UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

LISA DAVIS,

Plaintiff,

v.

C.R. BARD, INC., ET AL.,

Defendants.
_____/

Case No. 11-12556

SENIOR UNITED STATES DISTRICT JUDGE ARTHUR J. TARNOW

MAGISTRATE JUDGE LAURIE J. MICHELSON

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT [29]

Before the Court is Defendants' Motion for Summary Judgment [29]. On October 29, 2012, the Court heard oral argument on the motion. For the reasons stated below, Defendants' Motion for Summary Judgment is **GRANTED IN PART AND DENIED PART**.

I. Procedural Background

Plaintiff originally filed her Complaint [1] on June 13, 2011. Defendants filed their Motion for Summary Judgment [29] on June 29, 2012. Plaintiff filed a Response [42] on August 15, 2012. Defendants filed their Reply [44] on August 30, 2012. On October 29, 2012, the Court heard argument on the motion.

II. Factual Background

This case concerns the claims of Plaintiff Lisa Davis against Defendant C.R. Bard, Inc., and its affiliated company, Bard Peripheral Vascular, Inc., regarding the G2 vena cava filter, a device used to prevent deep vein thrombi from traveling to the lungs and heart. A G2 filter was implanted in Plaintiff in 2006, and has since fractured. A fragment of the device has lodged in Plaintiff's right ventricle, allegedly causing Plaintiff continued health problems. Plaintiff alleges that Defendants

engaged in negligent design and manufacture of the G2, failed to warn her physician of its dangers, breached implied warranty, and engaged in negligent misrepresentation.

The Bard G2 is designed to prevent blood clots from traveling from veins in the lower body to the heart and lungs (which can result in pulmonary embolism and death). Plaintiff Lisa Davis underwent surgery to have a G2 filter implanted in her inferior vena cava in July 2006. In June 2008, Plaintiff began experiencing heart palpitations, shortness of breath, and vertigo. She was diagnosed as suffering from arrhythmia. At the same time, a piece of metallic "wire" was discovered in her right ventricle. It was later determined that Plaintiff's G2 filter had fractured and that a fragment of the broken filter had "migrated" to Plaintiff's right ventricle. To have the fragment removed would require open-heart surgery, something that Plaintiff declined to undergo. Instead, Plaintiff is on lifetime anticoagulation therapy and takes metoprolol to control her arrhythmia. Plaintiff also states that she must regularly visit her physicians for imaging studies to determine whether any additional fractures in the G2 have developed. Plaintiff alleges that the fractured device has caused her physical trauma, anxiety, and has impaired her ability to earn wages.

The G2 filter is constructed of "Nitinol," a nickel-titanium alloy. "G2" stands for "second generation." The device is so named because it is based on a device previously manufactured by Defendants called the "Recovery Filter System." Defendants designed the device to be a removable filter system, that is, one that is not designed to be permanently placed within a patient but is instead removed after a number of years. The Recovery Filter System had problems that resulted in some cases of the system fracturing and the fragments migrating to various parts of patients' bodies. This is a problem that is, according to Defendants, common to all filters. Tr. p. 10.

The rate of fracture for the Recovery was, according to Plaintiff, appraised in some studies as being as high as 21 to 31.7%. Compl. at ¶ 21. Plaintiff's expert, Dr. Robert Ritchie, opines that

the reason the rate of fracturing was so high is due to a design and manufacturing defect on the device, namely, that the device is not electropolished and thus rough "draw marks" on the device allow too much pressure to build up, eventually shattering the device. Plaintiff's expert contends that the device is "unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*." Pl.'s Ex. B at 10-13.

In 2005, Defendants submitted an application to the FDA for the introduction of their G2 Filter. Under the applicable section of the United States Food, Drug, and Cosmetic Act of 1976, 21 U.S.C. § 321, *et seq.*, a medical manufacturer may represent that a device offered for approval is "substantially similar" to a "predicate device." Defendants represented to the FDA that the G2 was substantially similar to the Recovery Filter, described above.

On their website, Defendants state that the fracture rate of the G2 Filter is 1.2%. Plaintiff argues that this number is inaccurate based on a review by Defendants' own consultants utilizing various available databases. *See* Pl.'s Exs. J and O. Plaintiff argues that the G2 and Recovery Filters are, in fact, more dangerous and prone to fracture than filters designed by competitors. Plaintiff alleges that Defendants have been aware since 2005 that the G2 is dangerous and has a higher failure rate than the rate published by Defendants.

III. Analysis

Summary judgment is appropriate under Fed. R. Civ. P. 56(c)(2) where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that movant is entitled to judgment as a matter of law." The facts and all inferences drawn from the facts must be viewed in the light most favorable to the nonmoving party. *Abeita v. TransAmerica Mailings, Inc.*, 159 F.3d 246, 250 (6th Cir. 1998) (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)). A genuine issue for trial exists if "the

evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Once a moving party produces evidence establishing lack of a genuine issue of material fact, the non-moving party must "set forth specific facts showing that there is a genuine issue for trial." *Id*. The mere existence of "a scintilla of evidence" in support of a plaintiff's position is not sufficient to create a genuine issue of material fact. *Anderson*, 477 U.S. at 252.

In terms of tort claims for product liability and negligence, Michigan law applies to Plaintiff's substantive claims.

A. Punitive Damages Unavailable

Defendants note that Michigan does not generally permit punitive damages; rather, any exemplary damages are awarded only "as an element of compensatory damages." *Eide v. Keisey-Hayes Co.*, 427 N.W.2d 488, 498-99 (1988). Punitive or exemplary damages may be available where such damages are expressly authorized by statute. *Id.* at 500. However, Defendants argue that Mich. Comp. Law § 600.2946, upon which Plaintiff's claims are premised, does not expressly authorize punitive damages. Plaintiff concedes this point. Accordingly, the Court finds that punitive damages are not available to Plaintiff and GRANTS summary judgment to Defendants on this issue.

B. Summary Judgment Inappropriate on Question of Defective Design

In Michigan, "whether a suit is based upon negligence or implied warranty, we require the plaintiff to prove that the product itself is actionable - that something is wrong with it that makes it dangerous . . . the plaintiff must . . . show that the product was defective." *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 181-82 (Mich. 1984). The plaintiff must also demonstrate "that this defect caused the plaintiff's injury." *Bullock v. Gulf & Western Mfg.*, 340 N.W.2d 294, 295 (Mich. Ct. App. 1983). A product is defective "if it is not reasonably safe for its foreseeable uses." *Id.* at 296

(citations omitted). Michigan law provides that a product's defectiveness is judged based upon:

> According to generally accepted production practices at the time specific unit of the product left the control of the manufacturer . . . a practical and technologically feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others. An alternative production practice is practical and feasible only if the technical, medical, or scientific knowledge relating to production of the product, at the time the specific unit of the product left the control of the manufacturer or seller . . . and was economically feasible . . . [an alternative production practice] is not economic feasible . . . if use of that knowledge in production . . . would significantly compromise the product's usefulness or desirability.

Mich. Comp. Law. § 600.2496(2).

Defendants argue, based on *Owens v. Allis-Chalmers Corp.*, 326 N.W.2d 372, 378-79 (Mich. 1982), that a plaintiff must present evidence "concerning magnitude of the risks involved and the reasonableness of the proposed alternative design." In *Owens* the court affirmed dismissal of a plaintiff's case because the plaintiff presented no evidence of "how likely" a particular dangerous event was, and also gave "no indication" how the proposed safer design presented by the plaintiff "would affect a forklift operator's ability to do his or her job or the operator's safety in other circumstances."

Here, the parties have disputed whether (a) Defendants' G2 filter does in fact fracture at an unreasonable rate, (b) whether reasonable alternative designs existed. Defendant alleges that Plaintiff has "not offered any evidence that the G2 filter implanted in Plaintiff was not reasonably safe." The Court disagrees. First, Plaintiff provides a number of clinical studies from 2010 to 2012 that highlight the fact that Defendant's G2 filter is susceptible to fracture. *See* Pl.'s Ex. A. Second, Plaintiff provides the testimony of their expert witness, Dr. Robert Ritchie, a metallurgical engineer, that the G2 is prone to fracture because of its unacceptably rough surface and improperly sharp edges. *See* Pl.'s Ex. B at 10-13. Third, Plaintiff's other mechanical engineer experts, doctors Robert

McMeeking and Matthew Begley, also provide testimony that the sharp edges of the G2's "sleeve" made it prone to fractures. Pl.'s Ex. C at 6-8. Fourth, Plaintiff's expert Dr. Jeffrey Hull, an interventional radiologist, also noted that the sharp edge's of the G2's cap led to a rough surface that increased the chances of the device fracturing, and notes studies that place the G2's fracture rate as high as 12%. Pl.'s Ex. D at 3-4.

At the motion hearing, Defendant asserted that there was nothing "in the record . . . that does show an unusual fracture rate in the G2." Tr. p. 11. This is incorrect. As noted above, Plaintiffs can point to a large amount of evidence discussing the fracture rate of the G2. Viewed in the light most favorable to Plaintiff, there is sufficient evidence from which a reasonable jury could conclude that the G2's fracture rate is high. Defendants are free to argue, as they do in their briefs, that the studies represent an inaccurate snapshot of filter fracture rates, or that Plaintiff's expert's reports are flawed. However, these are factual questions that are to be decided by the jury. As such, Defendants have failed to demonstrate that there is no genuine issue of material fact as to this issue.

Defendants also argued that Plaintiff "has failed to offer any evidence of an alternative design." In particular, Defendant alleges that Plaintiff has "provided nothing" in regards to the requirement that an alternative design "would have been effective as a reasonable means of minimizing the risk of foreseeable danger." *Zettle v. Handy Mfg. Co.*, 998 F.2d 358, 360 (6th Cir. 1993). However, Plaintiff's experts all agreed that by "electropolishing" the device Defendants could have smoothed the rough and sharp edges of the device, thus reducing the chance of fractures. Plaintiff's experts also state that a "beveled" or "chamfered" edge to the filter, rather than a "sharp" ninety-degree edge, would have helped correct the fracturing problem. Defendants may argue as to whether this technique would truly be effective, but the Court finds that sufficient evidence is presented by Plaintiff as to establish a genuine issue of material fact.

Defendants also argued during the hearing that the above studies, most of which are from 2010 to 2012, were not known to Bard in 2006. However, Plaintiff provides other evidence that Defendants were aware of the fracturing problem associated with the G2. Plaintiff notes that the "edge" on the G2, which Plaintiff argues is dangerous because it is rough and sharp-edged, is identical to that on the earlier Recovery model (which Plaintiff notes was also prone to fracture). Plaintiff argues that Defendants used the same fatigue testing for the G2 as it has for the recovery because the designs were "substantially similar." Plaintiff also points to an e-mail from Bard's director of clinical affairs, David Ciavarella, in which he notes that a consultant hired by Defendants had reviewed various databases and found that the Recovery filter fractured five times more often than competitors' devices. Pl.'s Ex. J. Plaintiff also notes that Defendants were aware of the alternative design suggested by Plaintiff. Plaintiff points to an e-mail from one of Bard's engineers to a superior in which the engineer states that "by electropolishing, it will aid with corrosion, it will be less ragged and may help with fracture resistance." Pl's Ex. E. Plaintiff notes that another engineer Thomas Ferari, stated in deposition that the fractures that occurred in the G2 generally occurred in the same location as with the Recovery filter, near the cap. Pl.'s Ex. 148-49. Another engineer of Defendants, Rob Carr, referred to chamfered edges (which reduce stress on the cap) as "good, but not mandatory." Pl.'s Ex. L. Finally, Plaintiff notes that, as described above, a beveled edge and electropolishing would have improved the design of the G2 filter. Plaintiff's expert Dr. Ritchie noted that "[m]ost manufacturers of [nickel-tin alloy] medical devices choose to polish, or better still electropolish, the surface of their components" to eliminate surface defects. Pl.'s Ex. B at 11.

Defendants argue in response that the comments above are generally directed towards Defendants' Recovery filter rather than the G2. However, the question of the extent of the similarity

of the Recovery and the G2 filter, and whether Plaintiff's proposed alternative designs would in fact make the G2 safer, are factual issues best left to the jury to decide. These questions, which require the weighing of expert testimony and evidence, are quintessentially questions for the jury.

Accordingly, Defendant's Motion for Summary Judgment DENIED as to the question of defective design.

C. Defendants' Compliance with FDA Standards

Defendants argue that the approval of their G2 filter by the FDA creates a rebuttable presumption that they are not liable for any injury stemming from their product. Defendants rely on Mich. Comp. Law § 600.2946(4), which 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. Noncompliance with a standard relevant to the event causing the death or injury set forth in a federal or state statute or lack of approval by, or noncompliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency does not raise a presumption of negligence on the part of a manufacturer or seller. Evidence of compliance or noncompliance with a regulation or standard not relevant to the event causing the death or injury is not admissible.

Plaintiff responds that while it is true that there is a rebuttable presumption created by FDA approval, Mich. Comp. Law § 600.2949a states that:

> If the court determines that at the time of manufacture or distribution the defendant had actual knowledge that the product was defective and that there was a substantial likelihood that the defect would cause the injury that is the basis of the action, and the defendant willfully disregarded that knowledge in the manufacture or distribution of the product, then sections 2946(4) . . . do not apply.

Thus, Defendants argument regarding FDA compliance creating a presumption of a lack of liability is only true if there is not a genuine issue of material fact as to whether the Defendants had actual knowledge that the G2 filter was defective and that there was a substantial likelihood that the defect would the injury that is the basis of this action (fracture). If there is a genuine issue of material fact as to this question, summary judgment should be denied.

Plaintiff argues that the Recovery filter was unacceptably prone to fracture, as discussed above. Plaintiff argues that because the G2 filter was based on the Recovery filter, Defendants knew that it, too, would be unacceptably prone to fracture but failed to remedy the problem. Plaintiff argues that Defendants also knew that fractures could lead to migration, the problem suffered by Plaintiff. Plaintiff attaches a health hazard evaluation from Bard's director of clinical affairs that notes that "[m]igration of metal fragments to the heart or lung presents the possibility of cardiac or pulmonary injury with serious clinical consequences." Pl.'s Ex. P (referring to the Recovery filter). As noted above, a genuine issue of material fact exists as to the similarity in design between the Recovery and G2, and this issue of material fact in turn applies to whether Defendants knew how dangerous the G2 filter was, and whether they were aware that fractures could lead to migration of the fragments. As such, summary judgment is not appropriate.

However, even if Defendants were not aware of the danger of their product and did not know of the effects it might produce, this creates only a "rebuttable presumption" that the product was not defective. *See Makki v. OSI Sealants, Inc.*, 2009 WL 4644688, at *2 (E.D. Mich. 2009) (Zatkoff, J.) (finding that jury could have reasonably been persuaded that a plaintiff rebutted the presumption of non-liability). Plaintiff argues that she may still prove that the product is, in fact, defective and unreasonably unsafe. Plaintiff references her arguments, advanced by her expert witnesses, that the G2 filter was defective in design and manufacture and were prone to break. Plaintiff also references

the various studies that she presents that appear to allow the inference that the G2 is unsafe compared to its competitors and is unreasonably likely to fracture and cause major health issues.

The Court finds that a reasonable jury could conclude either that Defendants were aware of the risks of the G2 by the time Plaintiff's G2 filter left their control, or that Plaintiff has rebutted the finding of non-liability by demonstrating that the G2 filter is unreasonably unsafe and therefore defective. Accordingly, Defendants' Motion for Summary Judgment is DENIED as to Defendants' compliance with FDA standards.

D. Cause of Injuries

Defendants next argue that "litigants do not have any right to submit an evidentiary record to the jury that would allow the jury to do nothing more than guess." *Skinner v. Square D. Co.*, 516 N.W.2d 475, 484 (Mich. 1994). A plaintiff must "set forth specific facts that would support a reasonable inference of a logical sequence of cause and effect . . . [not] a causation theory premised on mere conjecture and possibilities." *Id.* at 484. Defendants argue that Plaintiff has provided "no evidence that the fractured limb is the proximate cause of her alleged medical problems." Defendants note that Plaintiff has a history of obesity, deep-vein thrombosis, and what Defendants describe as a "history of hospital visits for . . . shortness of breath, heart palpitations, and chest pains." Defs'. Exs. A and F. Defendants also argue that Plaintiff "has not provided any evidence to demonstrate that the systems she alleges . . . are not . . . due to her age, weight, pre-existing medical conditions, or subsequent, independent medical conditions." Defs'. Ex. G.[1] Defendants also allege that "Plaintiff's own physicians have . . . stated that her alleged symptoms are not related

[1] The Court notes the difficulty of proving a negative.

to the filter fracture." Def's. Ex. C and B.[2]

In response, Plaintiff notes several pieces of evidence. First, the testimony of Dr. Eric Ayers, Plaintiff's general care physician for 10 years, who by affidavit stated that, with a reasonable degree of medical certainty, that he thought that the fragment of G2 filter in the Plaintiff's ventricle was either the cause of or contributing to Plaintiff's chest pain, and that he had ruled out other facts. Pl.'s Ex. P, at 116-19. He also opined that he did not think that one could reasonably say that the fragment *could not* be causing or contributing to Plaintiff's pain. *Id.* at 118. Finally, Dr. Ayers indicated that he thought that Plaintiff's anxiety regarding the fragment in her heart was reasonable, particularly given the ongoing monitoring she would be required to undergo in the years ahead. *Id.* at 120-21.

In response, Defendant again relies on the testimony of Dr. Jahania (who testified that he does not think there is a link between Plaintiff's symptoms and the fragment) and Dr. Gedwill. Finally, Defendants argue that because "Dr. Ayers, Plaintiff's primary care doctor, is not a cardiothoracic surgeon like Dr. Jahania, or an interventional radiologist like Dr. Gedwell . . . [he] cannot affirmatively rule out existing co-morbidities as the cause of Plaintiff's symptoms." Accordingly, Defendants argue, "[h]is testimony . . . is mere speculation." This, however, is an

---

[2]In Defendants' Exhibit B, Dr. Michael Gedwill does not in any way appear to say that Plaintiff's symptoms are not caused by the fractured piece of the G2, but rather is discussing what often happens when a fractured piece is fixed in place in the vascular system.

In Defendants' Exhibit C, Dr. M. Salik Jahania states that when trying to determine whether Plaintiff should undergo open-heart surgery, he told her that "if it was not causing any problems, not related to her symptoms, then the harm taking it out would have been more" than leaving the fragment in her ventricle. Dr. Jahania goes on to state that the fragment "didn't really have any obvious link to the symptoms that [Plaintiff] . . . would have been having." Further, he stated "I'm not an expert in . . . arrhythmia disorders, but based on the information at that point I didn't really feel like it was correlated."

argument regarding credibility and/or the weight to be assigned an expert opinion, i.e., a question for the jury. Defendants present no case law or medical textbook that states that a primary care physician cannot offer a diagnosis or rule out other issues in this sort of case.

Accordingly, Defendants' Motion for Summary Judgment with respect to the issue of Plaintiff's cause of injuries is DENIED.

E. Manufacturing Defect

Defendants argue that Plaintiff has failed to provide any evidence that there was a manufacturing defect on the G2 filter implanted in Plaintiff. To prove a manufacturing defect, a Plaintiff must provide evidence that "something [has gone] wrong in the manufacturing process and the product is not in its intended condition." *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 182 (Mich. 1984). Defendants argue that Plaintiff has not offered any evidence that the G2 filter at issue was manufactured "under a production standard different than the accepted standard that is used for Bard's other equivalent products."

Plaintiff acknowledges that it is her burden to establish that a product has a manufacturing defect. She notes, however that Michigan courts have held that a plaintiff "is not . . . obliged to eliminate all possible causes of the accident consistent with the view that there was no manufacturing defects. [A plaintiff] sustains his burden when he establishes with direct or circumstantial evidence a reasonable probability that the defect is attributable to the manufacturer." *Holloway v. Gen. Motors Corp. Chevrolet Div.*, 271 N.W.2d 777, 780 (Mich. 1978). "Questions of comparative probability are to be resolved by the trier of fact." *Id.* at 781. As noted by the Michigan Supreme Court:

> "It is true that where an injury occurs that cannot be accounted for, and where the occasion of it rests wholly in conjecture, the case may fail for want of proof . . . But such cases are rare, and that rule should never be so extended as to result in a failure

> of justice, or in denying an injured party a right of action, where there is room for balancing the probabilities, and for drawing reasonable inferences better supported upon one side than the other . . . (T)he question of whether the inference suggested by the plaintiff's theory is the correct one, or whether it was sufficiently rebutted, was a question for the jury.

Holloway, 271 N.W.2d at 781 (quoting *Kujawski v. Cohn*, 224 N.W.2d 908, 911 (Mich. Ct. App. 1974)).

Plaintiff argues that she has established that the breakage of the filter was likely due to a manufacturing defect based on the testimony of Dr. Ritchie, who examined a number of examples of G2 filters that had fractured. In examining the fractured filters, Dr. Ritchie stated that the poor surface finish of the filter's limbs likely a manufacturing defect on those components that could have been removed by post-manufacture electropolishing, or improvement in manufacturing procedures and quality control. Pl.'s Ex. B at 12-13. Plaintiff notes that "unless Bard's position is that the G2 is designed to have serious surface flaws that rendered it prone to fracture, the device as manufactured was not in its intended condition . . . ."

Defendants respond that Plaintiff has provided "no concrete, contextual evidence showing that a defect . . . caused Plaintiff's filter to fracture." Defendants argue that the fact that Plaintiff's experts have not been able to examine the fractured filter that remains within Plaintiff's body means that it cannot be determined what caused the fracture. Defendants also argue that they are protected by the "unavoidably unsafe" doctrine - however, this doctrine only applies if the manufacture provided "adequate warning in light of the information then available" regarding the possible risks and complications of a medical product. This issue is addressed above.

The Court finds that Plaintiff has provided sufficient evidence - expert opinion, based on review of a number of other fractured G2 filters - that establishes that there is a genuine issue of

material facts as to whether manufacturing defects contributed to or caused Plaintiff's filter to fracture. As such, Defendants motion is DENIED as to this issue.

F. Failure to Warn Claims - Learned Intermediary/Sophisticated User

Defendants argue that Michigan courts have applied the sophisticated user doctrine, in which "a manufacturer does not have a duty to warn the ultimate user of a product's danger if the purchaser is a 'sophisticated user' of the product." *Landberg v. Ricoh, Int'l*, 892 F. Supp. 938, 942-43 (E.D. Mich. 1995) (Gadola, J.). "A purchaser/employer is deemed a sophisticated user and knows or should know of a product's dangers where either (1) the manufacturer has provided an adequate explicit warning of such dangers; or (2) where information on the product's dangers is available in the public domain." *Id.* at 943.

Defendants contend that their G2 filter had adequate, explicit warning of the dangers possible in its use. Defendants state that all G2 filters had an information section that warned of the danger of filter fracture and embolization under bolded sections entitled "potential complications" and "warnings." Specifically, the warning stated that "[f]ilter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments . . . Most cases of filter fracture, however, have been reported without any adverse clinical sequelae." Defendant points to the testimony of Dr. Gedwill, who stated in affidavit that he always reads the information-for-user prior to using a new device, and that while he could not recall the specific date he did so for the G2 filter, he was certain he had read its information packet. Defs.' Ex. B at 10-11.

Plaintiff contends in response that Defendants' own internal knowledge, not in the public domain, regarding the G2 filter creates a genuine issue of material fact. Plaintiff contends that Defendants were aware that the Recovery, the predecessor to the G2, was reported to fracture far

more often than competitors' filters,[3] was aware of the serious medical consequences that a fracture could cause,[4] knew that the rough finish and sharp edges of the G2 and Recovery filters were causing fractures and knew that electropolishing could solve this problem,[5] and yet nevertheless failed to improve the fracture-resistance of the G2. Plaintiff also argues that the very general warning on the G2 filter, and the downplaying of any risks associated with fracture, is inadequate, particularly given Plaintiff's contention that the G2 fractured more often than other filters on the market.

Defendants also contend that in a failure to warn case, the plaintiff must prove that their injuries were proximately caused by the failure to warn. That is, that a plaintiff alleging inadequate warning must demonstrate that an adequate warning would have altered a doctor's choice to utilize

---

[3]Pl.'s Ex. J, a discussion by Defendants' director of clinical affairs of the report of a consultant hired by Defendants to evaluate the dangers of the Recovery filter, notes that a review of the literature establishes that the Recovery filter was reported to have fractured at a rate of 4-5 times more than competitors' filters. The report notes that this is statistically significant. The report also notes that the literature is not yet fully developed and likely has sampling errors and, thus, that this number may not reflect reality, and thus cautions against drawing conclusions regarding the failure rate from the studies.

[4]Pl.'s Ex. O is a second report on the Recovery filter by the same consultant. In it, the consultant discusses the medical consequences of fragment migration, including cardiac arrhythmia caused by tissue erosion in the heart, precisely the issue complained of by Plaintiff. *See* p.2.

[5]Pl.'s Ex. E is an e-mail between two of Defendants' engineers where one engineer notes that he believes it is necessary to add electropolishing to the manufacturing process to "improve fracture resistance." Pl.'s Ex. K, the deposition of Thomas Ferari, another engineer, does not provide much support and merely establishes that Ferari knew that the G2's tended to fracture at the point of attachment of the "arm" of the filter to the base, but that in October 2010 Bard had not, as far as Ferari knew, changed its manufacturing process. Pl.'s Ex. L mentions the "sharp edge" that Plaintiff's are concerned about, but does not support the contention that Defendants' knew the sharp edge was problematic. In response to the question whether an "abrupt/sharp ninety-degree" edge causes "any concern," engineer Robert Carr says the edge can be "square but not rough." This implies that Carr thought a "sharp" ninety-degree edge was acceptable, and thus does not seem to demonstrate that he "knew" such a design was problematic.

the drug or device, "[o]therwise, the failure to warn is not the proximate cause of injury." *Dunn v. Lederle Lab.*, 328 N.W.2d 73, 85 (Mich. Ct. App. 1982). Defendant contends that because filter fracture is a known risk with all filters of a similar class to the G2, there is no way that failure to warn caused Plaintiff's injuries, as there is no evidence that a different warning would have altered Dr. Gedwell's decision to use the G2 filter.

Plaintiff counters that Dr. Gedwell testified that he would consider it important information and would want to know if a particular filter fractured more often than a competitor's filter, and that "safety was paramount" in his choice of filter. Pl.'s Ex. S at 34-35.

Defendants respond that Dr. Gedwell testified that he was aware of the fracture risks yet still made an informed decision to use the G2 filter. Defendants argue that, as no comparative study of fracture rates was available, they were not required to provide such a warning. Defendants cite to *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th Cir. 1990), a case that applied Ohio law to find that a drug manufacturer did not have to compare the risks of its drug to those of other companies.

The Court finds that Plaintiff has established a genuine issue of material fact as to whether the warning included with the G2 filter was adequate, and, if not, whether the inadequate warning was the proximate cause of Plaintiff's injuries. While the warning in the G2 filter's information packet did disclose fracture as a risk, it did not provide any estimation of the magnitude of said risk and, in fact, downplayed the risk by saying that "[m]ost cases of fracture" did not result in significant harm to the patient. As the Court noted at the motion hearing, the warning in the G2 packet was also printed in very small print that was not prominently displayed for a doctor to read.

While Defendants are correct that they did not necessarily have reliable studies to use to determine the exact risk of fracture, Plaintiff has provided evidence that Defendants had the reports from their consultants, Pl.'s Exs. J and O, that indicated that their Recovery filter seemed to fracture

at a significantly higher rate than other filters. Further, it is unclear what evidence Defendants had to support the statement in their information packet that "most cases of fracture" had not resulted in harm.

Finally, "[t]he reasonableness of a failure to warn and the question of whether a manufacturer has provided adequate warnings are both questions of fact for the jury using a standard of reasonable care under the circumstances." *Bronkema v. Ferwerda Enters., Inc.*, 2009 WL 1066110, at *2 (Mich. Ct. App. 2009) (citing *Taylor v. Wyeth Labs.*, 362 N.W.2d 293 (1984)).

Therefore, Defendants' Motion for Summary Judgment is DENIED as to the failure to warn issue.

G. Count II - Implied Warranty

Defendant notes that "[t]he same rationale that bars a [third party] of a sophisticated user from recovering . . . based on a failure to warn theory is also applicable to claims based on an implied warranty theory." *Jodway v. Kennametal, Inc.*, 525 N.W.2d 883, 890 (Mich. Ct. App. 1994). Thus, as with the sophisticated user doctrine, Plaintiff may not claim breach of an implied warranty if her physician, Dr. Gedwell, "knows or should know of a product's dangers where either (1) the manufacturer has provided an adequate explicit warning of such dangers; or (2) where information on the product's dangers is available in the public domain." *Landberg v. Ricoh, Int'l*, 892 F. Supp. at 943.

The arguments of Plaintiff and Defendants are essentially the same as in the failure to warn claim. Defendants argue that Dr. Gedwill knew of the risk of a fracture of the filter and read the information packet for the G2 and its warnings, and that said warnings were "adequate explicit warnings" of the actual danger of the filter. Plaintiff contends the warnings were not adequate, in that they did not convey the magnitude of risk, particularly in comparison to other filters on the

market, and downplayed the actual possible harm that might be caused by filter fragments.

Accordingly, the Court finds that Plaintiff has established a genuine issue of material fact with respect to whether the warnings on the G2 filter were "adequate explicit warnings" in light of the available evidence. Defendants motion for summary judgment on the issue of breach of implied warranty is DENIED.

H. Count III - Negligent Misrepresentation Claim

Negligent misrepresentation requires a plaintiff to prove a misrepresentation of fact, which may be shown where the defendant had a duty to disclose facts but suppressed them. *Boumelhem v. Bic Corp.*, 535 N.W.2d 574, 579 (Mich. Ct. App. 1995).

Defendants argue that Plaintiff's claim for negligent misrepresentation fails because "Plaintiff has adduced no evidence that Dr. Gedwill justifiably relied on any Bard representation or any alleged misrepresentation in choosing the Bard G2 filter to treat Plaintiff." Defendants also repeat their argument regarding proximate causation of Plaintiff's injury to their alleged misrepresentation.

Plaintiffs respond that the misrepresentation relied upon by Dr. Gedwill was the inadequate warning in the G2 information packet, which did not convey the magnitude of risk, particularly in comparison to other filters on the market, and downplayed the actual possible harm that might be caused by filter fragments. Plaintiff notes that "[a] party who remains silent when fair dealing requires him to speak may also be guilty of fraudulent concealment." *Steel Strip Wheels, Ltd. v. Gen. Rigging, LLC,* at *12 (E.D. Mich. 2009) (Rosen, J.). Plaintiff thus argues that Defendants' inadequate warning, when Defendants possessed additional knowledge regarding the level of danger of their product, constituted negligent misrepresentation.

The resolution of this argument concerning fraudulent representation rests on the determination of several factual issues - (1) whether Defendants' existing warnings were adequate; (2) if not, whether Defendants misrepresented the danger of the G2 filter; and (3) if Defendants then "suppressed" facts they should have disclosed regarding the safety of the G2 filter. All of these facts are contested by evidence presented by Plaintiff, as discussed above. As such, Defendants' motion with respect to Plaintiff's negligent misrepresentation claim is DENIED.

IV. Conclusion

The Court finds that there exist adequate facts in the record, taken in the light most favorable to Plaintiff, to establish genuine issues of material fact from which a reasonable jury could find for Plaintiff on the issues of design and manufacturing defect, failure to warn, and negligent misrepresentation. Accordingly, Defendant's Motion for Summary Judgment [29] with respect to these issues is **DENIED**.

Defendants' Motion for Summary Judgment [29] is **GRANTED** with respect to the issue of punitive damages.

SO ORDERED.

s/Arthur J. Tarnow
ARTHUR J. TARNOW
SENIOR UNITED STATES DISTRICT JUDGE

Dated: December 6, 2012

CERTIFICATE OF SERVICE

I hereby certify on December 6, 2012 that I electronically filed the foregoing paper with the Clerk of the Court sending notification of such filing to all counsel registered electronically. I hereby certify that a copy of this paper was mailed to the following non-registered ECF participants on December 6, 2012: **None.**

s/Michael E. Lang
Deputy Clerk to
District Judge Arthur J. Tarnow
(313) 234-5182