UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

CLAUDIA HEPBURN,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

Case No. 3:17-cv-00530-DCN

MEMORANDUM DECISION AND ORDER

I. INTRODUCTION

This matter comes before the Court on Defendant Boston Scientific's Second Motion to Dismiss. Dkt. 18. 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 potential health risks associated with the device.

The Court held oral argument on January 9, 2019. During that hearing, the Court again ordered any reference to punitive damages struck from Hepburn's Amended Complaint.[1] The Court took the remaining issue—whether it should dismiss Hepburn's

[1] The Court already addressed this issue and ultimately struck Hepburn's reference to punitive damages from her original Complaint. However, Hepburn's Amended Complaint inexplicably includes a request for punitive damages once again. As the Court already explained, Idaho Code section 6–1604(2) clearly prohibits such a request, and the Court does not appreciate Hepburn's disregard for the Court's prior order.

fraudulent misrepresentation claim—under advisement. For the reasons set forth below, the Court now GRANTS Boston Scientific's Second Motion to Dismiss.

II. BACKGROUND

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.[2] 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

[2] 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. 17, at 5.

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. 17, 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 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 10.

Specifically, she alleges she has an "increased risk of DVT, despite the implanted device, constant pain in the abdominal region and 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, as well as other complications." *Id.* at 10.

Hepburn filed this case in November 2017, in the Second Judicial District, in and for the County of Nez Perce. In her original Complaint, Hepburn brought ten claims against Boston Scientific. Boston Scientific removed the case to this Court on December 28, 2017, and filed its first Motion to Dismiss on January 12, 2018, which the Court granted in part, and denied in part. Specifically, the Court dismissed Hepburn's warranty claims, fraudulent concealment claim, and negligent misrepresentation claim with prejudice. Dkt. 16, at 4. It also dismissed Hepburn's fraudulent misrepresentation claim

without prejudice and granted her leave to amend her complaint. The Court denied Boston Scientific's Motion to Dismiss as to Hepburn's negligence claim, and products liability claims.

Hepburn filed her Amended Complaint on June 7, 2018. Boston Scientific filed its Second Motion to Dismiss on July 6, 2018, which only seeks dismissal of Hepburn's fraud claim (Count V) and asks the Court to strike Hepburn's request for punitive damages.

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

In Count V, 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). Fraud claims must also comply with the requirements of Federal Rule of Civil Procedure 9(b), laid out above.

In dismissing Hepburn's fraud claim previously, the Court found that there were "some significant weakness[es] in the first element." The Court explained:

> It is 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 specify 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.

Dkt. 16, at 19-20.

In her Amended Complaint, Hepburn attempts to remedy these deficiencies. It appears her updated allegations of fraudulent misrepresentation fall into four main categories: (1) statements made by Boston Scientific via its current website and brochures, (2) the labeling materials Boston Scientific submitted with its device; (3) statements made by Boston Scientific's "sale representatives" to Hepburn's healthcare providers and the medical community as a whole; and (4) statements made by Dr. John Mannschreck to Hepburn. Although there is a certain amount of overlap within these four categories, the Court will discuss each category individually.

1. *Current website and brochures*

In its prior order, the Court already explained that Boston Scientific's current website and brochures "have no bearing on the relevant false statement." Dkt. 16, at 20. Hepburn's Amended Complaint, however, reasserts these theories. Hepburn argues that the current website and brochures "allow the Plaintiff to allege upon information and belief what representations were made by Defendants to her physicians and implanting surgeon." Dkt. 19-1, at 6. However, this appears to be little more than speculation as to what representations Boston Scientific *may have* made prior to implantation of the device. Such speculation is not enough to meet Rule 9(b)'s heightened pleading

standards. *See* FRCP 9(b) ("[A] party *must state with particularity* the circumstances constituting fraud or mistake.") (emphasis added).

Rather than relying on brochures and other content that was in use at the time Hepburn received the device, she simply claims that at the time of implantation, "Dr. John Mannschreck made similar representations to her as the advertising materials [currently in use.]" *Id.* at 7. However, it is unclear whether Hepburn or Dr. Mannschreck ever read such advertising materials, what those advertising materials said, or whether the materials contained false statements. Rule 9(b) requires more.

2. *Labeling Materials*

Hepburn's Amended Complaint also alleges that "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 to those said healthcare providers, medical facilities and the medical community as a whole." Dkt. 17, at 31. She asserts that based upon these materials, the "Plaintiff's medical providers and the medical community believed the Defendant's device was safe for long-term use." *Id.* This argument fails for two primary reasons. First, Hepburn's Amended Complaint once again fails to include what the labelling materials *actually* said—leaving the Court unsure of whether the labels contained misrepresentations. Second, the Amended Complaint lacks any particularized facts indicating, at the very least, where and when the labeling was viewed by Hepburn or her physicians, whether they actually relied upon the labelling materials, and why such reliance was justified. Without more, Hepburn's labelling theory

cannot sustain her fraud claim.

3. Statements made by sales representatives

Next, Hepburn's asserts that "Defendant, through its sale representatives, represented to Plaintiff's healthcare providers, the medical community and/or the FDA that its device was safe for long-term use, efficient in preventing further blood clot complications and other assertions over the safety of its Greenfield filter such as protection from perforation and prevention of blood clots." Dkt. 17, 30-31. Again, the crucial "who, what, when, where, and how" of the misconduct charged remains largely unknown. Hepburn fails to identify who the alleged sales representatives were and merely speculates as to what they said. It also remains unclear when and where the alleged conversations took place. This is not enough to satisfy Rule 9(b).

4. Statements made by Dr. Mannschreck

Hepburn's final theory relies on statements made by Dr. Mannschreck prior to implantation of the device. She alleges that Dr. Mannschreck told her that the device was safe and effective, and claims that he "made these representations based on information he had received from Defendant and/or its agents, relied upon, and thus induced him to use, recommend, implant, and/or deploy the Greenfield Filter into Plaintiff." Dkt. 17, at 31-32.

Here, Hepburn does include more detail. She states that Dr. Mannschreck "relayed Defendant's representations of the Greenfield Filter's 'high clinical patency with low fracture, migration and penetration' and 'Established filter performance,'" and that "the

device would filter out her blood clots from moving to her lungs even after long term use." *Id.* at 30.

Despite this greater particularity regarding what was said, Hepburn's fraud claim is still lacking. For starters, Hepburn's Amended Complaint lacks any *particularized* detail as to where Dr. Mannschreck received this information. As recounted above, the Court has no idea whether Boston Scientific (through advertising, labelling, or its agents) actually conveyed this information to Dr. Mannschreck, when that occurred, or whether Dr. Mannschreck relied upon that information. Hepburn merely speculates that such reliance occurred. It is entirely plausible that Dr. Mannschreck's representations to Hepburn could have been based upon his own prior experience with the device, rather than anything Boston Scientific communicated to him. The Court simply has no way of knowing. [3]

Finally, Hepburn argues that the Court should allow this claim to move forward—despite the lack of particularized detail in her Amended Complaint—because Boston Scientific "would be the best source of information to obtain the specific materials, advertising, representative statements made to Plaintiff's doctors prior to the date of

[3] This theory may also fail because Hepburn has not alleged the existence of an agency relationship between Dr. Mannschreck and Boston Scientific. While the existence of such a relationship is not a required element of fraud claims under Idaho law, it may be necessary in order to hold Boston Scientific liable for statements made by Dr. Mannschreck. *See Triad Leasing & Fin., Inc. v. Rocky Mt. Rogues, Inc.*, 224 P.3d 1092, 1100 (Idaho 2009) (where a lessee's fraud claim against a seller failed because it was actually the broker who made the alleged fraudulent statement, and the lessee failed to "cite to any evidence establishing an agency relationship between Broker and . . . Seller."). The Court need not reach this issue, however, because even if no agency relationship is required, Hepburn's fraud claim still falls woefully short of Rule 9(b) requirements.

implant to induce them to use the device." Dkt. 19-1, at 4-5.

It is true that, although"[a]llegations of fraud based on information and belief usually do not satisfy Rule 9(b) . . . the Rule may be relaxed as to matters peculiarly within the opposing party's knowledge." *Muzinich & Co. v. Raytheon Co*., No. CV-01-284-S-BLW, 2002 U.S. Dist. LEXIS 26962, at *16 (D. Idaho Apr. 30, 2002) (citing *Wool v. Tandem Computers Inc.,* 818 F.2d 1433, 1439 (9th Cir. 1987)). However, this exception only applies if the "allegations are accompanied by a statement of the facts upon which the belief is founded." *Wool*, 818 F.2d at 1440. *See also Grassi v. Moody's Investors Servs.*, 540 Fed. Appx. 737, 738 (9th Cir. 2013). Here, the Amended Complaint falls short of this requirement.

In *Wool*, the Ninth Circuit found the statement of facts sufficient because "the paragraphs alleging misleading statements, misrepresentations, and specific acts of fraud [were] very precise. Each alleged misstatement [was] identified by content, date, and the document or announcement in which it appeared. . . and the manner in which such representations were false and misleading [was provided]." *Wool*, 818 F.2d at 1439-40. Here, the Amended Complaint lacks such specificity—relying instead on speculation and irrelevant material.

Additionally, pleading standards are generally only relaxed when "the relevant facts are known *only* to the defendant." *Concha v. London*, 62 F.3d 1493, 1503 (9th Cir. 1995) (emphasis added); *see also United States ex rel. Insoon Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1052 (9th Cir. 2001) ("Rule 9(b) may be relaxed to permit

discovery in a limited class of corporate fraud cases where the evidence of fraud is within a defendant's *exclusive possession*.") (emphasis added). Here, while Boston Scientific may arguably be in a better position than Hepburn to know the relevant facts that—as explained above—are missing from her Amended Complaint, Hepburn does not claim, nor does it seem likely, that such information is exclusively within Boston Scientific's possession. For all of these reasons, the Court GRANTS Defendant's Second Motion to Dismiss, and dismisses Hepburn's fraudulent misrepresentation claim WITH PREJUDICE.[4]

V. ORDER

The Court HEREBY ORDERS:

1. Boston Scientific's Second Motion to Dismiss (Dkt. 18) is GRANTED, and Hepburn's fraudulent misrepresentation claim (Count V) is DISMISSED WITH PREJUDICE. Accordingly, the only remaining claims are Hepburn's negligence claim (Count I), and strict products liability claims (Counts II-IV).
2. Any and all references to punitive damages are stricken from Hepburn's Amended Complaint (Dkt. 17). Hepburn does not need to file an updated version of her Amended Complaint removing those references. Likewise, Boston Scientific does not need to respond to those references in its answer to

[4] The Court is dismissing Hepburn's fraudulent misrepresentation claim with prejudice because it finds that it would be futile to allow Hepburn another opportunity to amend this claim. She has already been allowed to amend it once before, which resulted in the Amended Complaint—a document that continues to rely primarily on speculation and guesswork to justify the fraudulent misrepresentation claim.

the Amended Complaint.

DATED: January 23, 2019

David C. Nye
Chief U.S. District Court Judge