

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
PADUCAH DIVISION
CIVIL ACTION NO. 5:20-CV-00060-GNS-CHL

RHONDA DUFF

PLAINTIFF

v.

C.R. BARD INC., et al.

DEFENDANTS

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Defendants’ Motion to Dismiss (DN 26). The motion has been fully briefed and is ripe for decision. For the reasons stated below, the motion is **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

This action is brought by Rhonda Duff (“Plaintiff”) asserting claims against C.R. Bard, Inc. and Bard Access Systems, Inc. (“Defendants”) arising from the “design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling” of their PowerPort medical device (“PowerPort”), which is an “implantable vascular access device designed to provide repeated access to the vascular system for the delivery of medication, intravenous fluids, parental nutrition solutions, and blood products.” (Am. Compl. ¶¶ 1, 11, 20).

On February 6, 2019, Plaintiff underwent placement of a PowerPort to treat her lymphoma. (Am. Compl. ¶ 40). Approximately two months later, it was discovered that the PowerPort had fractured and migrated to Plaintiff’s heart, necessitating that the device be surgically removed. (Am. Compl. ¶ 43). Plaintiff alleges the defective device and its removal has caused her physical, emotional, and psychological injury. (Am. Compl. ¶ 44).

Plaintiff filed this action on March 30, 2020, and filed the Amended Complaint on June 22, 2020. Defendants have moved to dismiss Plaintiff’s claim for failure to state a claim. (Defs.’ Mot. Dismiss, DN 26). The motion is ripe for adjudication.

II. JURISDICTION

This Court has subject matter jurisdiction over these claims pursuant to 28 U.S.C. § 1332(a) because the amount in controversy exceeds \$75,000 and there is diversity of citizenship.

III. STANDARD OF REVIEW

To survive dismissal for failure to state a claim under Fed. R. Civ. P. 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted) (citation omitted). A claim is facially plausible “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.* When considering a defendant’s motion to dismiss, the Court will “accept all the [plaintiff’s] factual allegations as true and construe the complaint in the light most favorable to the [plaintiff].” *Hill v. Blue Cross & Blue Shield of Mich.*, 409 F.3d 710, 716 (6th Cir. 2005) (citation omitted). “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 assertion[s] devoid of further factual enhancement.” *Iqbal*, 556 U.S. at 678 (internal quotation marks omitted) (citation omitted).

IV. DISCUSSION

In Kentucky,¹ “[a] party injured by a product can bring suit for that injury under three different theories: (1) breach of warranty under the Uniform Commercial Code, (2) negligence,

¹ The parties rely on Kentucky law in addressing Plaintiff’s claims.

or (3) strict liability in tort.” *Ostendorf v. Clark Equip. Co.*, 122 S.W.3d 530, 535 (Ky. 2003) (citing *Williams v. Fulmer*, 695 S.W.2d 411, 413 (Ky. 1985)). In this case Plaintiff has asserted claims of negligence, strict liability, breach of express warranty, breach of implied warranty, and fraud by omission.

A. Negligence

Plaintiff brings a general negligence claim alleging Defendants violated their “duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, selling and conducting post-market surveillance of the PowerPort.” (Am. Compl. ¶ 56). “In any negligence case, a plaintiff must prove the existence of a duty, breach of that duty, causation between the breach of duty[,], and the [plaintiff’s] injury and damages.” *Hayes v. D.C.I. Props.-D KY, LLC*, 563 S.W.3d 619, 622 (Ky. 2018).

There is no plausible argument that Defendants do not owe a duty to Plaintiff in the creation and distribution of the PowerPort because “[t]he rule is that every person owes a duty to every other person to exercise ordinary care in his activities to prevent foreseeable injury.” *Grayson Fraternal Order of Eagles, Aerie No. 3738, Inc. v. Claywell*, 736 S.W.2d 328, 332 (Ky. 1987), *superseded by statute on other grounds as stated in DeStock No. 14, Inc. v. Logsdon*, 993 S.W.2d 952, 957 (Ky. 1999) (citations omitted); *C.D. Herme, Inc. v. R.C. Tway Co.*, 294 S.W.2d 534, 536 (Ky. 1956) (manufacturer owes duty of reasonable care to consumer). Plaintiff has outlined numerous ways Defendants breached that duty in the Amended Complaint. (Am. Compl. ¶ 57). Specifically, Plaintiff asserts the faulty PowerPort catheter fractured and migrated to Plaintiff’s heart, requiring surgery. (Am. Compl. ¶ 43).

“The ‘sole question in a products liability case,’ regardless of whether the case involves failure to adequately warn, defective design, or other products liability theories, is whether the

product is defective.” *Leslie v. Cincinnati Sub-Zero Prods.*, 961 S.W.2d 799, 803 (Ky. App. 1998) (citation omitted). “Thus, like a claim for strict products liability, a claim for negligent products liability requires the plaintiff to establish that the product was defective and that it was the legal cause of the injury.” *Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 747 (W.D. Ky. 2013). To be clear, “[a] plaintiff’s . . . claims of negligence . . . and strict liability . . . have [a] common denominator which is that causation must be established.” *Holbrook v. Rose*, 458 S.W.2d 155, 157 (Ky. 1970). “The causation analysis is the same under a negligence theory in a products liability case as . . . under a strict liability theory.” *Red Hed Oil, Inc. v. H.T. Hackney Co.*, 292 F. Supp. 3d 764, 773 (E.D. Ky. 2017) (internal quotation marks omitted) (quoting *Halsey v. AGCO Corp.*, No. 16-cv-461-JMH, 2017 WL 4767679, at *1 (E.D. Ky. Oct. 20, 2017)). To prove causation in a products liability case in Kentucky, the “plaintiff has the burden . . . to establish causation under the substantial factor test—that is, plaintiff must prove that defendant’s conduct was a substantial factor in bringing about a plaintiff’s harm.” *Id.* (quoting *King v. Ford Motor Co.*, 209 F.3d 886, 893 (6th Cir. 2000); *Burgett v. Troy-Bilt LLC*, 970 F. Supp. 2d 676, 681 (E.D. Ky. 2013)).

In the Amended Complaint, Plaintiff alleges numerous times that her injuries were caused by Defendants’ defective product. Plaintiff makes clear that her physician followed the instructions for implanting the device. (Am. Compl. ¶ 50). No other cause is claimed, therefore Plaintiff has adequately pleaded that the design of the product caused it to break off and injure her. Plaintiff claims she has suffered numerous injuries as a result, including undergoing a major surgery, risk of future injuries, and emotional distress. (Am. Compl. ¶ 44). Because these allegations are sufficient for all four prongs of negligence, the Court denies Defendants’ motion with respect to the negligence claim.

B. Punitive Damages

“In order to justify punitive damages, there must be first a finding of failure to exercise reasonable care, and then an additional finding that this negligence was accompanied by wanton or reckless disregard for the lives, safety, or property of others.” *Horton v. Union Light, Heat & Power Co.*, 690 S.W.2d 382, 389-90 (Ky. 1985) (internal quotation marks omitted). “Even when a single act of negligence might not constitute gross negligence, gross negligence may result from several acts.” *Id.* at 338 (citation omitted). “The threshold for the award of punitive damages is whether the misconduct was ‘outrageous’ in character, not whether the injury was intentionally or negligently inflicted.” *Peoples Bank of N. Ky., Inc. v. Crowe Chizek & Co.*, 277 S.W.3d 255, 267 (Ky. App. 2008) (citation omitted). Reckless disregard for the rights of others may be implied from the nature of the misconduct. *Id.* It is the flagrant indifference to the safety of others that justifies an award of punitive damages. *See Bowling Green Mun. Utils. v. Atmos Energy Corp.*, 989 S.W.2d 577, 581 (Ky. 1999). Moreover, to support an award of punitive damages Kentucky law requires a finding of a failure to exercise even slight care. *See Phelps v. Louisville Water Co.*, 103 S.W.3d 46, 51-52 (Ky. 2003). “The plaintiff must establish the reckless or wanton disregard for others by clear and convincing evidence.” *Colyer v. Speedway, LLC*, 981 F. Supp. 2d 634, 645 (E.D. Ky. 2013) (citing *Embry v. Geo*, 478 F. Supp. 2d 914, 920 (E.D. Ky. 2007)).

Plaintiff claims Defendants were grossly negligent and an award of punitive damages is warranted. (Am. Compl. ¶ 59). Plaintiff alleges not only that the defective product caused her injury, but also that Defendants knew the product had the potential to cause dangerous side effects and misrepresented these risks to Plaintiff and her physician. (Am. Compl. ¶¶ 28-30). Taken as

true, this is enough to show a reckless disregard for the safety of others, therefore Plaintiff's request for punitive damages survives dismissal.²

C. Strict Liability - Failure to Warn

In *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758 (Ky. 2004), the Kentucky Supreme Court adopted the “learned intermediary doctrine” in the context of claims against prescription drug manufacturers for failure to warn patients of the adverse side effects of those drugs. *Id.* at 770.

The Court described the doctrine as follows:

Section 6(d)(1) [of the Restatement (Third) or Torts: Products Liability] states the learned intermediary rule, an exception to the general rule that a manufacturer's duty to warn of any risks or dangers inherent in the product runs to the ultimate consumer. “The obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care provider's prescription traditionally has required warnings directed to health-care providers *and not to patients.*”

Id. at 762 (emphasis added) (internal citation omitted) (citation omitted). The Court in *Larkin* engaged in extensive analysis of the learned intermediary rule, recognizing the doctrine as an exception to the rule of strict liability which applies in the context of claims premised on faulty medical devices. *Id.* at 761. The Court identified a comment to Section 402A of the Restatement (Second) of Torts as the source of the learned intermediary rule:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to

² “[A] claim for punitive damages is not a separate cause of action, but a remedy potentially available for another cause of action.” *Dalton v. Animas Corp.*, 913 F. Supp. 2d 370, 378-79 (W.D. Ky. 2012) (citation omitted).

supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k. The learned intermediary rule does not completely eliminate all potential liability owed from the manufacturer to the patient for alleged insufficient warnings. *Larkin*, 153 S.W.3d at 765. Rather, “[e]ven though the manufacturer’s duty to warn runs only to the learned intermediary, that warning must still be adequate. If the manufacturer fails to adequately warn the learned intermediary, then it may be liable to the injured patient-consumer.” *Id.* at 764 (internal citation omitted) (citation omitted). Thus, the learned intermediary doctrine does not absolve a manufacturer of liability owed to a patient-plaintiff premised on the failure to warn; the doctrine simply modifies the elements of such a claim, so that the warning issued by the manufacturer to the medical provider must still be adequate. *Id.* at 764-65.

The learned intermediary doctrine does not warrant dismissal. Plaintiff not only alleges that Defendants did not inform her of the dangers of this treatment, but also alleges Defendants failed to warn her healthcare-provider of the dangers of the treatment. (*See* Am. Compl. ¶ 65 (“[N]o reasonable health care provider, including Plaintiff’s, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers or the consumers of the device.”)). Taking Plaintiff’s allegations as true, as the Court must at this juncture, the learned intermediary doctrine does not warrant dismissal. *See Larkin*, 153 S.W.3d at 762.

D. Strict Liability - Defective Design

Under Kentucky law, a product design is defective if it creates such a risk of injury that an ordinarily prudent manufacturer, being aware of the risk, would not have put it on the market. *C & S Fuel, Inc. v. Clark Equip. Co.*, 552 F. Supp. 340, 344-45 (E.D. Ky. 1982); *Nichols v. Union Underwear Co.*, 602 S.W.2d 429, 433 (Ky. 1980). “The maker is not required to design the best

possible product or one as good as others make or a better product than the one he has, so long as it is reasonably safe.” *Sturm, Ruger & Co., Inc. v. Bloyd*, 586 S.W.2d 19, 21-22 (Ky. 1979).

Kentucky law requires a plaintiff to establish:

(1) that there is a product, which is (2) in a defective condition unreasonably dangerous to the user or consumer or his property, and (3) which reaches the user or consumer without substantial change in the condition in which it is sold; (4) that the product is sold by one who engaged in the business of selling such a product which (5) results in physical harm to the ultimate user or consumer or his property. A plaintiff must also offer proof of an alternative, safer design that is practicable under the circumstances.

Vanden Bosch v. Bayer Healthcare Pharms., Inc., 13 F. Supp. 3d 730, 742 (W.D. Ky. 2014)

(internal citation omitted) (citation omitted).

Plaintiff alleges that the PowerPort device was defective and significantly more dangerous than similar devices. (Am. Compl. ¶ 63). Plaintiff alleges Defendants erred in design and manufacture of the PowerPort, and there is no allegation the device was modified in any way. (See Am. Compl. ¶ 21). The Amended Complaint claims that Defendants are engaged in the business of selling medical products. (Am. Compl. ¶ 2). As noted above, Plaintiff has adequately pleaded causation and injury. Lastly, Plaintiff has stated that there are similar devices on the market that do not pose such serious injury risk. (Am. Compl. ¶ 63). Therefore, Plaintiff has sufficiently stated a design defect claim.

E. Strict Liability - Manufacturing Defect

A products liability claim premised on a manufacturing defect can be based upon the failure of the product to meet specifications or an error in the manufacturing process. *Greene v. B.F. Goodrich Avionics Sys., Inc.*, 409 F.3d 784, 788-89 (6th Cir. 2005); *Ford Motor Co. v. McCamish*, 559 S.W.2d 507, 509 (Ky. App. 1977). Defendants can be liable if a plaintiff proves a product is “unreasonably dangerous” because it is in a defective condition when sold. *Est. of DeMoss by and*

through *DeMoss v. Eli Lilly & Co.*, 234 F. Supp. 3d 873, 879-80 (W.D. Ky. 2017) (citations omitted). Thus, a product may be designed appropriately but manufactured with a defect not part of the design. See *Greene*, 409 F.3d at 788 (citing *McCamish*, 559 S.W.2d at 509-11).

Plaintiff claims the PowerPort implanted in her contained a manufacturing defect, which existed at the time it left Defendants' possession and that the defect caused the device to differ from its design. (Am. Compl. ¶¶ 76-78). The healthcare providers implanting the device did so in a way that was reasonably foreseeable, and as a result of the manufacturing defect, Plaintiff alleges that she was injured. (Am. Compl. ¶¶ 79-80). Therefore, Plaintiff has alleged a valid manufacturing defect claim.

F. Breach of Express Warranty

Plaintiff alleges that Defendants breached an express warranty through their representatives, literature, and advertising. (Am. Compl. ¶ 98). Kentucky law provides three ways a seller can create express warranties:

- (a) Any 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 creates an express warranty that the goods shall conform to the affirmation or promise.
- (b) Any 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.
- (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

KRS 355.2-313(1).

1. *Affirmation of Fact or Promise*

The seller does not have to intend to create an express warranty or formally grant a guarantee for an express warranty to exist. *Id.* However, simply stating the value of the goods, or a seller expressing an opinion on the goods does not create a warranty. *Id.* It is up to the trier of fact to determine whether the statements by seller are mere puffing engaged in by salespeople or

the circumstances have created an express warranty. *See Mitchell v. Gen. Motors LLC*, No. 3:13-CV-CRS, 2014 WL 1319519, at *7 (W.D. Ky. Mar. 31, 2014) (citations omitted).

“The test is ‘whether the seller assumes to assert a fact of which the buyer is ignorant, or whether he merely states an opinion or expresses a judgment about a thing as to which they may each be expected to have an opinion and exercise a judgment.’” *Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 734 (W.D. Ky. 2013) (citing *Overstreet v. Norden Labs., Inc.*, 669 F.2d 1286, 1290-91 (6th Cir. 1982)).

Plaintiff alleges Defendants falsely stated that their product was proven to be safe and “did not produce dangerous side effects,” but the product produced a multitude of dangerous side effects causing serious injury. (Am. Compl. ¶ 99). The statement that a product is safe and does not come with dangerous side effects goes beyond mere puffery or an exaggeration; it is an affirmation of fact. *See Naiser*, 975 F. Supp. 2d at 735 (“‘[P]uffing’ is generally defined as an ‘expression of an exaggerated opinion—as opposed to a factual misrepresentation—with the intent to sell a good or service.’” (citing *Black’s Law Dictionary* 1353 (9th ed. 2009))). Plaintiff’s allegation is enough to establish a claim for breach of warranty. *See* KRS 355.2-313(1); *Naiser*, 975 F. Supp. 2d at 736 (“Whether Unilever’s identification of the product as having ‘smoothing’ effects is actually an affirmation of fact or promise is a fact question that cannot be decided on this motion to dismiss.”).

2. Basis of Parties’ Bargain

It is not enough that Defendants made an affirmation or promise pertaining to the PowerPort to Plaintiff, but that factual misrepresentation must have also become a part of the “basis of the bargain”. *See* KRS 355.2-313(1)(b). Plaintiff alleges that she “reasonably relied upon the Defendants’ express warranties” (Am. Compl. ¶ 101); *see Naiser*, 975 F. Supp. 2d at 735 (“Under Kentucky law, ‘[r]eliance is an element of a cause of action for express

warranty” (citations omitted)). Thus, Plaintiff has sufficiently pleaded a claim for breach of express warranty.

3. Privity of Contract

Under Kentucky law, privity of contract is generally required to make out a breach of warranty claim. *Naiser*, 975 F. Supp. 2d at 738 (citing *Waterfill v. Nat’l Molding Corp.*, 215 F. App’x 402, 405 (6th Cir. 2007)). Plaintiff makes two arguments as to why privity of contract exists: (1) Plaintiff’s physician acted as a “purchasing agent”; and (2) Plaintiff was a third-party beneficiary of the subject contract. (Am. Compl. ¶ 102). Plaintiff’s second argument has merit. *See Levin v. Trex Co., Inc.*, No. 3:10-cv-692-CRS, 2012 WL 7832713, at *4 (W.D. Ky. Mar. 5, 2012) (“Under Kentucky law, ‘an actual and direct promise for the benefit of a third party will be sufficient to create privity between the promisor and the third party beneficiary.’” (quoting *Louisville Gas & Elec. Co. v. Cont’l Field Sys., Inc.*, 420 F. Supp. 2d 764, 770 (W.D. Ky. 2005))).

In *Levin*, the Court denied the defendant’s motion to dismiss because the express warranty was intended for the benefit of the third-party. *See id.* (“Defendant’s express limited warranty was intended to benefit the residential homeowners and not the distributors who sold Defendant’s product. Thus, Plaintiff’s express warranty claim may also be based on Plaintiff’s position as the expressly intended beneficiary of the warranty issued by Defendant.”). Plaintiff’s claim here for breach of express warranty is analogous to *Levin*. Plaintiff’s physician purchased the PowerPort, but it was intended to be used on Plaintiff as a medical device. (Am. Compl. ¶ 103). Therefore, Plaintiff has sufficiently pleaded privity of contract to support a breach of express warranty claim.

G. Breach of Implied Warranty

Kentucky law generally requires privity of contract to state a breach of warranty claim. *Naiser*, 975 F. Supp. 2d at 738 (citing *Waterfill v. Nat’l Molding Corp.*, 215 F. App’x 402, 405

(6th Cir. 2007)). The exception for privity discussed above with respect to express warranty claims does not apply to a claim for breach of implied warranty. *See Est. of DeMoss*, 234 F. Supp. 3d at 882 (distinguishing between the breach of express warranty in *Naiser* and the claim for breach of implied warranty). “The Court’s ruling in *Naiser* had no impact on the privity of contract requirement with respect to implied warranty causes of action.” *Id.* (quoting *Bosch v. Bayer Healthcare Pharms., Inc.*, 13 F. Supp. 3d 730, 749 (W.D. Ky. 2014)). Thus, the requirement of privity of contract persists for claims of breach of implied warranty. *See id.* (“Under Kentucky law, privity of contract is an essential element of a claim for breach of an implied warranty.” (citations omitted)). “[P]rivacy of contract does not extend beyond the buyer-seller setting” *Id.* (citations omitted). In this case, the PowerPort implanted in Plaintiff was purchased by her physician. (Am. Compl. ¶ 102). The Amended Complaint does not allege privity because there is no claim of a buyer-seller relationship between Plaintiff and Defendants. Thus, Plaintiff’s breach of implied warranty claim fails as a matter of law and will be dismissed.

H. Fraud by Omission

A claim of fraud by omission should not be confused with a claim of fraud by misrepresentation, each claim requires the proof of substantially different elements. *Republic Bank & Tr. Co. v. Bear Sterns & Co., Inc.*, 683 F.3d 239, 254-55 (6th Cir. 2012) (citing *Rivermont Inn, Inc. v. Bass Hotels & Resorts, Inc.*, 113 S.W.3d 636, 641 (Ky. App. 2003)). “Unlike fraud by misrepresentation, which hinges on an affirmative statement, ‘a fraud by omission claim is grounded in a duty to disclose.’” *Id.* at 255 (quoting *Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 747 (Ky. 2011)).


To make out a claim of fraud by omission a plaintiff must satisfy four elements: “(1) the defendant had a duty to disclose the material fact at issue; (2) the defendant failed to disclose the

fact; (3) the defendant's failure to disclose the material fact induced the plaintiff to act; and (4) the plaintiff suffered actual damages as a consequence." *Id.* (citations omitted). However, "mere silence does not constitute fraud where it relates to facts open to common observation or discoverable by the exercise or ordinary diligence." *Id.* (citations omitted). "If a party might have learned the truth 'by ordinary vigilance and attention, it is the party's own folly if he neglected to do so, and he is remediless.'" *Id.* (quoting *Mayo Arcade Corp. v. Bonded Floors Co.*, 41 S.W.2d 1104, 1109 (Ky. 1931)).

Plaintiff sufficiently pleaded that Defendants had a duty to warn Plaintiff about the dangers of the PowerPort; failed to disclose these dangers; Plaintiff and her physician would not have used the product had they been warned; and the allegedly defective product caused Plaintiff injury. (Am. Compl. ¶¶ 107-13). Therefore, Plaintiff's fraud by omission claim survives dismissal as well.

V. CONCLUSION

For the reasons set forth herein, **IT IS HEREBY ORDERED** that Defendants' Motion to Dismiss (DN 26) is **GRANTED IN PART** and **DENIED IN PART**. Plaintiff's claim for breach of implied warranty is **DISMISSED**, but Plaintiff's remaining claims may proceed.



Greg N. Stivers, Chief Judge
United States District Court

March 4, 2021

cc: counsel of record