UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

RENEE ANNETTE RICHARDS, individually, and as executrix of the ESTATE OF ROBERT E. RICHARDS, deceased,

5:17-cv-00178 (BKS/ATB)

Plaintiff,

v.

JOHNSON & JOHNSON, INC., CORDIS CORPORATION, and DOES 1–100,

Defendants.

APPEARANCES:

For Plaintiff:
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For Defendant Cordis Corporation:
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Hon. Brenda K. Sannes, United States District Judge:

MEMORANDUM-DECISION AND ORDER

I. INTRODUCTION

Plaintiff Renee Annette Richards brings this action individually and as the executrix of the estate of her late husband, Robert E. Richards, alleging that his death was caused by a defective medical device designed, manufactured, and sold by Johnson & Johnson, Inc. ("J&J"),

Cordis Corporation ("Cordis"), and one hundred unidentified Doe defendants.[1] (*See generally* Dkt. No. 28). Cordis has moved to dismiss the First Amended Complaint (the "Amended Complaint") and dismiss or strike Plaintiff's request for punitive damages. (Dkt. No. 35). In its March 30, 2018 Memorandum-Decision and Order (the "March Decision"), the Court denied Cordis' motion with leave to renew so as to allow the parties to clarify Plaintiff's representative status—a threshold issue going to Plaintiff's capacity to sue and status as a real party in interest. (*See* Dkt. No. 54, at 26–27). Plaintiff subsequently proffered letters testamentary proving that she is the personal representative of her late husband's estate; accordingly, Cordis renewed its motion. (*See* Dkt. No. 58). For the reasons discussed below, Cordis' motion is granted in part and denied in part.

II. BACKGROUND

The Court assumes the parties' familiarity with the March Decision, (Dkt. No. 54), which contains a full recitation of the factual allegations in the Amended Complaint. On February 3, 2015, a doctor at the Upstate University Hospital in Syracuse, New York, implanted a Cordis TrapEase® inferior vena cava ("IVC") filter in Mr. Richards. (Dkt. No. 28, ¶ 25). Approximately two weeks later, on February 18, 2015, Mr. Richards started complaining of chest pains, with symptoms including nausea, vomiting, coughing, difficulty breathing, weakness, and dizziness. (*Id.* ¶ 26). Mr. Richards and his daughter departed to see his general physician, but Mr. Richards became unresponsive while still in the car. (*Id.*). He was rerouted to the emergency department at Upstate University Hospital, where he was placed on advanced cardiac life support. (*Id.*). Mr. Richards was unable to be revived and he died on February 18, 2015. (*Id.* ¶ 27). The autopsy revealed that the TrapEase filter had migrated to the right ventricle of his heart. (*Id.*).

[1] On March 30, 2018, the Court dismissed Confluent Medical Technologies, Inc. as a defendant for lack of personal jurisdiction. (*See* Dkt. No. 54, at 27).

Following her husband's death, Plaintiff filed this action, asserting ten survival claims: (i) design defect; (ii) failure to warn; (iii) manufacturing defect; (iv) negligence; (v) negligent misrepresentation; (vi) fraudulent misrepresentation; (vii) fraudulent concealment; (viii) breach of express warranty; (ix) breach of implied warranty; and (x) violations of sections 349 and 350 of the New York General Business Law.[2] (Dkt. No. 28, ¶¶ 84–202). Cordis moves, under Rule 12(b)(6) of the Federal Rules of Civil Procedure, to dismiss these claims as insufficiently pled. (*See* Dkt. No. 35-1, at 14).

III. STANDARD OF REVIEW

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must provide 'enough facts to state a claim to relief that is plausible on its face.'" *Mayor & City Council of Balt. v. Citigroup, Inc.*, 709 F.3d 129, 135 (2d Cir. 2013) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The plaintiff must provide factual allegations sufficient "to raise a right to relief above the speculative level." *Id*. (quoting *Bell*, 550 U.S. at 555). The Court must accept as true all factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor. *See EEOC v. Port Auth.*, 768 F.3d 247, 253 (2d Cir. 2014) (citing *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007)). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

IV. DISCUSSION

A. Group Pleading

Cordis contends, as an initial matter, that the Amended Complaint improperly "lumps its allegations against an infinite number of defendants and fails to distinguish the conduct

[2] Plaintiff also asserts a loss-of-consortium claim (Count XI) and a wrong death claim (Count XII). However, Cordis only seeks to dismiss Counts I through X as insufficiently pleaded. (*See* Dkt. No. 35-1, at 14).

attributed to each individual defendant," in violation of Rule 8 of the Federal Rules of Civil Procedure. (*Id.* at 14–15). As Cordis notes, (*id.* at 14), the Amended Complaint differentiates between the various Defendants only in the section identifying the parties, (*see* Dkt. No. 28, ¶¶ 8–23), whereas the allegations concerning allegedly actionable conduct refer to "Defendants" collectively without distinguishing each Defendant's particular role, (*see id.* ¶¶ 42–210). Rule 8(a)(2) requires that a complaint contain only "a short and plain statement of the claim showing that the pleader is entitled to relief." It suffices for such a statement to simply "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Wynder v. McMahon*, 360 F.3d 73, 77 (2d Cir. 2004) (quoting *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 512 (2002)); *see also Howard v. Mun. Credit Union*, No. 05-cv-7488, 2008 WL 782760, at *12, 2008 U.S. Dist. LEXIS 124085, at *40 (S.D.N.Y. Mar. 25, 2008) ("While Rule 8 does not prohibit collective allegations against multiple defendants, it does require that the allegations be sufficient to put each [d]efendant on notice of what they allegedly did or did not do." (alteration in original) (internal quotation marks and citation omitted)). Fair notice is "that which will enable the adverse party to answer and prepare for trial, allow the application of res judicata, and identify the nature of the case so that it may be assigned the proper form of trial." *Id.* at 79 (quoting *Simmons v. Abruzzo*, 49 F.3d 83, 86 (2d Cir. 1995)). To determine whether Cordis received fair notice of Plaintiff's claims against it, the Court will examine its objections to group pleading in the course of discussing the legal sufficiency of the Amended Complaint's various claims below.

B. Strict Products Liability

"A strict products liability claim arises against a manufacturer, a retailer, or a commercial lessor of a product if (1) the product is defective, and (2) the defect caused plaintiff's injury." *Lewis v. Abbott Labs.*, No. 08-cv-7480, 2009 WL 2231701, at *4, 2009 U.S. Dist. LEXIS

131328, at *8 (S.D.N.Y. July 24, 2009). There are three types of product defects that are actionable under New York law: "(1) a manufacturing defect, which results when a mistake in manufacturing renders a product that is ordinarily safe dangerous so that it causes harm; (2) a warning defect, which occurs when the inadequacy or failure to warn of a reasonably foreseeable risk accompanying a product causes harm; and (3) a design defect, which results when the product as designed is unreasonably dangerous for its intended use." *McCarthy v. Olin Corp.*, 119 F.3d 148, 154–55 (2d Cir. 1997) (citations omitted). Plaintiff asserts, and Cordis moves to dismiss, all three types of strict products liability claims in the Amended Complaint.

1. Design Defect Claim (Count I)

A "defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use; that is one whose utility does not outweigh the danger inherent in its introduction into the stream of commerce." *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 107 (1983) (quoting *Robinson v. Reed-Prentice Div. of Package Mach. Co.*, 49 N.Y.2d 471, 479 (1980)). This standard, which balances a product design's social and individual utility against the risk of harm associated with such design, taking into account the availability and feasibility of safer designs, is known as the "risk-utility" test. *See Maxwell v. Howmedica Osteonics Corp.*, 713 F. Supp. 2d 84, 91 (N.D.N.Y. 2010); *Robinson*, 49 N.Y.2d at 479 ("Since no product may be completely accident proof, the ultimate question in determining whether an article is defectively designed involves a balancing of the likelihood of harm against the burden of taking precaution against that harm."). Ultimately, to prevail on a design defect claim, Plaintiff must show that: "(1) the product, as designed, posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." *Maxwell*, 713 F. Supp. 2d at 90. To survive dismissal, the complaint must

contain plausible, nonconclusory facts from which the Court may infer that the product, as designed, was unreasonably dangerous for its intended use and caused the plaintiff's injury. *See Parillo v. Stryker Corp.*, No. 15-cv-155, 2015 WL 12748006, at *6, 2015 U.S. Dist. LEXIS 191834, at *9 (N.D.N.Y. Sept. 29, 2015) (quoting *Twombly*, 550 U.S. at 555).

Cordis contends that all the Amended Complaint offers is the "bare allegation that the device did not work" as intended, and that Plaintiff has failed to adequately allege a design defect. (Dkt. No. 35-1, at 15–16). In its view, Plaintiff's allegation that the actual design of the device did not ensure that the IVC filter would remain in place in the inferior vena cava is insufficient because "plaintiff does not articulate or identify any particular issue with the IVC filter's design which could have this result." (*Id.* at 16–17). "At best," Cordis adds, "plaintiff refers generally to product design features, or potential consequences of product failure—most of which do not relate to the failure mode (migration) she alleges in the decedent's device." (*Id.* at 17 (citation omitted)). Cordis also charges that the Amended Complaint is "devoid of any support for the conclusory assertion that an alternative, safer design was possible." (*Id.*).

The Court does not share Cordis' view of Plaintiff's allegations. According to the Amended Complaint, an autopsy revealed that the TrapEase filter was discovered in the right ventricle of Mr. Richards' heart, a fact which supports the allegation that Mr. Richards died as a result of the migration of the device from his inferior vena cava to his heart. (*See* Dkt. No. 28, ¶ 27). After detailing the specific configuration of the TrapEase filter's anchoring mechanism, Plaintiff posits that Cordis' filters were "designed in such way that when exposed to expected and reasonably foreseeable in-vivo conditions the devices [would] . . . migrate" and that the filters' anchoring mechanism was "insufficient to prevent tilting and migration post-placement." (*Id.* ¶¶ 47, 50, 52; *see also id.* ¶ 91 (alleging that the TrapEase filter is designed with, inter alia,

"[i]nsufficient strength or structural integrity to withstand normal placement within the human body"). In support of this assertion, Plaintiff states that "studies have also revealed that these devices [i.e., Cordis' IVC filters] suffer common failure modes such as migration." (*Id.* ¶ 40). Although the Amended Complaint does not detail whether the studies involved TrapEase filters in particular,[3] these allegations are sufficient for to plausibly allege a design defect.

Plaintiff alleges that "safer alternative designs were commercially, technologically, and scientifically attainable and feasible." (*Id.* ¶ 89). The Amended Complaint states that IVC filters "have been on the market for decades," that there are "several different designs," and that the TrapEase filter poses a higher risk of failure for, inter alia, migration than other similar IVC filters. (*Id.* ¶¶ 29, 34, 98; *see also id.* ¶ 60 (alleging that Cordis IVC filters have higher failure rates than other available filters)). The allegations are sufficient to put Cordis on notice of the nature of Plaintiff's claim and to clear the plausibility hurdle.[4] *See, e.g.*, *Cowan v. Costco Wholesale Corp.*, No. 15-cv-05552, 2017 WL 59080, at *3, 2017 U.S. Dist. LEXIS 1714, at *6–8 (E.D.N.Y. Jan. 5, 2017); *Sullivan v. Aventis, Inc.*, No. 14-cv-2939, 2015 WL 4879112, at *7, 2015 U.S. Dist. LEXIS 107360, at *24–25 (S.D.N.Y. Aug. 13, 2015); *Parillo v. Stryker Corp.*, No. 15-cv-155, 2015 WL 12748006, at *6, 2015 U.S. Dist. LEXIS 191834, at *12 (N.D.N.Y.

[3] The Court did not consider Plaintiff's allegations concerning migration risk for the OptEase filter, (*see, e.g.*, Dkt. No. 28, ¶ 59), given that Mr. Richards was implanted with a TrapEase filter, which allegedly has a different anchoring mechanism than the OptEase filter, (*see id.* ¶ 49).

[4] The Court notes that Plaintiff has argued that she does not need to allege a specific defect under the circumstantial theory of products liability. (Dkt. No. 43, at 16). *See Speller ex rel. Miller v. Sears, Roebuck & Co.*, 100 N.Y.2d 38, 41 (2003) ("New York has long recognized the viability of this circumstantial approach in products liability cases. . . . In order to proceed in the absence of evidence identifying a specific flaw, a plaintiff must prove that the product did not perform as intended and exclude all other causes for the product's failure that are not attributable to defendants."). As described below, Plaintiff has sufficiently alleged a product defect under this circumstantial theory. *See infra* pp. 12-13.

Sept. 29, 2015); *Ohuche v. Merck & Co.*, No. 11-cv-2385, 2011 WL 2682133, at *2, 2011 U.S. Dist. LEXIS 73904, at *9 (S.D.N.Y. July 7, 2011).[5]

Nor does Plaintiff's group pleading vitiate the design defect claim as against Cordis. Although the design defect allegations refer to "Defendants" as a group of undifferentiated persons, the allegations clearly relate to filters "designed" by Cordis. (*See id.* ¶ 11). Cordis, therefore, cannot be said to have lacked fair notice of allegations that the design of its TrapEase filters made them unreasonably dangerous for their intended use. Accordingly, the Court denies the motion to dismiss the design defect claim (Count I) against Cordis.

2. Warning Defect Claim (Count II)

"A manufacturer has a duty to warn against latent dangers resulting from foreseeable uses of its product of which it knew or should have known." *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 (1998). Cordis moves to dismiss the warning defect claim, arguing that the Amended Complaint fails to identify "the content of any allegedly deficient warning, nor alleges how those warnings were not adequate." (Dkt. No. 35-1, at 18). Further, Cordis contends that the claim is plagued by "a fundamental causal defect" because the only alleged medical study that would have placed Cordis on notice of problems with the IVC filters postdate the February 2015 implantation of the TrapEase filter into Mr. Richards. (*Id.* at 19–20). In response, Plaintiff quotes

[5] Cordis cites several district court cases to argue that Plaintiff's allegations are conclusory. (*See* Dkt. No. 35-1, at 15–16). Unlike the pleadings in those cases, however, the Amended Complaint here identifies a plausible design defect (insufficient anchoring mechanism and structural integrity) as the cause of Plaintiff's injury (migration of the IVC filter to the heart) and states that lower-risk designs for IVC filters exist in the marketplace. It appears that the cases relied on by Cordis lacked even those basic allegations. *See Goldin v. Smith & Nephew, Inc.*, No. 12-cv-9217, 2013 WL 1759575, at *4, 2013 U.S. Dist. LEXIS 58811, at *11 (S.D.N.Y. Apr. 24, 2013) (finding that the plaintiff did not "identify any particular problem in the design of the product or identify an alternative design" for the constrained liner used in her hip replacement); *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012) ("[E]schewing the opportunity to plead facts identifying [the product's] design defect, the [plaintiffs] merely plead the legal conclusion that [the product] was defective."); *Am. Guar & Liab. Ins. Co. v. Cirrus Design Corp.*, No. 09-cv-8357, 2010 WL 5480775, at *3, 2010 U.S. Dist. LEXIS 137527, at *8 (S.D.N.Y. Dec. 30, 2010) ("In their Amended Complaint, Plaintiffs do not specify a particular design defect, nor do they make any mention of a feasible alternative design."); *Lewis*, 2009 WL 2231701, at *4, 2009 U.S. Dist. LEXIS 131328, at *10–11 ("[P]laintiff has not alleged that it was feasible for Abbott Laboratories to design Depakote in a safer manner.").

paragraphs 98 and 100 of the Amended Complaint for the proposition that "[n]othing in the packaging or device information discusses the risk of filter migration, the risk of migration to the heart, or death." (Dkt. No. 43, at 21). Plaintiff also appears to argue that the source of Cordis' knowledge of the TrapEase defects is not limited to the study mentioned in the Amended Complaint. (*See id.* at 22 ("This is the Defendant's product and it is alleged that the defendant received adverse event reports.")).

Plaintiff has adequately alleged a deficient warning. The Amended Complaint alleges that the "warnings and directions Defendants provides with its TrapEase filters, including the device implanted in Plaintiff, failed to adequately warn of the above-described risks and side effects," including "as to existence of the risk." (Dkt. No. 28, ¶ 100). One such risk allegedly posed by TrapEase filters was "migration" of the device. (*Id.* ¶ 98). Contrary to Cordis' contention, the Amended Complaint identifies the absence of a warning regarding the risk of device migration. Cordis' citations are inapposite because, in those cases, the plaintiffs failed to identify what information was supposedly missing from the defendants' warnings. *See Parillo*, 2015 WL 12748006, at *7, 2015 U.S. Dist. LEXIS 191834, at *15 ("Plaintiff fails to state a plausible failure to warn claim because he does not allege any facts whatsoever as to the what the warning was, or how it was inadequate."); *Goldin*, 2013 WL 1759575, at *5, 2013 U.S. Dist. LEXIS 58811, at *11–12 ("Plaintiff does not identify the allegedly defective warnings, nor does she allege facts in support of her claim that these warnings were, in fact, defective."); *Reed*, 839 F. Supp. 2d at 575 ("[P]laintiffs plead nothing about the content of Lybrel's warnings. This is likely because, as defendants note by reference to the FDA's website, Lybrel's FDA-approved warning labels warn of the very injuries plaintiffs have pled.").

The Court is likewise unpersuaded by Cordis' argument about the supposed insufficiency of Plaintiff's allegations concerning the risks of which Cordis knew or should have known. The Amended Complaint states that the "TrapEase filters had potential risks and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at, and after the manufacture, distribution, and sale of the devices implanted in Plaintiffs." (Dkt. No. 28, ¶ 97). More specifically, Plaintiff alleges that "Defendants knew or should have known at the time they distributed the devices implanted in Plaintiffs that the TrapEase filters posed a significant and higher risk of failure than other similar IVC filters, including for . . . migration." (*Id.* ¶ 98). These allegations do not stand in a vacuum. As discussed above, the Amended Complaint describes the configuration of the TrapEase filters' allegedly insufficient anchoring mechanism and the "reasonably foreseeable in-vivo conditions" to which the filters are exposed. (*See id.* ¶¶ 47, 50, 52). Given the filters' placement in the human body and the need to anchor them to vein walls, it seems plausible that one type of risks that Cordis should have known about was the risk that the filters would migrate to the heart. At this early stage of the litigation, plausibility is all that is required. *See Twombly*, 550 U.S. at 570. If Cordis' argument is that Plaintiff had to allege Cordis' actual knowledge of the migration risk through preexisting medical studies or other reports, that argument fails because it suffices that Cordis should have known of the risk; here, the Amended Complaint sufficiently alleges that the migration risk was foreseeable. *See In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig.*, 725 F.3d 65, 123 (2d Cir. 2013) ("The duty to warn extends 'to third persons exposed to a foreseeable and unreasonable risk of harm by the failure to warn.'" (quoting *McLaughlin v. Mine Safety Appliances Co.*, 11 N.Y.2d 62, 68–69 (1962))). Moreover, since Cordis allegedly designed, manufactured, and distributed the filters, (*see* Dkt. No. 28, ¶ 11), the allegations that

"Defendants" should have known about the migration risk clearly gave Cordis fair notice of the warning defect claim against it, despite Plaintiff's group pleading. Therefore, the Court denies Cordis' motion to dismiss the warning defect claim (Count II).

3. Manufacturing Defect Claim (Count III)

"To state a claim for manufacturing defect . . . the plaintiff must allege that (1) the product was defective due to an error in the manufacturing process and (2) the defect was the proximate cause of plaintiff's injury." *Williamson v. Stryker Corp.*, No. 12-cv-7083, 2013 WL 3833081, at *4, 2013 U.S. Dist. LEXIS 104445, at *10 (S.D.N.Y. July 23, 2013); *see also Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001) (explaining, in a decision denying summary judgment on a manufacturing defect claim, that a strict liability claim for manufacturing defect requires a showing that a product was "defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,'" that the defect rendered the product "not reasonably safe," and that "the defect was the cause of plaintiff's injury." (quoting *Caprara v. Chrysler Corp.*, 52 N.Y.2d 114, 129 (1981) (Jasen, Jones, Meyer, JJ., dissenting))). "In other words, a manufacturing flaw exists when the unit in question deviates in quality and other performance standards from all of the other identical units." *Colon*, 199 F. Supp. 2d at 85. Identifying a specific manufacturing defect, however, is not always required: "it is well-settled that a plaintiff may rely upon the circumstances of an accident to prove the existence of a manufacturing defect if the product did not perform as intended and the possibility of other causes has been excluded." *Williamson*, 2013 WL 3833081, at *5, 2013 U.S. Dist. LEXIS 104445, at *11–12.

Cordis argues that the Amended Complaint's manufacturing defect claim rests on "conclusory and conjectural allegations that defendants must have maintained certain 'design and manufacturing specifications' and that Cordis' IVC filters did not conform to these

specifications." (Dkt. No. 35-1, at 21). According to Cordis, the Amended Complaint contains "no facts about what these hypothetical specifications might be, how the decedent's particular device failed to meet these specifications, or how an alleged failure was connected to the decedent's injury." (*Id.*).

The Court finds that Plaintiff has alleged sufficient facts to state a manufacturing defect claim. Plaintiff maintains that "the manufacturing process employed by Defendants . . . resulted in surface damage to the wire and weakening of the structural integrity of Defendants' IVC filters, thus increasing the risk of . . . migration." (Dkt. No. 28, ¶ 110). Plaintiff further alleges that the "degrees of surface damage present" in Mr. Richards' IVC filter "was above the acceptable level as set by Defendants' design and manufacturing specifications." (*Id.* ¶ 111). Plaintiff is not required to pin down what may have gone wrong in the manufacturing process to maintain a manufacturing defect claim if the circumstances indicate that the device did not function as intended and other possible causes for the malfunction are excluded.[6] First, Plaintiff has alleged that Cordis' TrapEase filter did not perform as intended. Mr. Richards was implanted with a TrapEase filter in his inferior vena cava. (*See* Dkt. No. 28, ¶ 25). The filter was "designed to remain in place once implanted in the inferior vena cava." (*Id.* ¶ 90). Yet the device migrated to and was found in his heart upon his death. (*Id.* ¶ 27). Second, while the Amended Complaint does not explicitly rule out other causes for the migration of the device, it states that the filter was implanted on February 3, 2015, that Plaintiff and the health care providers used the device "in a manner that was reasonably foreseeable to Defendants," and that on February 18, 2015, approximately two weeks after it had been implanted, Mr. Richards "began complaining of chest

[6] *Ortiz v. Allergan, Inc.*, No. 14-cv-8188, 2015 WL 5178402, at *3–4, 2015 U.S. Dist. LEXIS 118543, at *9–12 (S.D.N.Y. Sept. 4, 2015), on which Cordis relies, does not address the "circumstantial approach in products liability cases" recognized by the New York Court of Appeals in *Speller*, 100 N.Y.2d at 41. Plaintiff's allegations suffice under that approach to avoid dismissal.

pains" and died the same day. (*Id.* ¶¶ 25–26, 92). Drawing all reasonable inferences in Plaintiff's favor, these factual allegations allow a conclusion that the migration of the TrapEase filter was not caused by anything that Mr. Richards, the implanting surgeon, or emergency room medical personnel did. Thus, the Amended Complaint sufficiently alleges that the TrapEase filter suffered from a manufacturing defect. *See Williamson*, 2013 WL 3833081, at *5, 2013 WL 104445, at *13–14 (denying motion to dismiss manufacturing defect claim where the plaintiffs alleged that a knee device did not perform as intended and where it could reasonably be inferred that "nothing [the patient] or her physician did caused the knee devices to break," and further noting that "at this early stage in the litigation, prior to discovery, Plaintiffs do not have all the facts to eliminate all other plausible causes of the breakages"); *Miccio v. Conagra Foods, Inc.*, 224 F. Supp. 3d 200, 206 (W.D.N.Y. 2016) (finding that, at the pleading stage, "it is sufficient that Plaintiff has alleged that the canister exploded, and that nothing Plaintiff did caused the explosion"). Lastly, as discussed above in relation to the design defect claim, the allegations support an inference that the migration of the TrapEase filter caused Mr. Richards' death. (*Id.*).

With respect to the manufacturing defect claim, Cordis' objection to group pleading fails for the same reasons as those discussed above in connection with the design defect and warning defect claims. The Amended Complaint alleges that Cordis "manufactured, prepared, compounded, assembled, [and] processed" the TrapEase filters implanted in patients in the United States. (Dkt. No. 28, ¶ 11). Cordis thus received fair notice that the conduct allegations concerning any manufacturing defect were directed at Cordis, even if those allegations refer to "Defendants" collectively. Accordingly, the Court denies the motion to dismiss the manufacturing defect claim (Count III) against Cordis.

C. Negligence Claim (Count IV)

Aside from strict products liability, a plaintiff may allege that a product is defective under a negligence theory of recovery. The following elements must be pled: (1) "the manufacturer owed plaintiff a duty to exercise reasonable care"; (2) the manufacturer breached "that duty by fail[ing] to use reasonable care so that a product is rendered defective, *i.e.* reasonably certain to be dangerous"; (3) "the defect was the proximate cause of the plaintiff's injury"; and (4) the plaintiff sustained "loss or damage." *Colon*, 199 F. Supp. 2d at 82. These elements are "not markedly dissimilar" from the requirement for strict products liability in New York.[7] *See McCarthy*, 119 F.3d at 170 (Calabresi, J., dissenting) (explaining that the "primary difference between the two causes of action is that a plaintiff may recover in strict products liability without showing that the defendant's *conduct* was wrongful, so long as its *product* was defective").

Based on the view that strict products liability claims have the "same," "identical," or "virtually identical" elements as those of a negligence claim, Cordis does not advance separate arguments for dismissing the negligence claim. (*See* Dkt. No. 35-1, at 15 n.3, 18 n.5, 20 n.8). The Court has already concluded that design defect, warning defect, and manufacturing defect are sufficiently pled under a strict liability theory. Further, "[w]here liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent," *Martin v. Hacker*, 83 N.Y.2d 1, 8 n.1 (1993); therefore, the warning defect claim can proceed on a negligence theory without further analysis. As for the design and manufacturing defect claims, they can proceed on a negligence theory as long as the Amended Complaint contains allegations that Cordis' conduct was wrongful—i.e., Cordis failed to use reasonable care in designing or

[7] The Court notes that, even where the theory of recovery is negligence, products liability cases may be proved by circumstantial evidence that the product did not perform as intended and by excluding other possible causes of the accident. *See Jarvis v. Ford Motor Co.*, 283 F.3d 33, 45 (2d Cir. 2002); *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 125 (2d Cir. 2006), *aff'd*, 552 U.S. 312 (2008).

manufacturing the TrapEase filter.[8] *See Nelson v. Ranger, Inc.*, No. 05-cv-93, 2009 WL 3851622, at *5, 2009 U.S. Dist. LEXIS 107014, at *17 (N.D.N.Y. Nov. 17, 2009) ("Where the plaintiff claims negligence under a design defect theory, the focus shifts from the characteristics of the product itself to the conduct of the manufacturer; plaintiff must additionally prove that the manufacturer could have foreseen the injury and, therefore, acted unreasonably in designing the product." (quoting *Mustafa v. Halkin Tool, Ltd.*, No. 00-cv-4851, 2007 WL 959704, at *10, 2007 U.S. Dist. LEXIS 23096, at *35–36 (E.D.N.Y. Mar. 29, 2007))); *Pahuta v. Massey-Ferguson, Inc.*, 942 F. Supp. 161, 165 (W.D.N.Y. 1996) (stating that, under New York negligence law, "a manufacturer has a duty to use reasonable care in designing its product").

Plaintiff alleges that the injury at issue in this case was caused by the migration of the implanted TrapEase filter from Mr. Richards' inferior vena cava to the right ventricle of his heart. As discussed above, Plaintiff has sufficiently pled that the migration risk was foreseeable and that Cordis acted unreasonably in designing and manufacturing filters presenting such migration risk. (*See, e.g.*, Dkt. No. 28, ¶¶ 40, 50–57, 90–91, 110–112). Further, the allegations concerning negligent conduct, though referring to "Defendants" collectively, concern Cordis' role as the designer and manufacturer of the filters, thus giving it fair notice of the claim. The Court concludes that the negligence claim against Cordis (Count IV) survives dismissal.

[8] As the Second Circuit has observed, "[n]either this Court nor the New York Court of Appeals has squarely endorsed" the proposition that negligence and strict products liability claims are the same for design defect claims. *See Jarvis*, 283 F.3d at 63 (noting the "unsettled nature of the law in this area" and "stat[ing] no opinion" in that regard). Nevertheless, the *Jarvis* court acknowledged dicta in *Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 257 (1995), indicating that the analysis was similar under both theories of liability. *See Jarvis*, 283 F.3d at 63; *Denny*, 87 N.Y.2d at 257 ("The adoption of this risk/utility balance as a component of the 'defectiveness' element has brought the inquiry in design defect cases closer to that used in traditional negligence cases, where the reasonableness of an actor's conduct is considered in light of a number of situational and policy-driven factors.").

D. Fraud-Based Claims (Counts V, VI, and VII)

Cordis seeks to dismiss Plaintiff's negligent misrepresentation claim (Count V), fraudulent misrepresentation claim (Count VI), and fraudulent concealment claim (Count VII) on the ground that the Amended Complaint has not pled those claims with particularity, as required by Rule 9(b) of the Federal Rules of Civil Procedure. (Dkt. No. 35-1, at 23–27). In relevant part, the rule provides that "[i]n alleging fraud . . . a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Pleading fraud with particularity means specifying the "who, what, when, where, and how" of the fraud. *Papworth v. Steel Hector & Davis*, No. 06-cv-1237, 2007 WL 2903944, at *8, 2007 U.S. Dist. LEXIS 72864, at *24 (N.D.N.Y. Sept. 30, 2007). It "requires that the plaintiff (1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." *Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 187 (2d Cir. 2004) (internal quotation marks omitted). That heightened pleading requirement applies to misrepresentation claims, whether the misrepresentation is negligent or intentional,[9] as well as to fraudulent concealment claims. *See Nissan Motor Acceptance Corp. v. Dealmaker Nissan, LLC*, No. 09-cv-0196, 2011 WL 94169, at *2, 2011 U.S. Dist. LEXIS 2627, at *8 (N.D.N.Y. Jan. 11, 2011) ("Just as with intentional misrepresentation, negligent misrepresentation must be pled with particularity." (quoting *B & M Linen, Corp. v. Kannegiesser, USA, Corp.*, 679 F. Supp. 2d 474, 484 (S.D.N.Y. 2010))); *Zap v. Mortg. Elec. Registration Sys., Inc.*, No. 15-cv-624, 2016

[9] Although the Second Circuit has not decided whether Rule 9(b) applies to negligent representation claims, *see Eternity*, 375 F.3d at 188, courts in this Circuit have applied the Rule 9(b) heightened pleading standards. *See Directv, LLC v. Wright*, No. 15-cv-474, 2016 WL 3181170, at *9, 2016 U.S. Dist. LEXIS, at *27 (W.D.N.Y. June 3, 2016) ("[S]ince negligent misrepresentation is a type of fraud, a party pleading negligent misrepresentation is once again subject to a heightened pleading standard under Federal Rule of Civil Procedure 9(b)."); *BNP Paribas Mortg. Corp. v. Bank of Am., N.A.*, 949 F.Supp.2d 486, 508 (S.D.N.Y. 2013) (collecting district court cases that apply Rule 9(b) to negligent misrepresentation claims).

WL 6471229, at *6, 2016 U.S. Dist. LEXIS 150988, at *17 (N.D.N.Y. Nov. 1, 2016) (stating that a fraudulent concealment claim must be pled with particularity).

Cordis contends that the Amended Complaint fails the particularity requirement because it "lump[s] multiple defendants together" and "fails to distinguish which conduct is attributed to which defendants in purportedly misleading" Plaintiff "regarding the safety and efficacy of Cordis' IVC filters." (Dkt. No. 35-1, at 23–24). Additionally, Cordis argues that "Plaintiff does not allege, specifically or otherwise, who made any purported misrepresentations, when those representations were made, how the representations were communicated, and who specifically received those representations." (*Id.* at 24–25). Lastly, Cordis maintains that the Amended Complaint does not allege the requisite reliance and, with regard to fraudulent misrepresentation and concealment, the requisite fraudulent intent. (*Id.* at 26–27).

While the Amended Complaint arguably specifies the relevant statements or omissions that are alleged to be fraudulent,[10] it does not specify who made such statements or omitted the requisite information. (*Compare, e.g.*, Dkt. No. 28, ¶ 139 (attributing the negligent representations to "Defendants"), *and id.* ¶ 141 (ascribing the representations to "Cordis, J&J, Confluent, and DOES 1 through 100"), *with id.* (stating that the source of the information was "Cordis and/or J&J")). Even more nebulous than the negligent representation claim are the fraudulent misrepresentation and concealment claims, which refer to "Defendants" collectively without specifying who said what. (*See id.* ¶¶ 156–175). Additionally, the Amended Complaint is vague about when such representations or omissions took place. (*See, e.g.*, *id.* ¶ 139 (alleging the representations were made "[p]rior to, on, and after the date the devices were implanted in Plaintiffs, and at all relevant times")). Because these allegations are insufficiently specific to

[10] Some of the alleged statements and omissions do not relate to the harm suffered by Mr. Richards and are therefore irrelevant. (*See* Dkt. No. 28, ¶¶ 139, 158, 170).

state fraud-based claims, the Court grants Cordis' motion to dismiss the negligent misrepresentation claim (Count V), fraudulent misrepresentation claim (Count VI), and fraudulent concealment claim (Count VII), with leave to amend.[11]

E. Warranty Claims (Counts VIII and IX)

Cordis moves to dismiss the express and implied warranty claims for lack of presuit notice of a breach, the express warranty claim for Plaintiff's failure to identify the terms of the warranty, and the implied warranty claim for Plaintiff's failure to allege a product defect. (Dkt. No. 35-1, at 27–30). Plaintiff responds that presuit notice was not required, that the Amended Complaint "makes clear references to what the express warranties are," and that she clearly "indicates why this product is not fit for its ordinary purpose." (Dkt. No. 43, at 28–30).

To recover on a warranty claim under New York law, a plaintiff "must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." N.Y. U.C.C. § 2-607(3). The Amended Complaint, however, does not allege that Plaintiff notified Cordis of a breach "within a reasonable time" of discovering it. Plaintiff contends that "notice is typically reserved for consumer purchase cases under the UCC," (Dkt. No. 43, at 28), but cites no authority in support. Likewise, she cites no case law to support the proposition that the notice requirement does not apply to "goods intended for use in the human body." (*Id.* at 28–29). Further, even if section 2-607(3) of the New York Uniform Commercial Code ("UCC") only requires notice to the seller, Plaintiff does not allege

[11] Given its disposition of those claims, the Court does not reach the question of whether Plaintiff sufficiently alleged reliance and fraudulent intent. *See Beasley v. Indy Mac Bank*, No. 16-cv-4629, 2018 WL 1611667, at *10, 2018 U.S. Dist. LEXIS 31883, at *28 (E.D.N.Y. Feb. 26, 2018) (declining to decide the sufficient of reliance allegations where the plaintiff had failed to plead fraud claims with particularity), *report and recommendation adopted*, 2018 WL 1611382, 2018 U.S. Dist. LEXIS 56841 (Mar. 31, 2018).

that she notified the seller of the TrapEase device[12]—for that matter, she does not allege that the seller is some person other than Cordis.[13] Plaintiff's failure to notify Cordis is cause for dismissal of the express and implied warranty claims, with leave to amend. *See Tomasino v. Estee Lauder Companies Inc.*, 44 F. Supp. 3d 251, 260 (E.D.N.Y. 2014); *Tyman v. Pfizer, Inc.*, No. 16-cv-6941, 2017 WL 6988936, at *23, 2017 U.S. Dist. LEXIS 212879, at *60 (S.D.N.Y. Dec. 27, 2017) (recommending dismissal of warranty claims, without prejudice, because of the plaintiffs' failure to allege pre-suit notice), *report and recommendation adopted*, 2018 WL 481890, 2018 U.S. Dist. LEXIS 8222 (Jan. 18, 2018); *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 544 (S.D.N.Y. 2013) (same).

F. Consumer Fraud Claims (Count X)

Sections 349 and 350 of the New York General Business Law make unlawful any deceptive acts, practices, and false advertising "in the conduct of any business, trade or commerce or in the furnishing of any service." N.Y. Gen. Bus. Law § 349 (deceptive acts and practices); *id.* § 350 (false advertising). Consumers harmed by violations of these provisions have a private right of action created by statute. *See id.* § 349(h) (private right of action for violations of section 349); *id.* § 350-e(3) (private right of action for violations of section 350). "A plaintiff under section 349 must prove three elements: first, that the challenged act or practice was consumer-oriented; second, that it was misleading in a material way; and third, that the plaintiff suffered injury as a result of the deceptive act." *Stutman v. Chem. Bank*, 95 N.Y.2d 24, 29 (2000). Section 350 has the same elements but, unlike section 349, it requires reliance on the allegedly false advertisement. *See Andre Strishak & Associates, P.C. v. Hewlett Packard Co.*,

[12] To the extent Plaintiff asserts that the "adverse event reports" provided notice, (Dkt. No. 43, at 28 n.14), the Court observes again that the only adverse event reports alleged in the Amended Complaint relate to the OptEase filters, not the TrapEase filters at issue in this case. Therefore, even assuming that adverse event reports are legally sufficient to provide notice, the allegations are unavailing.

[13] The Amended Complaint alleges that Cordis "sold the TrapEase" filters. (*See* Dkt. No. 28).

300 A.D.2d 608, 609 (2d Dep't 2002) (stating that, under section 350, a "a plaintiff must demonstrate that the advertisement (1) had an impact on consumers at large, (2) was deceptive or misleading in a material way, and (3) resulted in injury," and dismissing the section 350 claim because "plaintiffs failed to show that they relied upon or were aware of the allegedly false advertisement"); *accord Pelman ex rel. Pelman v. McDonald's Corp.*, 396 F.3d 508, 511 (2d Cir. 2005) ("Unlike a private action brought under § 350, a private action brought under § 349 does not require proof of actual reliance."). For a claim under section 350, a plaintiff must point to a specific advertisement or public pronouncement upon which she relied. *Henson v. Wright Medical Technology, Inc.*, No. 12-cv-805, 2013 WL 1296388 at *4, 2013 U.S. Dist. LEXIS 44295, at *11 (N.D.N.Y. Mar. 28, 2013).

Cordis seeks dismissal of consumer fraud claims under sections 349 and 350 on the ground that Plaintiff has not alleged any facts in support of actionable consumer-oriented conduct, material misrepresentations likely to mislead a reasonable consumer, or causation. (Dkt. No. 35-1, at 31–32). Cordis asserts that the Plaintiff relies on conclusory, generalized allegations that are insufficient to state a plausible claim. Additionally, Cordis argues that Plaintiff has not identified a specific advertisement on which she or Mr. Richards relied. (*Id.* at 32).[14] The Court agrees. The allegations refer to "Defendants" and fail to plausibly allege consumer-oriented conduct engaged in by Cordis. *Cf. Williamson v. Stryker Corp.*, No. 12-cv-7083, 2013 WL 3833081, at *14, 2013 U.S. Dist. LEXIS 104445, at *35–36 (S.D.N.Y. July 23, 2013) (finding

[14] Cordis cites *Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 173 (W.D.N.Y. 2014), where the court dismissed a section 349 claim against prescription drug manufacturers on the ground that, "because a drug manufacturer's duty to warn of a drug's side effects runs to the doctor prescribing the drug, and not to the user of the drug, the issuance of drug warnings . . . is not a 'consumer-oriented act' actionable under Section 349." But as the court in *Williamson* explained in the context of considering representations made on a website, the "standard for establishing consumer-oriented conduct is very liberal, and where a defendant deals with a plaintiff in the same way as it would deal with any other customer, such conduct is considered 'consumer-oriented.'" *See* 2013 WL 3833081, at *14, 2013 U.S. Dist. LEXIS 104445, at *35–36 (citing *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 85 N.Y.2d 20, 24–25 (N.Y. 1995)). The crux of the inquiry is whether the defendant's "acts or practices have a broader impact on consumers at large." *Oswego Laborers*, 85 N.Y.2d at 25.

allegations for claims under sections 349 and 350 sufficient where defendants made representations about knee device on their website "directed and available to the public at large through the Internet"). And the Amended Complaint fails to identify a specific advertisement by Cordis underlying her section 350 claim. The consumer fraud claims under section 349 and 350 (Count X) are therefore dismissed with leave to amend.

G. Punitive Damages

Finally, Cordis asks the Court to strike or dismiss Plaintiff's request for punitive damages under Rule 12(b)(6) and Rule 12(f). (Dkt. No. 35-1, at 11, 32–33). In her opposition, Plaintiff argues that the alleged conduct—"that Cordis developed this product without sufficient testing, that they concealed and misrepresented the risks"—is "sufficient for the request to strike punitive damages to be denied at this time." (Dkt. No. 43, at 32–33).

Under New York law,

> punitive or exemplary damages may be awarded where the defendant's conduct amounts to such gross, wanton or willful fraud, dishonesty, or malicious wrongdoing as to involve a high degree of moral culpability, making it appropriate to deter the defendants from engaging in similar conduct in the future and to induce the victim to take action against the wrongdoer.

Whitney v. Citibank, N.A., 782 F.2d 1106, 1118 (2d Cir. 1986). As the Court has determined that Plaintiff's design defect and manufacturing claims can proceed based on allegations that the TrapEase filter is unreasonably dangerous, the Amended Complaint has sufficiently alleged moral culpability for the punitive damages request to survive dismissal at the pleading stage. *See James v. Lan-O-Tone Prod., Inc.*, No. 88-cv-7716, 1989 WL 61852, at *4, 1989 U.S. Dist. LEXIS 6333, at *10–11 (S.D.N.Y. June 7, 1989) (denying motion to strike punitive damages in a negligence and strict products liability case whether the "plaintiff has alleged that the lotion

contained an excessive amount of formaldehyde which allegedly causes harm to the public"). Accordingly, the Court denies Cordis' motion to dismiss the request for punitive damages.

V. CONCLUSION

For these reasons, it is hereby

ORDERED that Cordis' motion to dismiss the First Amended Complaint (Dkt. No. 28) and dismiss or strike Plaintiff's request for punitive damages (Dkt. No. 35) is **GRANTED in part** and **DENIED in part**; and it is further

ORDERED that the negligent misrepresentation claim (Count V), the fraudulent misrepresentation claim (Count VI), the fraudulent concealment claim (Count VII), the express warranty claim (Count VIII), the implied warranty claim (Count IX), and the consumer fraud claims (Count X) are **DISMISSED without prejudice**; and it is further

ORDERED that Cordis' motion to dismiss (Dkt. No. 35) is otherwise **DENIED**; and it is further

ORDERED that Plaintiff **may file an amended complaint within THIRTY (30) days** of the date of this Order, in accordance with the conclusions stated above.

IT IS SO ORDERED.

Dated: June 12, 2018
Syracuse, New York

Brenda K. Sannes
U.S. District Judge