Historically, the South Carolina Supreme Court "has reserved imposition of fiduciary duties to legal or business settings, often in which one person entrusts money to another, such as with lawyers, brokers, corporate directors, and corporate promoters." Hendricks, 578 S.E.2d at 716.

metoclopramide to prescribing physicians, and under the doctrine of negligence per se, failure to fulfill these duties results in a cause of action under South Carolina law." Pl.'s Resp. to PLIVA's Mot. for Summ. J., p. 27 (Doc. # 130). As explained by the South Carolina Supreme Court, the concept of a special duty arises in the context of the public duty rule:

> Many statutes impose a duty on public officials to perform certain acts. Generally, however, such officials enjoy an immunity from a private cause of action under the public duty rule. This rule holds that public officials are generally not liable to individuals for their negligence in discharging public duties as the duty is owed to the public at large rather than anyone individually.
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> Jensen v. Anderson Cnty. Dep't of Soc. Serv., 403 S.E.2d 615, 617 (S.C. 1991).

"The public duty rule is [thus] a negative defense which denies an essential element of the plaintiff's cause of action: the existence of a duty of care to the individual plaintiff." Arthurs ex rel. Estate of Munn v. Aiken Cnty., 551 S.E.2d 579, 582 (S.C. 2001). An exception to the public duty rule "exists when a duty is owed to individuals rather than the public only." Jensen, 403 S.E.2d at 617. South Carolina courts have developed a six element test for determining "when such a 'special duty' exists." Id. (emphasis added). Therefore, the concept of a special duty is an exception to the public duty rule. See id; Arthurs, 551 S.E.2d at 583; Tanner v. Florence Cnty. Treasurer, 521 S.E.2d 153, 158 (S.C. 1999); Bellamy v. Brown, 408 S.E.2d 219, 220-21 (S.C. 1991).

PLIVA is entitled to summary judgment on the plaintiffs' cause of action for breach of undertaking a special duty because South Carolina, as discussed in the preceding paragraph, has not recognized a separate cause of action for breach of undertaking special duty but rather describes the concept of a special duty as an exception to the public duty rule. Therefore, PLIVA's motion for summary judgment is **GRANTED** as to the plaintiffs' claim for breach of undertaking a special duty. However, this ruling is limited to the issue of whether breach of

undertaking a special duty is a separate cause of action maintainable under South Carolina law under the facts of this case. For purposes of the plaintiffs' other causes of action, this ruling does not impact the plaintiffs' ability to argue, under the doctrine of negligence per se, that certain statutes and regulations establish the duty of care owed by PLIVA to the plaintiffs and that PLIVA breached that duty by violating said statutes and regulations. See Whitlaw v. Kroger Co., 410 S.E.2d 251, 252-53 (S.C. 1991) (per curiam); Norton v. Opening Break of Aiken, Inc., 443 S.E.2d 406, 408-09 (S.C. Ct. App. 1994); Seals ex rel. Causey v. Winburn, 445 S.E.2d 94, 96 (S.C. Ct. App. 1994); Rayfield v. S.C. Dep't of Corr., 374 S.E.2d 910, 914-15 (S.C. Ct. App. 1988); Coleman v. Shaw, 314 S.E.2d 154, 156 (S.C. Ct. App. 1984).

j. Claim for Violation of the South Carolina Unfair Trade Practices Act

PLIVA seeks summary judgment on the plaintiffs' cause of action for violation of the South Carolina Unfair Trade Practices Act ("UTPA"). The UTPA makes it unlawful to engage in "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." S.C. Code Ann. § 39-5-20(a). "In order to bring an action under the UTPA, the plaintiff must demonstrate (1) that the defendant engaged in an unlawful trade practice, (2) that the plaintiff suffered actual, ascertainable damages as a result of the defendant's use of the unlawful trade practice, and (3) that the unlawful trade practice engaged in by the defendant had an adverse impact on the public interest." Havird Oil Co. v. Marathon Oil Co., 149 F.3d 283, 291 (4th Cir. 1998) (applying South Carolina law). "An act is 'unfair' when it is offensive to public policy or when it is immoral, unethical, or oppressive. An act is 'deceptive' when it has a tendency to deceive." Gentry v. Yonce, 522 S.E.2d 137, 143 (S.C. 1999).

The UTPA does not apply to "[a]ctions or transactions permitted under laws administered by any regulatory body . . . of this State or the United States or actions or transactions permitted

by any other South Carolina State law." S.C. Code Ann. § 39-5-40(a). The South Carolina Supreme Court has "interpreted this exemption to exclude from the UTPA those actions or transactions which are allowed or authorized by a regulatory agency or other statutes." Taylor v. Medenica, 479 S.E.2d 35, 44 (S.C. 1996) (citing Ward v. Dick Dyer & Assoc., Inc., 403 S.E.2d 310 (S.C. 1991)). PLIVA argues that its labeling is subject to the exclusion to the UTPA outlined in § 39-5-40(a) applying the same reasoning it asserts in its motion to dismiss based on federal preemption. However, PLIVA's motion for summary judgment on this issue is denied for the same reason its motion to dismiss is denied. More specifically, PLIVA has not indicated that any federal law or regulation prevented it from adding the 2003 and 2004 warnings to its generic metoclopramide labeling once the changes were approved for the brand-name Reglan label.

In its reply in support of its motion for summary judgment, PLIVA also argues that the pharmaceutical industry is heavily regulated by the FDA, and as such, it is not subject to the UTPA. The UTPA defines "trade" and "commerce" as including "the advertising, offering for sale, sale or distribution of any services and any property . . . ." S.C. Code Ann. § 39-5-10(b). PLIVA has not presented any authority demonstrating that the pharmaceutical industry is not covered by the UTPA, and applying the definitions in the UTPA for trade and commerce, this Court does not conclude a clear basis exists for finding that the pharmaceutical industry is exempt from the UTPA. The one case PLIVA cites in support is a case where the South Carolina Supreme Court held that medical laboratory services constitute a trade under the UTPA. See Taylor, 479 S.E.2d at 44. Therefore, PLIVA is not entitled to summary judgment with respect to the plaintiffs' UTPA claim.

k. Intentional Infliction of Emotional Distress Claim

PLIVA asserts it is entitled to summary judgment on the plaintiffs' cause of action for intentional infliction of emotional distress ("IIED"). "In order to recover for intentional infliction of emotional distress, a plaintiff must establish . . . (1) the defendant intentionally or recklessly inflicted severe emotional distress, or was certain, or substantially certain, that such distress would result from his conduct; (2) the conduct was so 'extreme and outrageous' so as to exceed 'all possible bounds of decency' and must be regarded as 'atrocious, and utterly intolerable in a civilized community;' (3) the actions of the defendant caused plaintiff's emotional distress; and (4) the emotional distress suffered by the plaintiff was 'severe' such that 'no reasonable man could be expected to endure it.'" Argoe v. Three Rivers Behavioral Health, L.L.C., 710 S.E.2d 67, 74 (S.C. 2011) (citing Hansson v. Scalise Builders of S.C., 650 S.E.2d 68, 70 (S.C. 2007)). "Initially, it is for the trial court to determine whether the defendant's conduct may be considered so extreme and outrageous as to permit recovery, and only where reasonable minds might differ should the issue be submitted to the jury." Williams v. Lancaster Cnty. Sch. Dist., 631 S.E.2d 286, 293 (S.C. Ct. App. 2006) (citing Hainer v. Am. Med. Int'l, Inc., 465 S.E.2d 112, 117 (S.C. Ct. App. 1995)). "[P]hysical illness or some other non-mental damage" is not essential for recovery under an IIED claim. Ford v. Hutson, 276 S.E.2d 776, 780 (S.C. 1981). But "where physical harm is lacking, . . . courts should look initially for more in the way of extreme outrage as an assurance that the mental disturbance claimed is not fictitious." Id.

PLIVA seeks summary judgment on the plaintiffs' IIED claim because the plaintiffs have presented no evidence showing that PLIVA acted with the intention to cause Mr. Fisher emotional distress, because PLIVA's alleged conduct does not rise to the level of extreme and outrageous, and because the plaintiffs have not presented any evidence that Mr. Fisher suffers

from severe emotional distress due to PLIVA's actions. After careful consideration, this Court does not find that PLIVA is entitled to summary judgment. More specifically, the Court does not conclude that PLIVA's conduct in failing to include the 2004 warning on some or all of its labels could not, as a matter of law, be considered reckless conduct. Additionally, the Court finds at this stage of the litigation that reasonable minds can differ such that a factual issue exists over whether PLIVA's conduct can be considered so extreme and outrageous as to permit recovery. Finally, the plaintiffs have presented evidence that Mr. Fisher suffered an injury as a result of taking metoclopramide—Tardive Dyskinesia and its accompanying impact on his life. As a result, PLIVA's motion for summary judgment with respect to the plaintiffs' intentional infliction of emotional distress claim is denied.

l. Loss of Consortium Claim

PLIVA argues it is entitled to summary judgment on Ms. Fisher's loss of consortium claim because all of Mr. Fisher's causes of action fail. See Lee v. Bunch, 647 S.E.2d 197, 202 (S.C. 2007). Because the Court is not granting summary judgment with respect to all of Mr. Fisher's claims, PLIVA is not entitled to summary judgment on Ms. Fisher's loss of consortium claim.

m. Punitive Damages

PLIVA argues that the plaintiffs' claim for punitive damages should be stricken. "In order for a plaintiff to recover punitive damages, there must be evidence the defendant's conduct was wilful, wanton, or in reckless disregard of the plaintiff's rights." McCourt ex rel. McCourt v. Abernathy, 457 S.E.2d 603, 607 (S.C. 1995). The Court finds that sufficient evidence has been presented in the record to conclude that PLIVA is not entitled to summary judgment on the punitive damages issue.

III. The Plaintiffs' Motion for Partial Summary Judgment

The plaintiffs seek summary judgment establishing that, as a matter of law:

1. PLIVA was charged by the federal regulations with a duty to perform surveillance of the scientific literature for safety hazards associated with the drugs it manufactured;
2. PLIVA was required to ensure the accuracy and adequacy of the labels accompanying the drugs it manufactured; and
3. PLIVA breached this duty by failing to perform surveillance of the scientific literature and by failing to evaluate its product labeling for adequacy and accuracy.

In Mensing, the Supreme Court held that "state tort-law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic metoclopramide" are preempted by federal drug regulations. Mensing, 131 S. Ct. at 2572. The Court accepted the FDA's interpretation that generic drug manufacturers cannot use the "changes being effected" process to unilaterally strengthen their warning labels in a manner inconsistent with the brand-name label or issue additional warnings through "Dear Doctor" letters. Id. at 2575-76. Even assuming generic drug manufacturers have a duty to seek the FDA's help in strengthening their warning labels if they believe stronger warnings are needed, the Court concluded preemption exists because requesting FDA assistance would satisfy their federal duties but not their state tort-law duties to provide adequate labeling. Id. at 2576-78. The Court reasoned preemption applied because generic drug manufacturers could not independently do under federal law what state law required of them. Id. at 2579.

Assuming a generic drug manufacturer has a duty to monitor scientific literature and discovers the labeling on its product understates the risk of a certain side effect, unless it has the ability to legally change its labeling or inform a prescribing physician about the issue, the fact

that it performed this duty will not prevent the patient from being harmed by its drug. In light of the decision in Mensing, the plaintiffs have not demonstrated a method consistent with federal law in which PLIVA can, without the FDA's assistance, change its labeling or notify treating physicians that its labeling, which is the same as the brand-name label, understates the risk of a certain side effect. See Mensing, 131 S. Ct. at 2580-81. Therefore, the Court does not reach a conclusion that a generic drug manufacturer's failure to monitor scientific literature, by itself, can serve as a basis for liability.

As for the plaintiffs' argument that PLIVA has a duty to ensure the adequacy and accuracy of its label, the parties recently indicated to the Court that at least some of PLIVA's generic metoclopramide labels did not include certain warnings added to the labeling for Reglan in 2003 and 2004. The plaintiffs seek a finding of negligence per se based on a breach by PLIVA of duties arising from certain federal and/or state statutes. However, the Court does not reach such a conclusion at this stage of the proceedings. The parties have cited no case law where a Court reached a finding of negligence per se because a generic drug manufacturer did not include a warning added to the brand-name label. Additionally, the evidence of record indicates that the warnings in question were not included on some of PLIVA's metoclopramide package inserts. The extent to which PLIVA's package inserts were missing these warnings has not been made clear at this time. Therefore, the plaintiffs' motion for partial summary judgment seeking a finding as a matter of law of the applicable duty of care and a breach of that duty (Doc. # 160) is **DENIED**.

IV. Motion for Entry of Final Judgment by Defendants Wyeth and Schwarz

This Court previously granted summary judgment to defendants Wyeth and Schwarz and dismissed them from this action. (Doc. # 89). Wyeth and Schwarz seek the entry of final

judgment under Federal Rule of Civil Procedure 54(b). Rule 54(b) provides that "[w]hen an action presents more than one claim for relief—whether as a claim, counterclaim, crossclaim, or third-party claim—or when multiple parties are involved, the court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines that there is no just reason for delay." Thus, determining whether to enter judgment under Rule 54(b) involves a two-step process. Curtiss-Wright Corp. v. General Electric Co., 446 U.S. 1, 7-8 (1980). First, a district court must determine that "it is dealing with a 'final judgment,'" which means "[i]t must be a 'judgment' in the sense that it is a decision upon a cognizable claim for relief, and it must be 'final' in the sense that it is 'an ultimate disposition of an individual claim entered in the course of a multiple claims action.'" Id. at 7 (quoting Sears, Roebuck & Co. v. Mackey, 351 U.S. 427, 436 (1956)). Second, "[o]nce having found finality, the district court must go on to determine whether there is any just reason for delay." Id. at 8. To make this assessment, "a district court must take into account judicial administrative interests as well as the equities involved." Id. Appropriate considerations include "whether the claims under review [are] separable from the others remaining to be adjudicated and whether the nature of the claims already determined [is] such that no appellate court would have to decide the same issues more than once even if there were subsequent appeals." Id.

As explained by the Fourth Circuit, "[t]he chief purpose of a Rule 54(b) certification is to prevent piecemeal appeals when multiple claims are resolved in the course of a single lawsuit. The Rule also allows the district court to provide relief to litigants that would suffer undue hardship if final judgment is not entered on the adjudicated claim prior to the resolution of the unadjudicated claims." Braswell Shipyards v. Beazer East, Inc., 2 F.3d 1331, 1335 (4th Cir. 1993). "Rule 54(b) certification is recognized as the exception rather than the norm. It should

neither be granted routinely nor as an accommodation to counsel." Id. (citations omitted). "The burden is on the party endeavoring to obtain Rule 54(b) certification to demonstrate that the case warrants certification." Id. (citation omitted). The Fourth Circuit has outlined five factors a district court should consider in evaluating where there is no just reason for delay:

> (1) the relationship between the adjudicated and unadjudicated claims; (2) the possibility that the need for review might or might not be mooted by future developments in the district court; (3) the possibility that the reviewing court might be obliged to consider the same issue a second time; (4) the presence or absence of a claim or counterclaim which could result in a set-off against the judgment sought to be made final; (5) miscellaneous factors such as delay, economic and solvency considerations, shortening the time of trial, frivolity of competing claims, expense, and the like.
>
> Id. at 1335-36 (citation omitted)

Having considered the arguments of both parties, this Court finds that the second and fifth factors set forth by the Fourth Circuit, at a minimum, weigh in favor of denying the instant motion. While the Court understands that Wyeth and Schwarz wish to bring a conclusive end to the litigation against them, granting the motion would force the plaintiffs to pursue a preemptory appeal or abandon their right to appeal the dismissal of their claims against Wyeth and Schwarz. Furthermore, the litigation between the plaintiffs and the remaining defendants is proceeding to the trial stage in light of this Order. Requiring the plaintiffs to pursue an appeal at the same time they are preparing their remaining claims for trial may negatively impact case management. See Meade v. Parsley, No. 2:09-cv-00388, 2010 WL 3432821, at *1 (S.D.W. Va. Aug. 31, 2010). In addition, depending on the outcome of the current litigation, the plaintiffs may decide to no longer pursue an appeal. See id. Therefore, the motion for entry of final judgment pursuant to Rule 54(b) filed by defendants Wyeth and Schwarz (Doc. # 102) is **DENIED**.

CONCLUSION

For the reasons set forth herein, PLIVA's motion to dismiss based on federal preemption (Doc. # 104) is **DENIED**, and its motion for summary judgment (Doc. # 112) is **GRANTED** in part and **DENIED** in part. It is **GRANTED** with respect to the plaintiffs' (1) fourth cause of action for strict liability based on design defect, (2) fifth cause of action for breach of express warranty, (3) eighth cause of action for negligent misrepresentation, (4) ninth cause of action for breach of undertaking special duty, (5) tenth cause of action for fraud and misrepresentation, and (6) eleventh cause of action for constructive fraud. The remainder of PLIVA's motion for summary judgment is **DENIED**. PLIVA's motions to exclude expert testimony of Philip Seeman (Doc. # 108) and David Ross (Doc. # 110) are also **DENIED** but may be reconsidered upon request when this case is scheduled for trial. Additionally, the plaintiffs' motion for partial summary judgment (Doc. # 160) is **DENIED**. Finally, the motion for entry of judgment under Rule 54(b) filed by defendants Schwarz and Wyeth (Doc. # 102) is **DENIED**.[18]

The plaintiffs' request to amend the allegations in their complaint regarding the date of Mr. Fisher's diagnosis of Tardive Dyskinesia is **GRANTED**. The plaintiffs shall have twenty (20) days from the filing date of this Order to file an amended complaint.

[18] The parties have not indicated that the other motions to exclude testimony pending in this case impact the Court's ruling on PLIVA's motion for summary or the plaintiffs' motion for partial summary judgment. Therefore, the motions to exclude expert testimony of the following individuals are **DENIED** but may be reconsidered upon request when this case is scheduled for trial: Suzanne Parisian (Doc. # 106), Mark Pelstring (Doc. # 103), Raymond D. Harbison (Doc. # 157), Steven Lamm (Doc. # 158), and James Morrison (Doc. # 159). In addition, the motions for hearings on the various motions before the Court (Docs. 105, 107, 109, 111, 113, 126) are **DENIED**.

IT IS SO ORDERED.

s/Terry L. Wooten
TERRY L. WOOTEN
United States District Judge

September 30, 2011

Florence, South Carolina