IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:10-cv-3104-DME-BNB

GLENN A. WOLLAM and BONNIE J. SCHOENSTEIN,

Plaintiffs,

v.

WRIGHT MEDICAL GROUP, INC., a Delaware corporation; WRIGHT MEDICAL TECHNOLOGY, INC., a Delaware corporation; WRIGHT MEDICAL EUROPE S.A., a foreign corporation; JOHN DOE, an individual; and JANE DOE, an individual,

Defendants.

ORDER

This matter comes before the Court on two matters: 1) The motion of Defendants Wright Medical Group, Inc., Wright Medical Technology, Inc., and Wright Medical Europe S.A. (collectively "Wright Medical") to dismiss and for summary judgment (Doc. 133); and 2) the objection of Plaintiffs Glenn A. Wollam and Bonnie Schoenstein ("Plaintiffs") to the magistrate judge's recommendation to deny their motion to amend the complaint a second time in order to request an award of exemplary damages (Doc. 126). After considering these pleadings, as well as the evidence and argument the parties have submitted, the Court 1) GRANTS in part and DENIES in part Wright Medical's motion to dismiss and for summary judgment, and 2) OVERRULES Plaintiffs' objection, ADOPTS the magistrate judge's recommendation and DENIES Plaintiffs' motion to file a second amended complaint.

I. BACKGROUND

On April 18, 2005, Plaintiff Glenn Wollam had a double hip replacement. In performing this surgery, Wollam's surgeon, Daniel Ward, M.D., used two artificial joints, known as PROFEMUR® Total Hip Systems, which were designed and manufactured by Wright Medical. These modulating hip systems are each comprised of four parts - a cap, a femoral head, a neck, and a femoral stem. Three and one-half years after Wollam's surgery, on October 30, 2008, the neck of Wollam's right artificial hip broke in two and had to be surgically removed and the artificial joint replaced.

Wollam and his wife, Plaintiff Bonnie Schoenstein, Colorado residents, sued Defendants Wright Medical, citizens of Delaware, Tennessee, and France, alleging twelve causes of action.[1] This court has diversity jurisdiction over these claims. See 28 U.S.C. § 1332(a).

II. WRIGHT MEDICAL'S MOTION TO DISMISS AND FOR SUMMARY JUDGMENT

In their motion currently before this Court, Wright Medical first seeks dismissal of Plaintiffs' fraud claim (Claim 11), pursuant to Fed. R. Civ. P. 12(b)(6) and (c). Plaintiffs concede that claim should be dismissed.

Wright Medical seeks summary judgment as to Plaintiffs' remaining claims. In response, Plaintiffs concede that their claims alleging negligence per se (Claim 9), negligent misrepresentation (Claim 8), strict product liability due to nonconformance

[1] Plaintiffs also initially asserted two causes of action against Dr. Ward (Claims 12 and 13), which Plaintiffs later voluntarily dismissed.

with representations (Claim 3), and violations of the Colorado Consumer Protection Act (Claim 10) should also be dismissed.

As to Plaintiffs remaining claims, the Court must grant summary judgment if Wright Medical, as the movant, shows that there is no genuine dispute as to any material fact and Wright Medical is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(a).

A. Plaintiffs' strict product liability claims (Claims 1, 2, 4)

In Claims 1, 2 and 4, Plaintiffs allege that Wright Medical is liable for the harm caused Plaintiffs as the result of Wollam's right artificial hip joint fracturing, under strict product liability theories. The parties agree that Colorado law governs Plaintiffs' claims.

Colorado has "expressly adopted the doctrine of strict liability in tort, based on the Restatement (Second) of Torts § 402A." Union Supply Co. v. Pust, 583 P.2d 276, 280 (Colo. 1978) (citing Hiigel v. Gen. Motors Corp., 544 P.2d 983 (Colo. 1975)). Applying strict liability to product manufacturing, Colorado recognizes "three general areas of the manufacturing process that lead to strict liability claims . . . : (1) Physical flaws due to improper manufacture; (2) inadequacies in Design; and (3) inadequate Warnings concerning the hazards or proper methods for safe use." Id. at 280 n.1. Plaintiffs allege all three types of strict product liability claims.

1. Defective design and defective manufacture (Claims 1 and 2)

The Court will address together Plaintiffs' claims alleging defective manufacture and defective design because they share common elements. Most relevant here, in order to recover for strict product liability based on either a design or a manufacturing

defect, Plaintiffs must establish, among other things, that the product was "in a defective condition unreasonably dangerous" to the user or consumer.[2] Barton v. Adams Rental, Inc., 938 P.2d 532, 536 (Colo. 1997); see also Mile-Hi Concrete, Inc. v. Matz, 842 P.2d 198, 205 (Colo. 1992). In moving for summary judgment on these claims, Wright Medical contends that Plaintiffs have failed, as a matter of law, to establish a triable issue of fact as to whether Wright Medical's PROFEMUR® Total Hip System was "in a defective condition unreasonably dangerous" to users and consumers. See Luster v. Vilsack, 667 F.3d 1089, 1096 (10th Cir. 2011) (noting at summary judgment stage of proceeding, non-moving party cannot rest on mere allegations, but must bring forward specific facts showing a genuine issue for trial as to those dispositive matters for which he has burden of proof).

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[2] To succeed on a strict product liability claim for a design defect, Plaintiffs must prove the following elements:

> (1) the product is in a defective condition unreasonably dangerous to the user or consumer; (2) the product is expected to and does reach the consumer without substantial change in the condition in which it is sold; (3) the design defect caused the plaintiff's injury; (4) the defendant sold the product and is engaged in the business of selling products; and (5) the plaintiff sustained damages.

Barton v. Adams Rental, Inc., 938 P.2d 532, 536-37 (Colo. 1997). Similarly, to succeed on a strict product liability claim premised on a manufacturing defect, Plaintiffs must prove: the defendant manufactured the product, engaged in the business of selling the product, and sold the product; the product was defective and, because of the defect, was unreasonably dangerous to a person who might reasonably be expected to use it; the product was defective at the time the manufacturer sold it; the product was expected to, and did, reach the user without substantial change; plaintiff was a person reasonably expected to use the product, was injured, and the product's defect caused plaintiff's injuries. See Price v. Wilson Sporting Goods Co., No. Civ.A 03CV02639WYDOE, 2005 WL 1677512, at *3 (D. Colo. July 18, 2005) (unreported) (citing Colo. Civ. Jury Instruction 14:1).

a. Presumed not to be defective

As an initial matter, Wright Medical asserts that, under Colo. Rev. Stat. § 13-21-403(1)(b), its PROFEMUR® Total Hip System should be presumed not to be defective. Section § 13-21-403(1)(b) provides the following:

> (1) In any product liability action, it shall be rebuttably presumed that the product which caused the injury, death, or property damage was not defective and that the manufacturer or seller thereof was not negligent if the product:
>
> . . . .
>
> (b) Complied with, at the time of sale by the manufacturer, any applicable code, standard, or regulation adopted or promulgated by the United States or by this state, or by any agency of the United States or of this state.

Wright Medical claims that this rebuttable presumption applies here because Wright Medical obtained the approval of the federal Food and Drug Administration ("FDA") to market its PROFEMUR® Total Hip System.[3] Plaintiffs counter that Wright Medical is not entitled to a rebuttable presumption under § 13-21-403(1)(b) because the FDA never considered and approved the safety of the PROFEMUR® Total Hip System, but instead concluded only that Wright Medical's PROFEMUR® Total Hip System was substantially equivalent to an already legally marketed device and therefore Wright Medical was exempt from having to obtain FDA approval of its Total Hip System.

[3] Wright Medical also invokes § 13-21-403(1)(a), which provides that "it shall be rebuttably presumed that the product . . . was not defective and that the manufacturer or seller . . . was not negligent if the product . . . [p]rior to sale by the manufacturer, conformed to the state of the art, as distinguished from industry standards applicable to such product in existence at the time of sale." Because Wright Medical makes no specific argument as to how that that provision applies here, the Court need not consider that statutory provision.

The Court need not resolve this dispute here. If the rebuttable presumption applies, Plaintiffs must come forward with evidence to rebut that presumption and create a triable issue on their claims alleging a manufacturing defect and a design defect. And if the rebuttable presumption does not apply, Plaintiffs still must come forward with such evidence in order to survive summary judgment. Therefore, the question the Court considers here is whether Plaintiffs asserted sufficient evidence to warrant their claims going to the jury. See Bertsch v. Overstock.com, 684 F.3d 1023, 1028 (10th Cir. 2012); see also Mile Hi Concrete, 842 P.2d at 205-06 & n.17 (addressing directed verdict).

b. Plaintiffs failed to submit evidence that the neck of the implanted right hip system was unreasonably dangerous due to a manufacturing defect (Claim 1)

In their first claim for relief, Plaintiffs alleged Wright Medical was liable on a manufacturing-defect theory. Under such a theory, the question is whether the product as produced conformed to the manufacturer's specification. See Arkansas-Platte & Gulf P'ship v. Dow Chem. Co., 886 F. Supp. 762, 767 (D. Colo. 1995) (applying Colorado law). In their complaint, Plaintiffs alleged generally that Wright Medical's hip systems "were defective in their manufacture and construction . . . ." (Doc. 20 ¶ 88.) But Plaintiffs failed to define their claim more specifically or to submit any evidence suggesting that there was a manufacturing defect. and Plaintiffs' own experts indicated there was no manufacturing defect in Wollam's artificial hip that broke.

In response to Wright Medical's motion for summary judgment on this claim, Plaintiffs asserted only the following:

> Of [Wollam's] two identical Wright Profemur modular necks implanted in his right and left hips on April 18, 2005, the right modular neck has fractured, the left modular neck has not. Defendants cannot explain how or why the testing of two identical Profemur titanium modular necks resulted in one fracture after 546,000 cycles while the other did not fracture after 4.5 million cycles. While there is no physical direct evidence that the Profemur neck implanted in plaintiff's right hip was defectively manufactured, if there are not defects in manufacture, then why, when identical modular necks are subjected to the identical tests or in vivo use, does one fracture and the other does not?

(Doc. 143 at 15-16.) That assertion, however, is insufficient to support a jury finding that Wollam's right hip system was defectively manufactured.

Plaintiffs further contend that they are asserting a "res ipsa argument that, if not a design defect, then the device that failed in [Wollam's] right hip must be defective in its manufacture, while the device in his left hip is not." (Id. at 16.) But res ipsa locquitor is an evidentiary rule providing for a rebuttable presumption that an event would not have occurred absent the defendant's negligence. See Stone's Farm Supply, Inc. v. Deacon, 805 P.2d 1109, 1114 (Colo. 1991). Plaintiffs fail to cite any cases applying that doctrine to a strict product liability claim alleging a manufacturing defect, and the Court declines to apply that doctrine to this claim.

For these reasons, Wright Medical is entitled to summary judgment on Plaintiffs' strict product liability claim alleging that Wright Medical defectively manufactured their hip systems (Claim 1).

c. Plaintiffs presented sufficient evidence of a design defect to avoid summary judgment on Claim 2

In their second claim, Plaintiffs alleged that Wright Medical is strictly liable for a design defect in the PROFEMUR® Total Hip System. Briefly summarized, Plaintiffs'

defective-design theory is this: Wright Medical failed to test their hip system adequately before distributing it. In particular, Wright Medical only tested their titanium neck component of the system under 500 pounds of stress. This represented twice the body weight of a 250-pound individual, or two and one-half times the body weight of a 200-pound individual. Yet it is commonly accepted that routine activities such as walking exert from one to five times a person's body weight on that person's hip joint. And more strenuous activities, such as fast walking, will exert from four to eight times a person's body weight on the hip joint. Had Wright Medical properly tested the titanium neck component of their hip system, they would have discovered that the neck could not withstand stress resulting from the ordinary wear and tear of active patients or those weighing over 220 pounds, and was likely to fracture under those circumstances. (Wollam weighed approximately 250 pounds at the time he underwent the surgical replacement of both hips, and also at the time his right hip prosthesis fractured.) If Wright Medical had made the neck of their hip system out of cobalt chrome instead of titanium, this would have significantly increased the strength of the neck and significantly decreased the possibility that the neck would fracture.

As previously mentioned, in order to succeed on this defective-design claim, Plaintiffs must establish, among other elements, that the hip system as designed was "in a defective condition unreasonably dangerous" to the user or consumer. Barton, 938 P.2d at 536-37. "[T]he determination of whether a product is 'unreasonably dangerous' is made through a risk-benefit analysis." Armentrout v. FMC Corp., 842 P.2d 175, 183 (Colo. 1992). Thus, Plaintiffs must "demonstrate that the risks of the design of the

[PROFEMUR® Total Hip System] outweighed any benefits." Barton, 938 P.2d at 538. In making that determination, the jury is to weigh such factors as the seven non-exclusive factors identified in Armentrout, 842 P.2d at 183-84. Those factors include 1) the product's usefulness and desirability; 2) its safety aspects; 3) the availability of a safer product; 4) the manufacturer's ability to eliminate the unsafe characteristics; 5) the user's ability to avoid any danger through the exercise of care; 6) the user's anticipated awareness of the inherent danger; and 7) the feasibility of the manufacturer spreading any loss among its customers.

To survive summary judgment here, Plaintiffs must present sufficient evidence to enable the jury to weigh these factors relevant to the required cost-benefit analysis. See Barton, 938 P.2d at 538 (addressing whether there was sufficient evidence to instruct jury on such a claim). Plaintiffs have presented sufficient evidence from which a jury, weighing the seven factors plus any other relevant factor, could find that the risks of using the PROFEMUR® Total Hip System's titanium necks outweighed the benefits of using such artificial hip necks. The product is useful and desirable. Plaintiffs offer evidence that the titanium neck of the hip system can fracture, but the evidence is disputed as to the rate of fracture and whether that rate of failure is medically acceptable. Plaintiffs also presented evidence that a safer product, a neck made of cobalt chrome, is available and safer because it is stronger and less apt to fret and corrode, which could reduce the strength of the neck. This evidence suggests that a cobalt chrome neck could have endured greater wear and tear than the titanium hip implanted in Wollam and would have significantly decreased the possibility of fracturing.

This evidence is sufficient to permit a jury to conduct the required cost-benefit analysis in determining whether the titanium neck was in defective condition unreasonably dangerous to the user. Therefore, Plaintiffs' strict product liability design defect claim (Claim 2) survives summary judgment.

d. Wright Medical's defense that their hip system is unavoidably unsafe

Notwithstanding that Plaintiffs presented sufficient evidence in support of their design-defect claim (Claim 2), Wright Medical asserts that it is, nevertheless, still entitled to summary judgment on that claim because the PROFEMUR® Total Hip System is unavoidably unsafe. Colorado recognizes such a defense, adopted from comment k of the Restatement (Second) of Torts § 402A. See Belle Bonfils Mem'l Blood Bank v. Hansen, 665 P.2d 118, 122 (Colo. 1983), superseded by statute on other grounds, United Blood Servs., a Div.of Blood Sys., Inc. v. Quintana, 827 P.2d 509, 522 n.9 (Colo. 1992). In asserting this defense, Wright Medical bears the burden of establishing that the total hip system's "utility must greatly outweigh the risk created by its use, the risk must be a known one; the product's benefits must not be achievable in another manner; and the risk must be unavoidable under the present state of knowledge." Id. at 122. Wright Medical failed to make this showing here as a matter of law, in light of Plaintiffs' evidence indicating that Wright Medical could have built a stronger neck, less susceptible of fracturing, if it had used cobalt chrome for its necks, instead of titanium. Therefore, Wright Medical's motion seeking summary judgment on this claim is denied.

2. Failure to warn (Claim 4)

Next, Plaintiffs allege Wright Medical is strictly liable because they failed to warn Wollam of the risk that the titanium neck would break. In their complaint, Plaintiffs alleged only generally that Wright Medical "failed to provide adequate and timely warnings or instructions regarding the Wright Medical PROFEMUR® Total Hip System devices and their known defects." (Doc. 20 ¶ 111.) But in response to Wright Medical's summary judgment motion, Plaintiffs make clear that they are asserting the following two theories underlying their failure-to-warn claim.

a. The pre-surgery warnings to the physician were inadequate

Under Colorado law, "failure to warn adequately can render a product otherwise free of defect, defective for purposes of [Restatement (Second) of Torts] § 402A." Barton, 583 P.2d at 173 (internal quotation marks omitted). "This defective condition is 'unreasonably dangerous' to the user or consumer if the manufacturer does not give sufficient warnings of dangers inherent in the product or its intended use in order to make it safe." Id. Here, however, where the failure-to-warn claim involves "a medical device installed operatively when it is available only to physicians," the "learned intermediary" doctrine applies. O'Connell v. Biomet, Inc., 250 P.3d 1278, 1280-81 (Colo. Ct. App. 2010). Under that doctrine, the manufacturer is obligated to advise the surgeon of any potential risks that may result from implantation of the hip system; it is the surgeon, then, who "is trained to assess the risks and benefits of the [hip system] as applied clinically to a particular patient." Id. at 1281. Plaintiffs first assert that the

warnings Wright Medical provided Wollam's surgeon prior to his surgery were inadequate.

Wright Medical is entitled to summary judgment on this claim because Plaintiffs have not submitted any evidence suggesting that any failure to warn or inadequacy of the warnings Wright Medical gave was the proximate cause of Wollam's harm. Said another way, Plaintiffs failed to submit evidence indicating that additional or different warnings would have made any difference because Dr. Ward testified in his deposition that he never read the warnings or instructions Wright Medical included with its PROFEMUR® Total Hip System. Therefore, Wright Medical is entitled to summary judgment on Claim 4 to the extent that claim is premised on the inadequacy of the pre-surgery warnings Wright Medical gave to Wollam's surgeon.

b. Wright Medical had a duty to warn the surgeon of defects discovered after the hip systems had been implanted

Plaintiffs also allege that Wright Medical had a duty, after Wollam's artificial hip joints were implanted, to warn Wollam's surgeon and Wollam himself, after the factures occurring in the PROFEMUR® Total Hip System came to light. Colorado law does recognize that a manufacturer has a duty to warn where a design defect makes a product dangerous, but the defect does not become known to the manufacturer until after the manufacturer sells and delivers the product. See Downing v. Overhead Door Corp., 707 P.2d 1027, 1033 (Colo. Ct. App. 1985);[4] see also Perlmutter v. U.S. Gypsum

[4] The Colorado Supreme Court has not addressed a post-sale failure-to-warn claim. See Perlmutter v. U.S. Gypsum Co., 4 F.3d 864, 869-70 (10th Cir. 1992) (applying Colorado law).

Co., 4 F.3d 864, 869-70 (10th Cir. 1992) (applying Colorado law and noting post-sale duty to warn recognized in Downing is limited to claims alleging that a design defect existed at the time of sale). In their summary judgment pleadings, Wright Medical never specifically addressed Plaintiffs' post-sale warning theory of recovery. Therefore, Plaintiffs' failure-to-warn claim will survive Wright Medical's summary judgment motion to the extent that claim is premised on Wright Medical's alleged failure to warn Wollam and his surgeon after the artificial joints had been implanted.

3. Conclusion as to Plaintiffs' strict product liability claims

For the foregoing reasons, Wright Medical is entitled to summary judgment on Plaintiffs' strict product liability claims alleging a manufacturing defect and alleging a pre-operative failure to warn. But Plaintiffs' strict product liability claims alleging a design defect and post-operative failure to warn survive summary judgment.

B. Negligence (Claim 5)

While the focus of Plaintiffs' strict product liability claims, discussed above, is on the condition of the product, the focus of Plaintiffs' negligence claim is instead on Wright Medical's conduct. See Boles v. Sun Ergoline, Inc., 223 P.3d 724, 727 (Colo. 2010). To recover for negligence, Plaintiffs must establish that 1) Wright Medical owed Wollam a legal duty; 2) Wright Medical breached that duty; 3) Wollam was injured, and 4) the breach of that duty caused Wollam's injuries.[5] See Vigil v. Franklin, 103 P.3d 322, 325

[5] Although Wright Medical again argues it is entitled to a rebuttable presumption that its PROFEMUR® Total Hip System is not defective, the relevant issue here, for summary judgment purposes, is instead whether Plaintiffs have submitted sufficient evidence to permit a reasonable jury to find that Wright Medical was negligent.

(Colo. 2004). Plaintiffs allege that Wright Medical, in the following three ways, breached a duty of reasonable care owed to Wollam.

1. Negligently failing to test the neck component of the PROFEMUR® hip system adequately

In support of their negligence claim, Plaintiffs first allege that Wright Medical acted negligently in testing the neck component of the PROFEMUR® Total Hip System. Plaintiffs' theory underlying this claim is similar to their theory, set forth above in support of their defective-design claim. Briefly summarized, that theory is this: Wright Medical only tested their titanium neck using 500 pounds of stress. This represented twice the body weight of a 250-pound individual, or two and one-half times the body weight of a 200-pound individual. Yet routine activities such as walking exert from one to five times a person's body weight on a person's hip joint; more strenuous activities exert from four to eight times a person's body weight on the hip joint. Had Wright Medical properly tested the titanium neck component of Wright Medical's the hip system, they would have discovered that their neck could not withstand stress resulting from the ordinary wear and tear of active patients or those weighing over 220 pounds, and was likely to fracture under those circumstances. Because Plaintiffs sufficient submitted evidence to support this theory of recovery, Wright Medical is not entitled to summary judgment on this negligence claim.

2. Negligently failing to warn surgeons adequately that the PROFEMUR® Total Hip System should not be used in a patient who weighs over 220 pounds

Plaintiffs next allege that Wright Medical was negligent in failing specifically to warn doctors, as learned intermediaries, that the titanium PROFEMUR® Total Hip

System should not be used for patients weighing over 220 pounds or those engaged in strenuous activities. But Wollam's surgeon, Dr. Ward, testified that he did not read or otherwise rely on any warnings Wright Medical gave about its PROFEMUR® Total Hip System. In light of that, Plaintiffs cannot establish that any failure to warn prior to Wollam's surgery was the proximate cause of Wollam's injuries. See Fraley v. Am. Cyanamid Co., 589 F. Supp. 826, 827 (D. Colo. 1984) (noting plaintiff must show that failure to warn was proximate cause of her injury).

Assuming Plaintiffs are also alleging that Wright Medical was negligent in failing to warn Dr. Ward and Wollam, after the hip replacements, that there was a risk the titanium necks in the implanted hip systems would fracture, Plaintiffs have submitted sufficient evidence to create a triable issue on the question of whether Wright Medical knew of this risk and could have warned Wollam and his surgeon prior to Wollam's right hip fracturing. Therefore, Wright Medical is entitled to summary judgment on this negligence claim only to the extent the claim is premised on allegations that Wright Medical failed to warn the surgeon adequately prior to Wollam's surgery.

3. Negligently failing to use a cobalt chrome neck instead of a titanium one

Plaintiffs also allege that Wright Medical was negligent in using a neck made of titanium, rather than cobalt chrome, in its hip system. Because Plaintiffs submitted evidence suggesting that the cobalt chrome neck would have been stronger and significantly less susceptible to fretting and corrosion than the titanium neck, and thus would have significantly reduced the chance of the neck fracturing, summary judgment for Wright Medical is not warranted on this claim.

4. Conclusion as to negligence theories of recovery

Wright Medical is entitled to summary judgment on Plaintiffs' negligence claim, but only to the extent it is premised on allegations that Wright Medical negligently failed to warn surgeons adequately, prior to Wollam's surgery, of the risks that the titanium neck of a PROFEMUR® Total Hip System might fracture if implanted in individuals weighting 220 pounds or more. The remainder of Plaintiffs' theories of recovery for negligence – negligent testing, negligent failure to warn Wollam and his surgeon post-operatively of the risks the neck of the implanted hip system might fracture, and negligent failure to use cobalt chrome to make the neck component of the hip system – warrant submission to a jury.

C. Breach of express and implied warranties (Claims 6 and 7)

Plaintiffs allege that Wright Medical breached their express warranty "that the Wright Medical PROFEMUR® Total Hip System devices were safe and effective devices for those patients requiring a hip replacement." (Doc. 20 ¶ 125 (Claim 6). Plaintiffs also alleged that Wright Medical breached their implied warranties that "the Wright Medical PROFEMUR® Total Hip Systems were of merchantable quality and sale for their intended use" and that these hip replacement systems "were in compliance with all federal requirements." (Id. ¶ 130 (Claim 7).) Wright Medical contends that these claims are time-barred, and Plaintiffs do not dispute that.

Colorado requires that a claim alleging the breach of a sales contract, as well as a claim for the breach of a warranty arising from such a sales contract, be commenced within three years of the alleged breach. See Colo. Rev. Stat. § 4-2-725 (incorporating

Colo. Rev. Stat. § 13-80-101). "A breach of warranty occurs when tender or delivery is made . . . ." Id. § 4-2-725(2). Here, Wright Medical delivered the two hip systems to Wollam no later than the date of the surgery, April 18, 2005. See Norris v. Baxter Healthcare Corp., 397 F.3d 878, 888 (10th Cir. 2005) (applying Colo. Rev. Stat. § 4-2-725 to case alleging breach of warranties regarding breast implants). But Plaintiffs did not commence this litigation until November 2010.

Section 4-2-725 does contain an exception: "where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance, the cause of action accrues when the breach is or should have been discovered." Colo. Rev. Stat. § 4-2-725(2). But Plaintiffs do not rely on this exception, which applies when there has been "a warranty for future performance [that] guarantees the performance of the product . . . for a stated period of time," Boyd v. A.O. Smith Harvestore Prods., Inc., 776 P.2d 1125, 1128-29 (Colo. Ct. App. 1989) (internal quotation marks omitted). Plaintiffs do not allege that Wright Medical made such a warranty of future performance here.

Therefore, because Plaintiffs' breach-of-warranty claims accrued no later than April 18, 2005, and because Plaintiffs did not commence this litigation until November 2010, Plaintiffs' breach-of-warranty claims are time-barred.

D. Plaintiff Schoenstein's claim for loss of consortium (Claim 14)

Because Schoenstein's loss-of-consortium claim is derivative of Plaintiffs' other claims, see Colo. Compensation Ins. Auth. v. Jorgensen, 992 P.2d 1156, 1164 & n.6

(Colo. 2000), it remains viable based on the other claims that survive summary judgment.

III. PLAINTIFFS' OBJECTION TO MAGISTRATE JUDGE'S RECOMMENDATION

Plaintiffs moved to file a second amended complaint. The magistrate judge recommended granting that motion in part, and denying it in part. Specifically, the magistrate judge recommended granting the motion to the extent it eliminated Plaintiffs' claims asserted against John and Jane Doe and corrected the spelling of Plaintiff Bonnie Schoenstein's name. No party objected to that part of the recommendation, and the Court adopts those recommendations.

Plaintiffs did object to the magistrate judge's recommendation to deny their motion to file a second amended complaint in order to add a request for exemplary damages. The Court reviews the magistrate judge's recommendation de novo. See Fuller v. Mickelson, No. 07-cv-00291-WYD-MJW, 2007 WL 3232595, at *1-*2 (D. Colo. Oct. 31, 2007) (unreported).

Plaintiffs have already amended their complaint once. Therefore, under Fed. R. Civ. P. 15(a)(2), Plaintiffs require leave of the court, although "the court should freely give leave when justice so requires." In this case, however, Plaintiffs' motion for leave to amend is intertwined with Colo. Rev. Stat. § 13-21-102. Section 13-21-102(1.5)(a) precludes plaintiffs from seeking exemplary damages at the outset of an action, and instead requires plaintiffs to wait until the parties exchange their initial discovery disclosures before amending their complaint to seek exemplary damages. Then in

order to amend a complaint to seek exemplary damages, the plaintiffs must further "establish[] prima facie proof of a triable issue" on exemplary damages. Id.

Courts sitting in diversity ordinarily apply federal procedural law and state substantive law. Hanna v. Plumer, 380 U.S. 460, 465 (1965). A state statute with a procedural impact nevertheless governs where "there is no direct conflict between the state statute and federal rule," and where application of the state law coheres with Erie's[6] "twin goals of discouraging forum shopping and avoiding inequitable administration of the law." Jones v. Krautheim, 208 F.Supp.2d 1173, 1174-75 (D. Colo. 2002). In Krautheim, the court adroitly applied these principles to determine that a nearly identical Colorado punitive-damages statute controlled that case. Id. (considering Colo. Rev. Stat. § 13–64–302.5). Courts in this district have since held that Colo. Rev. Stat. § 13–21–102 "does not conflict with the Federal Rules of Civil Procedure and that Erie's twin aims are best satisfied by applying the Colorado statute." See, e.g., Richfield Hospitality, Inc. v. Charter One Hotels & Resorts, Inc., No. 12-CV-01937-REB-MEH, 2012 WL 4097722 (D. Colo. Sept. 18, 2012); Am. Econ. Ins. Co. v. William Schoolcraft, M.D., P. C., No. 05–cv–01870–LTB–BNB, 2007 WL 160951, at * 1 (D.Colo. Jan. 17, 2007) (unreported). Therefore, the Court will decide Plaintiffs' motion to amend their complaint by applying Colo. Rev. Stat. § 13-21-102. See Deckard v. Sterling Constr. Co., No. 10-cv-02667-MSK-KMT, 2011 WL 3489698, at *1-*3 (D. Colo. Aug. 9, 2011) (unreported) (citing cases).

[6] Erie R. Co. v. Tompkins, 304 U.S. 64 (1938).

Section 13-21-102 permits exemplary damages "in all civil actions" where "damages are assessed by a jury for a wrong done to the person or to personal or real property, and the injury complained of is attended by circumstances of fraud, malice, or willful and wanton conduct." Colo. Rev. Stat. § 13-21-102(1)(a). Plaintiffs, in their motion to amend their complaint, allege only that Wright Medical acted willfully and wantonly. "Willful and wanton conduct" is "conduct purposefully committed which the actor must have realized was dangerous, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, particularly the plaintiff." Id. § 13-21-102(1)(b). This definition, at a minimum, requires "conduct that creates a substantial risk of harm to another and is purposefully performed with an awareness of the risk in disregard of the consequences." Muniz v. Kmart Corp., No. CivA 06CV00084WDMPAC, 2007 WL 1964069 *2 (D. Colo. July 2, 2007) (unreported) (citing Palmer v. A.H. Robins Co., 684 P.2d 187, 215 (Colo.1984) (en banc)). Stated differently, "[w]here the defendant is conscious of his conduct and the existing conditions and knew or should have known that injury would result, the statutory requirements of section 13-21-102 are met." Coors v. Sec. Life of Denver Ins. Co., 112 P.3d 59, 66 (Colo. 2005).

"A claim for punitive damages is not a separate and distinct cause of action; rather, it is auxiliary to an underlying claim. An award of punitive damages can be entered only after awarding damages in conjunction with an underlying and successful claim for actual damages." Pulliam v. Dreiling, 839 P.2d 521, 524 (Colo. Ct. App. 1992) (citing Kirk v. Denver Publ'g Co., 818 P.2d 262 (Colo. 1991)). Thus, at this point, having

granted Wright Medical summary judgment on several of Plaintiffs' claims in this Order, their request for exemplary damages must arise from their remaining claims for (1) strict product liability based on a defective design and failure to warn post-operatively, and (2) Plaintiffs' claims for negligence, including those based on testing, failure to warn post-operatively, and for using titanium rather than cobalt chrome for the neck component of their hip replacement systems.

A plaintiff can recover exemplary damages on strict product liability and negligence claims like the ones at issue here. See Jacobs v. Commonwealth Highland Theatres, Inc., 738 P.2d 6, 10 (Colo. Ct. App. 1986) (citing Tri-Aspen Construction Co. v. Johnson, 714 P.2d 484 (Colo.1986)) ("While mere negligence cannot support an award of exemplary damages, repeated failure to correct a known dangerous condition may convert mere negligence into wanton and reckless disregard."); Palmer, 684 P.2d at 218 (extoling the virtues of punitive damages in strict product liability actions where manufacturers engage in "gross misconduct, . . . flagrant misbehavior, and . . . similar disregard for the public welfare"); see also Bartholic v. Scripto-Tokai Corp., 140 F. Supp. 2d 1098, 1119 (D. Colo. 2000).

As previously mentioned, § 13-21-102(1.5)(a) provides that plaintiffs may only seek exemplary damages "by amendment to the pleadings . . . after the exchange of initial disclosures . . . and the plaintiff establishes prima facie proof of a triable issue." Prima facie proof of a triable issue of exemplary damages is established by a showing of a reasonable likelihood, viewing the evidence in the light most favorable to the moving party, that the issue of exemplary damages will ultimately be submitted to the

jury for resolution. Stamp v. Vail Corp., 172 P.3d 437, 449 (Colo. 2007); Am. Econ. Ins. Co., 2007 WL 160951 *4. The question the Court must decide here, then, is whether Plaintiffs "establishe[d] prima facie proof" that there is a triable issue on their request for exemplary damages. Plaintiffs have failed to make prima facie showing that a jury could find that Wright Medical acted willfully and wantonly. See Stamp, 172 P.3d at 449.

Plaintiffs premised their request for exemplary damages first on Wright Medical's failure to stop distributing the PROFEMUR® Total Hip System once Wright Medical discovered, in April 2005, that one of the titanium necks in its system fractured, in January 2005. Nor did Wright Medical notify surgeons who were implanting the hip replacement systems of the first fracture. These allegations, however, are insufficient to establish a triable issue as to whether Wright Medical acted willfully and wantonly.

Next, Plaintiffs asserted that Wright Medical knew of other factures by the time Wollam's right hip replacement broke, in October 2008, yet Wright Medical never warned Wollam or his surgeon about the risk of fracture. But the percentage of Wright Medical hip systems that fractured during this time was much less than one percent. Plaintiffs have, thus, failed to establish that a jury could find that Wright Medical's failure to warn in light of that failure rate was willful and wanton.

Plaintiffs further asserted that Wright Medical's improper testing of their titanium neck supports an award of exemplary damages. But Plaintiff's allegations of improper

testing, considered along with its supporting evidence, also do not rise to the level of willful and wanton conduct.[7]

For these reasons, more fully explained by the magistrate judge in his Recommendation, the Court OVERRULES Plaintiffs' objections, ADOPTS the magistrate judge's recommendation, and DENIES Plaintiffs' motion to amend their complaint to add a request for exemplary damages.

IV. CONCLUSION

For the foregoing reasons, it is ORDERED as follows:

1. Pursuant to the unobjected portion of the magistrate judge's recommendation, Plaintiffs' claims against Defendants John and Jane Doe are dismissed with prejudice and the caption shall reflect the proper spelling of Plaintiff Schoenstein.

2. Based on Plaintiffs' concession, their claim for fraud (Claim 11) is dismissed with prejudice.

3. Based on Plaintiffs' further concession, Wright Medical is entitled to summary judgment on Plaintiffs' claims for negligence per se (Claim 9), negligent misrepresentations (Claim 8), strict product liability due to non-conformance with representations (Claim 3), and violations of the Colorado Consumer Protection Act (Claim 10).

4. As explained in this Order, Wright Medical is also entitled to summary judgment on Plaintiffs' claims alleging strict product liability based on a manufacturing

[7] Having reached this conclusion, the Court need not consider Wright Medical's additional argument that Plaintiffs unduly delayed seeking to amend their complaint to add a request for exemplary damages.

defect (Claim 1), strict product liability for failure to warn (Claim 4) to the extent that claim is based on pre-surgery warnings, negligent failure to warn (Claim 5) to the extent that claim is based on pre-surgery failure to warn, breach of express warranties (Claim 6), and breach of implied warranties (Claim 7).

5. Plaintiffs' objections to the magistrate judge's recommendation to deny their motion to amend the complaint are OVERRULED. The Court ADOPTS the magistrate judge's recommendation and DENIES Plaintiffs' motion to amend their complaint.

Dated this 30th day of September, 2012.

BY THE COURT:

s/ David M. Ebel

U. S. CIRCUIT COURT JUDGE