UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA
STATESBORO DIVISION

THEOTIS CONEY,

Plaintiff,

v. **6:11-cv-35**

MYLAN PHARMACEUTICALS, INC., et al.,

Defendants.

ORDER

I. INTRODUCTION

Plaintiff Theotis Coney ("Coney") filed a complaint, individually and as personal representative of the estate of his wife, Bertha Coney ("Bertha"), seeking to "recover damages for loss of consortium damages sustained by Theotis Coney related to the wrongful death of his wife." *See* Doc. 1-3 at 14.

Bertha developed a severe skin rash following her treatment with a prescription drug called "Dilantin." *See id.* at 19. Bertha died of these complications a month later. *See id.* Coney alleged nine counts: (1) strict liability for failure to warn; (2) strict liability for defective design/manufacture; (3) negligence; (4) fraudulent concealment; (5) breach of implied warranty; (6) gross negligence; (7) joint and several liability; (8) punitive damages; and (9) loss of consortium. *See id.* at 21-37.

Defendants Pfizer, Inc., Warner-Lambert Company LLC, and Pfizer Pharmaceuticals LLC ("collectively, Pfizer") removed this case from the State Court of Screven County, alleging diversity jurisdiction and claiming fraudulent joinder of Georgia resident Defendant Ross Drugs, Inc. ("Ross"). *See* Doc. 1. The Court agreed that Ross Drugs, Inc. was fraudulently joined. *See* Doc. 29 at 4.

All Defendants filed motions to dismiss. *See* Docs. 6 (motion to dismiss filed by Pfizer); 8 (motion to dismiss filed by Mylan Bertek Pharmaceuticals Inc., Mylan Laboratories, Inc., and Mylan Pharmaceuticals, Inc. (collectively, "Mylan") (with Pfizer and Ross, "Defendants"); 15 (motion to dismiss filed by Ross). The Court dismissed all of Coney's claims against Ross, as well as Coney's claim of loss of consortium based on breach of implied warranty against Pfizer and Mylan. *See* Doc. 29.

Now before the Court is Mylan's "Motion for Summary Judgment Based on the Doctrine of Federal Preemption." *See* Doc. 36.

II. FACTS

In November 2007, Bertha was hospitalized for treatment of seizures associated with her breast cancer after it metastasized to her brain. *See* Doc. 29 at 1. Her treating physician prescribed and administered Dilantin. *See id.*

Dilantin is the brand name under which Pfizer markets the drug Phenytoin Sodium. *See id.* Mylan distributes a generic form of Dilantin (hereinafter, "Phenytoin"). *See id.* Bertha's physician wrote her a prescription for Dilantin upon her discharge from the hospital. *See id.* at 2. She filled that prescription at Ross. *See id.* Ross filled the prescription with Phenytoin. *See id.*

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Bertha developed a severe skin rash in February 2008. *See id.*. On February 22, 2008, physicians diagnosed her with Stevens-Johnson Syndrome ("SJS") and Toxic Epidermal Necrolysis Syndrome ("TENS"), potentially fatal diseases known to develop in African-American patients on Dilantin. *See id.* Bertha died on March 21, 2008 as a result of these diseases. *See id.*

Coney filed this suit on March 2, 2011. *See* Doc. 12 at 3.

III. ANALYSIS

Mylan has moved for summary judgment, alleging that Coney's claims are preempted by federal law. *See* Doc. 36; *see also PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Mylan also argues that Coney's design defect claims are inadequately pled. *See* Doc. 45 at 5. The Court accordingly construes Mylan's motion for summary judgment as one for judgment on the pleadings in the alternative. *See* FED. R. CIV. P. 12(h)(B); *see also Strategic Income Fund, L.L.C. v. Spear, Leeds & Kellogg Corp.*, 305 F.3d 1293, 1295 n.8 (11th Cir. 2002).

A. Standards

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). In ruling on summary judgment, the Court views the facts and inferences from the record in the light most favorable to the non-moving party. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *United States v. Four Parcels of Real Prop. in Greene & Tuscaloosa Cntys.*, 941 F.2d 1428, 1437 (11th Cir. 1991).

"The moving party bears 'the initial responsibility of informing the . . . court of the basis for its motion, and identifying 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 issue of material fact.'" *Four Parcels*, 941 F.2d at 1437 (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)) (internal quotation marks removed).

The nonmoving party then "may not rest upon the mere allegations or denials of the [nonmoving] party's pleadings, but . . . must set forth specific facts showing that there is a genuine issue for trial." *Gonzalez v. Lee Cnty. Hous. Auth.*, 161 F.3d 1290, 1294 (11th Cir. 1998). "A factual dispute is genuine 'if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.'" *Four Parcels*, 941 F.2d at 1437 (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). A fact is material only if it might affect the outcome of the suit under governing law. *See Anderson*, 477 U.S. at 248.

Courts may consider all materials in the record, not just those cited by the parties. FED. R. CIV. P. 56(c)(3).

"Rule 12(c) permits judgment on the pleadings when there are no material facts in dispute and judgment may be rendered by considering the substance of the pleadings and any judicially noticed facts." *Scottsdale Ins. Co. v. Pursley*, 2012 WL 48035, at *1 (11th Cir. Jan. 10, 2012). In the context of a motion to dismiss that has been converted

into a motion for judgment on the pleadings, the Court must determine whether the complaint states a claim for relief. *See Strategic Income Fund, L.L.C. v. Spear, Leeds & Kellogg Corp.*, 305 F.3d 1293, 1295 n.8 (11th Cir. 2002). Thus, the pleading standard established in *Bell Atl. Corp. v. Twombly* is also relevant in this case. 550 U.S. 544 (2007).

"Factual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555; *see also Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (claim must have "facial plausibility"); *Edwards v. Prime, Inc.*, 602 F.3d 1276, 1291 (11th Cir. 2010).

The *Iqbal* Court further explained the required level of specificity:

> 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. The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully.

129 S. Ct. at 1949 (internal citation and quotation omitted).

In order to assess the plausibility of a complaint, a court must be mindful of two principles. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.* "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 1950.

B. *PLIVA, Inc. v. Mensing*

In *Mensing*, the Supreme Court considered whether federal drug regulations preempted state law failure to warn claims against generic drug manufacturers. *See* 131 S. Ct. at 2572.

Warning labels for the drug at issue in *Mensing*, metoclopramide, had been strengthened and clarified several times. *See id.* at 2572. Ultimately, the labels were updated to warn of the risk of "tardive dyskinesia, a serious movement disorder that is often irreversible." *Id.* at 2573. Before the label reflected the true risk of contracting tardive dyskinesia, the *Mensing* plaintiffs had received prescriptions for and had taken generic metoclopramide. *See id.* The plaintiffs sued, alleging that the generics' manufacturers were liable under state law failure to warn theories. *See id.*

The Supreme Court held that these claims were preempted. *See id.* at 2577. The Court first identified the duties owed by generics' manufacturers under state and federal law. *See id.* at 2573-77. The Court concluded that liability in state tort law imposes a duty "to use a different, stronger label than the label they actually used." *Id.* at 2577.

On the other hand, "[f]ederal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels." *Id.* Thus, federal law required "sameness" of labeling between brand-name and generic drugs. *See id.* at 2575.

The Court then went through Supremacy Clause analysis, noting "that state and federal law conflict where it is 'impossible for a private party to comply with both state and federal requirements.'" *Id.* at 2577. (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

The Court found impossibility. *See id.* "It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law." *Id.* at 2577-78.

C. Coney's Claims

Coney currently has strict liability/failure to warn, strict product liability/defective design or manufacture, negligence, fraudulent concealment, and gross negligence claims pending against Mylan. *See* Docs. 1-3 at 14; 29. Mylan moves to dismiss all of these claims, asserting that all of these claims are founded upon failure to warn reasoning. *See* Doc. 36. Mylan also asserts that Coney's product defect claims are inadequately pled. *See* Doc. 45 at 23. The Court takes each of Coney's claims up in turn.

1. Strict Liability Failure to Warn

Mensing established that failure to warn claims against generics manufacturers who satisfied federal law's abbreviated drug application requirements were preempted because they conflicted with federal law. *Mensing*, 131 S. Ct. at 2577-78. To the extent that Coney alleges failure to warn premised on the lack of additional warnings on Phenytoin's label, that claim is preempted.

Coney attempts to circumvent *Mensing* by arguing that his failure to warn claim targets not Mylan's failure to include information not contained on the FDA-approved labeling, but Mylan's failure to include warnings that were included on the FDA-approved label. *See* Doc. 41 at 3.

Coney's argument is unavailing. This distinction does not appear in Coney's complaint. *See* Doc. 1-3 at 21-23. Thus, this variation of the claim is not facially plausible, due to the lack of any supporting factual allegations in the complaint.

Coney next claims that Mylan had a duty to communicate the warnings on Phenytoin's label. *See* Doc. 41 at 4. Coney asserts that this duty could have been accomplished through a "Dear Doctor" letter, training programs, continuing education, patient access programs, specialized packaging, and "Changes Being Effected" ("CBE") procedures. *See id.* at 4-5.

Coney once again attempts to articulate a claim in a manner unsupported by his complaint. Coney's complaint indicates that Phenytoin "was *sold* without adequate warnings regarding the risk of serious skin reactions, exfolliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome and other risks associated with its use." *See* Doc. 1-3 at 22 (emphasis added); *see also id.* at 18-19 ("Defendants represented its product Phenytoin as a drug to control seizures, but failed to include adequate information in its label, package insert, and sales literature regarding the

serious and potentially fatal side effects related to its use."). Hence, Coney's complaint does not allege that Mylan failed to communicate warnings that had already been adequately detailed on the warning label; Coney alleged that any warning attached to Phenytoin was per se inadequate. Coney's complaint simply does not support the argument he is now espousing. Accordingly, Coney's pleadings do not sufficiently take this configuration of his claim beyond the realm of mere possible liability.

Coney cites *Brasley-Thrash v. Teva Pharms. USA, Inc.* for the proposition that failure to disseminate Dear Doctor letters can still result in post-*Mensing* liability. *See* 2011 WL 4025734, at *3 (S.D. Ala. Sept. 12, 2011). Coney, however, ignores the facts of *Brasley-Thrash*. In that case, the FDA had already approved a label change to the drug Reglan. *See id.* at *1. The plaintiff attempted to amend her claims to include a charge of failing to send a Dear Doctor letter reflecting the approved changes. *See id.* The court decided that the amendment was not futile because the claim was not preempted by federal law. *See id.* at *3. The court noted that manufacturers at the time would not have needed federal government involvement to take the steps the plaintiff alleged were needed. *See id.* Thus, the plaintiff had actually attempted to amend her complaint to include a claim premised upon the failure to send a Dear Doctor letter containing FDA-approved language. Coney has not properly alleged such a claim in this case.

Coney next argues that discovery might show that Mylan breached its duty "to timely modify its label or track label changes for branded Dilantin." *See* Doc. 41 at 5. Coney never asserted this theory in his complaint. *See* Doc. 1-3 at 18-19, 21-23. Accordingly, this claim is barred as implausible based on his pleading.

Coney next argues that Mylan could have simply chosen to take Phenytoin off the market. *See* Doc. 41 at 7. Other courts have considered and rejected this argument. *See, e.g., Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011); *Fullington v. PLIVA, Inc.*, 2011 WL 6153608, at *6 (E.D. Ark. Dec. 12, 2011). Finding that state law prohibits Mylan from doing what federal law explicitly requires Mylan to do would be tantamount to conferring supremacy upon the state law. *See City of Detroit v. Comcast of Detroit, Inc.*, 771 F. Supp. 2d 781, 790 (E.D. Mich. 2011); *see also United States v. State*, 2011 WL 446994, at *45 (N.D. Ala. Sept. 28, 2011).

Finally, Coney asks the Court to postpone preemption of his failure to warn claim against Mylan until the Court evaluates the adequacy of Pfizer's warning. *See* Doc. 41 at 8. Preemption of Coney's claims against Mylan, however, is not based on Pfizer's actions; if Coney's claims against Mylan are preempted, it is because *Mylan* could not act in accord with both state and federal law. *See Mensing*, 131 S. Ct. at 2579 ("The question for "impossibility" is whether *the private party* could independently do under federal law what state law requires of it." (emphasis added)). *But see Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) (stating in pre-*Mensing* dicta that generics'

manufacturers could be liable for negligent misrepresentations on labels the manufacturers merely adopt because "[t]he statutory scheme governing premarketing approval for drugs simply does not evidence Congressional intent to insulate generic drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law").

Finding Mylan liable for replicating, as required by federal law, the FDA-approved warnings used by Pfizer for Dilantin simply because a third party (Pfizer) or the Federal Government might bring about conditions that enable Mylan to comply with both state and federal law would eviscerate the Supremacy Clause. *See Mensing*, 131 S. Ct. 2579. Accordingly, the Court will not hang Mylan's fate on Pfizer's liability.

Because Coney's failure to warn claim is either preempted or improperly pled, it is ***DISMISSED***.

2. Defective Design and Manufacture

Mylan argues that Coney's defective design and manufacture claim claims are actually founded upon a failure to warn theory and must also be preempted. *See* Doc. 36-1 at 3. In the alternative, Mylan argues that Coney's defective design and manufacture claims are impliedly preempted under the frustration of purpose doctrine. *See* Doc. 45 at 18-23. Mylan also insists that Coney's design defect claim is inadequately pled. *See* Doc. 45 at 23. Coney asserts that these claims are independent of his failure to warn claims and are based upon Mylan's duty not to sell the drug at all. *See* Doc. 41 at 10.

The Court finds that Coney has inadequately pled this claim. The Georgia Code states:

> The manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort, irrespective of privity, to any natural person who may use, consume, or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.

O.C.G.A. § 51-1-11(b)(1). Georgia law utilizes a cost-benefit analysis to determine whether a product is defective; a product's utility must outweigh the product's risk in order for the product to be effective. *See Bryant v. Hoffman-La Roche, Inc.*, 262 Ga. App. 401, 406 (2003).

The existence of a defect is an essential element of both strict liability and negligence product defect claims. *See Udoinyion v. Michelin N. Am., Inc.*, 2011 WL 6091218, at *2 (Ga. App. Dec. 8, 2011). Thus, a complaint is deficient if it fails to allege a specific design or manufacturing defect. *See Moore v. Mylan Inc. f/k/a/ Mylan Labs. Inc.*, No. 1:11-cv-03037, at 13 (N.D. Ga. Jan. 5, 2012).

Coney has failed to allege a specific design or manufacturing defect. *See* Doc. 1-3 at 23-26. Furthermore, "because the complaint is silent as to a design or manufacturing defect, the Court cannot draw the reasonable inference that a design or manufacturing defect caused the decedent's injuries." *Moore*, No. 1:11-cv-03037, at 13; *see also Hall v. Scott USA, Ltd.*, 198 Ga. App. 197, 200 (1990) (noting that proximate cause is a "necessary element" under either a strict liability or negligence theory of products liability).

Because Coney fails to allege a plausible defective design or manufacture claim against Mylan, Coney's defective design and manufacture claims against Mylan are preempted and ***DISMISSED***.

3. Negligence and Gross Negligence Claims

Coney contends that his negligence claims survive because they are focused on Phenytoin's design, development, and manufacturing, not labeling. *See* Doc. 41 at 12.

Coney's complaint alleges that Mylan was negligent in part because it provided inadequate warnings on Phenytoin's label. *See* Doc. 1-3 at 26-27. For the reasons stated *supra*, Coney's negligence claim is preempted to the extent it relies on Mylan's purported failure to warn. *See supra* Part **III.C.***1*.

Insofar as Coney's negligence claims focus on Phenytoin's design and manufacture, those claims are inadequately pled.

The following elements are essential to a negligence claim in Georgia:

> (1) A legal duty to conform to a standard of conduct raised by the law for the protection of others against unreasonable risks of harm; (2) a breach of this standard; (3) a legally attributable causal connection between the conduct and the resulting injury; and (4) some loss or damage flowing to the plaintiff's legally protected interest as a result of the alleged breach of the legal duty.

Dixie Grp., Inc. v. Shaw Indus. Grp., Inc., 303 Ga. App. 459, 466-67 (2010).

As stated *supra*, the existence of a defect is an essential element of both strict liability and negligence product defect claims. *See Udoinyion*, 2011 WL 6091218, at *2. Coney failed to allege a specific defect in Phenytoin that would support his negligence claim. *See* Doc. 1-3 at 26-29. The Court is thus unable to draw the inference that a defect proximately caused the decedent's injuries. *See Moore*, No. 1:11-cv-03037, at 13. Thus, Coney fails to adequately plead negligence claims to the extent that they are based on Phenytoin's design and manufacture.

Because Coney's negligence claims are either preempted or insufficiently pled, those claims are ***DISMISSED***.

4. Fraudulent Concealment

Coney's fraudulent concealment claim must also be dismissed. Coney asserted that Mylan fraudulently failed to disclose test

results showing the risks of Phenytoin, failed to include warnings about potential risks, provided false or misleading information regarding Phenytoin's risks, and concealed known incidents of adverse reactions to the drug. *See* Doc. 1-3 at 30.

"The tort of fraud has five elements: (1) a false representation or omission of a material fact; (2) scienter; (3) intention to induce the party claiming fraud to act or refrain from acting; (4) justifiable reliance; and (5) damages." *ReMax N. Atlanta v. Clark*, 244 Ga. App. 890, 893 (2000). Thus, finding Mylan liable for fraudulent concealment means finding that Mylan falsely omitted a material fact.

To the extent that Coney alleges fraudulent concealment claims based on omissions on Phenytoin's warning label or Mylan's communications with health providers, his claim is preempted. "Any claim based on the errors in the label—or omissions in labeling or communications with health providers—is pre-empted by the FDA regulations for the same reason that failure-to-warn claims are pre-empted." *Grinage v. Mylan Pharm., Inc.*, 2011 WL 6951962, at *7 (D. Md. Dec. 30, 2011); *see also Fisher v. Pelstring*, 2011 WL 4552464, at *20 (D.S.C. Sept. 30, 2011). Mylan was forced to comply with federal law in determining what warnings and other written materials to communicate. *See Mensing*, 131 S. Ct. at 2576; *see also* 21 U.S.C. § 321(m); 21 C.F.R.§ 201.100(d)(1); 21 C.F.R.§ 202.1(*l*)(2). Finding Mylan guilty of fraudulent omission would indicate that Mylan had a state-law duty to issue more detailed warnings. Because it would be impossible for Mylan to comply with both state and federal law, Coney's fraudulent concealment claim, to the extent it is premised on Phenytoin's warning label, is also preempted.

Insofar as Coney alleges fraudulent concealment premised on materials outside of the label and already approved by the FDA, Coney has pled these claims inadequately. Fraud claims are subject to heightened pleading requirements. *See* FED. R. CIV. P. 9(b). Rule 9(b) requires a complaint to set forth:

> (1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or, in the case of omissions, not making) same, and (3) the content of such statements and the manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud.

Mizzaro v. Home Depot, Inc., 544 F.3d 1230, 1237 (11th Cir. 2008) (quoting *Tello v. Dean Witter Reynolds, Inc.*, 494 F.3d 956, 972 (11th Cir. 2007)).

With regards to fraudulent omissions outside the context of Phenytoin's warning label, Coney has failed to identify the time and place of Mylan's omissions, the content omitted and the manner in which the omissions misled Coney, and what Mylan obtained as a result of its omissions. *See* Doc. 1-3 at 29-30. Accordingly, Coney's complaint fails to articulate the factual allegations necessary to meet the Rule 9(b) pleading standard.

Because Coney's fraud claim is either preempted or insufficiently pled, the claim must be ***DISMISSED***.

IV. CONCLUSION

Mylan's motion for summary judgment, *see* Doc. 36, is ***GRANTED***. Coney's claims against Mylan Bertek Pharmaceuticals Inc., Mylan Laboratories, Inc., and Mylan Pharmaceuticals, Inc. are ***DISMISSED***.

This 19th day of January 2012.

B. AVANT EDENFIELD, JUDGE
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA