UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

JANICE E. MILLER, et al.,	)	
	)	
Plaintiffs	)	
	)	
v.	)	2:17-cv-00265-JDL
	)	
ZIMMER BIOMET INC., et al.,	)	
	)	
Defendants	)	

RECOMMENDED DECISION ON DEFENDANTS' MOTION TO DISMISS

In this products liability action, Plaintiffs Janice and Donald Miller seek to recover for injuries they claim were caused by a defective hip implant designed and manufactured by Defendants.

The matter is before the Court on Defendants' motion to dismiss. (Motion to Dismiss, ECF No. 16.) Through their motion, Defendants ask the Court to dismiss three of the ten claims asserted by Plaintiffs. Specifically, Defendants have moved to dismiss Plaintiffs' claims of fraud, negligence per se, and punitive damages.

Following a review of the pleadings, and after consideration of the parties' arguments, I recommend the Court grant in part and deny in part the motion.

BACKGROUND

The following facts are drawn from Plaintiffs' complaint and are accepted as true for purposes of evaluating the pending motion to dismiss. Beddall v. State St. Bank & Trust Co., 137 F.3d 12, 16 (1st Cir. 1998).

Plaintiff Janice Miller underwent right hip replacement surgery on March 22, 2012. Defendants designed and manufactured the hip implant components, specifically the Zimmer VerSys Hip System Femoral Head 12/14 Taper and the Zimmer M/L Taper Prostehesis ("the product").[1] (Complaint ¶¶ 1 – 2, 24.) On July 1, 2016, Plaintiff required a revision surgery because, according to Plaintiffs, the implant was emitting metal debris through a process known as "mechanically assisted crevice corrosion" (MACC), which debris caused metallosis and necrosis. (Id. ¶¶ 3, 28, 30, 31.) Subsequently, Plaintiff underwent two irrigation and debribement procedures, and a further procedure to address an infection. (Id. ¶¶ 4, 36, 42.) On January 26, 2017, Plaintiff received "an antibiotic laden total hip replacement, followed on February 6, 2017, by a sixth surgical procedure. (Id. ¶¶ 44 – 45.) Plaintiff suffers from a staph infection as a consequence of the surgeries. (Id. ¶¶ 4 – 5, 40 – 41, 46.)

Plaintiffs assert that Defendants' product is defective because the location at which the femoral head and neck of the prosthesis join is susceptible to fretting and corrosion, which process releases metal particles and ions that negatively impact blood and local tissue. (Id. ¶¶ 63.) Plaintiffs also allege that Defendants knew or should have known of the defect prior to the hip replacement surgeries, misrepresented that the product was safe for its intended use, and purposefully failed to disclose the defect to surgeons and the

[1] Plaintiff's left hip also was replaced with the product. Plaintiff has not received revision surgery on her left hip. The product also includes an acetabular cup component that replaces the hip socket. The allegations of defect do not involve the acetabular cup component.

public, in violation of the requirements of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (Id. ¶¶ 62 – 113.)

Plaintiffs assert claims of negligence (count I), strict product liability (counts II – IV), negligent misrepresentation (count V), fraudulent misrepresentation and concealment (count VI), negligence per se (count VII), breach of implied warranties (count VIII), punitive damages (count IX), and loss of consortium (count X).

DISCUSSION

A. Motion to Dismiss Standard

Pursuant to Federal Rule of Civil Procedure 12(b)(6), a party may seek dismissal of "a claim for relief in any pleading" if that party believes that the pleading fails "to state a claim upon which relief can be granted." In its assessment of the motion, a court must "assume the truth of all well-plead facts and give the plaintiff[] the benefit of all reasonable inferences therefrom." Blanco v. Bath Iron Works Corp., 802 F. Supp. 2d 215, 221 (D. Me. 2011) (quoting Genzyme Corp. v. Fed. Ins. Co., 622 F.3d 62, 68 (1st Cir. 2010)). To overcome the motion, a plaintiff must establish that the allegations raise a plausible basis for a fact finder to conclude that the defendant is legally responsible for the claim at issue. Id.

B. Fraudulent Misrepresentation and Concealment (count VI)

Defendants argue Plaintiffs have failed to plead fraud with particularity, and have failed to assert facts that would support an inference of detrimental reliance. (Motion at 3 – 5, ECF No. 16.) To prove a claim of fraudulent misrepresentation, a plaintiff must show that the defendant supplied false information concerning a material fact, with knowledge

of the falsity or in reckless disregard of the falsity of the statement, in order to induce another to act or refrain from acting based on the false representation. Knowlton v. Shaw, 791 F. Supp. 2d 220, 261 (D. Me. 2011). Similarly, to prove a claim of fraudulent concealment, a plaintiff must show a failure to disclose a material fact, where there is a legal or equitable duty to disclose, with the intention of inducing another to act or refrain from acting in reliance on the non-disclosure. Picher v. Roman Catholic Bishop of Portland, 2013 ME 99, ¶ 3, 82 A.3d 101, 102 – 103. A plaintiff must also show that he or she actually relied on the misrepresentation or concealment to his or her detriment and that the reliance was justified. Id.; Knowlton, 791 F. Supp. 2d at 261.

Federal Rule of Civil Procedure 9(b) provides that a party alleging fraud "must state with particularity the circumstances constituting fraud." "[T]he purpose of the heightened pleading requirement of Rule 9(b) is 'to give notice to defendants of the plaintiffs' claim, to protect defendants whose reputation may be harmed be meritless claims of fraud, to discourage 'strike suits', and to prevent the filing of suits that simply hope to uncover relevant information during discovery." J.S. McCarthy Co. v. Brausse Diecutting & Converting Equip., Inc., 340 F. Supp. 2d 54, 59 (D. Me. 2004) (quoting Doyle v. Hasbro, 103 F.3d 186, 194 (1st Cir. 1996)).

Plaintiffs argue that to the extent their claim is based on fraudulent concealment, they need not allege with particularity the details of any particular non-disclosure, but can rely on allegations that Defendants represented the product was safe for its intended use, and knew the product was defective. (Opposition at 6 – 7.) In Taylor v. Ford Motor Company, this Court denied a motion to dismiss for want of specificity, where the plaintiff

alleged that the defendant knew a vehicle was not crashworthy based on crash tests it conducted, but nevertheless falsely described the vehicle as "tough" in a marketing campaign. No. 1:06-cv-00069, 2006 WL 2228973, at *7 (D. Me. Aug. 3, 2006). Plaintiffs maintain that the reasoning of Taylor demonstrates that a plaintiff is not required to specify the time and place of a failure to disclose where the allegations are sufficient to notify the defendant of the "precise misconduct with which they are charged." (Opposition at 7, quoting Southco, Inv. v. *Penn Eng'g & Mrg.* Corp., 768 F. Supp. 2d 715, 720 (D. Del. 2011).)[2]

Plaintiffs argue their misrepresentation and concealment allegations are specific, and that their case "is on all fours with Taylor." (Opposition at 6.) They rely on the following allegations. (See Opposition at 7 – 9.)

> 25. On or about January 3, 2013, Plaintiff Janice E. Miller underwent a total hip arthroplasty of her left hip with insertion of the Products performed by Brian McGrory, M.D., at Maine Medical Center in Portland, Maine.
> ….
>
> 30. Based upon these findings and in light of worsening symptoms, Plaintiff underwent a complex revision surgery of her right prosthesis on July 1, 2016, performed by Brian McGrory, M.D., at Maine Medical Center in Portland, Maine.
> ….
>
> 56. The Zimmer M/L Taper was approved pursuant to a 510(k) on or about May 12, 2006, and Zimmer proceeded to sell the components to be used together with the Zimmer VerSys femoral head.
> ….

[2] In Southco, the district court considered a challenge to a claim of inequitable conduct associated with the defendant's prosecution of a patent. 768 F. Supp. 2d at 723. The plaintiff alleged that the defendant misrepresented material facts and concealed material information in specific communications made to the patent examiner. Id. Under the circumstances, the court concluded that the pleadings identified who, what, when, and where for purposes of Rule 9(b). Id.

61. Defendant Zimmer failed to disclose the greater risk of wear, metal debris and corrosion associated with these devices.

62. Defendant Zimmer used its distributors and its sales representatives to communicate with the doctors, such as Dr. McGrory and the doctors at Maine Medical Center.

63. Defendant Zimmer and its sales representatives intentionally or negligently failed to accurately describe the risks of fretting and corrosion, release of metal debris and metal ions into the surrounding tissue and the blood associated with the use of the M/L Taper and the VerSys femoral head.

64. Had Zimmer disclosed the accurate information about this particularly dangerous failure mode, i.e., fretting and corrosion, Plaintiff and her surgeon may never have used these components.

65. Despite their knowledge of the serious injuries associated with use of these Products, the Zimmer Defendants engaged in a marketing and advertising program which, as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the these Products w[as] safe.

66. At all relevant times, Zimmer knew or should have known that the M/L Taper and the VerSys femoral head were not safe for the patients in whom it was implanted, including Plaintiff, because of the unacceptable failure rate.

….

119. In placing the Products onto the market, Zimmer was careless, reckless and negligent by virtue of the following acts or omissions, which are listed herein as illustrative and not exhaustive:

…

f. Failing to warn the public in general, Dr. Brian McGrory, and the medical community and the patients, such as Janice E. Miller in particular, of the risks and dangers associated with the use of its products;

g. Failing to take reasonably prompt steps to withdraw the products, notify learned intermediaries such as physicians, or otherwise remove the products from the stream of commerce as soon as the defects therein were discovered; and

h. Zimmer failed to adequately disclose the fretting and corrosion caused by these devices to the medical community, to the medical journals and to

the medical community at large who depended on Zimmer for accurate and truthful information about its products so that the physicians could make appropriate judgments and choices of products for their patients;

i. And, as the information increased that there was an increasing risk of failure, Zimmer failed to disclose it to the medical community and the patients who had been implanted with these devices that there was a previously undisclosed increased rate of corrosion, fretting and the release of metal debris and metal ions.

….

156. At the time the hip joint implant products were supplied to Plaintiff, the products were defective as a result of Zimmer's failure to adequately test for safety, and to give adequate warnings, labeling, or instructions regarding the development of medical problems associated with the presence of metal ions in Plaintiff's body and/or intended users as described herein and other dangers which might be associated with the use of the hip joint implant.

….

161. A final Failure Modes and Effects Analysis (FMEA) table is included in the submission to the FDA as part of the approval process. One of the "potential failure modes" listed was "wear debris generated with mating tapers." The severity is listed as "minor" (not "serious"), and the probability is "low" and not "moderate" or "high."

162. However, the test results of the bench testing show a higher incidence of fretting and chemical accumulation than that predicted by Zimmer.

163. The "level of failure is described Fretting >10% of the contact surface, debris accumulation, discoloration." Separate testing results also observed that fretting debris generated were higher than the "low probability" statement in the FMEA table submitted to the FDA and released to the medical community. That meant that the incidence of fretting and accumulation of debris was more probable than predicted by Zimmer when it submitted this information to the FDA.

164. Zimmer failed to warn of these increased incidents of fretting and corrosion, or that the data demonstrated a greater probability of failure than was initially described to FDA. Zimmer's failure to warn was willful and malicious in that Zimmer's conduct was carried on with a conscious disregard for the safety and the rights of Plaintiff.

….

168. Zimmer falsely represented to Plaintiff, her physicians, and other members of the general public, that Zimmer's hip joint implant products were safe for use in hip replacement surgery; were fit for their intended purposes; that Zimmer's hip joint implant products were not dangerous and did not impose any health risks; did not cause metallosis or the release of metal debris because the femoral ball was metal and the cup was polyethylene; the doctors were not informed of the risk of mixed metals at the junctures which caused trunnionosis; and that Zimmer's hip joint implant products would function without defect. The representation by Zimmer was, in fact, false. The true facts were that Zimmer's hip joint implant products were not safe for use in hip replacement surgery and were, in fact, dangerous to the health and body of Plaintiff and their intended consumers.

169. Defendants, by their Executives, Directors, Staff and/or Research Engineers and/or other employees expressly warranted in its written literature, advertisements and representations of its representatives and agents that:

a. The hip implant was safe, effective, fit and proper for the use for which it was intended and for future use;

b. The hip implant would not fail during normal usage and would perform for its proper use in the future;

c. The hip implant would not develop corrosion, metal figure[3] or stress fractures;

d. The hip implant was properly designed, manufactured and included adequate warnings about the risks involved in their use;

e. The hip implant used adequate materials that were not susceptible to corrosion, metal fatigue, stress fracture and failure;

f. The hip implant minimized stress concentrations on the neck/stem components;

g. Defendants adequately studied and/or tested the hip implant for the possibility of developing corrosion, metal fatigue, stress fracture and/or failure;

h. The hip implant was inspected for signs of corrosion, metal fatigue, stress fracture and/or faulty manufacture prior to the device's sale, distribution or supply;

[3] I assume Plaintiffs intended to reference "metal fatigue" as they did in paragraph 169(e).

i. Defendants had proper quality control procedures in place with respect to the hip implant[.]

….

174. In reliance on Zimmer's representations, Plaintiff and her surgeon were induced to, and did, use Zimmer's hip joint implant in hip replacement surgery. Plaintiff's surgeon relied on the medical conferences and the journal articles to get information about the safety of the devices. However, the journal articles and the medical conferences did not have the information that was available to Zimmer.

175. Had Plaintiff known the actual facts, she would not have permitted her surgeon to proceed as usual, using the Zimmer components. And had Plaintiff's surgeon been informed, it is unclear how he would have handled the information. He went blindly into the surgery, relying on the concealed information and the misrepresentations made to the FDA and the public that there was not an increased rate of revisions due to metal pathology.

176. Plaintiff's surgeon, a seasoned physician who was trained to rely and expect information that he believed was accurate and truthful. Zimmer failed to deliver that accurate, truthful and complete information to the medical community, to the journals, to the teaching doctors and ultimately to Plaintiff's surgeon.

Plaintiffs incorporated the above factual allegations into the fraud count (Complaint ¶ 182), and introduced the following fraud-specific allegations:

183. Throughout the relevant time period, Defendants knew that the Zimmer hip joint implant products were defective and unreasonably unsafe for its intended purpose because it was associated with metallosis, trunnionosis, high cobalt and/or chromium levels, corrosion, pseudotumors, adverse tissue reaction and/or necrotic tissue, need for revision and/or explanation, and other adverse medical conditions as described herein.

184. Defendants were under a duty to Plaintiff and Plaintiff's physicians to disclose and warn of the defective nature of the Zimmer hip joint implant products because:

a. Defendants were in a superior position to know the true quality, safety and efficacy of the Zimmer hip joint implant products;

b. Defendants knowingly made false claims about the safety and quality of the Zimmer hip joint implant products in the documents Defendants provided to the FDA, physicians, and the general public;

c. Defendants fraudulently and affirmatively concealed the defective nature of the Zimmer hip joint implant products from Plaintiff and Plaintiff's physicians;

d. In 2006, Defendants failed to disclose the accurate information to the FDA. Zimmer downplayed the accurate results of the bench testing that demonstrated more than 10% increased incidents of fretting and corrosion in the FMEA report;

185. The facts concealed or not disclosed by Defendants to Plaintiff and Plaintiff's surgeon were material facts that a reasonable person would have considered to be important in deciding whether or not to undergo a procedure or surgery using the Zimmer hip joint implant products.

186. Defendants, by concealment or other action, intentionally prevented Plaintiff and Plaintiff's surgeon from acquiring material information regarding the lack of safety and effectiveness of the Zimmer hip joint implant products, and are subject to the same liability to Plaintiffs for Plaintiffs' pecuniary losses, as though Defendants had stated the non-existence of such material information regarding the Zimmer hip joint implant products' lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiff was thus prevented from discovering the truth.

Plaintiffs' allegations must be assessed in the context of the Rule 9 pleading standard. This Court recently explained the standard as follows:

> Allegations of fraud are subject to the higher pleading standard of Federal Rule of Civil Procedure Rule 9(b). See Fed. R. Civ. P. 9(b). The complaint must "be specific about the 'time, place, and content of an alleged false representation[.]'" *Murtagh v. St. Mary's Reg'l Health Ctr.*, No. 1:12-cv-00160, 2013 WL 5348607, at *6 (D. Me. Sep. 23, 2013) (quoting Hayduk v. Lanna, 775 F.2d 441, 444 (1st Cir. 1985)). Mere conclusory allegations will not satisfy the particularity requirement. See Hayduk, 775 F.2d at 444. Rule 9(b) also requires that plaintiffs identify a basis for inferring scienter on the part of the defendant. N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale, 567 F.3d 8, 13 (1st Cir. 2009).

Winne v. Nat'l Collegiate Student Loan Tr. 2005-1, No. 1:16-CV-00229-JDL, 2017 WL 3573813, at *2 (D. Me. Aug. 17, 2017). Here, as the referenced allegations reflect, Plaintiffs assert that despite testing which revealed a higher incidence of fretting and chemical accumulation than Defendants reported to the FDA, Defendants did not disclose the increased risk of failure to the medical community or the public, and continued to market and promote the product as one that was not subject to corrosion or failure. Plaintiffs, therefore, have alleged the time, place and content of the false statements. In addition, implicit in Plaintiffs' allegations is that Defendants were aware of the test results before Plaintiff Janice Miller's initial surgery. Plaintiffs have thus identified "a basis for inferring scienter on behalf of" Defendants. Id. Finally, Plaintiffs have sufficiently alleged detrimental reliance. (Complaint, ¶¶ 174, 175, 176, 177, 178, 182, 185).

C. Negligence Per Se (count VII)

Defendants argue the claim for negligence per se must be dismissed because the Maine Supreme Judicial Court has not recognized the tort. (Motion at 6.) See Binette v. *Dyer Library Ass'*n, 688 A.2d 898, 904 (Me. 1996) ("Although Maine does not recognize the doctrine of negligence per se, violation of a safety statute constitutes evidence of a breach of duty of reasonable care owed to those the statute is designed to protect.") Plaintiffs "do not opposed the dismissal." (Opposition at 1.)

D. Punitive Damages (count IX)

Defendants argue Plaintiffs have not alleged sufficient facts to state an actionable claim for punitive damages because their alleged facts cannot support a finding of implied malice. (Motion at 7 – 8.)

Under Maine law, a punitive damage award is permitted on a showing, by clear and convincing evidence, that the defendant's tortious conduct was motivated by actual ill will or was so outrageous that malice can be implied. Weaver v. New England Mut. Life Ins. Co., 52 F. Supp. 2d 127, 134 (D. Me. 1999) (citing Tuttle v. Raymond, 494 A.2d 1353, 1354 (Me. 1985)). Plaintiffs allege that Defendants not only sold a defective product, but that Defendants knew the product would cause injuries to users of the product, yet continued to market the product as safe for its intended purpose. (Complaint ¶¶ 210 – 215.) The alleged facts that support Plaintiffs' fraud claim (e.g., that Defendants knew of and concealed or misrepresented the risks of the product) also support Plaintiffs' claim for punitive damages at this stage of the proceedings.

CONCLUSION

Based on the foregoing analysis, I recommend the Court grant in part and deny in part Defendants' Motion to Dismiss. (ECF No. 16.) Specifically, I recommend the Court grant the motion as to Plaintiffs' claim of negligence per se, and otherwise deny the motion.

NOTICE

A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. 636(b)(1)(B) for which de novo review by the district court is sought, together with a supporting memorandum, and request for oral argument before the district judge, if any is sought, within fourteen (14) days of being served with a copy thereof. A responsive memorandum and any request for oral argument before the district judge shall be filed within fourteen (14) days after the filing of the objection.

Failure to file a timely objection shall constitute a waiver of the right to de novo review by the district court and to appeal the district court's order.

/s/ John C. Nivison
U.S. Magistrate Judge

Dated this 30th day of November, 2017.