UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

HOMER W. McCLARTY, and VICKI RIVERA, Plaintiff, vs. **C.R. BARD INC., and BARD PERIPHERAL VASCULAR, INC.,** Defendant.	**4:14-CV-13627-TGB-RSW** **ORDER DENYING IN PART AND GRANTING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

This is a products liability action regarding a medical device designed to prevent blood clots from traveling to the heart and lungs. Plaintiff Vicki Rivera[1] underwent surgery in 2006 to have an inferior

[1] The other named Plaintiff in this case is Homer W. McClarty (the "Trustee"), who is the appointed and acting Chapter 7 Trustee of Vicki Rivera's bankruptcy estate. Pl.'s Compl., ECF No. 1, PageID.2. Under the Bankruptcy Code, the bankruptcy estate includes "all legal or equitable interests of the debtor in property as of the commencement of the [bankruptcy] case." 11 U.S.C. § 541(a)(1). This includes "causes of action." *Bauer v. Com. Union Bank, Clarksville, Tenn.*, 859 F.2d 438, 441 (6th Cir. 1988) (quoting *Gochenour v. Cleveland Terminals Bldg. Co.*, 118 F.2d 89, 93 (6th Cir. 1941)). Further, because the "trustee in bankruptcy acts as a representative of the estate," the trustee is the one who has the "capacity to sue and be sued." *Bauer*, 859 F.2d at 441 (quoting 11 U.S.C. § 323(b)). The Trustee is included in the caption of this case as a Plaintiff because the injury at the center of this complaint occurred prior to the commencement of the bankruptcy case. ECF No. 1,

vena cava filter ("IVC filter") implanted. In 2011, medical professionals discovered that the IVC filter had fractured and migrated to her left lung. Plaintiff claims that the manufacturer and seller of the filter, C.R. Bard, Inc. and its affiliated company Bard Peripheral Vascular, Inc., violated products liability law. Plaintiff's complaint alleges claims of defective design, defective manufacture, failure to warn of the device's harm, breach of implied warranty, and negligent misrepresentation.

Defendants have moved for summary judgment. ECF No. 27. The motions have been fully briefed and the Court heard oral argument on August 26, 2020. For the reasons stated below, Defendant's motion for summary judgment is **DENIED** with respect to Plaintiff's defective design and breach of implied warranty claim, and **GRANTED** with regard to Plaintiff's negligent misrepresentation claim.

I. Background

C.R. Bard, Inc. ("Bard") is a developer, manufacturer, and distributor of medical technologies and devices. Bard is one of many manufacturers that creates and sells inferior vena cava filters ("IVC filters"), which are medical devices that are surgically implanted in the inferior vena cava to prevent blood clots from traveling into the lungs and heart. Def.'s Mot. Summ. J., ECF No. 27, PageID.3134. The inferior vena cava is the central vein that returns blood to the heart from the lower

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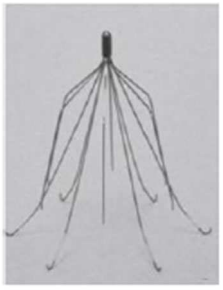
PageID.2. Therefore, the cause of action is part of the bankruptcy estate which the Trustee may pursue.

portions of the body. *Id.* at PageID.3135. In certain individuals, blood clots ("thrombi") can develop in the deep leg veins, known as deep venous thrombi ("DVT"). If these blood clots travel from the legs up into the heart or lungs, they can cause blockage in the smaller vessels. This is known as a pulmonary embolism. Pulmonary embolisms may cause a variety of health problems, the symptoms of which can be chest pain, shortness of breath, and brain damage which can result in death. *Id.* A doctor may recommend an IVC filter for individuals who have experienced, or are at increased risk for developing, DVT and pulmonary embolisms.

In 1992, Bard began distributing the Simon Nitinol Filter ("SNF"), an IVC filter, under a distribution agreement with Nitinol Medical Technologies ("NMT"). Ex. P, ECF No. 33-2, PageID.3434. After distributing the SNF for several years, Defendant developed a modified design which would allow the filter to be removed called the Recovery Filter. *Id.* In November of 2002, Bard obtained clearance to market the Recovery Filter by submitting a 510(k) application to the Food and Drug Administration ("FDA"). A 510(k) application is an FDA approval process based on the "substantial equivalence" of a device with a "legally marketed predicate device." Ex. E, ECF No. 32-5, PageID.3322. The FDA approved the application based on representations by Bard that the Recovery Filter was "substantially equivalent" to the predecessor SNF device. *Id.* at PageID.3324. The FDA also approved the Recovery Filter for optional removal in 2003. Ex. F, ECF No. 32-6, PageID.3329.

Beginning in 2005, Bard manufactured and sold an IVC filter design called the G2 Filter System ("G2 Filter"). Pl.'s Resp. Mot. Summ. J., ECF No. 32, PageID.3284. Like other IVC filters, the G2 Filter is designed to prevent blood clots from traveling from the lower portion of the body to the heart and lungs. The G2 Filter is constructed out of nickel-titanium alloy ("Nitinol") and "consists of two tiers of struts that make up its 'arms' and 'legs.'" ECF No. 27, PageID.3135. Using a catheter, the collapsed filter is inserted into a patient through the jugular vein or femoral vein. When the filter, a photo of which is below, is properly in place within the inferior vena cava, the arms and legs of the filter open up and anchor onto the walls of the vein. *Id.*

 [2]

Once in place, the filter's struts will catch, or break up, blood clots that are traveling up from the legs and prevent them from traveling through the inferior vena cava to the heart and lungs.

As it had done previously with the Recovery Filter, Defendant obtained clearance to market the G2 Filter by submitting a 510(k)

[2] Illustration of the Bard G2 Filter. ECF No. 27, PageID.3135.

application to the Food and Drug Administration ("FDA"). Ex. G, ECF No. 32-7, PageID.3336. Here, the application was based on the assertion by Bard that the G2 Filter was identical in its description and indications for use to a predicate device that had been manufactured by Bard and approved by the FDA, the Recovery Filter System. *Id.* The primary modifications were dimensional. *Id.* at PageID.3335. The FDA approved Bard's 510(k) application in 2005 for the G2 Filter as a permanent placement IVC filter. In 2008, the FDA also approved the G2 Filter as a retrievable option IVC filter. ECF No. 33-2, PageID.3525.

Plaintiff, Vicki Rivera, is a resident of Michigan. ECF No. 27, PageID.3135. Prior to undergoing surgery for weight loss on March 17, 2006, due to her history of DVT, Plaintiff underwent a surgical procedure to implant a Bard G2 Filter. Five years later, during a CT scan to evaluate gastrointestinal issues on September 19, 2011, medical professionals discovered a fractured filter strut from the Bard G2 Filter in her abdomen. *Id.* A second fractured strut was discovered in Plaintiff's right lung in December of 2014 during an x-ray to evaluate broken ribs. *Id.* at PageID.3136. The G2 Filter, and its associated fractured parts, remain inside Plaintiff's body. ECF No. 32, PageID.3183.

Plaintiff alleges Bard was aware that both the G2 Filter and its predicate device, the Recovery Filter, had higher reported failure rates

than the SNF or other IVC filters on the market.[3] ECF No. 32, PageID.3284. To support these allegations Plaintiff relies upon a report conducted by an independent consultant hired by Bard which states,"[r]eports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rates for all other filters." Ex. K, ECF No. 32-11, PageID.3350. Plaintiff also highlights various internal Bard communications suggesting that Bard was aware and attempted to conceal the disproportionate failure rates of the G2 Filter and Recovery Filter. See Ex. J, ECF No.32-10, PageID.3347 ("Comparison with other filters is problematic in many ways, and we should avoid/downplay this as much as possible.").

In addition to internal Bard documents, the record includes several reports by Plaintiff's experts. The expert reports primarily describe two design defects present in both the G2 Filter and Recovery Filter. First, the reports allege that both filters lacked an appropriately rounded

[3] Plaintiff asserts that the G2 Filter and its predicate device, the Recovery Filter, are similar in a multitude of ways: the devices look alike, share the same filtration design, are made of the same material, and are inserted the same way. ECF No. 1, PageID.8-9. Most critically, Plaintiff alleges that the G2 Filter also shares some of the same defects as the Recovery Filter. *Id.* at PageID.9. For this reason, while the device implanted in Plaintiff was a G2 Filter device, the Recovery Filter and its properties are also discussed.

"chamfer," that is, a sloped or angled corner to prevent sharp edges, on the rim of the filter from which the arms and legs of the device deploy. Ex. R, ECF No. 33-4, PageID.3737. As the arms emerge from the top of the cap, they may come into contact with the rough, unpolished edge as they try to deploy out. The reports opine that this contact and stress can cause fatigue, cracks, and bends in the arms. *Id.* at PageID.3742. Next, the experts point out that Bard did not polish away rough grinding marks on the bottom of the wires called the "feet." *Id.* at PageID.3746. The rough surface condition on the bottom of these struts can increase the stress on the wires and result in fracture. A fracture in the arm or leg of the filter may result in tilting or migration of the device, or pieces of it, as the feet help hold the device in position. *Id.* at PageID.3758.

To remedy the fracturing caused by the sharp rim, the expert reports recommend adding a rounded chamfer where the wires emerge from the device during deployment. ECF No. 33-4, PageID.3745. The experts also recommend smoothing the surface of the bottom of the wires through electropolishing to prevent abnormal strain on the arms and legs of the device. *Id.* at PageID.3748. Additionally, Plaintiff's experts refer to internal Bard communications to support the view that the SNF is an alternative permanent filter because it did not receive the same complaints regarding fracture and migration. Ex. M, ECF No. 32-13, PageID.3362. Specifically, the expert reports note that the SNF

possessed an adequate chamfer to prevent premature failure of the filter arms. ECF No. 33-4, PageID.3744-45.

Plaintiff brings this suit against Bard alleging design defect, manufacturing defect, failure to warn, breach of implied warranty, and negligent misrepresentation. Bard moves for summary judgment on all of Plaintiff's claims. ECF No. 27.

II. Standard of Review

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material only if it might affect the outcome of the case under the governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

On a motion for summary judgment, the Court must view the evidence and any reasonable inferences drawn from the evidence in the light most favorable to the non-moving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Redding v. St. Edward*, 241 F.3d 530, 531 (6th Cir. 2001).

The moving party has the initial burden of demonstrating an absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). If the moving party carries this burden, the party opposing the motion "must come forward with specific facts showing that there is a genuine issue for trial." *Matsushita*, 475 U.S. at 587. "[A] mere scintilla of evidence in support of the nonmovant's position is not

sufficient to create a genuine issue of material fact." *Towner v. Grand Trunk Western R. Co.*, 57 Fed.App'x. 232, 235 (2003) (citing *Anderson*, 477 U.S. at 251-52). Rather, the non-moving party must present sufficient evidence as to each element of the case such that a trier of fact could reasonably find for the plaintiff. *Davis v. McCourt*, 226 F.3d 506, 511 (6th Cir. 2000).

Summary judgment is appropriate "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322.

III. Discussion

In the original complaint, Plaintiff brought claims for (1) design defect, (2) manufacturing defect, (3) failure to warn, (4) breach of implied warranty, and (5) negligent misrepresentation. ECF No. 1, PageID.27-34. In their response brief, Plaintiff voluntarily withdrew the second and third claims for manufacturing defect and failure to warn. ECF No. 32, PageID.3295. The Court therefore evaluates the remaining claims of design defect, breach of implied warranty, and negligent misrepresentation.

Based on the evidentiary record presented, material issues of fact preclude summary judgment on Plaintiff's claims for design defect and breach of implied warranty. However, Defendant C.R. Bard is entitled to summary judgment on Plaintiff's claim for negligent misrepresentation

as Plaintiff is unable to present evidence demonstrating reliance. The reasoning in support of these conclusions is discussed below.

a. Design Defect

According to Defendant, Plaintiff's claim of design defect is insufficient because it failed to (1) demonstrate that a safer alternative design was feasible, (2) show causation, or (3) overcome the rebuttable presumption of nonliability. ECF No. 27, PageID.3132. Michigan has adopted a risk-utility test to evaluate products liability claims based on an alleged design defect. *Peck v. Bridgeport Mach., Inc.*, 237 F.3d 614, 617 (6th Cir. 2001). The test requires a plaintiff to show that (1) the product was not "reasonably safe" at the time it left the control of the manufacturer or seller, and (2) a "practical and technically feasible alternative production practice" exists. M.C.L. § 600.2946(2); *Croskey v. BMW of N. Am., Inc.*, 532 F.3d 511, 515-16 (6th Cir. 2008). To survive a motion for summary judgment, a plaintiff must provide evidence showing that:

(1) the severity of the injury was foreseeable by the manufacturer;

(2) the likelihood of occurrence of the injury was foreseeable by the manufacturer at the time of distribution of the product;

(3) there was a reasonable alternative design available;

(4) the available alternative design was practicable;

(5) the available and practicable reasonable alternative design would have reduced the foreseeable risk of harm posed by defendant's product; and

(6) the defendant's omission of the available and practicable reasonable alternative design rendered its product not reasonably safe.

Peck, 237 F.3d at 617. These elements may be supported by direct or circumstantial evidence, including expert testimony or evidence of similar incidents. *Croskey*, 532 F.3d at 516. The Court should grant summary judgment when the plaintiff fails to make out a prima facie design defect claim based on the six elements in the risk-utility test outlined above.

i. Risk-Utility Test

Defendant does not dispute that Plaintiff has provided evidence of the first and second prongs of the risk-utility test, which demonstrate the "magnitude of risks involved." *Peck*, 237 F.3d at 618 (quoting *Owens v. Allis-Chalmers Corp.*, 326 N.W.2d 372, 378 (Mich. 1982)). As there is no dispute that Plaintiff satisfies the first two prongs of the risk-utility analysis, the Court need only address whether Plaintiff satisfied the remaining prongs, all of which focus on the issue of an alternative design.

The second part of the risk-utility test requires Plaintiff to present a reasonable alternative design. *Peck*, 237 F.3d at 618. To survive summary judgment, a plaintiff must present evidence of a "practical and

feasible" alternative that would have reduced the risk of particular injury at issue without impairing the product's usefulness or desirability. M.C.L. § 600.2946(2). See *Dow v. Rheem Mfg. Co.*, 2011 WL 4484001, at *17 (E.D. Mich. Sept. 26, 2011); *Zettle v. Handy Mfg. Co.*, 998 F.2d 358, 362 (6th Cir. 1993).

As to the factors requiring plaintiff to show there was a reasonable alternative design that was available, practicable, and would have reduced the risk, Defendant asserts that Plaintiff has failed to satisfy these elements because it says the proposed alternative, the company's predecessor SNF Filter,[4] is a different product and not sufficiently similar to the alleged defective G2 Filter to serve as a reasonable substitute. Def.'s Reply to Resp. Mot. Summ. J., ECF No. 34, PageID.3892. Further, Defendant argues that Plaintiff has not provided sufficient evidence of a practicable and feasible alternative design because there is no evidence that the designs would improve fracture rates without impairing the usefulness of the product. *Id.* at PageID.3893; M.C.L. § 600.2946(2).

[4] As discussed in the Background section, the Recovery Filter was the predicate device to the G2 Filter. Prior to that, the SNF was the predicate device to the Recovery Filter. Bard obtained clearance to market the Recovery Filter based on representations by Bard that the Recovery Filter was "substantially equivalent" to the SNF device. ECF No. 33-2, PageID.3434.

Defendant's argument fails to address the multitude of design alternatives presented by Plaintiff's experts. In addition to discussing the SNF Filter, Plaintiff's experts propose two design alternatives to prevent fracturing and migration: (1) electropolishing the rough grinding marks on the bottom of the wires, and (2) adding a rounded chamfer onto the rim of the filter from which the arms and legs of the device deploy. ECF No. 33-4, PageID.3745. See *Davis v. C.R. Bard, Inc.*, 2012 WL 6082933, at *4 (E.D. Mich. Dec. 6, 2012) (denying summary judgment as to the design defect claim where experts propose smoothing edges of device to reduce chance of fracture). The Plaintiff's expert opines that there are grinding marks on the bottom of the wires, or "feet," of the device because Defendant failed to polish the struts of the G2 Filter. ECF No. 33-4, PageID.3746. According to the report, rough surfaces lead to local stress concentrations, which can result in fatigue fractures in the arms and legs of the filter. *Id.* at PageID.3778. Local stress concentrations in the "ankle" region of the wire, which leads to anchoring hooks that keep the filter in place, can result in tilting or migration of the device. *Id.* at PageID.3789. Tilting and migration increase the likelihood of perforation or penetration of the filter limbs and may result in strut fractures and possible fragment migration. According to the expert report, to remedy these rough surfaces, the wires could be electropolished to remove any scratches, slip markings, or gouging. *Id.* at PageID.3778.

The expert reports also recommend the addition of an appropriately rounded "chamfer." ECF No. 33-4, PageID.3737. When the G2 Filter is initially implanted, the arms and legs are collapsed. Once the device is in place, the arms and legs deploy from the cap of the device. Experts opine that the cap, or rim, from which the arms and legs deploy had sharp, rough edges. *Id.* When the arms and legs tried to deploy, they could come into contact with these unpolished edges, *Id.* at PageID.3742, potentially causing fatigue, cracks, and bends in the arms and legs. Plaintiff's expert proposes adding an appropriately rounded "chamfer" to this rim. *Id.* at PageID.3737. A chamfer is a sloped or angled corner that can reduce the sharpness of an edge. The expert claims that an appropriately rounded chamfer on the inner surface of the rim would reduce, or eliminate, the contact between the rim and arms and legs as they deploy. *Id.* at PageID.3787. This reduction, or elimination, of contact would decrease stress and potential failure of the struts of the device.

As evidence of the feasibility of these alternatives, Plaintiff's expert notes that subsequent IVC filters designed by Bard did in fact polish down the sharp edges of the rim to create an appropriately rounded chamfer. ECF No. 33-4, PageID.3746. Plaintiff also points to internal communications where Bard employees discuss the feasibility and advantages of utilizing the SNF Filter as an alternative permanent filter because it had not received the same complaints as the G2 Filter. ECF No. 32-13, PageID.3362. These communications support Plaintiff's

argument that Bard employees themselves believed there to be feasible alternatives to the G2 Filter that were available, practicable and indeed, already in use. Both the expert recommendations for specific design improvements and the internal communications regarding use of the SNF Filter are sufficient to raise a question of fact that the third and fourth elements of the risk-utility test are satisfied because they point with specificity to practical and available alternative designs.

In addition to presenting alternative designs, the remaining elements of the risk utility test require a plaintiff to articulate how the proposed alternative design would have reduced harm without sacrificing utility. *See Zettle*, 998 F.2d at 362. For evidence that the proposed alternative designs would reduce the risk of harm posed by the G2 Filter, Plaintiff compares fracture rates for the G2 against other filters and argues that the lower fracture rates for the SNF Filter demonstrate that the alternative design it offered would decrease the risk of a fracture. In one report, Plaintiff's expert asserts that a Bard employee had recommended the SNF Filter specifically to address complications in patients who were undergoing bariatric surgery, the same medical procedure Plaintiff was set to undergo. ECF No.33-2, PageID.3491. Another expert report compares the rims and sleeves of the G2 Filter with other IVC filters and concludes that the polishing down of the sharp edges would reduce the stress that could lead to fracture. ECF No. 33-4, PageID.3745. *Cf. Dow*, 2011 WL 4484001, at *13 (finding alternative

designs insufficient where expert failed to conduct comparative testing or analysis). Having reviewed this record, the Court concludes that Plaintiff has presented sufficient evidence to raise a question of fact regarding the fifth and sixth elements of the risk-utility test by presenting evidence of comparative evaluation that demonstrate safer alternative filters and designs which Plaintiff's experts claim could reduce the risk of fracture without impeding utility.

Because Plaintiff has presented evidence to demonstrate all six elements of the risk-utility test, Plaintiff has successfully made out a prima facie case of design defect that is sufficient to avoid summary judgment.

ii. Causation

Defendant also contends that Plaintiff has not demonstrated causation because she has failed to present evidence from a treating physician or expert witness expressing the opinion that the fracturing of the G2 Filter is the cause of Plaintiff's specific medical conditions. ECF No. 27, PageID.3142. Defendant argues that the medical symptoms Plaintiff identifies were not caused by the fractured parts of the device being present in her body, but rather because of certain pre-existing medical conditions from which she suffered. *Id*. However, during oral argument, Defendant conceded that the migration of a strut within a patient to a place where it is not supposed to be is in fact a form of injury. While such an admission suggests that Defendant's arguments about the

connection between Plaintiff's specific conditions and the fractured struts relates more to the issue of whether the damages arising from her medical conditions can be connected to the injury—rather than whether the defect in the device caused an injury—the Court will nevertheless examine Defendant's arguments on causation below.

Under Michigan's products liability law, Plaintiff must show a causal connection between the defect and injury to prevail. *Skinner v. Square D Co.*, 516 N.W.2d 475, 478 (Mich. 1994); *Glaser v. Thompson Med. Co., Inc.*, 32 F.3d 969, 971 (6th Cir. 1994). Plaintiff must provide sufficient evidence that would allow a jury to determine that it was "more likely than not that the defendant's conduct in fact caused the injury." *Glaser*, 32 F.3d at 971. It is not enough to present evidence that shows a "mere possibility" of causation. *Id.* (quoting *Mulholland v. DEC Int'l Corp.*, 443 N.W.2d 340, 350 n.18 (Mich. 1989)). However, the plaintiff does not have to present evidence that "positively eliminates every other potential cause" to meet the burden. *Skinner*, 516 N.W.2d at 478. Evidence of causation is adequate if it "establishes a logical sequence of cause and effect, notwithstanding the existence of other plausible theories, although other plausible theories may also have evidentiary support." *Id.* (quoting *Mulholland*, 443 N.W.2d at 415).

The Court is not persuaded by Bard's argument that Plaintiff has failed to present any evidence to demonstrate that the fractured medical device is the proximate cause of her alleged medical problems. It is

undisputed that the G2 Filter implanted in Plaintiff fractured and the two struts that failed are still inside Plaintiff's body. ECF No. 32, PageID.3282-83. *Cf. Skinner,* 516 N.W.2d at 484 (finding experts' theories deficient because experts were asked to assume without explanation critical facts in the chain of causation). The fractured filter was discovered by medical imaging. Ex. B, ECF No. 33, PageID.3391. Plaintiff has provided materials which show the range of health consequences that can result from an IVC fracture and notes that by Bard's own criteria the migration of a filter in and of itself is considered a serious injury. Ex. C, ECF No. 27-4, PageID.3210. While not a treating physician, Plaintiff's expert finds that her medical records are consistent with the experience of a fractured G2 Filter. Ex. S, ECF No. 33-5, PageID.3865. Plaintiff offers her medical records as circumstantial evidence of her physical and emotional injury. In addition to complaints of abdominal pain, the medical records state that Plaintiff attributes her anxiety and mental anguish to knowledge that a fractured piece of the filter had migrated to her lung. Ex. T, ECF No. 33-6, PageID.3869, 3878. Finally, Plaintiff claims she will have to undergo continuous medical care including imaging studies, clinical visits, and physical examinations in order to monitor the effects of the fractured G2 Filter. ECF No. 1, PageID.13.

While Defendant contends that Plaintiff's health problems could have been caused by her pre-existing conditions, this attack is not

sufficient to support summary judgment. Plaintiff does not have to produce evidence which eliminates every potential cause of injury. *Skinner*, 516 N.W.2d at 480. Plaintiff's medical records certainly provide some evidence that her pre-existing conditions could have caused the abdominal pain she has suffered. But that reasonable inference must be balanced against the evidence of Plaintiff's undeniable experience of the fractures, the migration of the fragments to her abdomen and lung, as well as injuries such as continued costs of monitoring and mental and emotional stress. Given this conflict in the proof, Defendant's arguments regarding causation are not sufficient to prevail at the summary judgment stage. *See Swartz v. Proctor and Gamble Mfg. Co.*, 2018 WL 2239558, at *4 (E.D. Mich. May 16, 2018) (denying summary judgment even when the defendant offered a study to rebut causation).

Upon review of the medical records, Plaintiff's testimony, and the expert reports, the Court concludes that Plaintiff has presented enough evidence for a reasonable jury to determine that the allegedly defective G2 Filter caused Plaintiff's injuries. Defendant may of course seek to persuade the jury that a preponderance of the evidence shows Plaintiff's pre-existing conditions caused her injuries at trial, but the Court is not persuaded that Plaintiff's medical history entitles Bard to summary judgment.

For these reasons, the Court denies Defendant's summary judgment claim on Plaintiff's design defect claim on the basis that Plaintiff failed to present sufficient evidence of causation.

iii. Rebuttable Presumption of Non-Liability

Under Michigan's products liability law, there is a rebuttable presumption of nonliability for manufacturers who develop products that comply with safety regulations or standards. M.C.L. § 600.2946(4). The statute states:

> In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm was in compliance with standards relevant to the event causing the death or injury set forth in a federal or state statute or was approved by, or was in compliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency responsible for reviewing the safety of the product.

Id. The presumption applies to the four theories of products liability, which includes design defect and breach of implied warranty claims. *Peter v. Stryker Orthopaedics, Inc.*, 2009 WL 235639, at *3 (E.D. Mich. Jan. 29, 2009).

However, the presumption is not absolute and to survive summary judgment the plaintiff must bring forth evidence that rebuts the presumption of nonliability. *See Makki v. OSI Sealants, Inc.*, 2009 WL

4644688, at *2 (E.D. Mich. Dec. 2, 2009) ("The jury's conclusion meant one of two things, either (a) Defendant did not convince the jury that its product was in compliance with applicable standards, or (b) even if the jury was persuaded that the product was in compliance with applicable standards, the jury also concluded that Makki rebutted the presumption of non-liability."); *Wendorf v. JLG Indus., Inc.*, 683 F.Supp.2d 537, 546 (E.D. Mich. 2010); *Peter,* 2009 WL 235639, at *3 (E.D. Mich. Jan. 29, 2009) (finding summary judgment appropriate where the plaintiff failed to submit any evidence to rebut the presumption of no liability).

According to Defendant, because the G2 Filter was in compliance with FDA standards of design and manufacturing, the burden must shift to Plaintiff to rebut a presumption of non-liability. ECF No. 27, PageID.3138. Plaintiff contends that it meets this burden with evidence that the G2 Filter suffered a high failure rate compared to other filters, and that such evidence successfully rebuts the presumption. ECF No. 32, PageID.3289.

Defendant directs the Court to *Peter v. Stryker Orthopaedics, Inc.*, to support their argument that Plaintiff has failed to meet the burden in providing evidence to rebut the presumption of nonliability. 2009 WL 235639, at *3 (E.D. Mich. Jan. 29, 2009). However, in that case, Plaintiff failed to submit "any" evidence of defect and did not respond at all to the motion for summary judgment. *Id.* Here, in addition to responding to the motion, Plaintiff has provided expert reports and studies that provide

evidence of disproportionate fracture rates in the G2 Filter. Plaintiff identifies a report from an independent consultant hired by Bard that reports the rates of death, filter migration, perforation, and fracture with the Recovery Filter to be "4.6, 4.4, 4.1, and 5.3 higher" than reporting rates for all other filters. ECF No. 32-11, PageID.3350. Plaintiff further points to an expert report which states that animal studies of the G2 Filter were stopped early as they showed risk for filter migration, perforation, hemorrhage, and more. ECF No. 33-2, PageID.3508. Even during oral argument, Defendant did not dispute that evidence of disproportionate fracture rate is the type of evidence that can allow a plaintiff to overcome the presumption of nonliability. The facts here are more closely aligned with *Davis v. C.R. Bard*, where the plaintiff, like Rivera, produced expert opinion that the product was defective and studies which "appear[ed] to allow the inference that the [product] is unsafe compared to its competitors and is unreasonably likely to fracture and cause major health issues." 2012 WL 6082933, at *5-6 (E.D. Mich. Dec. 6, 2012).

At summary judgment, the Court does not have to determine whether the presumption has been fully rebutted. *Davis*, 2012 WL 6082933 at *6. The Court needs only determine whether a reasonable jury could so conclude. *Id*. Here, Plaintiff has presented enough evidence to allow such a conclusion. Accordingly, Defendants are not entitled to summary judgment based on a presumption of nonliability.

In summary, Plaintiff has presented sufficient evidence to create a genuine issue of material fact as to the six elements of the risk-utility test, to support causation, and to rebut the presumption of nonliability, thereby presenting a question for the jury to resolve. Having met their evidentiary burden, the Court finds that Defendant is not entitled to summary judgment as to Plaintiff's design defect claim.

b. Breach of Implied Warranty

Defendant contends that Plaintiff is unable to establish a breach of implied warranty claim because the learned intermediary doctrine bars the claim. ECF No. 27, PageID.3133. Defendant also argues that Plaintiff has not shown proximate cause. *Id*. In particular, Defendant asserts that in withdrawing her failure to warn claim, Plaintiff concedes that she could not prove causation. ECF. No. 34, PageID.3896. Because the failure to warn and breach of implied warranty claims are based on the same questions, Defendant argues the implied warranty claim should also fail as Plaintiff is unable to demonstrate causation.

Michigan law recognizes breach of implied warranty as a distinct cause of action for product failure. *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 186 (Mich. 1984). To succeed on a breach of warranty claim, the plaintiff must show that the product was defective. *Kaminiski v. Libman Co.*, 748 Fed.App'x. 1, 4 (6th Cir. 2018). "To that end, the plaintiff must prove either defective manufacture or defective design, which may include a failure to warn." *Id*.

When the defendant is both the seller and manufacturer, the elements of proof for a breach of implied warranty claim are the same as those required in a negligence claim. *Prentis*, 365 N.W.2d at 186 ("[I]n an action against the manufacturer of a product based upon an alleged defect in its design, 'breach of implied warranty and negligence involve identical evidence and require proof of exactly the same elements.'" (quoting *Squibb v. E.R. Squibb & Sons, Inc.*, 273 N.W.2d 476, 479 (Mich. 1979))). *See Kaminiski*, 748 Fed.App'x. at 5 n.3; *Peak v. Kubota Tractor Corp.*, 559 Fed.App'x. 517, 523-24 (6th Cir. 2014). The Sixth Circuit has explained the logic behind the appropriate legal standard:

> The reason for this confluence is that a plaintiff alleging breach of implied warranty on the part of a seller must show that the purchased product was defective. That showing, in turn, requires proof that the product's manufacturer acted negligently, typically by omitting a safety feature or in failing to give warning of a latent danger. A suit for breach of implied warranty against a seller who is also the manufacturer will therefore require the same showing of negligence on the defendant's part as an ordinary products liability suit against a manufacturer.

Hollister v. Dayton Hudson Corp., 201 F.3d 731, 737 (6th Cir. 2000).

Defendant argues that because Plaintiff has conceded there is insufficient evidence of causation for a failure to warn claim, Plaintiff's breach of implied warranty claim must also fail due to the fact that the claims are based on the same underlying assertion. ECF No. 34. PageID.3896. Plaintiff concedes that breach of implied warranty claims

are similar to failure to warn claims, and fails to explain why, without the testimony of her implanting physician, her implied warranty claim should succeed. ECF No. 32, PageID.3297. Unlike in *Davis*, Plaintiff has not presented evidence that Bard's failure to update its disclosure material provided to surgeons caused her injury. If Plaintiff's only means for proving the G2 Filter was defective, as required for an implied warranty claim, was her failure to warn claim, Defendant would succeed.

However, Plaintiff also attempts to show the G2 Filter was defective through a design defect claim, which Defendant fails to address. To prevail on a breach of implied warranty claim, Plaintiff may demonstrate that a product was defective by proving "either defective manufacture or defective design, which *may* include a failure to warn." *Kaminski*, 748 Fed.App'x at 5 (emphasis added). As discussed in the preceding section, Plaintiff has successfully made out a prima facie case of design defect under the risk-utility test. As Defendant C.R. Bard is both the manufacturer and seller of the G2 Filter, "it is inconceivable that a jury could determine that the manufacturer had not breached its duty of reasonable care and at the same time find that the product was not reasonably safe for its reasonably foreseeable uses." *Prentis*, 365 N.W.2d at 187. Plaintiff has presented a prima facie case of design defect and in so doing has created a genuine issue of fact as to whether Bard breached its duty of reasonable care.

Accordingly, Defendant is not entitled to summary judgment on Plaintiff's breach of implied warranty claim.

c. Negligent Misrepresentation

Defendant contends that Plaintiff's negligent misrepresentation claim must fail because there is no evidence of any misrepresentations that Bard made to Plaintiff's implanting physician with regard to the G2 Filter. ECF No. 27, PageID.3147. Defendant further asserts that Plaintiff has not, and in fact cannot, offer any evidence that Plaintiff's implanting physician detrimentally relied on any misrepresentation by Bard with regard to the G2 Filter when treating Plaintiff. ECF No. 27, PageID.3147. In response, Plaintiff contends that Bard had knowledge that the G2 Filter had higher rates of fracture than other filters, but failed to include this information in its warnings to users. ECF No. 32, PageID.3298-3299.

"Michigan law recognizes the tort of negligent misrepresentation." *Gillett v. Sofamor, S.N.C.*, 2001 WL 1135304, at *6 (E.D. Mich. Sept. 13, 2001). To support a claim for this cause of action, a plaintiff must present "proof that a party justifiably relied to his detriment on information provided without reasonable care by one who owed the relying party a duty of care." *Law Offices of Lawrence J. Stockler P.C. v. Rose Stockle*r, 436 N.W.2d 70, 79 (Mich. Ct. App. 1989). In addition to reliance, under Michigan law, the elements of negligent misrepresentation are:

(1) the defendant made a material misrepresentation;

(2) the representation was false;

(3) the defendant was negligent in making the misrepresentation; and

(4) the plaintiff suffered damages as a result.

Cleveland Indians Baseball Co., L.P. v. New Hampshire Ins. Co., 727 F.3d 633, 641 (6th Cir. 2013) (referencing *Stockler,* 436 N.W.2d at 81).

A plaintiff may show a misrepresentation of fact where "the defendant had a duty to disclose facts but suppressed them instead." *Boumelhem v. Bic Corp.*, 535 N.W.2d 574, 579 (Mich. Ct. App. 1995) (referencing *In re People v. Jory*, 505 N.W.2d 228 (Mich. 1993)). The question of whether a manufacturer has a duty is one for the Court. *Avendt v. Covidien, Inc.*, 262 F.Supp.3d 493, 520 (E.D. Mich. 2017). "Michigan has adopted and follows the learned intermediary doctrine, which holds that a manufacturer has no duty to warn the ultimate consumer if the product is provided for use by a sophisticated consumer." *Id.* (referencing *Brown v. Drake-Willock, Intern., Ltd.*, 530 N.W.2d 510 (Mich. Ct. App. 1995)). Under the learned intermediary doctrine, a manufacturer is exempt from its duty to warn ultimate users of prescription drugs and medical devices of inherent dangers because patients rely on the expertise of a doctor when utilizing a medical device or prescribed drug and may not appreciate warnings provided by the manufacturer. *Knight v. St. Jude Med.*, 2011 WL 1230819, at *10 (W.D. Mich. Jan. 11, 2011).

In considering whether Plaintiff has presented sufficient evidence on this claim, the Court must first determine whether Bard owes a duty to Plaintiff, as well as her health care providers. *Avendt*, 262 F.Supp.3d at 520; ECF No. 1, PageID 33. Because Michigan has adopted the learned intermediary doctrine and the G2 Filter is a prescription medical device, Bard's duty to warn runs only to Plaintiff's physicians—not Plaintiff as the patient. *See Knight*, 2011 WL 1230819 at *11 (dismissing claim that the defendant withheld relevant information about a medical device because the defendant owed no duty to the patient—only their health care providers).

During oral argument, Plaintiff also asserted that Defendant owed a duty to her as a patient because she was a member of the class of persons to which Bard had a public duty to provide information. Plaintiff contends that Michigan has adopted Section 552 of the Restatement (Second) of Torts, which extends liability for negligence to "anyone under a public duty to provide information to any class of persons that benefits from the public duty." *Stockler*, 436 N.W.2d at 36. Plaintiff argues that Bard owed her a duty because the Restatement provides protection to injured third parties who were recipients of the misrepresentation.

Plaintiff's reliance on *Stockler* fails to take account of the context of that case. The Court in *Stockler* adopted the Restatement in "reviewing the scope of an accountant's potential third-party liability for negligent misrepresentation." 436 N.W.2d at 36 (emphasis added). Subsequent

cases have recognized the holding of *Stockler* as limited to particular professions and their associated duty of care. *See City of Birmingham Employees' Retirement Sys. v. Comerica, Inc.*, 2012 WL 13002132, at *3 (E.D. Mich. Aug. 28, 2012) (finding that Michigan only adopted Section 552 of the Restatement (Second) of Torts with respect to accountant's duties of care). As *Stockler* is inapplicable here, the scope of Bard's potential liability does not extend to Plaintiff as part of a class of persons.

Due to the learned intermediary doctrine and the inapplicability of *Stockler* to the current facts, Defendant did not owe a duty directly to Plaintiff to avoid making a negligent misrepresentation. As such, to the extent any negligent misrepresentation claim relies on the assertion that Bard failed to warn or withheld information from Plaintiff, Bard would be entitled to summary judgment on such claims.

But Plaintiff also alleges that Defendant withheld relevant warning information from Plaintiff's health care providers. ECF No. 1, PageID.33. Here, the learned intermediary doctrine does not bar Plaintiff's negligent misrepresentation claims as to Plaintiff's health care provider because the treating doctor is the proper recipient of any warnings and information about the G2 Filter. *See Avendt*, 262 F.Supp.3d at 521 (discussing *Brown*, 530 N.W.2d at 516). Defendant had a duty to provide adequate warnings to Plaintiff's implanting physician.

Accepting then that Bard owed a duty to Plaintiff's health care provider, Defendant contends that Plaintiff has not provided any

evidence that Bard misrepresented any information about the G2 Filter to her implanting physician. ECF No. 27, PageID.3133. As support for this argument, Defendant points to *Tice v. Zimmer Holdings, Inc.*, where the Court granted a motion to dismiss because the plaintiffs' claims did not "put Defendants on notice of any specific statements that were fraudulent, let alone explain why they were fraudulent, or indicate where and when they were made." 2015 WL 4392985, at *8 (W.D. Mich. July 15, 2015). But unlike *Tice*, Plaintiff specifically asserts that the information packet misrepresented the risks of the G2 Filter because it failed to convey the magnitude of risk for fracture, perforation, and migration compared to other filters on the market. Ex. H, ECF No. 32-8; 2012 WL 6082933, at *10-11. Where Plaintiff has provided the information packet as evidence of specific statements that omitted necessary information, the facts here are more closely aligned with *Davis v. C.R. Bard*. 2012 WL 6082933, at *10-11. In *Davis*, as here, Plaintiff presented a variety of expert reports showing that Bard was aware of the disproportionate rates of fracture, migration, and perforation, but Bard failed to update its materials to appropriately reflect the risks of the G2 Filter. Ex. Q, ECF No.33-3, PageID.3714. The Court views *Davis* as instructive in finding that evidence of disproportionate rates of failure and the lack of comparative information in the information materials to disclose this risk raises factual issues regarding negligent misrepresentations. As such, Plaintiff has submitted sufficient evidence to show there is a genuine

issue of material fact as to whether the higher rates of failure for the G2 Filter compared to other filters was made known to the implanting doctor or Plaintiff.

However, Plaintiff must also provide some evidence of reliance. *Petfreedom.com, L.L.C. v. Net Generation, Inc.*, 2009 WL 2382430, at *3 (Mich. Ct. App. Aug. 4, 2009). On this point, the Court is unable to find any evidence in the record to demonstrate that Plaintiff's health care provider relied to his detriment on information provided by Bard that failed to adequately reflect the risks posed by the G2 Filter. See *Knight*, 2011 WL 1230819 at *13 (holding that negligent misrepresentation requires evidence of reliance). Further, the surgeon who implanted the G2 Filter, Dr. Talbert, is now deceased and therefore unable to provide testimony to support the element of reliance. Ex. K, ECF No. 27-12. In *Davis*, the plaintiff presented the implanting doctor's deposition to demonstrate reliance on the inadequate warnings in the information packet. 2012 WL 6082933 at *10 (denying summary judgment with regard to the plaintiff's negligent misrepresentation claim). Here Plaintiff has no such evidence.

Plaintiff has not provided any evidence to create a genuine issue of material fact as to whether Dr. Talbert, or any other medical professional, relied on the alleged misrepresentation in treating Plaintiff with the G2 Filter. Because there is no evidence to support the element

of reliance, Defendant is entitled to summary judgment on Plaintiff's negligent misrepresentation claim.

IV. Conclusion

For the foregoing reasons, Defendant C.R. Bard's motion for summary judgment is **DENIED** with respect to Plaintiff Vicki Rivera's claims for design defect and breach of implied warranty, and **GRANTED** as to Plaintiff's claim for negligent misrepresentation.

SO ORDERED.

Dated: October 15, 2020 s/Terrence G. Berg
TERRENCE G. BERG
UNITED STATES DISTRICT JUDGE