UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

CELESTINE GORDON,	:	Case No. 1:19-cv-121
Plaintiff,	:	Judge Timothy S. Black
vs.	:	
B. BRAUN MEDICAL INC., *et al.*,	:	
Defendants.	:	

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS (Docs. 10, 11)

This civil case is before the Court on Defendants B. Braun Medical Inc. ("Braun Medical") and B. Braun Interventional Systems Inc. ("Braun Interventional")'s motion to dismiss (Docs. 10, 11) and the parties' responsive memoranda (Docs. 15, 19).

I. BACKGROUND

For purposes of Defendants' motions to dismiss, the Court must: (1) view the complaint in the light most favorable to Plaintiff, and (2) take all well-pleaded factual allegations as true. *Bickerstaff v. Lucarelli*, 830 F.3d 388, 396 (6th Cir. 2016).

Plaintiff Celestine Gordon brings this action against Defendants Braun Medical and Braun Interventional after experiencing complications from a medical device allegedly designed, manufactured, and sold by the Defendants. The device, called the "B. Braun VenaTech™ vena cava filter" ("Braun filter"), is a metal, cone-shaped filter that is inserted into the inferior vena cava vein ("IVC") to prevent pulmonary embolism by trapping blood clots before they travel to the heart and lungs from the lower extremities.

(Doc. 7 at ¶¶ 21, 24, 29, 41). The Braun filter is designed and marketed for permanent implantation. (*Id.* at ¶¶ 29, 40). The filter is "self-centering with patented, stabilizing legs" intended to prevent the possibility of tilting, perforation of the vena cava wall, or migration. (*Id.* at ¶¶ 29, 30).

Plaintiff had the Braun filter implanted in April 2014 for the treatment of medical issues related to blood clots. (*Id.* at ¶¶ 59, 60). After experiencing pain in the area the filter was implanted, Plaintiff received a scan that showed that the distal tip of her Braun filter had "moved into a position where it was slightly inferior to the left renal vein." (*Id.* at ¶¶ 66, 67).

The complaint points to several "MAUDE Adverse Event Reports" related to the Braun filter, including a 2013 report indicating that a patient underwent surgery to remove the filter after it became embedded in the patient's right ventricle, and a 2007 report noting an occurrence of defective filter "arms" that were bent, causing malalignment. (*Id.* at ¶¶ 45, 47). A third report indicated the legs of the filter did not properly deploy and became stuck, with a fourth report stating that the filter had migrated to the patient's heart, requiring surgical explant. (*Id.* at ¶¶ 46, 48). Plaintiff further points to a 2010 FDA warning concerning risks associated with leaving IVC filters implanted for extended periods of time, as well as two other FDA alerts regarding risks from both permanent and retrievable/temporary filters. (*Id.* at ¶¶ 49, 50, 51). A 2014 warning "began affirmatively urging doctors to remove IVC filters, especially retrievable filters, within one to two months after the danger of pulmonary embolism passed in the patient." (*Id.* at ¶ 51).

Plaintiff alleges that despite these warnings, Defendants continued to market the Braun filter for long-term use. (*Id.* at ¶ 52). The complaint alleges that in "various sources," Defendants advertised the filter's "[u]nique, patented[] stabilizing legs and hooks to ensure self-centering and optimal positioning." (*Id.* at ¶ 70). According to Plaintiff, "Defendants knew their [Braun filter] was defective and knew that the defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo." (*Id.* at ¶ 71). Further, Plaintiff alleges that "Defendants failed to disclose to physicians, patients, or to the Plaintiff that their [Braun filter], was subject to breakage, [and/or] collapse, causing thombus and/or that there was a risk of damage [to] the wall of the vena cava by the device after implantation." (*Id.* at ¶ 72).

As a result of Plaintiff's permanent implantation of the Braun filter, which has tilted in its position, Plaintiff allegedly suffers "complications and [a] heightened risk of future injuries," including an increased risk of deep vein thrombosis, constant pain in the abdominal region, filter migration, filter fracture or breakage, and perforation of the vena cava vein. (*Id.* at ¶ 83). Plaintiff seeks recovery for resulting "economic damages, severe permanent injuries, emotional distress and [the] psychological trauma of living with a defective product implanted in her body." (*Id.* at ¶ 84).

Based on these allegations, Plaintiff asserts the following claims under the Ohio Product Liability Act ("OPLA"), Ohio Revised Code §§ 2307.71-80: negligence (Count 1), defective design (Count 2), manufacturing defect (Count 3), and failure to warn (Count 4). (*Id.* at 17-34). Plaintiff also asserts the common-law claims of breach of

express warranty (Count 5), breach of implied warranty of merchantability (Count 6), breach of implied warranty of fitness (Count 7), fraudulent misrepresentation (Count 8), fraudulent concealment (Count 9), and negligent misrepresentation (Count 10). (*Id.* at 34-55). Plaintiff seeks monetary damages, including punitive damages. (*Id.* at 56).

Defendants seek to dismiss the complaint on several bases. Defendants first assert that Plaintiff's common-law claims are abrogated by OPLA. Alternatively, Defendants argue that all of Plaintiff's common-law claims and OPLA claims should be dismissed as insufficiently pled. In response, Plaintiff seeks leave to amend her common-law warranty claims in order to properly assert those claims under OPLA. In addition, Plaintiff asserts that all of her claims have been pled with the requisite level of specificity under either Rule 8(a) or Rule 9(b).

II. STANDARDS OF REVIEW

A. Failure to state a claim

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) operates to test the sufficiency of the complaint and permits dismissal of a complaint for "failure to state a claim upon which relief can be granted." To show grounds for relief, Federal Rule of Civil Procedure 8(a) requires that the complaint contain a "short and plain statement of the claim showing that the pleader is entitled to relief."

While Rule 8 "does not require 'detailed factual allegations,' . . . it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)). Pleadings offering mere "'labels and conclusions' or 'a formulaic recitation of the

elements of a cause of action will not do.'" *Id.* (citing *Twombly*, 550 U.S. at 555). In fact, in determining a motion to dismiss, "courts 'are not bound to accept as true a legal conclusion couched as a factual allegation[.]'" *Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265 (1986)). Further, "[f]actual allegations must be enough to raise a right to relief above the speculative level[.]" *Id.*

Accordingly, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678. A claim is plausible where a "plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Plausibility "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief,'" and the case shall be dismissed. *Id.* (citing Fed. R. Civ. P. 8(a)(2)). The defendant has the burden of demonstrating that the plaintiff has failed to state a claim for relief. *Allen v. Anderson Windows, Inc.*, 913 F. Supp. 2d 490, 497-98 (S.D. Ohio 2012) (citing *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007)).

B. Leave to amend

Rule 15 requires that "leave to amend be freely granted when justice so requires." Fed. R. Civ. P. 15(a)(2). Moreover, the Sixth Circuit has held that "where a more carefully drafted complaint might state a claim, a plaintiff must be given at least one chance to amend the complaint before the district court dismisses the action with

prejudice." *United States ex rel. Bledsoe v. Cmty. Health Sys.*, 342 F.3d 634, 644 (6th Cir. 2003) (quoting *EEOC v. Ohio Edison Co.*, 7 F.3d 541, 546 (6th Cir. 1993)). However, denial of an amendment may be appropriate where there is "[u]ndue delay in filing, lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and futility of amendments . . . ." *Coe v. Bell*, 161 F.3d 320, 341 (6th Cir. 1998).

III. ANALYSIS

A. Ohio law

Plaintiff initiated this action in the Butler County Court of Common Pleas, and Defendants removed the case to federal court on February 15, 2019 on the basis of diversity jurisdiction under 28 U.S.C.§§ 1332, 1441. (Doc. 1). Thus, this Court applies the substantive law of the forum state—Ohio. *Henry v. Wausau Bus. Ins. Co.*, 351 F.3d 710, 713 (6th Cir. 2003) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938)).

B. Plaintiff's common-law claims

i. Abrogation by OPLA and leave to amend

Defendants first argue that Plaintiff's common-law claims should be dismissed as abrogated by the Ohio Product Liability Act ("OPLA"). (Doc. 11 at 10). These claims include Count 5 (breach of express warranty), Count 6 (breach of implied warranty of merchantability), and Count 7 (breach of implied warranty of fitness).[1] (*Id.*).

[1] Plaintiff's common-law fraud claims are addressed separately below. *See infra* at II.D.

OPLA expressly "abrogate[s] *all common law* product liability claims or causes of action." Ohio Revised Code ("R.C.") § 2307.71(B) (emphasis added); *see Wimbush v. Wyeth*, 619 F.3d 632, 639 (6th Cir. 2010). Under OPLA, a "product liability claim" is defined as:

> a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:
>
> (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing or marketing of that product;
>
> (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
>
> (c) Any failure of that product to conform to any relevant representation or warranty.

R.C. § 2307.71(A)(13). Plaintiff does not dispute that her common-law warranty claims are abrogated by OPLA, and rather, seeks to amend her complaint to properly recast those claims under the applicable provisions of OPLA. (Doc. 15 at 3-4).

Rule 15 provides that "leave to amend be freely granted when justice so requires." Fed. R. Civ. P. 15(a)(2). Defendants argue that allowing Plaintiff to amend the complaint to reassert her common-law warranty claims under OPLA would be futile, because Plaintiff "has not alleged sufficient facts concerning how the product was defective or how such defect caused Plaintiff's claimed injury." (Doc. 19 at 13). A district court may deny leave to amend when the proposed amendment would be futile—meaning the amendment could not withstand a Rule 12(b)(6) motion to dismiss. *Middleton v. Rogers*

Ltd., Inc., 804 F. Supp. 2d 632, 638 (S.D. Ohio 2011) (citing *Kottmyer v. Maas*, 436 F.3d 684, 692 (6th Cir. 2006)).

For the reasons stated below, the Court finds that permitting Plaintiff to amend her complaint to reassert her breach of express warranty claim under OPLA would not be futile. However, Plaintiff's implied warranty claims are duplicative of the design defect and manufacturing defect claims already alleged in the complaint under OPLA. Thus, Plaintiff's common-law implied warranty claims are dismissed.

ii. Breach of express warranty

Claims for breach of express warranty at common law are preempted by R.C. § 2307.77, which governs "conformance to representation" claims. *See Lefker v. I-Flow Corp.*, No. 1:10-cv-350, 2010 WL 4806771, at *4 (S.D. Ohio Nov. 17, 2010); *Cervelli v. Thompson/Center Arms*, 183 F. Supp. 2d 1032, 1045 (S.D. Ohio 2002). Section 2307.77 states as follows:

> A product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

Accordingly, a plaintiff seeking recovery on this basis must show: (1) that the manufacturer made a representation as a to a material fact concerning the character or quality of the manufacturer's product; (2) that the product did not conform to that representation; (3) that the plaintiff justifiably relied on that representation; and (4) that the plaintiff's reliance on the representation was the direct and proximate cause of the

plaintiff's injuries. *Cervelli*, 183 F. Supp. 2d at 1045 (citing *White v. DePuy, Inc.*, 718 N.E.2d 450, 459 (Ohio 1998)).

Defendants argue, generally, that Plaintiff's express warranty claim fails because the complaint does "not allege[] sufficient facts concerning how the product was defective or how such defect caused Plaintiff's claimed injury." (Doc. 19 at 13). This criticisms maps onto the second and fourth elements of a conformance to representation claim—that the product did not conform to a representation made by Defendants and that Plaintiff's reliance on the representation caused her injuries. *Cervelli*, 183 F. Supp. 2d at 1045.

Accepting the facts alleged in the complaint as true, Plaintiff has adequately pled that the Braun filter did not conform to a representation made by Defendants. Plaintiff's complaint alleges that Defendants' webpage and brochure state that the Braun filter features "[u]nique, patented stabilizing legs and hooks to ensure optimal positioning," (Doc. 7 at ¶¶ 191, 193), and that the filter meets a "Trusted Standard for Permanent Filtration." (*Id.* at ¶ 192). Elsewhere in the complaint, Plaintiff alleges that the Braun filter's "defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo," and that the Braun filter "was subject to breakage, [and/or] collapse, causing thombus" and creating "a risk of damage [to] the wall of the vena cava by the device after implantation." (*Id.* at ¶¶ 71, 72).

Plaintiff also adequately pleads reliance and causation. The complaint specifically alleges that Plaintiff and her physicians relied on Defendants' express warranties about the safety and efficacy of the Braun filter, and that had Plaintiff's physicians been

properly apprised of the risks associated with implantation of the filter, "they would not have recommended this implant device to the Plaintiff." (*Id.* at ¶¶ 198, 202). Further, the complaint asserts that "[a]s a direct and proximate result of the Defendants' breach of the express warranty, Plaintiff has suffered economic damages, severe and possibly permanent injuries, and emotional distress. Plaintiff has also endured and continues to suffer the mental anguish and psychological trauma of living with this defective product implanted in Plaintiff's body." (*Id.* at ¶ 203). As discussed above, Plaintiff specifically alleges that her Braun filter has tilted, making her more susceptible to further complications. (*Id.* at ¶¶ 67, 83).

Accordingly, Plaintiff has adequately pled the elements of a failure to conform claim under OPLA, and thus, she may amend her complaint to reassert her common-law breach of express warranty claim under OPLA as a "conformance to representation" claim.

iii. Breach of implied warranty of merchantability and breach of implied warranty of fitness

Plaintiff's implied warranty of merchantability and implied warranty of fitness claims are also abrogated by OPLA. *Hendricks v. Pharmacia Corp.*, No. 2:12-cv-613, 2014 WL 2515478, at *4, 8 (S.D. Ohio June 4, 2014). Common-law implied warranty claims are subsumed by Ohio Revised Code §§ 2307.74, 2307.75, covering manufacturing and design defect claims, respectively. *See id.*, 2014 WL 2515478, at *8 (finding implied warranty claim overlaps with manufacturing defect claim under OPLA) (citing *Luthman v. Minster Supply Co.*, No. 2-06-43, 2008 WL 169999, at *7 (Ohio Ct.

App. Jan. 22, 2008)); *see also Tompkin v. Philip Morris USA, Inc.*, 362 F.3d 882, 903 (6th Cir. 2004) (holding implied warranty claim "virtually indistinguishable" from design defect claim under OPLA); *Stratford v. SmithKline Beecham Corp.*, No. 2:07-cv-639, 2008 WL 2491965, at *7 (S.D. Ohio June 17, 2008). Here, Plaintiff has alleged both "manufacturing defect" and "design defect" claims under OPLA, separate and apart from her common-law implied warranty claims. (Doc. 7 at ¶¶ 117-157). Accordingly, the Court need not grant Plaintiff leave to reassert her implied warranty claims under OPLA, which are dismissed as abrogated by OPLA and duplicative of existing claims.

C. Plaintiff's OPLA claims

Plaintiff also asserts the following claims under OPLA: negligence (Count 1), design defect (Count 2), manufacturing defect (Count 3), and failure to warn (Count 4). Defendant argues that Plaintiff has failed to adequately plead each of these claims under Federal Rule of Civil Procedure 8(c). However, based on the analysis below, the Court finds each claim sufficiently pled.

i. Negligence

Plaintiff's first claim under OPLA alleges that Defendants were negligent in that they breached "a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of the [Braun filter], including the duty to take all reasonable steps necessary to manufacture and sell a product that was not defective or unreasonably dangerous to consumers and users of the product." (Doc. 7 at ¶ 97). Plaintiff bring this negligence claim under R.C. § 2307.78(A), which provides that:

> a supplier is subject to liability for compensatory damages based on a product liability claim only if the claimant establishes, by a preponderance of the evidence, that either of the following applies:
>
> (1) The supplier in question was negligent and that, negligence was a proximate cause of harm for which the claimant seeks to recover compensatory damages;
>
> (2) The product in question did not conform, when it left the control of the supplier in question, to a representation made by that supplier, and that representation and the failure to conform to it were a proximate cause of harm for which the claimant seeks to recover compensatory damages. A supplier is subject to liability for such a representation and the failure to conform to it even though the supplier did not act fraudulently, recklessly, or negligently in making the representation.

(emphasis added). The term "supplier" is defined under OPLA as someone who "in the course of a business conducted for the purpose, sells, distributed, leases, prepares, blends, packages, labels, or otherwise participates in the placing of a product in the stream of commerce." R.C. § 2307.71(A)(15)(a)(i). A "supplier" expressly does not include a "manufacturer," which is defined separately as "a person engaged in a business to design, formulate, produce, create, make, construct, assemble, or rebuild a product or a component of a product." R.C. §§ 2307.71(A)(9), 2307.71(15)(b)(i). A supplier may also be held derivatively liable when the manufacturer of the product is subject to liability under OPLA, and one of eight other conditions is met; for example, when "[t]he supplier in question is owned or, when it supplied that product, was owned, in whole or in part, by the manufacturer of that product." R.C. § 2307.78(B)(1)-(8); *see Becton v. Starbucks Corp.*, 491 F. Supp.2d 737, 745 (S.D. Ohio 2007).

Defendants note that Plaintiff's complaint focuses on Defendants as *manufacturers* and not as *suppliers*. (Doc. 19 at 6-7). According to Defendants, neither

Braun Interventional nor Braun Medical manufactured the Braun filter, and only Braun Interventional supplied Braun filters during the relevant time period. (*Id.*). In addition, Defendants assert that Plaintiff's labeling of Defendants as "suppliers" is conclusory. (*Id.* at 6). Finally, Defendants claim that even if the Court accepts Plaintiff's allegation that Defendants are both suppliers, Plaintiff has failed to adequately plead the elements of a negligence claim under R.C. § 2307.78(A).

Plaintiff's complaint refers to Defendants Braun Medical and Braun Interventional both as manufacturers and as suppliers of the Braun filter, including under Count 1 for negligence. (*See* Doc. 7 at ¶ 104) (alleging that Defendants "breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the [Braun filter]"). Because the definition of "supplier" under OPLA expressly excludes "manufacturers," and because R.C. § 2307.78(A) applies only to suppliers, if either Defendant turns out to be a manufacturer of the Braun filter, Plaintiff's negligence claim under R.C. § 2307.78(A) will necessarily fail. *See Frey v. Novartis Pharms. Corp.*, 642 F. Supp.2d 787, 795 (S.D. Ohio 2009) (dismissing § 2307.78 claim where the plaintiffs "unequivocally" alleged in the complaint that the defendant was the manufacturer of the drug at issue).

However, at this early stage, Plaintiff is permitted to cover her bases and plead in the alternative that Defendants are liable as suppliers of the Braun filter. *Cf. Great N. Ins. Co. v. BMW of N. Am. LLC*, 84 F. Supp.3d 630, 649 (S.D. Ohio 2015) (permitting plaintiff to simultaneously bring OPLA claims for compensatory damages and a

common-law implied warranty claim for purely economic damages based on the same set of facts); *see also Grubbs v. Sheakley Grp., Inc.*, No. 1:13-cv-246, 2014 WL 202041, at *14 (S.D. Ohio Jan. 17, 2014) ("The particular role played by each corporate entity is 'a matter to be fleshed out during discovery. . . .'") (quoting *United States v. Osborne*, No. 1:11-cv-1029, 2011 WL 7640990, at *5 (N.D. Ohio Dec. 15, 2011)). Allowing Plaintiff's claim to proceed is particularly appropriate here, where Defendants allege, albeit only in their briefing, that neither Defendant is a manufacturer of the filter, and that one of the Defendants—Braun Interventional—was in fact a supplier of the device during the relevant period. (Doc. 19 at 7).

Moreover, Plaintiff has pled the elements of a negligence claim under § 2307.78(A) with adequate specificity. In order to show that a supplier was negligent under § 2307.78(A)(1), "a plaintiff must show that the defendant owed her a duty, the defendant breached that duty, and that the injury proximately resulted from the breach." *Brentar v. Ford Motor Co.*, No. 09-cv-2685, 2010 WL 3210955, at *7 (N.D. Ohio Aug. 10, 2010) (citing *Little v. Purdue Pharma, L.P.*, 227 F. Supp.2d 838, 848-49 (S.D. Ohio 2002)); *see also Becton*, 491 F. Supp.2d at 745-46. A supplier may be liable for negligence, "if it knew or had reason to know of the product defect" and failed to warn of the defect. *Bentar*, 2010 WL 3210955, at *7 (quoting *King v. Centerpulse Orthopedics, Inc.*, No. 1:05-cv-1318, 2006 WL 456478, at *4 (N.D. Ohio Feb. 24, 2006)).

Plaintiff's complaint states that Defendants "had a duty to exercise reasonable care in the . . . sale[] and distribution" of the Braun filter. (Doc. 7 at ¶ 97). The complaint further alleges that Defendants breached their duty of care in a litany of ways, including

by "distributing a product in which [Defendants] knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose due to their permanent nature" and by "failing to disclose or warn of the dangers known to Defendants to be connected with and inherent in the use of the [Braun filter]." (*Id.* at ¶ 105). In addition, the complaint specifically references certain MAUDE Adverse Event Reports regarding the Braun filter, which allegedly gave Defendants constructive knowledge that the Braun filter was "unsafe for long-term implantation." (*Id.* at ¶¶ 99, 100). Finally, Plaintiff alleges Defendants' negligence proximately caused her injuries, stating that "[a]s a result of the breach of duty by Defendants, Plaintiff Celestine Gordon sustained serious personal injuries and suffered from . . . post implantation medical issues from the [Braun filter]." (*Id.* at ¶ 109). Accordingly, Plaintiff's claim of supplier negligence under R.C. § 2307.78(A) is plausible based on the allegations contained in the complaint.

ii. Design defect

Plaintiff has also adequately pled a design defect claim under OPLA, R.C. § 2307.75(A), which provides that "a product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation . . . ." Under this "risk-benefit theory, a court weighs the existing design's foreseeable risks against its benefits." *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 529 (6th Cir. 2012) (citing *Clay v. Ford Motor Co.*, 215 F.3d 663, 669-70 (6th Cir. 2000)). Plaintiff alleges under Count 2 for defective design that the Braun filter was

defective because it was designed for long-term use, but that it was "not effective nor safe for long-term implantation and use." (Doc. 7 at ¶¶ 120, 125, 126). The complaint also more specifically states that the defect "was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted in vivo."[2] (*Id.* at ¶ 71). This design flaw allegedly resulted in "post filter tilt, perforation of the struts of the filter, and chronic pains." (*Id.* at 128). Thus, Plaintiff alleges that the filter, reaching consumers in substantially the same condition as when it left the control of Defendants had "foreseeable risks of harm" that "exceeded the claimed benefits of the product." (*Id.* 127). Accordingly, Plaintiff has done more than recite the language of the statute, and has provided factual allegations that, when accepted as true, support a plausible design defect claim.

Defendants argue in their reply brief that the *permanent* characteristic of the Braun filter was an "inherent characteristic" of the device, which cannot constitute a "defect." (Doc. 19 at 8) (citing R.C. § 2307.75(E) ("A product is not defective in design . . . if the harm for which the claimant seeks to recover compensatory damages was caused by an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability and which is recognized by the ordinary person with the ordinary knowledge common to the community.")). However, based on the complaint, it is apparent that Plaintiff does not take issue with the permanence of the Braun filter in and of itself, but rather, with the

[2] A court may consider factual allegations contained throughout the complaint to assess the plausibility of a claim. *Cahoo v. SAS Analytics Inc.*, 912 F.3d 887, 895 n.3 (6th Cir. 2019).

filter's alleged *failure to function on a permanent basis* due to a design defect. To the extent Defendants argue that the Braun filter was able to function on a long-term basis, that argument goes to the merits of Plaintiff's claim and is not properly assessed at the motion to dismiss stage. *See Redinger v. Stryker Corp.*, No. 5:10-cv-104, 2010 WL 1995829, at *3 (N.D. Ohio May 19, 2010).

iii. Manufacturing defect

Plaintiff has similarly pled a manufacturing defect claim under OPLA with sufficient detail to survive dismissal under Rule 12(b)(6). To allege a manufacturing defect under OPLA, a plaintiff must show that when a product left the control of its manufacturer, "it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units . . . ." R.C. § 2307.74. Here, Plaintiff alleges that the Braun filter implanted in her "contained a condition or conditions which was a manufacturing defect"—more specifically alleging that Defendants manufactured the filter for long-term implantation, but that a manufacturing defect prevented it from serving that purpose. (Doc. 7 at ¶¶ 148, 149, 150).

As noted above, Plaintiff does not pinpoint exactly what defect allegedly led to her complications, namely the filter's tilt, or its inability to stay in place, which has caused her pain and emotional distress. Nevertheless, based on the facts Plaintiff has alleged in the complaint, the Court finds that the filter plausibly exhibited either a design or manufacturing defect. This can be inferred from the outcome—the filter's tilt—in combination with the adverse MAUDE reports and other reports cited by the Plaintiff.

See Redinger, 2010 WL 1995829, at *3 (finding plausible manufacturing defect claim under § 2307.74 based on the medical device's malfunction and a recall of the product, despite the fact that the recall addressed a different problem); *see also Jones v. Staübli Motor Sports Div. of Staübli Am. Corp.*, 897 F. Supp. 2d 588, 610 (S.D. Ohio 2012) (noting that a plaintiff may rely on circumstantial evidence to support a manufacturing defect claim under OPLA, such as a product's failure to function as intended). Thus, Plaintiff's manufacturing defect claim may proceed.

iv. Failure to warn

Plaintiff's final OPLA claim—failure to warn—brought under R.C. § 2307.76 is also sufficiently pled. Section 2307.76(A) provides that:

> a product is defective due to inadequate warning or instruction if either of the following applies:
>
> (1) It is defective due to inadequate warning or instruction at the time of marketing if, when it left the control of its manufacturer, both of the following applied:
>
> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.
>
> (2) It is defective due to inadequate post-marketing warning or instruction if, at a relevant time after it left the control of its manufacturer, both of the following applied:
>
> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product

> and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

Defendants argue that Plaintiff's failure to warn claim should be dismissed because it fails under the "learned intermediary doctrine" and because Plaintiff has not alleged with specificity what warnings her physician received regarding risks associated with the Braun filter or what warnings she believes would have been adequate. (Doc. 11 at 16-17).

The OPLA provision governing failure to warn claims exempts a manufacturer from liability for an inadequate warning or instruction under the so-called "learned intermediary doctrine" when:

> [the] manufacturer provides [an] otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses [an] ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

R.C. § 2307.76(C) (emphasis added); *Yanovich v. Zimmer Austin, Inc.*, 255 F. App'x 957, 970 (6th Cir. 2007) (applying doctrine to medical device).

However, Plaintiff's complaint specifically alleges that Defendants failed to adequately warn her and her health care providers of the risks associated with the Braun filter. (*See* Doc. 7 at ¶¶ 163, 166, 167, 173). Furthermore, while certain statements in

Plaintiff's complaint are vague as to what risks or side effects Defendants allegedly failed to include in their literature to physicians, taken as a whole, the complaint sufficiently alleges a failure to warn claim.

For example, Plaintiff states that Defendants' warnings set forth "general complications of the [Braun filter], but fail[] to warn and state the actual extent of potential injuries caused by the [filter]." (*Id.* at ¶ 165). While this and similar statements leave the Court wanting of additional detail, Plaintiff does specifically identify the documents Defendants allegedly provided to Plaintiff and her health care providers—a product brochure and "Instructions for Use." (*Id.* at ¶ 163). In addition, the complaint states that Defendants should have "adequately warned that their product created a risk of serious and dangerous side effects, including but not limited to, perforation, the migration of the filter to other parts of the vena cava, heart or other organs, DVT, blood clots, fracture of the filter and other complications." (*Id.* at ¶ 171). Plaintiff further alleges that the Braun filter was defective "due to inadequate post-market warnings or instructions because [ ] Defendants knew, or should have known, of the risk of serious bodily harm from the long-term use and administration of their [filter]." (*Id.* at ¶ 183). Also relevant is Plaintiff's allegation that "[t]here was no warning or instruction to the surgeon or the consumer/patient recipient of this medical device to medically monitor [ ] their device or have it removed after a certain period of time." (*Id.* at ¶ 185(b)). Thus, Plaintiff has adequately described the specific risks Defendants allegedly failed to warn of.

Moreover, the complaint adequately ties these risks to the medical issues suffered by Plaintiff as a result of her use of the Braun filter. As discussed above, the complaint

alleges that after experiencing pain, Plaintiff received a scan showing that her Braun implant had moved, such that the tip had dipped slightly below her left renal vein. (*Id.* at ¶ 67). Plaintiff also alleges that she now has an increased risk of further complications, including filter migration and perforation of the vena cava vein, and that living with the defective product in her body has caused her emotional distress. (*Id.* at ¶¶ 83, 84). Accordingly, the Court finds that Plaintiff has pled sufficient facts to support a finding that Defendants' plausibly failed to adequately warn Plaintiff and/or her physician of the risks associated with the Braun filter, which resulted in the harm for which she now seeks to recover.

D. Plaintiff's common-law fraud claims

Plaintiff also brings three common-law fraud claims: fraudulent misrepresentation (Count 8), fraudulent concealment (Count 9), and negligent misrepresentation (Count 10). (Doc. 7 at ¶¶ 227-300). Defendants argue that OPLA has abrogated all common-law fraud claims in product liability cases. OPLA covers product liability claims arising from "[a]ny warning or instruction, or lack of warning or instruction, associated with [a] product." R.C. § 2307.71(A)(13)(b). Thus, courts have found that OPLA precludes common-law fraud claims to the extent they are based on a failure to warn. *Hogue v. Pfizer, Inc.*, 893 F. Supp.2d 914, 918-19 (S.D. Ohio 2012) (citing *Stratford*, 2008 WL 2491965, at *8).

However, courts have found that common-law fraud claims based on "a general duty not to *actively deceive*," as opposed to a mere failure to warn, fall outside the scope of OPLA and may proceed. *Id.*; *see also Kelley v. Insys Therapeutics, Inc.*, No. 3:18-cv-

1774, 2019 WL 329600, at *7-8 (N.D. Ohio Jan. 25, 2019); *cf. Glassner v. R.J. Reynolds Tobacco Co.*, 223 F.3d 343, 348-49 (6th Cir. 2000). For example, in *Z.H. v. Abbott Labs, Inc.*, the court found the plaintiff's fraud claim fell outside the scope of OPLA where the defendants' representation that no causal link existed between the medication at issue and birth defects was knowingly false. No. 1:14-cv-176, 2016 WL 5661582, at *12 (N.D. Ohio Sept. 30, 2016). Similarly, in *Kelley v. Insys Therapeutics, Inc.*, the court dismissed the plaintiff's fraud claim to the extent it was based on a failure to warn, while allowing the claim to proceed to the extent that the plaintiff alleged that the defendants "engaged in fraud . . . by actively misrepresenting information about [the product's] safety." 2019 WL 329600, at *5.

Consequently, Plaintiff's *negligent* misrepresentation claim is precluded by OPLA. *See Z.H.*, 2016 WL 5661582, at *12. In addition, the Court finds Plaintiff's fraudulent concealment claim precluded by OPLA, as that claim arises out of alleged omissions (*i.e.*, a failure to warn of safety issues associated with the Braun filter), as opposed to the propagation of false information or misrepresentations. *See Hogue*, 893 F. Supp. 2d at 919 (finding fraud claims based on a theory of omission and concealment to be, in substance, failure to warn claims abrogated by OPLA).

However, Plaintiff's fraudulent misrepresentation claim is not precluded by OPLA to the extent Plaintiff alleges active misrepresentation. Plaintiff's complaint asserts that Defendants "intentionally, willfully, and knowingly, fraudulently misrepresented to the medical community, the FDA, and consumers, including Plaintiff, Celestine Gordon, and Plaintiff's health care providers, that their [Braun filter] had been adequately tested in

clinical trials and was found to be safe and effective." (Doc. 7 at ¶ 243). The complaint further states that based on Defendants' misrepresentation, Plaintiff's medical providers "believed the Defendants' device was safe for long term use." (*Id.* at ¶ 247). These allegations support a claim of fraud based on a duty to not actively deceive.

In addition, Plaintiff has adequately pled a fraudulent misrepresentation claim under the heightened pleading standard of Federal Rule of Civil Procedure 9(b). Under Rule 9(b), a party must allege "the time, place, and content of the alleged misrepresentation on which he or she relied." *United States ex rel. Bledsoe v. Cmty. Health Sys.*, 501 F.3d 493, 509 (6th Cir. 2007) (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys.*, 342 F.3d 634, 643 (6th Cir. 2003)). In other words, a plaintiff must (1) specify the allegedly fraudulent statements, (2) identify the speaker, (3) plead when and where the statements were made, and (4) explain what made the statements fraudulent. *Republic Bank & Trust Co. v. Bear Sterns & Co.*, 683 F.3d 239, 247 (6th Cir. 2012) (citing *Ind. State Dist. Council of Laborers and HOD Carriers Pension and Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935, 942-43 (6th Cir. 2009)). This heightened pleading requirement "is designed, not only to put defendants on notice of alleged misconduct, but also 'to prevent fishing expeditions . . . and to narrow potentially wide-ranging discovery to relevant matters.'" *Id.* at 254 (citing *Chesbrough v. VPA. P.C.*, 655 F.3d 461, 466 (6th Cir. 2011)).

Plaintiff identifies particular statements Defendants made with respect to the efficacy and safety of the Braun filter, including a statement on their webpage that the filter features "[u]nique, patented stabilizing legs and hooks to ensure optimal

positioning[.]" (Doc. 7 at ¶ 232). Plaintiff also identifies a statement in Defendants' brochure that the Braun filter has "Proven Safety and Efficacy in the Prevention of Pulminary Embolism, A Trusted Standard for Permanent Filtration of the Vena Cava." (*Id.* at ¶ 233) (emphasis added). These statements constitute more than a bare assertion that the product was "safe for use," and speak to Plaintiff's allegation that the stabilizing legs were in fact not able to hold the filter in place in the vena cava vein on a long-term or permanent basis. (*Id.* at ¶¶ 67, 171); *Compare*, *Liming v. Stryker Corp.*, No. 1:11-cv-788, 2012 WL 1957287, at *4 (S.D. Ohio May 31, 2012) (finding bare assertion that pain pump was "safe for use" insufficiently specific under Rule 9(b)) *with Kiker v. Smithcline Beecham Corp.*, 2015 WL 5768389, at *7 (S.D. Ohio Sept. 30, 2015) (finding Rule 9(b) requirement met based on the defendant's specific averment that the cause of rat pup deaths during clinical testing was unknown where the plaintiff alleged that the drug at issue resulted in fatal congenital heart defect).

Plaintiff also explains how Defendants' statements were fraudulent and how Plaintiff and her physicians relied on the misrepresentations. The complaint describes how Plaintiff's Braun implant has tilted in place and also references several MAUDE Adverse Event Reports concerning the filter's failure to stay in place, as well as FDA reports warning, in general, that filters should be removed after one to two months. (Doc. 7 at ¶¶ 45-52, 67). Moreover, the complaint states that based on Defendants' representations, "Plaintiff's medical providers . . . believed the Defendants' device was safe for long term use" and that Plaintiff and her physicians relied on the information in deciding to use the Braun filter. (*Id.* at ¶¶ 245-247).

Defendants allege that Plaintiff has not adequately identified the "speaker" because Plaintiff refers to the Defendants collectively. (*See* Doc. 11 at 11 n.6, 20). Courts generally frown upon "group pleading." *See Kurek v. Ohio Dep't of Dev. Disabilities*, No. 3:16cv623, 2017 WL 1555930, at *6 (N.D. Ohio Jan. 20, 2017). This is especially so under the heightened pleading requirement for fraud claims. *See In re Duramax Diesel Litig.*, 298 F. Supp. 3d 1037, 1056 (E.D. Mich. 2018) (citing *Hoover v. Langston Equip. Assoc., Inc.*, 958 F.2d 742, 745 (6th Cir. 1992)).

Plaintiff alleges that both Defendants, Braun Medical and Braun Interventional, are responsible for manufacturing and promoting the Braun filter. (Doc. 7 at ¶¶ 92-94). Because Plaintiff's claims are against two, assumedly related corporate entities with similar names, it would be redundant for Plaintiff to separately allege her claims against each Defendant in the complaint. *See In re Nat'l Prescription Opiate Litig.*, No 1:17-md-2804, 2019 WL 3737023, at *3 (N.D. Ohio June 13, 2019). Further, Rule 9's particularity requirement is to be read in conjunction with Rule 8's "policy favoring simplicity in pleading." *Id.* Plaintiff has put Braun Medical and Braun Interventional on notice of the nature of her claims and her belief that both Defendants are jointly responsible for making averments regarding the efficacy of the Braun filter on the product's website and brochure. Discovery regarding the corporate structure of the Defendants and their relationship will illuminate which Defendant is the proper party. *See Nissan N. Am., Inc. v. Cont'l Auto. Sys.*, No. 3:19-cv-396, 2019 WL 4820477, at *4 (M.D. Tenn. Oct. 1, 2019) (finding no categorical rule against group pleading and noting tendency of plaintiffs unsure of corporate structure to name several affiliated corporate

defendants collectively); *Boroff v. Alza Corp.*, 685 F. Supp. 2d 704, 708 (N.D. Ohio 2010) (rejecting argument that complaint was insufficiently pled because claims were asserted against the defendants generally where complaint alleged that the defendants were both manufacturers and distributors of the product at issue).

Further, Plaintiff has adequately pled the time and place of the fraudulent misrepresentations, with the complaint stating that the information was "conveyed to Plaintiff sometime prior to her April 11th, 2014 surgery" and that her "physicians, by way of the misrepresentations made by Defendants, confirmed the representations Plaintiff had seen regarding the [Braun filter]." (Doc. 7 at ¶¶ 247-248). The complaint also specifies that Plaintiff received the Braun filter implant at the Hospital Pavia Santurce in San Juan, Puerto Rico. (*Id.* at ¶¶ 62-63). Thus, Plaintiff has adequately pled the time, place, and manner of the alleged fraudulent misrepresentation. *See Kiker*, 2015 WL 5768389, at *6 (finding fraud claim sufficiently pled where complaint specified the location and time-frame as a particular city in Ohio between sometime in 2000 through March 2001).

E. Punitive Damages

Finally, Defendants argue that Plaintiff's request for punitive damages should be denied. Punitive damages are available under OPLA when the plaintiff can show by clear and convincing evidence that the harm she experienced "was the result of misconduct of the manufacturer or supplier in question that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question." R.C. § 2307.80(A). However, punitive damages are not available when the product "was

manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration[.]" R.C. § 2307.80(C)(1)(a).

Courts have found that requiring a plaintiff to prove fraud on the FDA in order to collect punitive damages under OPLA is impliedly preempted by federal law, as the state statute's requirement "conflict[s] with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives" *See Garcia v. Wyeth-Ayest Labs.*, 385 F.3d 961, 965 (6th Cir. 2004) (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001)); *id.* at 966 (interpreting Michigan statute that provided immunity absent a showing of fraud on the FDA and holding that, "state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims"); *Monroe v. Novartis Pharms. Corp.*, 29 F. Supp. 3d 1115, 1129-30 (S.D. Ohio 2014).

Nevertheless, punitive damages may be available under OPLA for an FDA-approved drug if the FDA itself has made a finding of fraud. *See In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, MDL No. 1909, 2013 WL 587655, at *14 (N.D. Ohio Feb. 13, 2013); *see also Garcia*, 385 F.3d at 966 (noting that the "inter-branch-meddling concerns" that drove the finding of preemption in *Buckman* do not present "when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process")

Although a plaintiff must show that the FDA has made a determination of fraud to avoid application of OPLA's exception to punitive damages under § 2307.80(C)(1)(a),

courts have permitted requests for punitive damages to survive the motion to dismiss stage when the plaintiff has pled facts to support a finding that the product did not conform to the terms of the FDA approval. *See, e.g.*, *Marcum v. Deput Orthopedics, Inc.*, No. 1:12-cv-834, 2013 WL 1867010, at *7 (S.D. Ohio May 2, 2013); *Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-cv-602, 2014 WL 2874268, at *9 (S.D. Ohio June 24, 2014).

Plaintiff's complaint acknowledges that the Braun filter was approved by the FDA under Section 510(k) of the Medical Device Amendment. (Doc. 7 at ¶¶ 32-34). Yet, the complaint also notes several subsequent FDA MAUDE Adverse Event Reports concerning the Braun filter, as well as FDA reports related to IVC filters generally, and their efficacy as a long-term solution to preventing blood clots. (*Id.* at ¶¶ 42-53). In addition, Plaintiff alleges that "[b]y failing to disclose the known dangers and risks of the [Braun filter] . . . Defendants engaged in unfair and deceptive consumer-oriented acts which intentionally, willfully, and knowingly, fraudulently misrepresented to . . . the FDA . . . that the [Braun filters] had been adequately tested in clinical trials and [were] found to be safe and effective." (*Id.* at ¶ 243).

Thus, Plaintiff has adequately pled facts to support an award of punitive damages for her OPLA claims. Based on the interpretation of R.C. § 2307.80(C)(1)(a) discussed above, Plaintiff will be required to show more for her request for punitive damages to survive a motion for summary judgment. Plaintiff is also not precluded from seeking punitive damages pursuant to her common-law fraudulent misrepresentation claim. *See Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 760, 789 (S.D. Ohio 2015).

IV. CONCLUSION

Based upon the foregoing, Defendants' motion to dismiss (Docs. 10, 11) is **GRANTED in part and DENIED in part** as follows:

1. Defendants' motion to dismiss Count 6 (breach of implied warranty of merchantability), Count 7 (breach of implied warranty of fitness), Count 9 (fraudulent concealment), and Count 10 (negligent misrepresentation) is **GRANTED**, and those claims are **DISMISSED**;

2. Defendants' motion to dismiss Count 5 (breach of express warranty) is **DENIED**;

    a. Plaintiff shall file an amended complaint reasserting Count 5 under OPLA within twenty-one (21) days of this Order; and

3. Defendants' motion to dismiss Count 1 (negligence), Count 2 (design defect), Count 3 (manufacturing defect), Count 4 (failure to warn), and Count 8 (fraudulent misrepresentation) is **DENIED**, and those claims shall proceed.

IT IS SO ORDERED.

Date: 3/27/2020

/s/ Timothy S. Black
Timothy S. Black
United States District Judge