IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

WILLIAM WRIGHT	*	
Plaintiff,	*	
v.	*	Civil Action No. PX-1:19-3029
C.R. BARD, INC., a corporation; BARD ACCESS SYSTEMS, INC., a corporation; and DOES 1 through 10 inclusive,	*	
Defendants.	*	

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MEMORANDUM OPINION

This products liability action concerns serious injuries sustained by Plaintiff William Wright ("Wright") from Defendants' device that had been implanted to deliver necessary medications into Wright's bloodstream. Pending before the Court is Defendants' C.R. Bard, Inc., Bard Access Systems, Inc. and DOES 1 through 10 (collectively, the "Defendants") motion to dismiss. ECF No. 15. The motions are fully briefed, and no hearing is necessary. *See* Loc. R. 105.6. For the following reasons, the motion to dismiss is GRANTED in part and DENIED in part.

I. Factual Background[1]

Defendants have designed, manufactured, and sold the Bard PowerPort Implanted Port with Groshong Catheter (the "PowerPort") as one of several kinds of port and catheter systems. ECF No. 14 ¶¶ 1, 10, 16. Such systems are surgically inserted into the human body when the

[1] Wright amended his Complaint pursuant to Federal Rule of Civil Procedure 15(a)(1)(B). Accordingly, the Court construes the averred facts in the Amended Complaint as true and most favorably to Plaintiff. *See Ibarra v. United States*, 120 F.3d 472, 474 (4th Cir. 1997). The Court also denies Defendants' motion to dismiss the original Complaint as moot. ECF No. 9.

patient requires regular intravenous medication. *Id.* ¶¶ 11-12. The PowerPort consists of two components: the injection port which has a raised component where medication may be administered with a needle, and the silicone catheter which is surgically inserted into the blood vessel. *Id.* ¶¶ 13-14.

To manufacture and distribute the PowerPort, the Defendants obtained approval pursuant to Section 510(k) of the Medical Device Amendments to the Food, Drug and Cosmetic Act. *Id.* ¶ 19. Section 510(k) permits the marketing of medical devices that are substantially equivalent to other devices that have already withstood the more rigorous FDA pre-market approval process for safety and efficacy. *Id.* ¶¶ 18-20. Although approval via 510(k) may be less rigorous, Defendants are nonetheless obligated to investigate and report any adverse outcomes associated with the device. *Id.* ¶ 22.

Soon after Defendants began selling the PowerPort, and years before Wright's PowerPort was implanted, Defendants received several adverse-event reports from healthcare providers documenting that the devices were fracturing after implantation, and that the fractured pieces were traveling inside the patients' bodies. *Id.* ¶¶ 24-26. According to these reports, patients suffered severe and life-threatening injuries, including hemorrhage, heart attacks or similar symptoms, severe pain, and tearing of blood vessels and organs. *Id.*

After learning of these adverse outcomes, Defendants did not warn patients, treating physicians, or other healthcare providers about the risk of fracturing. *Id.* ¶¶ 26-31. Nor did Defendants change the design or manufacture of the device. *Id.* ¶ 33. Rather, Defendants suggested in its written warnings that fracture may occur only if the physician incorrectly implanted the device in a manner that caused it to compress or "pinch off." *Id.* ¶ 39. Defendants

at no time disclosed that such fracturing had already occurred in the absence of physician error. *Id.* ¶¶ 26-29, 31.

On September 30, 2011, Wright had the PowerPort implanted to facilitate medication administration. *Id.* ¶ 35. As a result of the PowerPort's implantation, Wright had to undergo extensive surgery to remove the fragmented, fractured catheter and has suffered physical injury and emotional distress as a result. *Id.* ¶¶ 37, 40.

Seeking compensation for the injuries he sustained, Wright filed suit in this Court bringing seven claims against Defendants: negligence (Count 1), failure to warn (Count 2), strict liability manufacturing defect (Count 3), strict liability design defect (Count 4), breach of implied and express warranties (Counts 5 and 6), and fraudulent concealment (Count 7). *Id.* at 1. Defendants challenge each count separately as insufficiently pleaded. ECF No. 15-1 at 2. As for Counts 5 and 6, Defendants also contend that the claims must be dismissed as time-barred. *Id.*

II. Standard of Review

A motion to dismiss is designed to test the sufficiency of the complaint. *Presley v. City of Charlottesville*, 464 F.3d 480, 483 (4th Cir. 2006). The Court accepts "the well-pled allegations of the complaint as true," and construes all facts and reasonable inferences most favorably to the plaintiff. *Ibarra*, 120 F.3d at 474. To survive a motion to dismiss, a complaint's factual allegations "must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations omitted).

As to the fraudulent concealment claim, Rule 9(b) of the Federal Rules of Civil Procedure applies, which requires that "the circumstances constituting fraud" be stated "with particularity." Fed. R. Civ. P. 9(b). Accordingly, a plaintiff "must, at a minimum, describe the

time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *United States ex rel. Smith v. Clark/Smoot/Russell*, 796 F.3d 424, 432 (4th Cir. 2015) (citation omitted); *see also United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008) ("the 'who, what, when, where, and how' of the alleged fraud"). Even under this heightened standard, "[a] court should hesitate to dismiss a complaint . . . if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." *Smith*, 796 F.3d at 432 (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999)).

III. Analysis

Broadly speaking, Defendants challenge the entirety of the Complaint as a boilerplate and without sufficient factual basis. The parties agree that for each of the claims, Maryland law applies. The Court will assess the sufficiency of each claim separately.

A. Negligence (Count 1)

To survive challenge, Wright must aver sufficient facts by which this Court could infer that (1) defendants owed a duty to protect the plaintiff from injury; (2) which they breached; (3) that Wright suffered actual injury; (4) and that Defendants' breach was the proximate cause of such injury. *See, e.g.*, *Horridge v. Saint Mary's Cty. Dep't of Soc. Servs.*, 382 Md. 170, 182 (2004). The Complaint sufficiently states a negligence action.

Defendants do not meaningfully challenge that they, as manufacturer-sellers of the PowerPort, owe a duty of care to the patients who use them. ECF No. 15-1 at 4-5. Rather, Defendants summarily contend that the Amended Complaint fails to aver "what, if anything, is

wrong" with the PowerPort and how such negligence was the proximate cause of Wright's injury. *Id.* Not so when reading the Amended Complaint most favorably to Wright. Wright specifically avers that the PowerPort catheter failed while in his body and through no fault of his treating physicians. ECF No. 14 at ¶¶ 37-39. Wright additionally avers that the PowerPort catheter's failure caused him to receive "unnecessary surgery" and subsequent injuries, to include "cardiac tamponade." *Id.* ¶ 37. Clearly, as pleaded, the PowerPort fracture was the proximate cause of Wright's injuries. The claim survives challenge.

B. Failure to Warn (Count 2)

Defendants next argue that the failure-to-warn count must be dismissed because the Amended Complaint does not allege the device warnings inadequately informed Wright's treating physician, and thus the claim is precluded under the learned intermediary doctrine. ECF No. 15-1 at 9-10. To sufficiently allege a failure to warn claim, a plaintiff must aver that defendant owed a duty to warn about adverse effects, breached that duty, and the breach caused plaintiff's injuries. *See, e.g.*, *Christian v. 3M*, 126 F. Supp. 2d 951, 958 (D. Md. 2001) (quoting *Higgins v. Diversey Corp.*, 998 F. Supp. 598, 604 (D. Md. 1997)). Under Maryland law, the learned intermediary doctrine limits the duty to warn of the product risks to the treating physicians. *See Miller v. Bristol-Myers Squibb Co*., 121 F. Supp. 2d 831, 838 (D. Md. 2000); *see also Doe v. Miles Laboratories, Inc*., 927 F.2d 187, 194 (4th Cir. 1991); Restatement (Third) of Torts: Products Liability § 6 cmt. a. The doctrine recognizes that the physician is the "learned intermediary" as the person who "best understands the patient's needs" and can "assess the risks and benefits of a particular course of treatment." *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 95 (D. Md. 1989), *aff'd sub nom Lee v. Baxter Health Care Corp.*, 898 F.2d 146 (4th Cir. 1990).

The Amended Complaint, construed most favorably to Wright, adequately accounts for this doctrine. Specifically, the Amended Complaint avers that Defendants failed to warn Wright's physicians of the risk of port migration and of "the true quantitative and qualitative risk of catheter migration or dislodgement." ECF No. 14 ¶¶ 41-42. The Amended Complaint further avers that Wright and his physicians relied on the recitation of risks, which omitted the risks at the heart of this claim, and that but for the failure to warn, Wright and his physicians would not have used the device. *Id.* at ¶ 68. Accordingly, this claim too survives challenge.

C. Manufacturing and Design Defects (Counts 3 and 4)

The Court next considers Counts 3 and 4 together. "A manufacturing defect claim . . . involves an examination of the conduct or procedures involved in the manufacturing and construction of the product." *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 411 (D. Md. 2001). "To recover under a strict liability theory for a manufacturing defect, a plaintiff must show that the defect in the product existed at the time it left the seller's control, that the product remained in substantially the same condition when it reached the plaintiff, and that it was unreasonably dangerous." *Koch v. Sports Health Home Care Corp.*, No. 94-1346, 1995 WL 290409, at *5 (4th Cir. May 15, 1995) (citing *Phipps v. General Motors Corp.*, 278 Md. 337, 344 (1976)). Plaintiff must show more than the defect arose because the device was manufactured not to specification. *Id.; see also Shaw v. Brown & Williamson Tobacco Corp.*, 973 F. Supp. 539, 548 (D. Md. 1997) (finding without analysis liability was not established simply because defendant placed "into the stream of commerce cigarettes that contain a manufacturing flaw."). For a design defect claim, the plaintiff must plausibly aver that the product was defective and unreasonably dangerous at the time that it left the possession or control of the seller. *Parker v. Allentown, Inc.*, 891 F. Supp. 2d 773, 791 (D. Md. 2012) (quoting *Phipps*, 278 Md. at 344).

"Thus, for a seller or manufacturer to be strictly liable for a design defect, 'the product must be both in a "defective condition,"' . . . 'and "unreasonably dangerous" at the time that it is placed on the market by the seller [or manufacturer].'" *Id.* (quoting *Phipps*, 278 Md. at 344). "Proof of one factor but not the other will defeat the plaintiff's claim." *Koch*, 1995 WL 290409, at *4 (quoting *Ziegler v. Kawasaki Heavy Indus., Ltd.*, 74 Md. App. 613, 619–20 (1988)).

At this juncture, Wright has failed to aver sufficient facts to survive dismissal as to either claim. For the manufacturing defect, the Complaint merely alleges that the PowerPort "did not have the specified material content, strength, size, durability," as well as "surface damage, pitting, *or* cracking" of the catheter increased the risk of fracture. ECF No. 14 ¶ 73. The design defect claim includes even fewer details. The Amended Complaint states only the PowerPort is itself susceptible to material fatigue because of unexplained flex fatigue and chemical degradation, and as such, the device was "unreasonably dangerous." *Id.* ¶¶ 39, 58. Generalized claims of design and manufacture defect without articulating, even on a basic level, what the design and manufacture defect is, cannot proceed. *See Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 743 (D. Md. 2015); *see also Koch*, 1995 WL 290409, at *4. Defendants' motion on these counts is granted.

The Court recognizes, however, that discovery may aid Wright in obtaining relevant facts about the design and manufacture of the PowerPort that could fortify the claims. The Court will therefore dismiss the claims without prejudice but grant leave to amend for cause if properly supported to render the cause of action plausible.

D. Fraudulent Concealment (Count 7)

Defendants next contend that Wright has failed to plead his fraud count to satisfy the heightened pleading requirements articulated in Rule 9(b) of the Federal Rules of Civil Procedure. Fed. R. Civ. P. 9(b). Allegations of fraud must be pleaded with particularity as to

defendants' knowing concealment of information that led to Wright's injuries. *See Doll v. Ford Motor Co.*, 814 F. Supp. 2d 526, 537 (D. Md. 2011) (citing *Lloyd v. General Motors Corp.*, 397 Md. 108, 138 (2007)) (elements of fraudulent concealment). Notably, this heightened pleading standard may be "less strictly applied with respect to claims of fraud by concealment or omission of material facts, as opposed to affirmative misrepresentations, because an omission cannot be described in terms of the time, place, and contents of the misrepresentation or the identity of the person making the misrepresentation." *Howes v. Wells Fargo Bank, N.A.*, No. ELH-14-2814, 2015 WL 5836924, at *22 (D. Md. Sep. 30, 2015) (quoting *Shaw*, 973 F. Supp. at 552).

With this standard in mind, the Court concludes that Wright has pleaded sufficient facts to survive challenge. Quite specifically, the Amended Complaint avers that the Defendants' withheld the adverse outcome reports that it had received when the PowerPort was first introduced on the market. ECF No. 14 ¶¶ 26-31. The Amended Complaint further avers that the reports included the kinds of injuries that Wright suffered, and that such information was withheld with the specific intent to deceive, that is, to induce Wright to use the PowerPort when he otherwise would not had he known of its defects. ECF No. 22 at 13. At this stage, the claim proceeds.

E. Breach of Implied and Express Warranty (Counts 5 and 6)

As to these claims, Defendants principally contend the warranty claims must be dismissed as time-barred. ECF No. 9-1 at 13. In Maryland, "[a]n action for breach of any contract for sale must be commenced within four years after the cause of action has accrued." Md. Code. Ann., Comm. Law § 2–725(1). "[T]he general rule is that a breach of warranty occurs when tender of delivery is made, and an action for breach of that warranty must be filed within four years after that event, even if the buyer is unaware of the breach." *Joswick v. Chesapeake Mobile Homes,*

Inc., 362 Md. 261, 267 (2001). In the medical device context, delivery is made when the device is surgically implanted. *See, e.g.*, *Miller*, 121 F. Supp. 2d at 838–39.

It is undisputed that the PowerPort was implanted in Wright on September 30, 2011, and suit followed eight years' later. Thus, the claim on its face appears time-barred. However, Wright counters that Defendants' fraudulent concealment of the device's known defects prevents this Court from crediting the affirmative defense at this stage. ECF No. 22 at 10. Wright is correct. *See Doll*, 814 F. Supp. 2d at 536 (quoting Md. Code Ann., Cts. & Jud. Proc. § 5-203) (limitations tolled if "a cause of action is kept from a party by the fraud of an adverse party."). The Complaint avers plausibly that because Defendants failed to disclose the true risks of the PowerPort, Wright was likewise kept in the dark about Defendants' breach of warranty until he required medical attention from the device's failure. That discovery occurred sometime thereafter, although the Amended Complaint does not make clear exactly when the discovery occurred.[2] Accordingly, the Court cannot find on the face of the Amended Complaint that the claims are time-barred. Defendant will be free to resurrect this defense on motion for summary judgment.

Defendants next contend that if the claims are timely, they nonetheless fail because the Complaint does not plausibly aver that PowerPort was the proximate cause of his injuries. ECF No. 24 at 3. As already discussed regarding the negligence claim, the Complaint sufficiently makes plausible that the PowerPort proximately caused Wright's injuries. The motion to dismiss the warranty counts is thus denied.[3]

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[2] The original Complaint averred that Wright discovered the PowerPort's malfunction in 2018 when he required surgery to repair damage caused from the device, but curiously, the Amended Complaint omitted this detail. *Compare* ECF No. 1 at ¶ 35 *with* ECF No. 14.

[3] Defendants raise for the first time in reply that these claims should be dismissed for failure to provide "pre-suit notice" as is required under Maryland law. ECF No. 24 at 10. Plaintiffs have not yet responded to this argument and sur-replies are disfavored. Thus, the Court will not dismiss the claims on this ground. Defendant is free to raise the argument again at the summary judgment stage, if applicable.

F. Punitive Damages

Defendants lastly urge dismissal of Wright's request for punitive damages. Under Maryland common law, a plaintiff may recover punitive damages only if the defendants acted with "actual malice" defined as "evil or wrongful motive, intent to injure, knowing and deliberate wrongdoing, ill will or fraud." *Montgomery Ward v. Wilson*, 339 Md. 701, 728 n.5 (1995); *see also Heinze v. Murphy*, 180 Md. 423, 430 (1942) (state constitutional torts). Wright has averred plausibly that Defendants knew of longstanding risks posed by implanting the PowerPort device and fraudulently withheld the same from Wright and his physicians. Read most favorably to Wright, the Amended Complaint makes plausible the availability of such damages as to knowing and deliberate wrongdoing or fraud. The Court will not dismiss this prayer for relief.

IV. Conclusion

Based on the foregoing, Defendants' motion to dismiss is granted in part and denied in part. The defective design and manufacture claims (Counts 3 and 4) are dismissed without prejudice. Defendants' motion is denied as to the remaining claims.

A separate Order follows.

6/8/2020
Date

/S/
Paula Xinis
United States District Judge