IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

*

MONICA JEFFRIES,	*
	*
Plaintiff,	*
	*
V.	*
	*
BOSTON SCIENTIFIC	*
CORPORATION, ET AL,	*
	*
Defendants.	*

Case No. RWT 15-cv-3480

MEMORANDUM OPINION

On November 16, 2015, Plaintiff Monica Jeffries, proceeding *pro se*, filed this product liability action, alleging that she had been harmed by a Greenfield Inferior Vena Cava ("IVC") Filter "designed, manufactured, prepared, compounded, assembling [sic], processed, labeled, marketed, distributed, and sold by" the Defendants Boston Scientific *et al.* and Boston Scientific/Ray Elliott CEO (collectively, "BSC"). ECF No. 1. On December 2, 2015, this Court granted Plaintiff leave to proceed *in forma pauperis*. ECF No. 3. On August 10, 2016, this Court granted Defendant's Motion to Dismiss, but allowed Jeffries thirty days in which to file an Amended Complaint addressing the numerous deficiencies outlined by the Court in its memorandum opinion. ECF Nos. 21, 22.

On September 8, 2016, Jeffries filed an Amended Complaint and requested an emergency hearing. ECF No. 23. On September 26, 2016, BSC filed a Motion to Dismiss. ECF No. 25. Jeffries filed a Response in Opposition to BSC's Motion to Dismiss on October 5, 2016, ECF No. 27, and filed an additional supporting memorandum on October 11, 2016, ECF No. 28. On October 25, 2016, Jeffries filed a "Motion for Leave to File an Amended Complaint Adding Southern Maryland Hospital A.K.A. Medstar Request [sic] for Emergency Hearing to Remove Greenfield IVC Filter At Defendant Boston Scientifics Exspence [sic] As Soon As Possible Time [sic] Is of the Essence." ECF No. 32. On November 16, 2016, Jeffries filed another Motion for Leave to File an Amended Complaint [ECF Nos. 36, 37], attaching medical records that for the first time indicated that she may have been implanted with a Greenfield IVC filter manufactured by BSC [ECF No. 37 Ex. A]. In the interest of fairness to a pro se litigant, on December 21, 2016, this Court granted Jeffries leave to file a Second Amended Complaint, along with all medical records and attachments previously submitted as well as a redline version identifying any additions or deletions in accordance with Local Rule 103.6(c). ECF No. 39. On January 17, 2017, because Jeffries had not yet filed a Second Amended Complaint, BSC filed a Motion to Dismiss Plaintiff's Amended Complaint with Prejudice [ECF No. 40] for reasons stated in its previously submitted Motion to Dismiss [ECF No. 25]. On February 2, 2017, Jeffries filed an Objection to Defendant's Motion to Dismiss [ECF No. 42] and another Motion to Amend Complaint and Request to Shield Plaintiffs [sic] Medical Records from Public Eye [ECF No. 43], attaching a redline version of her Second Amended Complaint and supporting medical records. On February 15, 2017, Defendant filed a Response in Opposition to Jeffries' Motion for Leave to File Amended Complaint [ECF No. 44], arguing that her proposed Second Amended Complaint did not address the deficiencies previously identified by the Court and did not allege plausible causes of action, so amendment would be futile. The issues have been briefed, and no hearing is necessary. Local Rule 105.6.

Because this Court has already granted Jeffries leave to file a Second Amended Complaint, her Motion to Amend Complaint and Request to Shield Plaintiffs Medical Records from Public Eye [ECF No. 43] will be granted, and Defendant's pending motions to dismiss [ECF Nos. 25, 40] will be denied as moot. However, Plaintiff is proceeding *in forma pauperis*, *see* ECF No. 3, and pursuant to 28 U.S.C. § 1915(e)(2)(ii), in cases in which the plaintiff is proceeding *in forma pauperis*, the court "shall dismiss the case at any time if the court determines that. . .the action or appeal. . .fails to state a claim on which relief may be granted." Because this Court determines that Jeffries' Second Amended Complaint [ECF No. 43-2] fails to state a claim on which relief may be granted, her Second Amended Complaint will be dismissed.

BACKGROUND

The facts underlying Jeffries' claims are laid out in this Court's August 10, 2016, Memorandum Opinion. ECF No. 21. In that opinion, this Court identified a number of problems with Jeffries' original Complaint.

First, Jeffries' Complaint failed to provide a colorable, factual basis for the claim that BSC manufactured the IVC Filter that she alleged had been implanted in her. *Id.* at 4. This alone was sufficient to dismiss her Complaint. *Id* at 5.

Second, Jeffries' claim for punitive damages did nothing more than recite the "actual malice" standard, without providing any factual allegations that would demonstrate actual malice. *Id.* at 6.

Third, while the statute of limitations for products liability claims in Maryland is three years, Jeffries waited roughly *twenty years* after implementation of her device to file a Complaint. *Id.* at 6-7. She claimed that the statute of limitations should be tolled until September 2015, when she first discovered that her IVC filter had migrated and perforated her vena cava, but also asserted that BSC publicized a recall of its Greenfield IVC Filter in 2005. *Id.* at 7. She did not provide any reason why she should not have known about the dangers of the filter in 2005 when BSC publicized its recall, and thus had not adequately alleged that her claim was timely. *Id.*

In the "interest of fairness to a *pro se* litigant," this Court granted Jeffries leave to file an Amended Complaint. The Court directed Jeffries to ensure that the Amended Complaint complied with the Federal Rules of Civil Procedure and included only "short and plain statements of jurisdiction' and facts asserted in good-faith." ECF No. 21 at 8 (quoting Fed R. Civ. P. 8, 11). After Jeffries submitted documentation indicating that her filter may have been manufactured by BSC, this Court again granted leave to file a Second Amended Complaint, and directed that the Second Amended Complaint "specifically address[] the deficiencies outlined by the Court in its previous Memorandum Opinion, and adequately allege[] a plausible claim that the IVC filter is, in fact, the cause of the injuries alleged by her." ECF No. 39 at 2.

DISCUSSION

A federal district court is charged with liberally construing a complaint filed by a *pro se* litigant to allow the development of a potentially meritorious case. *Hughes v. Rowe*, 449 U.S. 5, 9 (1980). Nonetheless, liberal construction does not mean that a court can ignore a clear failure in the pleading to allege facts that set forth a claim cognizable in a federal district court. *See Weller v. Dep't of Soc. Servs.*, 901 F.2d 387, 391 (4th Cir. 1990). A district court may not rewrite a complaint in order for it to survive a motion to dismiss. *See Beaudett v. City of Hampton*, 775 F.2d 1274, 1278 (4th Cir. 1985).

A motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) tests the sufficiency of the complaint. *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999). In considering a motion to dismiss, the Court considers whether the "complaint . . . contain[s] 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 citation and quotation marks omitted). "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.* A court must construe factual allegations in the light most favorable to the plaintiff. *See Lambeth v. Bd. of Comm'rs of Davidson Cnty.*, 407 F.3d 266, 268 (4th Cir. 2005). Nevertheless, a court is not required to accept as true "a legal conclusion couched as a factual allegation," *Papasan v. Allain*, 478 U.S. 265, 286 (1986), or "allegations that are merely conclusory, unwarranted deductions of fact or unreasonable inferences." *Veney v. Wyche*, 293 F.3d 726, 730 (4th Cir. 2002) (internal quotation marks omitted). Put simply, a complaint must "raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

I. Jeffries Stated a Plausible Claim that Her IVC Filter Is Affiliated with BSC.

BSC does not appear to dispute that BSC is the manufacturer of the Greenfield IVC Filter device. *See* ECF No. 30 at 6 n. 5 ("BSC has not argued that it was not the manufacturer of the BSC Greenfield IVC Filter device in its Motion to Dismiss. Instead, BSC argues that Plaintiff has not pled facts demonstrating that she identified her IVC Filter as a BSC Greenfield IVC Filter device, as opposed to another manufacturer's IVC Filter device.").

Jeffries has now provided some evidence that she was implanted with a Greenfield IVC filter device. A record from a September 30, 2016 visit to Dr. Brian Holly at Johns Hopkins Medicine indicates that she "had an IVC filter placed in 1999" and that "[b]ased on CT imaging appearance, this appear[s] to be a Greenfield filter." ECF No. 43 Ex. 8 at 1.

II. Jeffries Failed to Adequately Allege that Her IVC Filter Has Caused Her Injuries.

While Jeffries' new evidence does help to cure the defect in her previous complaints that there was no indication her IVC filter was manufactured by BSC, it is also fatal to the rest of her claims because it shows that the IVC filter has not plausibly caused her alleged injuries. Indeed, the assessment from Dr. Holly states that her "IVC filter is in place." ECF No. 43 Ex. 8 at 2. It also states that "IVC filter struts often protrude outside the lumen," and that it "is unlikely that the filter is responsible for her pain or anemia, which may be secondary to her multiple abdominal surgeries." ECF No. 43 Ex. 8 at 6. The assessment further states that "she would not likely benefit from. . .removal of the filter," and that "removing this non-retrievable, 17 year old filter would be challenging and high risk and would likely provide little to no benefit." *Id.* Dr. Holly wrote that Jeffries was "reassured that the filter is very likely scarred in place and is at extremely low risk for migration or fracture." *Id.* Similarly, a report from Radio Imaging Associates after an October 10, 2012 examination states that her "IVC filter is noted in place." ECF No. 43 Ex. 10.

Because Jeffries has provided records from her own doctor that her IVC filter is not the cause of her alleged injuries, she has not alleged factual matter that states a claim to relief that is plausible on its face. In other words, she has not "raise[d] a right to relief above the speculative level." *Twombly*, 550 U.S. at 555.

III. Jeffries Failed to Explain Why Her Products Liability Claims Are Not Barred by the Statute of Limitations.

Apart from the fatal omission of facts plausibly alleging that Jeffries' IVC filter caused her injury—and her submission of additional evidence indicating otherwise—Jeffries has still failed to explain why her product liability claims are not barred by the statute of limitations. In its original Memorandum Opinion, this Court explained that Jeffries' Complaint did not adequately address why her claims were not barred by the statute of limitations, given that Jeffries herself alleges that BSC publicized a recall of the Greenfield IVC Filter in 2005. ECF No. 21 at 6-7. "[A]pplication of the discovery rule in a product liability action requires that the statute of limitations should not begin to run until the plaintiff knows *or through the exercise of due diligence should know* of injury, its probable cause, and either manufacturer wrongdoing or product defect." *Pennwalt Corp. v. Nasios*, 550 A.2d 1155, 1165 (Md. 1988) (emphasis added). A plaintiff is on "inquiry notice," and the statute of limitations begins to run, "when the plaintiff has 'knowledge of circumstances which would cause a reasonable person in the position of the plaintiff[] to undertake an investigation which, if pursued with reasonable diligence, would have led to knowledge of the alleged [tort]." *Id.* at 1163 (quoting *O'Hara v. Kovens*, 503 A.2d 1313, 1324 (Md. 1986)).

Jeffries argues that the alleged perforation of her vena cava was not confirmed until November 2015, and so it was "not until 2015 that Plaintiff then discovered that Boston Scientific may have had a recall on the same filter implanted in her person" in 1995. She goes on to allege that she "had no other reason prior to 2015 when the perforation was discovered to do any research." ECF No. 43-2 at 13. But this is plainly contradicted by her assertions throughout the proposed Second Amended Complaint and prior filings that she "knew something was wrong during the lifetime of the IVC filter." Id. (emphasis added); see also id. at 12 ("[A]lthough Jeffries has experienced a number of health issues since the inception of the implantation, the perforation of the Vena Cava was confirmed sometime in 2014, after Jeffries continued to suffer stomach and chest pains and continues to do so each and every day."); ECF No. 28 at 7 ("this matter stems over a course of 20 years and counting"); id. at 10 ("Plaintiffs [sic] admission that there were health issues from the inception of the implantation only confirms that; plaintiff [sic] was very knowledgeable of her medical issues, as they were ongoing."). And as BSC points out, the "discovery rule is premised on the discovery of the harm, even if the aggrieved party may not be aware of the extent of the harm." Dual Inc. v. Lockheed Martin Corp., 857 A.2d 1095, 1104 (Md. 2004) (emphasis added); see also Brown v. Neuberger, Quinn, Gielen, Rubin & Gibber P.A., 731 F. Supp. 2d 443, 449 (D. Md. 2010), aff'd,

495 Fed. App'x 350 (4th Cir. 2012) (same); *Jacobson v. Sweeney*, 82 F. Supp. 2d 458, 463 (D. Md. 2000) (concluding that "Maryland courts have not adopted the maturation of harm rule" and that a "legal wrong must have been sustained to trigger the statute of limitations, but a precise amount of damages need not be known at that time."). The fact that the alleged perforation was not confirmed until 2015 is not sufficient to toll the statute of limitations until that time, when Jeffries, by her own admission, concedes that she had experienced problems with her IVC Filter *from the time of its implantation*. She was therefore on "inquiry notice" of her alleged claim no later than when BSC recalled the Greenfield IVC Filter in 2005.

IV. Jeffries' Allegations Do Not State Claims Upon Which Relief Can Be Granted.

Even apart from the fatal deficiencies described above, Jeffries' Second Amended Complaint must still be dismissed because she has failed to allege facts that would entitle her to relief on each of her claims. While the precise counts of her Second Amended Complaint are difficult to discern, the Court will address each of her claims below.

A. Strict Products Liability: Design Defect and Manufacturing Defect

Jeffries first brought strict liability claims alleging design and manufacturing defects. ECF No. 43-2 at 8. In order to recover under a theory of strict liability, the plaintiff must allege and prove "(1) [that] the product was in a defective condition at the time it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause of the injuries, and (4) that the product was expected to and did reach the consumer without substantial change in its condition." *Owens-Illinois, Inc. v. Zenobia,* 601 A.2d 633, 639 (Md. 1992) (quoting RESTATEMENT (SECOND) OF TORTS § 402(A)). In support of her product liability claims, Jeffries alleges only that her filter was "not properly manufactured to withstand normal, foreseeable, and intended use for the care and treatment of

deep vein thrombosis." ECF No. 43-2 at 6 ¶ 17. She also claims that when the device allegedly left BSC's control, it was "in a condition that was unsafe, unreasonably dangerous, and defective in that it was defectively manufactured or re-manufactured with inadequate, insufficient, and improper warnings as required by law." ECF No. 43-2 at 8 ¶ 21. In a past filing, she identified two primary defects: that the filter was "equipped with hooks on the end of each strut that now have perforated the plaintiff's vena cava," and that the filter was "unreasonably dangerous for plaintiffs [sic] use, since it has been left in plaintiffs [sic] person over twenty years, as the device was not designed to remain a permanent vessel in the plaintiff." ECF No. 28 at 19-20.

The mere allegation that Jeffries' IVC Filter perforated her vena cava is insufficient to push her claim that the device was defective "across the line from conceivable to plausible." *See Twombly*, 550 U.S. at 570. "[P]roof of a defect must arise above surmise, conjecture or speculation; and one's right to recovery may not rest on any presumption from the happening of an accident. . .The bare fact that an accident happens to a product. . .is usually not sufficient proof that it was in any way defective." *Virgil v. Kash N' Karry Serv. Corp.*, 484 A.2d 652, 657 (Md. Ct. Spec. App. 1984) (internal citations and quotation marks omitted). The allegation—contradicted by her own evidence—that the device caused injury to her is insufficient to support a claim that the product was defectively designed or manufactured, and Jeffries has alleged no facts to demonstrate the ways in which the product was defective.

B. Breach of Warranty

Plaintiff alleges that BSC breached an express and implied warranty that the Greenfield IVC filter was safe for use as a treatment for pulmonary embolism. ECF No. 43-2 at 7. To support a claim of breach of implied warranty of merchantability, a plaintiff must establish "that a warranty existed, that the warranty was breached, and that the breach was the proximate cause

of the injury." *Virgil*, 484 A.2d at 655 (citing *Mattos, Inc. v. Hash*, 368 A.2d 993 (Md. 1977)). As with a strict liability or negligence claim, "to recover on a claim for breach of implied warranty of merchantability. . .a plaintiff must prove the existence of a defect at the time the product leaves the manufacturer." *Grinage v. Mylan Pharmaceuticals, Inc.*, 840 F. Supp. 2d 862, 871 (D. Md. 2011) (citing *Ford Motor Co. v. General Acc. Ins. Co.*, 779 A.2d 362, 369-70 (Md. 2001)). Jeffries has provided only a conclusory allegation that her IVC Filter was "not safe and fit for ordinary and foreseeable. . .use as treatment for pulmonary embolism," in violation of express and implied warranties. ECF No. 43-2 at 7-8. She has not alleged any facts that would demonstrate that her device suffered from a design or manufacturing defect when it left the manufacturer. To the contrary, her medical records indicate that the filter is functioning as intended. Therefore, her breach of implied warranty of merchantability claim must fail.

C. Failure to Warn: Negligence and Strict Liability

Jeffries brings both strict liability and negligence claims based on BSC's alleged failure to warn her of the dangers of the Greenfield IVC Filter. ECF No. 43-2 at 7-8. She claims that BSC was negligent in "failing to give adequate warnings to purchasers and users of the Greenfield Filter, including Plaintiff, about its use and the risks associated with its use." *Id.* at 9. These failure to warn claims, however, suffer from the same fatal flaw: even assuming that BSC was the manufacturer of the device Jeffries received, BSC had no duty to provide Jeffries with any warnings about its safety or potential side effects.

Under the "learned intermediary" doctrine, "the manufacturer of medical devices. . .has no duty to warn the patient of the risks associated with products used under the supervision of a doctor." *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831, 838 (D. Md. 2000); *see also Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 95 (D. Md. 1989), *aff'd*, 898 F.2d 146 (4th Cir. 1990) (holding that "manufacturer of medical devices. . . had no duty to warn the plaintiff directly of the risks associated" with the device). Because Jeffries received her IVC Filter under the supervision of a doctor, BSC had no duty to warn her of the device's alleged dangers, and she has provided only conclusory allegations that BSC's warnings to her doctors were insufficient without describing any of the warnings or their alleged deficiencies. Therefore, Jeffries' failure to warn claims must be dismissed.

D. Gross Negligence

Under Maryland law, to state a claim for gross negligence, a plaintiff "must allege a duty of care, a breach of that duty, and damages as a proximate cause of the breach." *Pasternak & Fidis, P.C. v. Recall Total Info. Mgmt., Inc.*, 95 F. Supp. 3d 886, 895 (D. Md. 2015). "Additionally, the plaintiff must allege that the defendant intentionally failed to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another, or thoughtlessly disregarded the consequences of its breach of duty without the exertion of any effort to avoid them." *Id.* As with her other claims, Jeffries has not alleged facts that would show any breach of any duty of care, let alone facts that would show that BSC acted in reckless disregard of the consequences as affecting the life or property of another. Her gross negligence claim must be dismissed.

E. Punitive Damages

Jeffries' punitive damages claim likewise fails. "In a non-intentional tort action, the trier of facts may not award punitive damages unless the plaintiff has established that the defendant's conduct was characterized by evil motive, intent to injure, ill will, or fraud, *i.e.*, 'actual malice.'" *Owens-Illinois, Inc.*, 601 A.2d at 652. "[I]n order for actual malice to be found in a products liability case, regardless of whether the cause of action for compensatory damages is based on negligence or strict liability, the plaintiff must [allege and] prove (1) actual knowledge of the defect on the part of the defendant, and (2) the defendant's conscious or deliberate disregard of the foreseeable harm resulting from the defect." *Id.* at 653. Negligence alone will not suffice. *ACandS, Inc. v. Godwin,* 667 A.2d 116, 128 (Md. 1995).

Jeffries essentially claims that BSC is liable for punitive damages because it never notified her of any defects with the product. But she does not allege any facts that demonstrate that BSC had actual knowledge of the alleged defect when it was implanted, or that BSC consciously and deliberately disregarded the foreseeable harm resulting from any alleged defect. Jeffries has not sufficiently amended her Complaint with facts showing that she is entitled to punitive damages, so this claim must be dismissed.

V. "Catastrophic/Perhaps Eventual Death"

Jeffries seems to be bringing a claim on behalf of her family members "should [she] not survive resolution of this matter in a timely manner should she succumb to death due to the 'Greenfield Filter' and its implementation." ECF No. 43-2 at 10. Plaintiff lacks standing to bring a preemptive claim on behalf of her family members for her own future alleged wrongful death.

VI. Conclusion

For the foregoing reasons, Defendants' two pending Motions to Dismiss [ECF Nos. 25, 40] shall be denied as moot. Plaintiff's Motion to Amend Complaint and Request to Shield

Plaintiffs Medical Records from Public Eye [ECF No. 43] shall be granted. Plaintiff's Second Amended Complaint [ECF No. 43-2] shall be dismissed. A separate Order follows.

Date: June 20, 2017

/s/ ROGER W. TITUS UNITED STATES DISTRICT JUDGE