UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

| | |
|---|---|
| CLAUDIA HEPBURN,<br><br>Plaintiff,<br><br>v.<br><br>BOSTON SCIENTIFIC CORPORATION,<br><br>Defendant. | Case No. 3:17-cv-00530-DCN<br><br>**MEMORANDUM DECISION AND ORDER** |

## I. OVERVIEW

This matter comes before the Court on Defendant Boston Scientific's Motion to Dismiss. Dkt. 4. Plaintiff Claudia Hepburn asserts that she has an increased risk of future injury because she has a permanent, defectively designed, medical device—which Boston Scientific designed, manufactured, and sold—implanted inside of her. She claims that Boston Scientific failed to warn her about the potentially health risks associated with the device. For the reasons set forth below, the Court finds good cause to GRANT the Motion to Dismiss IN PART and give Hepburn leave to amend portions of her Complaint.

## II. FACTS

Boston Scientific designed, manufactures, and sells a medical device called the Greenfield Filter. The Greenfield Filter is designed to filter blood in the inferior vena cava ("IVC"), a vein that returns blood to the heart from the lower extremities. In certain

individuals, blood clots or "thrombi" travel from the blood vessels in the leg and pelvis, through the IVC and into the lungs, where they can block one or more arteries, causing a potentially deadly medical condition called a pulmonary embolism ("PE"). These thrombi can also develop and block blood flow in the deep leg veins, causing another potentially life-threatening medical condition called deep vein thrombosis ("DVT"). When implanted in the IVC, the Greenfield Filter prevents blood clots from traveling from the lower extremities to the heart and lungs. Boston Scientific designed the Greenfield Filter in 1973 as a permanent medical device.[1] In the 2000s, medical device companies began designing and selling retrievable IVC filters that a doctor can remove once a patient's risk of blood clots has passed.

In August 2010, the U.S. Food & Drug Administration ("FDA") issued a warning against leaving IVC filters implanted in patients for extended periods of time. The FDA issued an additional warning in 2014 about the health risks associated with leaving IVC filters in place for long periods and encouraged doctors to remove the devices "when the risk/benefit profile favors removal and the procedure is feasible given the patient's health status." Dkt. 1-2, at 5.

On December 23, 2009, Doctor John Mannschreck implanted a Greenfield Filter into Hepburn after she had been hospitalized for recurrent DVT episodes. The Filter remains inside of Hepburn to this day. Hepburn alleges that Boston Scientific failed to

[1] Even through the Greenfield Filter is a "permanent" IVC filter, some studies have shown that doctors are able to successfully retrieve permanent IVC filters in over 90% of patients. Dkt. 1-2, at 6.

disclose to physicians and patients the risks associated with the Greenfield Filter while promoting it as safe and effective. Hepburn asserts that she "is at risk of suffering from serious health complications due to the long-term implant of the filter." *Id.* at 9. Specifically, she alleges she has an "increased risk of DVT despite the implanted device, constant pains in the abdominal region and includes the risk of the filter migrating to the other parts of the vena cava, heart, lungs or other organs, DVT, fracture or breakage of the filter, perforation of the vena cava or other soft tissue, and other complications." *Id.* at 9–10.

Hepburn filed this case in November 2017, in the Second Judicial District, in and for the County of Nez Perce. In her Complaint, Hepburn asserts ten claims against Boston Scientific: I. negligence; II. strict products liability: defective design; III. strict products liability: manufacturing defect; IV strict products liability: failure to warn; V. breach of express warranty; VI. breach of implied warranty of merchantability; VII. breach of implied warranty of fitness; VIII. fraudulent misrepresentation; IX. fraudulent concealment; and X. negligent misrepresentation. Hepburn seeks "compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post judgment interest as allowed by law, costs of suit and attorneys' fees." *Id.* at 41.

Boston Scientific removed the case to this Court on December 28, 2017, and then filed the pending Motion to Dismiss on January 12, 2018. The Court held a hearing on the Motion at the Boise courthouse on May 3, 2018.

In her briefs, Hepburn does not argue that her warranty claims (Counts V, VI, and VII), her fraudulent concealment claim (Count IX), or her negligent misrepresentation claim (Count X) should survive the motion to dismiss stage. The Court, therefore, does not address those claims and will dismiss those claims with prejudice.

## III. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) permits a court to dismiss a claim if the plaintiff has "fail[ed] to state a claim upon which relief can be granted." "A Rule 12(b)(6) dismissal may be based on either a 'lack of a cognizable legal theory' or 'the absence of sufficient facts alleged under a cognizable legal theory.'" *Johnson v. Riverside Healthcare Sys., LP*, 534 F.3d 1116, 1121 (9th Cir. 2008) (citation omitted). Federal Rule of Civil Procedure 8(a)(2) requires a complaint to contain "a short and plain statement of the claim showing that the pleader is entitled to relief," in order to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554 (2007). "This is not an onerous burden." *Johnson*, 534 F.3d at 1121. A complaint "does not need detailed factual allegations," but it must set forth "more than labels and conclusions, and a formulaic recitation of the elements." *Twombly*, 550 U.S. at 555. The complaint must also contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Id.* at 570. In considering a Rule 12(b)(6) motion, the Court must view the "complaint in the light most favorable to" the claimant and "accept[] all well-pleaded factual allegations as true, as well as any reasonable inference drawn from them." *Johnson*, 534 F.3d at 1122.

At the pleading stage, Rule 9(b) of the Federal Rules of Civil Procedure requires a party alleging fraud to "state with particularity the circumstances constituting fraud," although "intent . . . may be alleged generally." "Rule 9(b) demands that the circumstances constituting the alleged fraud be specific enough to give defendants notice of the particular misconduct . . . so that they can defend against the charge and not just deny that they have done anything wrong." *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (quoting *Bly–Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001) (internal quotation marks omitted) "Averments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged." *Id.* (quoting *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003)). "Rule 9(b) serves three purposes: (1) to provide defendants with adequate notice to allow them to defend the charge and deter plaintiffs from the filing of complaints 'as a pretext for the discovery of unknown wrongs'; (2) to protect those whose reputation would be harmed as a result of being subject to fraud charges; and (3) to 'prohibit[ ] plaintiff[s] from unilaterally imposing upon the court, the parties and society enormous social and economic costs absent some factual basis.'" *Id.* at 1125.

## IV. ANALYSIS

Boston Scientific first argues that the Court should dismiss this case in its entirety because Hepburn has failed to allege a cognizable legal injury. Second, Boston Scientific argues Hepburn has failed to state a claim upon which relief can be granted with regard to Counts One through Four—Hepburn's negligence and strict liability claims. Third, Boston Scientific argues the Court should dismiss Hepburn's fraud claim—Count

Eight—because Hepburn has failed to plead that claim with particularity as required under Rule 9(b). The Court addresses each in turn.

*A. Whether Hepburn has alleged a cognizable injury*

Boston Scientific first argues that the Court should dismiss all claims because Hepburn has failed to allege a cognizable injury under Idaho law. This reads like a standing argument, but Boston Scientific never specifically frames it that way. Nevertheless, it is proper for the Court to examine standing along with Boston Scientific's arguments, as "[f]ederal courts are required sua sponte to examine jurisdictional issues such as standing." *Bernhardt v. Cty. of Los Angeles*, 279 F.3d 862, 868 (9th Cir. 2002) (quoting *B.C. v. Plumas Unified Sch. Dist.*, 192 F.3d 1260, 1264 (9th Cir. 1999).

"To establish Article III standing, an injury must be 'concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling.'" *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (citation omitted). "Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending." *Id.* The Ninth Circuit has clarified that "[i]f a plaintiff faces 'a credible threat of harm,' and that harm is 'both real and immediate, not conjectural or hypothetical,' the plaintiff has met the injury-in-fact requirement for standing under Article III." *Krottner v. Starbucks Corp.*, 628 F.3d 1139, 1143 (9th Cir. 2010).

Boston Scientific argues that Hepburn has failed to allege what injury she has suffered, when she suffered those injuries, or when and where she received treatment for those injuries. In addition, Boston Scientific asserts that, to the extent Hepburn seeks to recover for future injuries to which she might be susceptible, such injuries cannot support a damages award.

In her response brief, Hepburn clarifies that she has suffered "economic damages, emotional distress, [and] psychological trauma [from] living with a defective product implanted in her body." Dkt. 7, at 7. She also asserts that she "now requires regular medical monitoring to ensure her health and wellbeing as a result of the long-term implantation of the Greenfield Filter." *Id.* Thus, it appears Hepburn alleges three injuries: (1) increased risk of future harm cause by the allegedly defective medical device; (2) emotional distress caused by worrying about said future harm; and (3) costs associated with medical monitoring to prevent said future harm.

Hepburn cites several cases for the proposition that she can seek recovery for risk of future injuries under Idaho law. The first case Hepburn cites does not in fact support Hepburn's argument. In the first case, *Conner v. Hodges*, the plaintiff alleged both past injury (after her doctor failed to properly perform a sterilization procedure, she had an unwanted pregnancy with complications that required several surgeries) and potential future injuries (she was at risk of needing additional medical care in the future, due to the complications). 333 P.3d 130, 137 (Idaho 2014). Unlike Hepburn, the plaintiff in *Conner* alleged a concrete, past injury sufficient to establish standing. And, significantly, the

question of whether the plaintiff had standing or had alleged a cognizable injury was not before the *Conner* court.

The second case Hepburn cites, *Neal v. Neal*, is much more relevant. The plaintiff in *Neal* sought "to recover for emotional distress resulting from her fear that she may have contracted AIDS, herpes, or other sexually transmitted diseases." 873 P.2d 881, 886 (Idaho Ct. App. 1993), *aff'd in relevant part, rev'd in part*, 873 P.2d 871 (1994). When examining whether the injury was compensable, the court explained that "[m]any jurisdictions have allowed damages for emotional distress resulting from the present fear of developing a disease in the future where the disease has a latency or incubation period, such as cancer, tuberculosis, or AIDS." *Id.* at 887. "In such cases, damages are recoverable only if the mental injury alleged is shown to be sufficiently genuine and the fear reasonable." *Id.* Typically, the plaintiff must clearly establish that he or she was in fact exposed to a carcinogen or disease in order to recover damages. *Id.* at 887–88. Thus, a plaintiff cannot recover damages for injuries stemming only from the fear of exposure. *Id.* at 888–89 ("[A] plaintiff's fear of a disease must be based on more than the mere possibility of exposure to a disease or disease-causing agent."). Ultimately, the *Neal* court affirmed the district court's decision to dismiss the claims for emotional distress because the plaintiff had not established that her husband had actually exposed her to any diseases. *Id.*

In response, Boston Scientific relies heavily on *DeMoss v. City of Coeur D'Alene*, 795 P.2d 875 (Idaho 1990), in its reply brief and at oral argument. *DeMoss* is readily distinguishable from *Neal* and from this case. There, the Idaho Supreme Court found the

plaintiff's fear of contracting asbestosis or cancer in the future was "insufficient to establish a claim [specifically] under 42 U.S.C. § 1983." *Id.* at 879. Under that statute, a plaintiff is required to prove that he or she has in fact "been deprived of a constitutionally protected right." *Id.* In this case, as in *Neal*, the plaintiff has not asserted a § 1983 claim; rather, this case is comprised of Idaho state law tort claims. The *DeMoss* court specifically contrasted § 1983 claims with some state law tort claims, in which a chance of contracting a disease in the future can be a legally cognizable injury. For example, the *DeMoss* court cited *Sterling v. Velsicol*, in which the Sixth Circuit's explained:

> Where the basis for awarding damages is the potential risk of susceptibility to future disease, the predicted future disease must be medically reasonably certain to follow from the existing present injury. While it is unnecessary that the medical evidence conclusively establish with absolute certainty that the future disease or condition will occur, mere conjecture or even possibility does not justify the court awarding damages for a future disability which may never materialize.

855 F.2d 1188, 1204 (6th Cir. 1988). This decision, thus, accords with *Neal*, which requires plaintiffs to show they have been exposed to harm and they have a genuine and reasonable fear of future harm. Importantly, the *Sterling* case was at the post-judgment stage when the court gave the above explanation. Less is required at the pleading stage, where this case now lies.

Based on the above cases, the Court must examine whether Hepburn has alleged that she has been exposed to harm and whether her fear of future injury is "sufficiently genuine" and "reasonable." *Id.* Similarly, under the relevant cases discussing standing, the Court must look at whether Hepburn has alleged that her injury is "certainly

impending" and whether Hepburn faces "a credible threat of harm." *Krottner*, 628 F.3d at 1143.

The Court finds, first, that Hepburn has alleged that she has been exposed to harm: she alleged that a doctor implanted the Greenfield Filter in her, that it has remained in her for the last eight years, and that the long-term implantation subjects her to a high risk of experiencing an adverse event caused by the Filter. It is not as clear whether Hepburn has sufficiently alleged that her fear of future injury is reasonable or that the future harm is "certainly impending." Hepburn has explained that the FDA has issued warning about long-term use of IVC filters "following the receipt of some 900 adverse event reports." Dkt. 1-2, at 5. But Hepburn has given no context to this number. For example, Hepburn has not alleged how many of these adverse events involved the Greenfield Filter in particular, what percentage of IVC filter users suffered an adverse event, or how much the risk of experiencing an adverse event increases for someone, like Hepburn, who has had the Filter for eight years. Thus, Hepburn could strengthen her Complaint in these respects. Nevertheless, Hepburn does not need to allege the exact probability of future harm in order to establish standing.

Besides the increased risk of future harm, and the accompanying emotional distress, Hepburn has also alleged that she requires continual medical monitoring. Such "medical monitoring is a sufficient injury in fact to confer standing." *See Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 569-575 (6th Cir. 2005) (finding plaintiff had standing where he alleged he "has a device in his body which increases his risk for aortic bypass stenosis or occlusion and its resulting physical injuries") (collecting other cases

with similar holdings). Like with her claims of emotional distress over the fear of future harm, Hepburn could provide significantly more details to support this claim of harm. For example, Hepburn has not explained what type of medical monitoring she must endure, how invasive it is, how often she endures it, or how necessary the monitoring is. While Hepburn need not set forth "detailed factual allegations," a few more facts will push this on-the-line case definitively into the realm of cognizable legal injury.

Because, as explained below, the Court gives Hepburn leave to amend her Complaint, it will permit her to bolster her claims of injury on amendment.

The Court turns now to a discussion of whether Hepburn's causes of action state claims upon which the Court can grant relief.

*B. Products Liability Claims (Counts II, III, and IV)*

"Generally speaking, there are three general categories of strict liability in product liability cases——manufacturing flaws, design defects, or failure to warn." *Wilson v. Amneal Pharm., L.L.C.*, No. 1:13-CV-00333-CWD, 2013 WL 6909930, at *7 (D. Idaho Dec. 31, 2013) (citing *Toner v. Lederle Laboratories*, 732 P.2d 297, 306 (Idaho 1987)). To establish a case for strict liability based on any of the three available theories, "a plaintiff must establish that (1) the product in question was defective, (2) the defect existed at the time the product left the manufacturer's control, and (3) that the defective product was the proximate cause of the plaintiff's injuries." *Puckett v. Oakfabco, Inc.*, 979 P.2d 1174, 1179 (Idaho 1998). "Regardless of the theory under which recovery is sought in a products liability action, a plaintiff must establish that the injury is causally

related to defendant's act or omission." *Watson v. Navistar Int'l Transp. Corp.*, 827 P.2d 656, 674 (1992).

1. Design Defect/Manufacturing Flaw

Under a theory of design defect, "a product is defective when it exposes a user or bystander to an unreasonable risk of physical injury." *Id.* A product must be designed "so as to eliminate unreasonable risks of foreseeable injuries." *Puckett*, 979 P.2d at 1179. "A plaintiff may prove a design defect by presenting evidence of feasible alternative designs, available to the manufacturer, that would have lessened the risk associated with the product." *Wilson*, 2013 WL 6909930, at *8. Although Idaho courts recognize both "manufacturing flaws" and "design defects" as product liability theories, Idaho courts have also clarified that "[t]here is no rational distinction between [the] design and manufacture" theories.[2] *Id.* (quoting *Rindlisbaker v. Wilson*, 519 P.2d 421, 428 (Idaho 1974)). Thus, the Court treats these claims as one and the same.

Boston Scientific argues that Hepburn's design defect and manufacturing flaws claims do not meet the Rule 8 pleading standard because the Complaint baldly asserts that the Greenfield Filter was unreasonably dangerous to consumers without identifying how exactly it was defectively designed or what alternative designs were available to Boston Scientific. In her response brief, Hepburn alleges that the Greenfield Filter is defective because it exposes users to an unreasonable risk of physical injury including

[2] "In jurisdictions or cases that recognize a distinction between design and manufacture, the plaintiff must establish that the particular product at issue was not manufactured in conformity with the precise specifications for making the product." *Wilson*, 2013 WL 6909930, at *8 (citing *Snell v. Bell Helicopter Texton, Inc.*, 107 F.3d 744, 749 (9th Cir. 1997)).

"device migration, embolization, fragmentation or perforation of the filter into human tissue, and death." Dkt. 7, at 9. Hepburn further asserts that a feasible alternative design existed in 2009, when she had the Greenfield Filter implanted. Starting in 2003, other IVC filter manufacturers began producing and selling retrievable filters, designed for short-term use, which are much safer than permanent IVC filters, such as the Greenfield Filter.

The Court agrees with Boston Scientific that, in the section of the Complaint setting forth the claims for design defect and manufacturing flaw, Hepburn uses very conclusory language. *See* Dkt. 1-2, at 16-20. However, in the factual background section of the Complaint, Hepburn sets forth the specifics she reiterates in her response brief. Thus, the Court does not agree with Boston Scientific that Hepburn's clarifications in her response brief are a complete "departure from the Complaint."

Boston Scientific next argues that the Greenfield Filter is an "unavoidably unsafe product" because it is "incapable of being made [completely] safe for [its] intended and ordinary use." *See* Restatement (Second) of Torts § 402A (1965) cmnt. k. "Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." *Id.* Boston Scientific generally argues that the Greenfield Filter was properly prepared, accompanied by proper directions, and incapable of being made completely safe for its intended and ordinary use—long-term and permanent implantation. This argument misses the mark. In order to fall under the "unavoidably unsafe product" exception, "a seller . . . [] must establish that the product's risk is in fact 'unavoidable.'" *Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 732

P.2d 297, 305 (Idaho 1987). "[F]or this to be true, the design must be as safe as the best available testing and research permits." *Id.* In other words, "there must be, at the time of the subject product's distribution, no feasible alternative design which on balance accomplishes the subject product's purpose with a lesser risk." *Id.* Hepburn has alleged that such an alternative design existed in 2009: the retrievable IVC filter.

In sum, Hepburn, again, could strengthen her Complaint to clarify which exact facts support her design defect and manufacturing flaw claims. However, when considered as a whole, the Complaint likely contains all the necessary allegations for a strict liability design defect or manufacturing flaw products liability claim. However, as the Court will allow Hepburn to amend her Complaint, the Court will permit her to allege additional facts to strengthen these claims on amendment.

2. Failure to Warn

A product is defective under a failure to warn theory if "the defendant has reason to anticipate that danger may result from a particular use of his product and fails to give adequate warnings of such danger." *Puckett*, 979 P.2d at 1181 (quoting *Rindlisbaker*, 519 P.2d at 428). "This rule is, however, limited to situations where the danger is not obvious. However, if the danger is obvious, or if the danger is known to the person injured, the duty to warn does not attach." *Watson*, 827 P.2d at 673 (quoting *Mico Mobile Sales & Leasing, Inc. v. Skyline Corp.*, 546 P.2d 54, 60 (1975). A plaintiff also must establish that the failure to warn was the proximate cause of his or her injuries. *Puckett*, 979 P.2d at 1179.

Hepburn alleges in her Complaint that the Greenfield Filter was "unaccompanied by appropriate and adequate warnings regarding the risk of severe and permanent injuries associated with its use, including, but not limited to, the migration of the filter to the other parts of the vena cava, the heart or other organs and perforation of the vena cava or tissue. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer." Dkt. 1-2, at 21.

Boston Scientific first argues that Hepburn has failed to plead the causation element of her failure to warn claim. Specifically, Boston Scientific contends that Hepburn has not alleged that she has suffered any of the enumerated adverse outcomes about which she alleges Boston Scientific failed to warn. This argument is simply a reframing of its earlier assertion that Hepburn has not alleged a cognizable injury. Hepburn has alleged that Boston Scientific's failure to warn about the potential harms associated with long-term use of the Greenfield Filter caused her to agree to have her doctor implant the Filter inside of her. This decision has put her at an increased risk of suffering those harms and has caused her to undergo continual medical monitoring. These allegations sufficiently state a failure to warn claim.

Second, Boston Scientific argues that Hepburn has not sufficiently alleged that it failed to warn her physician about the potential adverse effects of long-term use of the Greenfield Filter. It is true that, "[u]nder Idaho law, a supplier positioned on the commercial chain remote from the ultimate consumer may, under certain circumstances, fulfill its duty to warn by adequately warning an intermediary." *Adams v. United States*, 622 F. Supp. 2d 996, 1006–07 (D. Idaho 2009) (citing *Sliman v. Aluminum Co. of*

*America*, 731 P.2d 1267, 1270–71 (Idaho 1986)). Nevertheless, Boston Scientific's argument on this point is unsuccessful for several reasons. First, it is premature. The "learned intermediary" argument is an affirmative defense that is better raised at summary judgment to defeat this claim. Hepburn is not necessarily required to allege that Boston Scientific failed to warn her physician at this stage. Hepburn has alleged that "no adequate warning was communicated to [her] physicians and/or healthcare providers." Dkt. 1-2, at 23. Boston Scientific wants Hepburn to give more details as to "how the Greenfield Filter [Directions for Use] failed to warn her implanting physician." Hepburn could identify her physicians and/or healthcare providers by name, and the specific materials Boston Scientific gave to her physicians and/or healthcare providers, but there are few other details Hepburn could supply to describe the absence of an adequate warning. Because a heightened pleading standard does not apply to this claim (unlike the fraud claim), Hepburn does not need to include such details in her Complaint.

In sum, the Court finds Hepburn has adequately alleged a failure to warn claim.

*B. Negligence Claim*

As a threshold matter, Hepburn and Boston Scientific cite different elements that are required to set forth a negligence claim. Boston Scientific maintains that, to assert "a products liability action based on negligence," Hepburn must assert that "1) . . . she was injured by the product, 2) the injury was the result of a defective or unsafe product, and 3) that a defect existed when the product left the control of the manufacturer." *Watson*, 827 P.2d at 674. Hepburn alleges that she must only set forth the elements of a simple negligence claim, which are: "(1) a duty, recognized by law, requiring a defendant to

conform to a certain standard of conduct; (2) a breach of that duty; (3) a causal connection between the defendant's conduct and the resulting injuries; and (4) actual loss or damage." *Grabicki v. City of Lewiston*, 154 Idaho 686, 691, 302 P.3d 26, 31 (2013) (citation omitted). Boston Scientific has correctly stated the law on this point. Significantly, Hepburn has failed to cite an Idaho case applying the elements of simple negligence to a negligence claim involving a product.[3]

Nevertheless, Hepburn has stated a prima facie case of negligence. As with her strict products liability claim, Hepburn has alleged that 1) she faces an increased risk of future injury due to the Greenfield Filter; 2) this increased risk is the result of the Greenfield Filter being defective or unsafe; and 3) that defect existed when the product left the control of Boston Scientific.

In attacking this claim, Boston Scientific simply reiterates the same arguments it made with regard to the strict products liability claims. As explained above, these

[3] The Court notes that "negligence and strict liability are separate, nonmutually exclusive theories of recovery, and that '[the] failure to prove one theory does not preclude proving another theory.'" *Toner*, 732 P.2d at 318 n.5 (quoting *Chancler v. Am. Hardware Mut. Ins. Co.*, 712 P.2d 542, 547 (Idaho 1986)). However, "[w]hether a [products liability] cause of action is based upon negligence or strict liability," the prima facie elements are the same. *Wilson*, 2013 WL 6909930, at *7; *see also Massey v. Conagra Foods, Inc.*, 328 P.3d 456, 462 (Idaho 2014). The claims do differ in important ways. For example, where a product is found to be "unavoidably unsafe, the plaintiff is deprived of the advantage of a strict liability cause of action, but may proceed under a negligence cause of action." *Id.* at 309-10. In addition, "contributory negligence is a defense to a products liability action founded solely on negligence," but not strict liability. *Shields v. Morton Chem. Co.*, 518 P.2d 857, 858 (Idaho 1974). Most importantly, an "action based on strict liability focuses on the condition of the product after manufacturing and the consumer's expectation, [while] an action based on negligence is concerned with the conduct and behavior of the manufacturer." *Pate v. Columbia Mach., Inc.*, 930 F. Supp. 451, 464 (D. Idaho 1996) (citation omitted).

arguments are largely unsuccessful. Therefore, the Court finds Hepburn has adequately stated a negligence claim.

*D. Fraud Claim (Count VIII)*

In Count VIII, Hepburn asserts a claim for fraudulent misrepresentation. "Under Idaho law, actual fraud consists of nine elements that a plaintiff must prove by clear and convincing evidence." *Doe v. Boy Scouts of Am.*, 356 P.3d 1049, 1054 (Idaho 2015). "Specifically, to prove actual fraud, a plaintiff must show: (1) a statement or a representation of fact; (2) its falsity; (3) its materiality; (4) the speaker's knowledge of its falsity; (5) the speaker's intent that there be reliance; (6) the hearer's ignorance of the falsity of the statement; (7) reliance by the hearer; (8) justifiable reliance; and (9) resultant injury." *Id.*; *see also Faw v. Greenwood*, 613 P.2d 1338, 1340 (Idaho 1980). This claim must comply with the requirements of Federal Rule of Civil Procedure 9(b), laid out above.

Hepburn alleges in her response brief that she has plead the nine requirements as follows:

> (1) Defendant expressed and represented that its Greenfield Filter was safe, effective, and fit for long-term and even permanent implantation; (2) these representations were false; (3) these representations were material because if Plaintiff and her physicians had known the information that Defendant fraudulently misrepresented and concealed, Plaintiff's physicians would not have prescribed or implanted it into Plaintiff; (4) Defendant knew that these representations were false; (5) Defendant intended for Plaintiff and/or her physician to rely on its misrepresentations to induce the continued purchase and use of its Greenfield Filter; (6) Plaintiff's physicians, the medical community, and Plaintiff herself, read and heard these misrepresentations; (7) Plaintiff's physicians relied upon these misrepresentations; (8) Plaintiff's physician's reliance was justifiable because Defendant, as the designer and manufacturer of the Greenfield Filter, had actual knowledge of facts of its

> serious risks and that knowledge was exclusively known by Defendant; Plaintiff's physicians thus had to rely upon Defendant's superior knowledge and representations; and that (9) Plaintiff's injuries were directly and proximately caused by Defendant's intentionally false and fraudulent misrepresentations.

Dkt. 7, at 14 (internal citations omitted).

The Court notes that Hepburn's response brief is much more succinct and clear than her Complaint. Her Complaint is, at times, vague, muddled, and repetitive. Accordingly, it is hard to determine if the above nine elements are actually contained in the Complaint. For the most part, the Court finds they do appear in the Complaint. However, the Court finds some significant weakness in the first element.

As to this element, it not clear from the Complaint that the "false statement" at issue is Boston Scientific's assertion that the Greenfield Filter is "safe, effective, and fit for long-term and even permanent implantation." Rather, Hepburn begins the section of her Complaint regarding fraudulent misrepresentation by stating, "Defendant engaged in commercial conduct by selling Greenfield Filters and misrepresented and omitted material information regarding this product by failing to disclose the known risks of their Greenfield Filter and predecessor devices." Dkt. 1-2, at 31. Later, Hepburn states, "At the time and place of the sale, distribution, and supply of the Defendant's Greenfield Filter to Plaintiff by way of Plaintiffs health care providers and medical facilities, Defendant expressly represented and warranted, by labeling materials submitted with the product, that the Greenfield Filter was safe and effective for its intended and reasonably foreseeable use." *Id.* at 33. This second statement helps to clarify what the alleged false statement is, but Hepburn still does not identify the crucial who, what, where, and when

of this interaction. She does not specific what agent of Boston Scientific sold the Greenfield filter to her "health care providers and medical facilities"—which are additional parties to this interaction she has failed to identify. Hepburn has not identified when this sale took place or what exactly the "labeling materials" stated. Hepburn has also asserted numerous allegations about what Boston Scientific's current website and brochures state. These materials have no bearing on the relevant "false statement," which Boston Scientific would have made sometime before Hepburn had the device implanted in December 2009.

In sum, Hepburn has not met the Rule 9(b) pleading requirements with respect to this claim. However, the Court believes Hepburn could provide the necessary allegations to state a fraud claim. Therefore, the Court gives Hepburn leave to amend this claim and assert the additional necessary details.

*E. Punitive Damages*

Finally, Boston Scientific argues that the Court should strike Hepburn's reference to punitive damages in her Complaint because she has failed to comply with Idaho Code § 6-1604.

Because this case is before the Court on diversity jurisdiction, Idaho Code section 6-1604(2) applies. *See Windsor v. Guarantee Trust Life Ins. Co.*, 684 F. Supp. 630, 633 (D. Idaho 1988) (holding Idaho Code section 6–1604(2) is substantive in nature and therefore controlling in federal court in a diversity case). "Under Section 6-1604(2), a party cannot make a claim for punitive damages in its prayer for relief; rather, the claim must be made by a pretrial motion to amend." *Doe v. Cutter Biological, a Div. of Miles*

*Inc.*, 844 F. Supp. 602, 610 (D. Idaho 1994). Specifically, Section 6–1604(2) provides as follows:

> [A] party may, pursuant to a pretrial motion and after hearing before the court, amend the pleadings to include a prayer for relief seeking punitive damages. The court shall allow the motion to amend the pleadings if the moving party establishes at such hearing a reasonable likelihood of proving facts at trial sufficient to support an award of punitive damages.

Idaho Code § 6-1604(2).

Hepburn's Complaint does request "Punitive and/or Treble Damages pursuant to state law." Dkt. 1-2, at 42. This request for punitive damages is not permissible under Section 6-1604(2) and, accordingly, the Court will strike it from the Complaint. However, the Court does acknowledge that Hepburn retains the right to make a pretrial motion to add such a request to her Complaint.

## IV. CONCLUSION

For the reasons set forth above, the Court hereby ORDERS:

1. The Motion to Dismiss (Dkt. 4) is GRANTED IN PART and DENIED IN PART as follows:
    a. The Court DISMISSES WITH PREJUDICE Counts V, VI, VII, IX, and IX.
    b. The Court DISMISSES WITHOUT PREJUDICE Count VIII (fraud). The Court grants Hepburn leave to amend this claim.
    c. The Court DENIES the Motion as to Counts I (negligence) and II-IV (products liability); however, the Court permits Hepburn to add additional details to strengthen these claims and to strengthen her asserted injury.

d. Hepburn shall have 21 days from the issuance of this Order to file her Amended Complaint.

DATED: May 17, 2018

David C. Nye
U.S. District Court Judge