UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NORTH CAROLINA CHARLOTTE DIVISION 3:09-cv-210-RJC-DSC

MARY CLEO COUICK,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**ORDER**
	)	
WYETH, INC., et al.,	)	
	)	
Defendants.	)	
	)	

THIS MATTER comes before the Court on Defendants Actavis, Inc., Actavis Elizabeth, LLC, (collectively "Actavis"), and PLIVA, Inc.'s ("PLIVA," collectively with Actavis "Defendants") Joint Motion to Dismiss, (Doc. No. 77), and the Magistrate Judge's Memorandum and Recommendation, recommending that the Court grant Defendants' motion, (Doc. No. 81). Plaintiff filed a timely objection. (Doc. No. 83).

I. STANDARD OF REVIEW

The district court may assign dispositive pretrial matters pending before the court to a magistrate judge for "proposed findings of fact and recommendations." 28 U.S.C. § 636(b)(1)(B). The Federal Magistrate Act provides that "a district court shall make a de novo determination of those portions of the report or specific proposed findings or recommendations to which objection is made." Id. at § 636(b)(1); Camby v. Davis, 718 F.2d 198, 200 (4th Cir. 1983). However, "when objections to strictly legal issues are raised and no factual issues are challenged, de novo review of the record may be dispensed with." Orpiano v. Johnson, 687 F.2d 44, 47 (4th Cir.1982). Similarly, de novo review is not required by the statute "when a party makes general or conclusory objections that do not direct the court to a specific error in the

magistrate judge's proposed findings and recommendations." Id.

In its review of a Rule 12(b)(6) motion, "the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff." Mylan Labs, Inc. v. Matakari, 7 F.3d 1130, 1134 (4th Cir. 1993). The plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." Id. at 563. A complaint attacked by a Rule 12(b)(6) motion to dismiss will survive if it contains "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (quoting Twombly, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id.

II. BACKGROUND

Plaintiff brought this action for damages she incurred after taking metoclopramide, a drug designed to speed the movement of food through the digestive system. (Doc. No. 1). Metoclopramide is the generic form of Reglan. Defendants are the generic manufacturers of metoclopramide. Plaintiff's case is largely based on Defendants' allegedly inadequate warnings contained in their products' package inserts ("PI"). (Id.).

The Court dismissed Plaintiff's claims against Reglan brand manufacturers Wyeth, Inc. and Schwarz Pharma, Inc. ("Former Defendants") on March 8, 2010. (Doc. Nos. 60; 64). The Court stayed Plaintiff's case against the remaining three defendants pending the Supreme Court's decision in PLIVA, Inc. v. Mensing, No. 09-993, 131 S. Ct. 817 (U.S. cert. granted Dec. 10, 2010). (Doc. No. 76). The SupremeCourt issued its opinion in that case on June 23, 2011.

See PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011). The Supreme Court held that the plaintiff's state law tort claims for inadequate warnings in these same defendants' same drug's PIs were precluded by federal labeling requirements. Id. at 2581. Here, Defendants filed a motion to dismiss all of Plaintiff's claims, arguing that they were likewise preempted.

The Magistrate Judge recommended dismissing Plaintiff's claims on August 12, 2011 based on the Supreme Court's ruling. (Doc. No. 81). Plaintiff objected to this recommendation, (Doc. No. 83), requiring this Court to review Defendants' motion de novo. 28 U.S.C. § 636(b)(1).

III. ANALYSIS

Plaintiff's eleven counts of relief largely relate to Defendants' allegedly inadequate warnings in their PIs. (Doc. No. 1 at 17-29). In its March 8, 2010 Order dismissing Plaintiff's claims against Former Defendants, this Court found that Plaintiff's eleven counts all fell within North Carolina's definition of a product liability action. (Doc. No. 60 at 3) (finding that a "'product liability action' includes any action brought for or on account of personal injury . . . caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling of any product"). North Carolina General Statutes § 99B-5 provides that a manufacturer may not be held liable "in any product liability action for a claim based upon inadequate warning or instruction" unless the elements of that statute are met. Thus, the Court "narrowed [Plaintiff's claims] to a claim for product liability" under section 99B-5. (Doc. No. 60 at 3). North Carolina General Statutes § 99B-1.2, however, provides that "[n]othing in this act shall preclude a product liability action that otherwise exists against a manufacturer or seller for breach of warranty." Plaintiff's counts 10 and 11 allege

breaches of express and implied warranties. (Doc. No. 1 at 27-29). These claims remain separate from Plaintiff's combined products liability count. Plaintiff also alleged that Defendants were negligent and breached a special duty by failing to abide by Food and Drug Administration ("FDA") requirements. (Id. at 18-19). These claims also remain separate from Plaintiff's products liability claim and are discussed below.

A. Product Liability Based on Inadequate Warnings

Defendants contend that all of Plaintiff's claims are preempted because of a direct conflict with federal law. (Doc. No. 78 at 2-3). The Court will find state law preempted "where it is impossible for a private party to comply with both state and federal law." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000). "Because pre-emption is an affirmative defense, a defendant seeking to set aside state law bears the burden to prove impossibility." Mensing, 131 S. Ct. at 2587.

Under North Carolina products liability law:

> No manufacturer or seller of a product shall be held liable in any product liability action for a claim based upon inadequate warning or instruction unless the claimant proves that the manufacturer or seller acted unreasonably in failing to provide such warning or instruction, that the failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought, and . . . [a]t the time the product left the control of the manufacturer or seller, the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer or seller knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant.

N.C. GEN. STAT. § 99B-5. In Mensing, the Supreme Court held that similar provisions of Minnesota and Louisiana product liability law "require a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe." 131 S. Ct. at 2573.

"Federal law imposes far more complex drug labeling requirements." Id. at 2574. Under the Hatch-Waxman Amendments:

> 'generic drugs' can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA. This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug. 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. As a result, brand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's.

Id. (internal citations and quotations omitted). A generic drug manufacturer may not change its warnings, labels, or package insert or send additional warnings to doctors unless the brand manufacturer does so first. Id. at 2575-76. The Court found that the brand and generic package inserts were the same for the years that Plaintiff took metoclopramide. Id. at 2572-73 (finding no PI changes between 1985 and 2004 and that Plaintiff took metoclopramide from 2001 to 2002).

The Supreme Court found that it was impossible for the generic manufacturers to abide by both federal and state law. Id. at 2577.

> If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking [the plaintiffs'] allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels.

Id. at 2578.

Defendants contend that Mensing requires dismissal here because the Supreme Court dismissed the same claims, for injuries stemming from the same drug, against these same

defendants, as preempted by federal law. (Doc. No. 78 at 2-3). But neither PLIVA nor Actavis have provided any proof to this Court that their package inserts matched Reglan's throughout the period that Plaintiff alleges she took metoclopramide. Without that evidence, this Court cannot conclude that every warning Plaintiff pled that Defendants should have included in their PI was impossible for Defendants to add. They have failed their burden to prove impossibility.

Contrary to Defendants' contention, this issue is no red herring. (Doc. No. 80 at 11). Plaintiff alleges that she took the drug from July 2002 through April 2007. (Doc. No. 1 at 4). The Supreme Court pointed out that "[i]n 2004, the brand-name Reglan manufacturer requested, and the FDA approved, a label change to add that 'therapy should not exceed 12 weeks in duration.'" Mensing, 131 S. Ct. at 2572. This passage formerly stated that "therapy longer than 12 weeks has not been evaluated and cannot be recommended." Id. It appears that PLIVA failed to update its labeling to include this change. (Doc. Nos. 79 at 19; 83 at 19-21); see also Fisher v. Pelstring, No. 4:09-cv-252, 2011 WL 4552464, at *3 n.1 (D.S.C. Sept. 30, 2011).

In Fisher, the plaintiff also alleged damages from PLIVA's inadequate warnings in its metoclopramide package inserts. 2011 WL 4552464. The plaintiff provided the court documents showing that the 2004 revisions to Reglan's label were not included in certain post-2004 metoclopramide package inserts. Id. at *3 n.1. The court held that "this possible deviation impacts the Court's analysis of [PLIVA's] 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."[1]

[1] This Court does not reach the issue of whether federal law would allow generic manufacturers to change their PIs as soon as the brand manufacturer does or whether they would instead have to wait for an FDA directive or announcement by the brand manufacturer.

Id. at *3. The court then denied PLIVA's motion. Id.

Defendant argues that this issue should not derail its motion to dismiss because: (1) Plaintiff did not allege damages resulting from Defendants' failure "to update their label to match that of the [brand-name drug]," (Doc. Nos. 80 at 11-12; 86 at 22-23), (2) Plaintiff was not prescribed PLIVA's metoclopramide after June 2003, (Doc. No. 86 at 22 n.10), and (3) any failure by Defendants to abide by their federal duty to match the brand's PI cannot be enforced through state tort law, (Id. at 22-23).

First, Plaintiff couched her inadequate warning or instruction claim in many ways. Some of them approach a claim that she was damaged by PLIVA's failure to include the brand's clear warning that "therapy should not exceed 12 weeks in duration." Plaintiff alleged that Defendants: (1) improperly represented that metoclopramide "was safe for use to treat nausea and or esopageal reflux for durations that exceeded twelve weeks," (Id. at 6); (2) "failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short term use and long term use," (Id. at 15); (3) "failed to disclose material safety information regarding the serious and permanent side effects caused by taking Reglan/metoclopramide for long periods of time," (Id.); and (4) "concealed the fact that the treatment of [gastric disorders] with Reglan/metoclopramide products for longer than 12 weeks is unlikely to be reasonably safe," (Id. at 16). The Court makes no ruling as to the sufficiency of these allegations because the Court cannot know whether it must reach this issue until Defendants provide copies of the brand and generic PIs. Without any showing that Defendants' PIs mirrored Reglan's in all other respects, the Court also cannot determine whether Plaintiff sufficiently pled that she was injured by the lack of other warnings that Defendants could have included.

Second, the Court cannot evaluate Defendants' claim that Plaintiff was not prescribed PLIVA's metoclopramide after June 2003 on a motion to dismiss. Plaintiff pled that she did. (Doc. No. 1 at 4). "Generally, courts do not consider extrinsic evidence in a motion to dismiss pursuant to Rule 12(b)(6) because the inquiry is limited to the complaint and the documents attached thereto or incorporated by reference." Void v. OneWest Bank, No. 11-0838, 2011 WL 3240478, at *4 (D. Md. July 27, 2011).

Third, Defendants misconstrue the issue caused by their possible failure to match the brand's PI. The Court agrees that private enforcement of FDA requirements is foreclosed by 21 U.S.C. § 337(a) ("proceedings for the enforcement, or to restrain violations, of [the Federal Food, Drug, and Cosmetic Act] shall be by and in the name of the United States."); see also Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions"). But if Defendants' PIs did not match the brand, there are at least some changes to their PIs that federal law would allow, or even require, Defendants to make. A state law claim for failure to include such warnings would not be preempted by federal law where the FDA would have permitted, or even required, such changes.

The Court cannot find that it was impossible for Defendants to abide by both federal and state law without any proof as to what, if any, additional warnings federal law would have allowed Defendants to include. Defendants' motion to dismiss is **DENIED**.

B. Warranty Claims

1. Express Warranty

The Mensing Court held that state tort claims were preempted where federal law

prohibited generic manufacturers from changing their PI in any way. 131 S. Ct. at 2577. In Fisher, the District of South Carolina court held that "the same reasoning applies to the plaintiffs' breach of express warranty claim." 2011 WL 4552464, at *17. The court explained:

> 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. 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.

Id. (internal citations omitted).

Plaintiff argues that the Supreme Court's decision in Cipollone v. Liggett Group, Inc., 505 U.S. 504, 525-26 (1992) precludes this Court from finding that a state warranty action can be preempted by federal law. (Doc. No. 79 at 7-8). The Supreme Court found that:

> A manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the "requirements" imposed by an express warranty claim are not "imposed under State law," but rather imposed *by the warrantor*. . . . a common-law remedy for a contractual commitment voluntarily undertaken should not be regarded as a "requirement . . . *imposed under State law* " within the meaning of § 5(b).

Cipollone, 505 U.S. at 525-26. Plaintiff argues that if the liability imposed in a warranty action is not state a requirement, then there is no conflict between state and federal law. Plaintiff argues that the warrantor must honor his contractual promise despite the federal law's dictates. But the Supreme Court's holding was limited to whether state warranty actions fell under the scope of the Public Health Cigarette Smoking Act's express preemption clause. Id. The federal

statute barred state law requirements or prohibitions regarding the adequacy of cigarette warnings or advertising. Id. The Court held that it did not preclude a breach of express warranty action. Id.

The Court's handling of Justice Scalia's dissent shows that Cipollone must be confined to the express preemption realm. Id. at 526 n. 24. Justice Scalia contended "that because the general duty to honor express warranties arises under state law, every express warranty obligation is a 'requirement . . . imposed under State law,' and that, therefore, the Act pre-empts petitioner's express warranty claim." Id. The Court answered that "Justice Scalia might be correct if the Act pre-empted "*liability*" imposed under state law (as he suggests . . .); but instead the Act expressly pre-empts only a "*requirement or prohibition*" imposed under state law." Id. (internal citation omitted). Here, preemption is based on an actual conflict and not the dictates of any particular preemption clause. Cipollone is not controlling. Where a generic manufacturer cannot obey federal law without being held liable under a state law warranty action, the state action is preempted. See Mensing, 131 S. Ct. at 2577.

Plaintiff's express warranty claim contends that Defendants' PIs warranted that their products could be used long term. (Doc. No. 1 at 27-28). Defendants claim that federal law required them to include this language and that they could not abide by both state and federal law. The Court cannot find impossibility on the record before it. Without proof of what Defendants' and Reglan's PIs stated, Defendants cannot show that this language was required. Defendants' motion is **DENIED** on this point as well.

2. Implied Warranty

Plaintiff's implied warranty claim charges that Defendants' products were neither merchantable nor fit for their intended purpose. (Doc. No. 1 at 28-29). While Plaintiff's

complaint again concentrates on Defendants' alleged "concealment and failure to warn," she also makes a general allegation that Defendants' products were "not of merchantable quality or safe or fit for its intended use, because the drugs were and are unreasonably dangerous." (Doc. No. 1 at 28-29). These latter claims are not dependent on the content of Defendants' PIs:

> A claim for breach of the implied warranty of merchantability pursuant to N.C. GEN. STAT. § 25-2-314 requires a plaintiff to prove first, that the goods bought and sold were subject to an implied warranty of merchantability; second, that the goods did not comply with the warranty in that the goods were defective at the time of sale; third, that his injury was due to the defective nature of the goods; and fourth, that damages were suffered as a result. Similarly, a claim for breach of the implied warranty of fitness for a particular purpose requires proof that the seller at the time of contracting had reason to know of 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. N.C. GEN. STAT. § 25-2-315.

Harbor Point Homeowners' Ass'n, Inc. ex. rel. Bd. of Dirs. v. DJF Enterprises, Inc., 697 S.E.2d 439, 447 (N.C. App. 2010). While Defendant's labeling and warnings may play a role in establishing their products' intended purpose or their customers' reliance, Plaintiff's claim is not that Defendants failed to adequately warn about the risks. These claims are not preempted by federal warning label requirements under Mensing. Fisher, 2011 WL 4552464, at *18-19 (denying PLIVA's motion to dismiss the plaintiff's implied warranty claims because "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"). Defendant's motion is **DENIED**.

C. Defendants' Failure to Test and Surveil their Products

Plaintiff's negligence claim includes charges that Defendants failed to: (1) place adequate warnings on their products, (2) conduct adequate testing, and (3) conduct adequate post-marketing surveillance of their product's safety. Plaintiff's warning claim falls under the umbrella of her products liability count, but her testing and surveillance theories must be

dismissed. Defendants argue that North Carolina law does not recognize an independent cause of action based on a failure to test or surveil one's product after marketing. (Doc. No. 86 at 17-18). The Court agrees. See N.C. GEN. STAT. §§ 99B-2, 3, 4, 5, and 6. A Minnesota district court explained why such theories are not recognized:

> Presumably, the reason that manufacturers are under a duty to test their products is to discover defects or dangers associated with use of the products. Once the manufacturer has discovered a defect or danger the manufacturer should either change the product's design or manufacturing process, or warn consumers of the danger associated with using the product. Thus, unless the manufacturer's breach of its duty to test leads the manufacturer to produce a product that is defective in design, manufacture, or warning, no injury can result.

Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517, 1527 (D. Minn. 1989). Plaintiff's negligence claims based solely on Defendants' alleged failures to conduct adequate testing or post-marketing surveillance are **DISMISSED**.

D. Defendants' Failure to Abide by FDA Requirements

Plaintiff's second count alleges that Defendants breached a special duty to Plaintiff by failing to abide by FDA requirements. This count must be **DISMISSED**. As discussed above, and contended by Defendants, (Doc. No. 86 at 15-16), private enforcement of FDA requirements is foreclosed by 21 U.S.C. § 337(a); see also Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001).

IV. CONCLUSION

Defendants failed to satisfy their burden to prove that compliance with state and federal law was impossible. Thus, the Court cannot find Plaintiff's products liability and express warranty claims preempted. Plaintiff's implied warranty claim is not confined to an inadequate warning claim and is not preempted by federal labeling requirements under Mensing. But Plaintiff's allegations that Defendants were negligent and breached a special duty to Plaintiff by

failing to abide by FDA requirements do not state a claim for relief under North Carolina law and are **DISMISSED**.

IT IS, THEREFORE, ORDERED that:

1. Defendants' Joint Motion to Dismiss, (Doc. No. 77), is **GRANTED IN PART AND DENIED IN PART**.

Signed: January 11, 2012

Robert J. Conrad, Jr.
Chief United States District Judge