

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

JOHN K. McCAULEY,)
)
 Plaintiff,)
)
 v.)
)
)
 HOSPIRA, INC. and)
 APP PHARMACEUTICALS, LLC,)
)
 Defendants.)

**ORDER AND
MEMORANDUM OPINION
AND RECOMMENDATION**

1:11CV108

This matter is before the court on Defendant Hospira, Inc.’s (“Hospira”) motion to partially dismiss Plaintiff’s First Amended Complaint pursuant to Rules 12(b)(6), 8(a)(2), and 9(b) of the Federal Rules of Civil Procedure and Local Rule 7.3 for failure to state a claim upon which relief can be granted [docket no. 18]. Defendant APP Pharmaceuticals, LLC’s (“APP”) motion to join Defendant Hospira’s motion to dismiss [docket no. 21] is also pending. The parties have either responded to the respective motions, or the time to do so has passed, and the matter is ripe for disposition. The parties have not consented to the jurisdiction of the magistrate judge; therefore, the motion to dismiss must be dealt with by way of recommendation. There is no opposition to APP’s motion to join Hospira’s motion to dismiss; accordingly, the court will grant this motion. For the reasons discussed herein, it will be recommended that the court deny Defendants’ motions to dismiss

Counts 1, 2, and 6 of Plaintiff's First Amended Complaint and grant Defendants' motion to dismiss Counts 5 and 7.

BACKGROUND

Plaintiff John K. McCauley, a resident of North Carolina, brought this diversity action seeking to hold liable APP and Hospira for injuries allegedly caused by Plaintiff's use of Defendants' pharmaceutical drug. (Am. Compl. ¶ 43). According to the amended complaint, Defendants are both "generic drug manufacturers and manufacture and market a generic form of vancomycin¹ in various dosages." (*Id.* ¶ 25). Plaintiff was allegedly administered Defendants' vancomycin products at Duke Hospital in Durham, North Carolina between January 15, 2008, and February 11, 2008. (*Id.* ¶ 41). Plaintiff allegedly developed "life threatening condition[s] . . . which necessitated prolonged hospitalization and continued medical care and treatment." (*Id.* ¶ 43).

Plaintiff asserts claims of products liability due to defective design or defect (Count 1), products liability due to failure to warn (Count 2), negligence (Count 3), violation of the North Carolina Unfair and Deceptive Trade Practices Act (Count 4), common law misrepresentation and concealment (Count 5), breach of implied warranties (Count 6), and breach of express warranties (Count 7). Defendant Hospira, joined by Defendant APP, has filed a motion to dismiss Counts 1-2 and 5-7.

¹ As alleged in the complaint, vancomycin is an antibiotic drug that is used to treat infections. (Am. Compl. ¶ 18).

STANDARD OF REVIEW

The purpose of a motion to dismiss for failure to state a claim under FED. R. CIV. P. 12(b)(6)) is to test the sufficiency of the complaint - not to decide the merits of the action. *Schatz v. Rosenberg*, 943 F.2d 485, 489 (4th Cir. 1991); *Food Lion, Inc. v. Capital Cities/ABC, Inc.*, 887 F. Supp. 811, 813 (M.D.N.C. 1995). Generally, the court looks only to the complaint itself to ascertain the propriety of a motion to dismiss. See *George v. Kay*, 632 F.2d 1103, 1106 (4th Cir. 1980). At this stage of litigation, a plaintiff's well-pleaded allegations are taken as true; and the complaint, including all reasonable inferences therefrom, are liberally construed in the plaintiff's favor. *McNair v. Lend Lease Trucks, Inc.*, 95 F.3d 325, 327 (4th Cir. 1996).

A plaintiff need not plead detailed evidentiary facts, but he must give each defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. See *Bolding v. Holshouser*, 575 F.2d 461, 464 (4th Cir. 1978). This duty of fair notice under Rule 8(a) requires the plaintiff to allege, at a minimum, the necessary facts and grounds that will support his right to relief. See *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

A plaintiff "fails to state a claim upon which relief may be granted," 28 U.S.C. § 1915A(b)(1), when the complaint does not "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" 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." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (emphasis added) (internal citations omitted) (quoting *Twombly*, 550 U.S. at 570). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557 (internal quotations omitted)).

This standard under Rule 8 "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' Nor does a complaint suffice if it tenders 'naked assertions' devoid of 'further factual enhancement.'" *Id.* (internal brackets and citations omitted) (quoting *Twombly*, 550 U.S. at 555, 557). In other words, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* Finally, in evaluating a complaint, the court may anticipate affirmative defenses which are clear on the face of the complaint. *Todd v. Baskerville*, 712 F.2d 70 (4th Cir. 1983); *Nasim v. Warden, Md. House of Corr.*, 64 F.3d 951, 954 (4th Cir. 1995) (en banc) (stating that a court may apply common sense and reject fantastic allegations and/or rebut them with judicially noticed facts). With these principles in mind, the court turns now to the motion to dismiss.

DISCUSSION

1. Defective Design and Failure to Warn (Counts 1 and 2 of First Amended Complaint)

In Count 1 of his First Amended Complaint, Plaintiff alleges that Defendants are responsible for his injuries resulting from his use of their vancomycin products because those products were defective. (Am. Compl. ¶¶ 44-55). In Count 2, Plaintiff alleges Defendants are responsible for his injuries because they failed to warn Plaintiff, his physician, and the public of the dangers associated with vancomycin products. (*Id.* ¶¶ 56-68). In brief, Plaintiff alleges that Defendants disregarded numerous medical studies which “documented that vancomycin has a proven risk of inducing adverse reactions to the skin and tissues, which are known in the scientific community as SCAR events (severe cutaneous adverse reactions).” (*Id.* ¶ 32).

Hospira, joined by APP, argues that Counts 1 and 2 are strict products liability claims prohibited by North Carolina law. According to Defendants, “[b]ecause Counts 1 and 2 are ‘brought for or on account of personal injury’ and allege that vancomycin was ‘defective’ and/or ‘unreasonably dangerous,’” they are solely claims of strict products liability. (Mem. in Supp. of Mot. to Dismiss 7). North Carolina does not recognize strict liability in products liability actions. See, e.g., N.C. GEN. STAT. § 99B-1.1; *Smith v. Fiber Controls Corp.*, 300 N.C. 669, 678, 268 S.E.2d 504, 509-10 (1980); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631 (E.D.N.C. 2009).

In Counts 1 and 2 of his First Amended Complaint, Plaintiff alleges that Defendants are liable for his injuries resulting from his use of their vancomycin product(s) based on the defective design of the product(s) and the Defendants' failure to warn of the dangers of the product(s). While these allegations could be construed as asserting a claim for strict liability, Plaintiff also alleges facts and/or reaches factual conclusions that, if true, support products liability claims under a negligence theory. Under North Carolina law, a products liability action based upon negligence requires the plaintiff to prove the following elements: (1) duty; (2) breach; (3) causation; and (4) damages. *Bryant v. Adams*, 116 N.C. Ct. App. 448, 465, 448 S.E.2d 832 (1994); *Smith v. Wyeth-Ayerst Labs. Co.*, 278 F. Supp. 2d 684, 706 (W.D.N.C. 2003). See N.C. GEN. STAT. § 99B-(6)(a). A duty to warn arises when the supplier of a product knows or has reason to know that the product is, or can be, dangerous for the use for which it is supplied. *Stegall v. Catawba Oil Co.*, 260 N.C. 459, 133 S.E.2d 138 (1963).

Allegations that a product is “defective” or “unreasonably dangerous” may be legal conclusions insufficient to support a claim for relief. The factual allegations and conclusions underlying them, however, are not. For example, Plaintiff here “alleg[es] that vancomycin was defective because ‘it had a negative risk-benefit profile as to certain patient populations, or for certain uses.’” (Am. Compl. ¶¶ 52-54). Even if the allegation that vancomycin is defective is a legal conclusion that cannot support a claim for relief, the allegation that vancomycin had a negative risk-benefit profile

is a factual allegation that may prove that the manufacturer acted unreasonably, as required for products liability claims under N.C. GEN. STAT. §§ 99B-5 and 99B-6. Similarly, allegations of “numerous labeling defects” — such as the label’s lack of a warning about the risk of adverse reactions — if true, plausibly support a products liability claim under a negligence standard. (Am. Compl. ¶¶ 58-67). Plaintiff has thus stated claims for products liability under North Carolina law, and Defendants’ motion should be denied as to Counts 1 and 2.

2. Breach of Implied Warranty (Count 6 of First Amended Complaint)

In Count 6, Plaintiff alleges that Defendants breached implied warranties. North Carolina law provides for claims of breach of implied warranties under three statutes: N.C. GEN. STAT. § 99B-1.2. Breach of warranty (as a products liability action); N.C. GEN. STAT. § 25-2-314. Implied warranty: Merchantability; usage of trade (as a North Carolina Uniform Commercial Code action); and N.C. GEN. STAT. § 25-2-315. Implied warranty: Fitness for particular purpose (as a North Carolina Uniform Commercial Code action). “An action for breach of implied warranty of merchantability [and, presumably, an action for breach of implied warranty of fitness for a particular purpose] . . . ‘is a “products liability action” within the meaning of the Products Liability Act if . . . the action is for injury to [a] person . . . resulting from a sale of a product.’” *DeWitt v. Eveready Battery Co.*, 355 N.C. 672, 682-83, 565 S.E.2d 140, 147 (2002) (quoting *Morrison v. Sears, Roebuck & Co.*, 319 N.C. 298, 303, 304, 354 S.E.2d 495, 498, 499 (1987)).

North Carolina common law generally requires privity of contract in order to assert an implied warranty claim. *Kelly v. Georgia-Pacific LLC*, 671 F. Supp. 2d 785, 796 (E.D.N.C. 2009) (citing *Terry v. Double Cola Bottling Co.*, 263 N.C. 1, 3, 138 S.E.2d 753, 754 (1964)). In certain situations, however, privity is not required. Under the North Carolina Products Liability Act, there is no privity requirement for implied warranty claims when an action is “brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture . . . of any product.” N.C. GEN STAT. § 99B-1(3). “A claimant who is a buyer, as defined in the Uniform Commercial Code, of the product involved, or who is a member or a guest of a member of the family of the buyer, a guest of the buyer, or an employee of the buyer may bring a products liability action directly against the manufacturer of the product involved for breach of implied warranty; and the lack of privity of contract shall not be grounds for the dismissal of such action.” N.C. GEN. STAT. § 99B-2(b). Because Plaintiff alleges personal injuries — as opposed to solely economic loss — his claim is a products liability action subject to the lessened privity requirements of N.C. GEN. STAT. § 99B-2(b). See *Gregory v. Atrium Door & Window Co.*, 106 N.C. Ct. App. 142, 144, 415 S.E.2d 574, 575 (1992).

Defendant Hospira, joined by Defendant APP, argues that Plaintiff fails to state a claim for breach of implied warranty under North Carolina law because Plaintiff does not allege that he is a “buyer” and, furthermore, because Plaintiff does not — and cannot — meet even the lessened privity requirements defined above.

(Reply 2 [docket no. 28]). Under North Carolina's Uniform Commercial Code, "[b]uyer' means a person who buys or contracts to buy goods." N.C. GEN. STAT. § 25-2-103. In his amended complaint – though not necessarily in the section pertaining to Count 6 – Plaintiff alleges that "[t]he Plaintiff purchased and used Vancomycin for personal, family or household purposes." (Am. Compl. ¶ 87). Plaintiff thus alleges facts supporting a claim that he is a buyer, as defined by the North Carolina Uniform Commercial Code. Furthermore, case law does not preclude Plaintiff from arguing — based on facts alleged in his first amended complaint — that he meets the requirements of one of the other listed categories of claimants.

Plaintiff's allegation that he purchased vancomycin is thus a plausible, factual allegation that Plaintiff is a "buyer." Plaintiff has pleaded sufficient facts to state a claim for breach of implied warranty under North Carolina law. Defendants' motion to dismiss should be denied as to Count 6.

3. Fraudulent Concealment and Misrepresentation Claim (Count 5)

In Count 5 of his amended complaint, Plaintiff alleges fraudulent concealment and misrepresentation on the part of Defendants. Plaintiff alleges that Defendants had a duty to disclose pertinent information about vancomycin and that they made false representations and/or failed to disclose information about the risks associated with the use of vancomycin.

Under North Carolina law, Plaintiff must allege that Defendants made a misrepresentation to Plaintiff and that Plaintiff relied upon that misrepresentation to

his detriment. *Wilson v. Dryvit Sys., Inc.*, 206 F. Supp. 2d 749, 755 (E.D.N.C. 2002); *Ragsdale v. Kennedy*, 286 N.C. 139, 138, 209 S.E.2d 494, 500 (1974). More specifically, “[t]he essential elements of fraud are: (1) [f]alse representation or concealment of a material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, (5) resulting in damage to the injured party.” *Wilson*, 206 F. Supp. 2d at 755; *Rowan County Bd. of Educ. v. U.S. Gypsum Co.*, 332 N.C. 1, 17, 418 S.E.2d 648, 658 (1992).

Defendants have moved to dismiss Count 5 for failure to comply with the particularity requirement of Rule 9(b) of the Federal Rules of Civil Procedure. Under Rule 9(b), “in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.” FED. R. CIV. P. 9(b). The particularity element requires that a plaintiff plead the “time, place, and contents of the alleged fraudulent representation, as well as the identity of each person making the misrepresentation and what was obtained thereby.” *Liner v. DiCresce*, 905 F. Supp. 280, 287 (M.D.N.C. 1994). Moreover, “where there are multiple defendants, plaintiffs must allege all claims with particularity as to each defendant.” *Dealers Supply Co., Inc. v. Cheil Indus., Inc.*, 348 F. Supp. 2d 579, 589 (M.D.N.C. 2004).

The amended complaint in this matter contains assertions that (1) “[d]efendants had a duty to fully and accurately disclose all material facts regarding the risks and benefits of vancomycin products to plaintiff and his prescribing physician;” (2) “[d]efendants made representations and failed to disclose” relevant

information and that “[d]efendants knew or should have known at the time [of the representations] that their representations were false and fraudulent regarding the dangers and risk of adverse health events associated with use of vancomycin;” (3) these “fraudulent misrepresentations and omissions were made knowingly, intentionally, and with the intent of defrauding and deceiving the medical community, plaintiff and the public;” (4) “[d]efendants’ fraudulent misrepresentations intentionally concealed . . . material information” of “statistically significant risk[s]” associated with vancomycin, risks which were available in scientific literature “of which defendants were or should have been aware . . .;” and (5) “[p]laintiff and his prescribing doctor had no knowledge of the falsity of defendants[’] actions and believed this drug to be safe for its intended use.” (Am. Compl. ¶¶ 95 - 101.) Because these allegations fail to set forth specific and particular facts concerning Defendants’ alleged misrepresentations, they are insufficient to satisfy the requirements of Rule 9(b). Moreover, the allegations are not asserted with particularity as to each defendant; rather, the allegations in the amended complaint refer to Defendants collectively. As such, the allegations are not sufficient under Rule 9(b).

A fraud claim based solely on a purported misrepresentation to a third party, moreover, must fail as a matter of law. *Wilson*, 206 F. Supp. at 755 (“The court has been unable to find any North Carolina cases in which a plaintiff has been permitted to recover on a fraud claim for misrepresentations that were made to third parties.”). As Defendants point out, Plaintiff does not allege that Defendants made any oral or

written misrepresentations directly to Plaintiff. Rather, Plaintiff claims that Hospira made statements to “prescribing physicians and consumers” about “the dangers and risks of adverse health events associated with the use of vancomycin” (Am. Compl. ¶ 96) and that Defendants’ “fraudulent misrepresentations intentionally concealed” various safety issues with regard to the use of vancomycin. (*Id.* ¶ 98). As such, Plaintiff has failed to state a claim for misrepresentations made to third parties.

4. Breach of Express Warranty Claim (Count 7)

In order to recover for a breach of express warranty under state or federal law, a plaintiff must allege that a defect exists, that a warranty covered the item, and that the seller breached the warranty. N.C. GEN. STAT. § 25-2-313 (2007); 15 U.S.C. § 2310(d); *see also Harbor Point Homeowners’ Ass’n, Inc. v. DJF Enter., Inc.*, 697 S.E.2d 439, 447 (N.C. Ct. App. 2010). An express warranty is defined as “[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain” N.C. GEN. STAT. § 25-2-313.

In Count 7 of the amended complaint, Plaintiff alleges that “Defendants’ [sic] expressly warranted that Vancomycin drug products were safe and effective” (Am. Comp. ¶ 110), that Plaintiff and his doctors relied on these warranties (*Id.* ¶ 111), that the express warranty “failed to disclose design, manufacturing and safety defects inherent in Vancomycin” (*Id.* ¶ 112) and that Defendants breached these warranties when they continued to market and sell Vancomycin while they “knew of

the design, manufacturing and safety defects and the risk[s]” described in the complaint (*Id.* ¶ 113). These “naked assertions” are “devoid of further factual enhancement.” *Twombly*, 550 U.S. at 557. Plaintiff has failed to identify any specific words, promises, affirmations, or statements made by Hospira or APP to Plaintiff or his physicians that would create an express warranty. Plaintiff does not further address the alleged express warranty or its contents and does not address at all how the warranty was made, to whom it was made, or any other details with regard to the alleged warranty. This conclusory recitation of the elements of a breach of warranty claim is simply insufficient to state a claim for breach of express warranty, and Defendants’ motion to dismiss should be granted as to Count 7.

CONCLUSION

For the reasons stated, Defendant APP’s motion to join Defendant Hospira’s motion to dismiss [docket no. 21] is **GRANTED**. Furthermore, **IT IS RECOMMENDED** that the motion to dismiss Counts 1, 2, and 6 of Plaintiff’s First Amended Complaint be **DENIED** and that the motion to dismiss Counts 5 and 7 [docket no. 18] be **GRANTED**.



WALLACE W. DIXON
United States Magistrate Judge

Durham, NC
August 5, 2011