IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge R. Brooke Jackson

Civil Action No 14-cv-00186-RBJ

EDWARD HAFFNER,

Plaintiff,

v.

STRYKER CORPORATION, a Michigan corporation,
STRYKER SALES CORPORATION, a Michigan corporation, and
HOWMEDICA OSTEONICS CORPORATION, d/b/a STRYKER ORTHOPAEDICS, a Michigan corporation,

Defendants.

ORDER

This matter is before the Court on Defendant's Motion to Dismiss [ECF No. 28] for failure to state a claim upon which relief may be granted. On August 1, 2014 the Court issued a show cause order asking the parties to explain why this case was not preempted by the Medical Devices Amendment to the Food, Drug & Cosmetic Act [ECF No. 36]. Upon review of each party's response [ECF Nos. 37 & 38] the Court is satisfied that this case can move forward under Colorado state law. The Court exercises jurisdiction over this action pursuant to 28 U.S.C. § 1332. For the reasons discussed below, the motion is granted in part and denied in part.

BACKGROUND

Since we are at the pleading stage, the Court considers true the plaintiff's factual allegations that are plausible on their face. On or about September 27, 2011 plaintiff Edward

Haffner underwent a total knee arthroplasty in which Dr. Roger Greenberg surgically removed his left knee and replaced it with a Stryker Triathlon Total Knee System ("the Knee System"). The Knee System contained cobalt and nickel. At the time of the surgery, Mr. Haffner was unaware that the Knee System contained these metals. It also appears he was unaware that he was allergic to either of these metals, one or both of which caused him to suffer an allergic reaction resulting in pain, inflammation, swelling, bone loss, and limited mobility. On August 7, 2012 Mr. Haffner underwent a total knee arthroplasty revision surgery to remove and replace the Knee System.

Mr. Haffner filed a tort action in Weld County, Colorado District Court on October 14, 2013. The defendants Stryker Corporation, Stryker Sales Corporation, and Howmedica Osteonics Corporation d/b/a Stryker Orthopaedics (collectively "Stryker") removed the case to this Court on the basis of diversity jurisdiction on January 22, 2014 [ECF No. 1] and filed their original motion to dismiss on February 3, 2014 [ECF No 11]. Mr. Haffner filed his First Amended Complaint on February 24, 2014 [ECF No. 13] and subsequently filed his Second Amended Complaint on April 1, 2014 [ECF No. 24]. Mr. Haffner states four causes of action against Stryker: (1) strict products liability; (2) negligent products liability; (3) breach of implied warranties of merchantability and fitness; and (4) breach of express warranty. On April 22, 2014 Stryker filed its current motion to dismiss for failure to state a claim upon which relief can be granted [ECF No. 28].

ANALYSIS

The Court views a Rule 12(b)(6) motion in the light most favorable to the nonmoving party and accepts all well-pleaded allegations as true. *Teigen v. Reffrow*, 511 F.3d 1072, 1079 (10th Cir. 2007). However, the facts alleged must be enough to state a claim for relief that is plausible, not merely speculative. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007). A plausible claim is a claim that "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Pleadings that offer only "labels and conclusions or a formulaic recitation of the elements of a cause of action will not do." *Id.* at 678 (quoting *Twombly*, 550 U.S. at 555).

"[I]n general, a motion to dismiss should be converted to a summary judgment motion if a party submits, and the district court considers, materials outside the pleadings." *Prager v. LaFaver*, 180 F.3d 1185, 1188 (10th Cir. 1999). However, "the district court may consider documents referred to in the complaint if the documents are central to the plaintiff's claim and the parties do not dispute the documents' authenticity." *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 941 (10th Cir. 2002).

A. Strict Liability.

"Colorado has 'expressly adopted the doctrine of strict liability in tort, based on the Restatement (Second) of Torts § 402A.'" *Wollam v. Wright Med. Grp., Inc.*, No. 10-CV-3014-DME-BNB, 2012 WL 4510695, at *2 (D. Colo. Sept. 30, 2012) (quoting *Union Supply Co. v. Pust*, 583 P.2d 276, 280 (Colo. 1980)). Section 402A is entitled "Special Liability of Seller of Product for Physical Harm to User or Consumer," and it describes the tort liability faced by sellers of all types of consumer products. In at least one prescription medical device case the

Colorado Court of Appeals has adopted a rule from the Restatement (Third) of Torts § 6. *See O'Connell v. Biomet, Inc.*, 250 P.3d 1278, 1281 (Colo. App. 2010). Section 6 is entitled "Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices," and it describes the tort liability surrounding manufacturers of prescription drugs and medical devices. The Restatement (Second) of Torts was published in 1965 and the Restatement (Third) in 1988.

There appear to be few medical device tort cases in Colorado. This may be a result of the Medical Devices Amendments of 1976, which have preempted many of these lawsuits. *See* Show Cause Order [ECF No. 36]. The only Colorado state court case concerning medical device products liability and citing the Restatement (Second) of Torts § 402A of which this Court is aware was decided in 1984, several years before the Restatement (Third) was published. *See Palmer v. A.H. Robins Co.*, 684 P.2d 187 (Colo. 1984). I found two cases from the District of Colorado also citing § 402A in medical device cases, one from 1984 and another from 2012. *See Hawkinson v. A.H. Robins Co.*, 595 F. Supp. 1290 (D. Colo. 1984); *Wollam*, 2012 WL 4510695.

As noted above, a medical device case decided by the Colorado Court of Appeals in 2010 cites the Restatement (Third) of Torts § 6, though only to adopt the learned intermediary doctrine. *See Biomet*, 250 P.3d at 1281. Sitting in diversity, I am bound to apply the law I believe the Colorado Supreme Court would apply. Given the decision in *Biomet* alongside the specific provision on prescription medical devices in the Restatement (Third) of Torts, the Court will look to both Restatements for guidance in determining the outcome of this motion.

1. Design Defect

In order to state a claim for defective design a plaintiff must allege that "(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." *Wollam*, 2012 WL 4510695 at *2 n.1. Under the risk-utility test, a product is "unreasonably dangerous" if its risks outweigh its benefits. *Armentrout v. FMC Corp.*, 842 P.2d 175, 183 (Colo. 1992). The Restatement (Second) of Torts takes into account that there may exist "unavoidably unsafe products," which are "especially common in the field of drugs." Restatement (Second) of Torts § 402A cmt. k. It is for this very reason that these products "cannot legally be sold except to physicians, or under the prescription of a physician." *Id.* The Colorado Supreme Court has recognized comment k as establishing a defense for the makers of certain drugs and medical products. *See, e.g.*, *Fibreboard Corp. v. Fenton*, 845 P.2d 1168, 1172 (Colo. 1993); *Camacho v. Honda Motor Co.*, 741 P.2d 1240, 1244 n.5 (Colo. 1987); *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).

The Restatement (Third) of Torts § 6 goes a step further. First, it establishes a different test for design defect with respect to prescription drugs and medical devices:

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

Restatement (Third) of Torts § 6(c). The drafters explain that "[t]he traditional refusal by courts to impose tort liability for defective designs of prescription drugs and medical devices is based on the fact that a prescription drug or medical device entails a unique set of risks and benefits. What may be harmful to one patient may be beneficial to another." *Id.* at cmt. b. The drafters conclude that "a prescription drug or medical device that has usefulness to any class of patients is not defective in design even if it is harmful to other patients." *Id.*

Mr. Haffner claims that the Knee System was defectively designed because it contained nickel and cobalt (substances to which 19% of the population is allegedly allergic or sensitive) despite the availability of viable hypoallergenic alternatives.[1] Stryker contends that Mr. Haffner did not plausibly allege that its product was defective or unreasonably dangerous simply because it contains cobalt and nickel. The Court is inclined to agree with the defendant. Prescription medical devices are not the same as ordinary consumer products. A variety of similar devices made with different materials can be developed and manufactured to address the needs of different classes of patients. Simply because a product would not be compatible with a certain class of individuals—in this case, those with cobalt and nickel allergies—does not mean the medical device is defectively designed. The Restatement (Second) considered the possibility that certain drugs could be unavoidably unsafe while still remaining beneficial. The Restatement (Third) took this conclusion one step further, reasoning that medical devices can be safe for

[1] The Court is unpersuaded by Mr. Haffner's argument that the device was defectively designed because it did not include an allergy test kit. Under both formulations of the law cited above, the focus is on the device itself, and not on any additional items that might be included to first determine whether the product at issue should be used. As will be discussed more fully below, the failure to include an allergy test kit might have been negligent on the part of the defendant, but it does not constitute a defect with respect to the design of the Knee System.

certain patient populations and not others without their risk outweighing their utility. It is for this reason that these devices can only be sold to doctors and administered by prescription. The plaintiff has failed to state a plausible claim that the Knee System is defectively designed. Therefore, this claim is dismissed.

2. Failure to Warn

Mr. Haffner also asserts a strict liability claim based on a failure to warn theory. "A failure to warn adequately can render a product, which is otherwise free of defect, defective for purposes of strict liability recovery." *Biomet*, 250 P.3d at 1280. "Under strict liability, the test is whether the manufacturer's failure to warn adequately of the potentially dangerous propensities of its product rendered the product unreasonably dangerous." *Barton v. Adams Rental, Inc.*, 938 P.2d 532, 539 (Colo. 1997). "[A] medical device is not reasonably safe if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings." *Biomet*, 250 P.3d at 1281 (citing the Restatement (Third) of Torts § 6(d)). The learned intermediary doctrine—the duty of prescription drug and medical device manufacturers to warn physicians rather than the individual patient—has been adopted in Colorado. *See id.* at 1281–82.

Mr. Haffner has sufficiently pled facts that, if true, could establish a violation of the duty to warn. In particular, he claims that the Knee System was not accompanied by adequate instructions or warnings to inform a healthcare provider of the full nature and extent of the risks associated with the product's use. Stryker points to the Knee System's product inserts in support of its motion to dismiss, which the plaintiff agrees the Court can review as documents referred to

in the Complaint that are central to his claim. Upon review of these inserts, only two warnings or advisements appear applicable to this suit, both found under the "Adverse Effects" section: (1) that metal sensitivity reactions have been reported following joint replacement, and (2) that adverse effects (of any type) may necessitate reoperation. *See* [ECF Nos. 28-1 at 7; 28-2 at 8; 32-1 at 5, 17]. The plaintiff concedes that these warnings were in the inserts but claims that they were inadequate for lack of specificity, and that the product should have included an instruction that patients be tested for metal allergies prior to having the Knee System implanted.[2]

The defendant counters by pointing to the Restatement (Second) of Torts § 402A comment j., which provides that "[t]he seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them." *See* [ECF No. 28 at 6–7]. While the defendant's quote ended there, the comment continues, "Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known . . . the seller is required to give warning against it . . . ." Restatement (Second) of Torts § 402A cmt. j. There is no reason to believe that individuals with metal sensitivities would be aware of them, especially sensitivities to metals that are not typically handled in our day-to-day lives or that would not cause a severe reaction unless implanted in a person's body. Furthermore, the plaintiff has alleged that a substantial percentage of the population suffers from these sensitivities. As such, Mr. Haffner has sufficiently pled that the defendant had a duty to warn of the specific dangers that could accompany the ordinary use of the Knee System and to

[2] The plaintiff also argues that the typeface was too small to make the warning sufficient as a matter of law. [ECF No. 32 at 14–15]. However, I have found no allegation concerning the inability to read the inserts anywhere in the Complaint.

include an instruction that individuals be tested prior to implantation of the device.[3] These allegations are sufficient to make out a claim of strict liability under a failure to warn theory.

B. Negligence.

While the focus of strict product liability claims is on the condition of the product, the focus of a negligence claim is on the manufacturer's conduct. *See Wollam*, 2012 WL 4510695 at * 7 (citing *Boles v. Sun Ergoline, Inc.*, 223 P.3d 724, 727 (Colo. 2010)). To make out a negligence claim sufficiently, Mr. Haffner must plausibly allege that (1) Stryker owed him a legal duty of care; (2) Stryker breached that duty; (3) Mr. Haffner suffered injury; and (4) Stryker's breach caused Mr. Haffner's injuries. *See, e.g.*, *id.*; *Ryder v. Mitchell*, 54 P.3d 885, 889 (Colo. 2002). "A legal duty to use reasonable care arises in response to a foreseeable risk of injury to others." *Palmer*, 684 P.2d at 209. A manufacturer is negligent "if it did not exercise reasonable care in marketing, selling, and labeling its product." *Pavelko v. Breg, Inc.*, No. 09-CV-01461-PAB-KMT, 2011 WL 782664 at *4 (D. Colo. Feb. 28, 2011). Overall, Stryker is held to the standard of care of a "reasonably prudent medical device manufacturer under the same or similar circumstances." *Id.*; *see also Hawkinson*, 595 F. Supp. at 1308 (applying same duty to pharmaceutical companies).

Mr. Haffner alleges that Stryker breached its duty of care in the following five ways: (1) Stryker designed the Knee System with cobalt and nickel despite knowledge of the risk that patients could have adverse reactions to such metals; (2) Stryker sold its Knee System without an

[3] Section 6 of the Restatement (Third) of Torts does not alter the Court's analysis. It provides that "[a] prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to" the health care provider or, in certain circumstances, to the patient directly. Restatement (Third) of Torts § 6(d). The plaintiff has certainly alleged that the risk of harm associated with the Knee System was foreseeable.

accompanying allergy testing kit despite knowledge that a substantial portion of the population has allergies or sensitivities to the metals contained in the implant; (3) Stryker failed to include warnings sufficient to fully inform physicians, health care providers, and/or consumers of the risk of an adverse reaction to the metals contained in the implant; (4) Stryker failed to include instructions indicating that patients should be tested for metal allergies and sensitivities prior to having the device implanted; and (5) Stryker failed to conduct adequate testing to determine whether the cobalt and nickel contained in the Knee System would cause allergic or other toxic reactions in a significant number of patients. The first and fifth of these claims must be dismissed, while the other three have been plausibly alleged.

"Regardless of whether a product liability action is grounded in negligence or strict liability, a plaintiff must prove that the product was defective." *Mile Hi Concrete, Inc. v. Matz*, 842 P.2d 198, 205 (Colo. 1992). As discussed earlier, the plaintiff cannot show that the product was defectively designed simply because it contains cobalt and nickel. Therefore, the claim that Strkyer was negligent by including these metals in its product must likewise fail. However, the contention that Stryker negligently failed to provide an allergy test kit remains. Effectively, Mr. Haffner is arguing that a reasonable medical device manufacturer would have included an allergy test kit with a product containing cobalt and nickel. Here we are not looking at the design of the product itself but instead at the conduct of the manufacturer. Thus, the claim stands even if the Knee System was not defectively designed.

"When a manufacturer or seller knows or should know of unreasonable dangers associated with the use of its product and not obvious to product users, it has a duty to warn of these dangers; and a breach of this duty constitutes negligence." *Palmer*, 684 P.2d at 198.

Stryker claims that, as a matter of law, it had no duty to warn because it is open and obvious that "[a] metal knee replacement is, by definition, metal." [ECF No. 28 at 8]. Yet Mr. Haffner never claimed that the Knee System was unreasonably dangerous because it is metal; his Complaint alleges that the component metals of nickel and cobalt, metals which a lay person may well not know were in a product simply by looking at it, were not obvious. Furthermore, the question of obviousness not only goes to the materials used in a product, but more importantly to the potential danger those materials create. It is not open and obvious that cobalt and nickel could make a metal implant dangerous for use. Mr. Haffner contends that a reasonably prudent medical device manufacturer would inform users of the component metals, warn them of the likelihood of suffering an allergic reaction, and instruct them to be tested for sensitivity prior to implantation of the device. Mr. Haffner sufficiently alleged not only that the duty to warn existed, but that Stryker breached this duty and that the breach caused his injuries. As such, his third and fourth negligence claims withstand Stryker's motion to dismiss.

Mr. Haffner's fifth claim, however, must be dismissed as it does not meet the plausibility standard set out in *Twombly* and *Iqbal*. In particular, no facts have been alleged that indicate that Stryker failed adequately to test the Knee System before marketing it. Instead, the Complaint contains just this one statement, a conclusory assertion of such an omission. If discovery leads to a plausible basis for this claim, the plaintiff may move for leave to amend the complaint at that time. However, at this time the claim must be dismissed.

C. Express and Implied Warranties.

Under Colorado law, an express warranty includes any affirmation of fact, promise, or description of the product by the seller of the goods. *See* C.R.S. § 4-2-313(1). Colorado further imposes an implied warranty of merchantability, effectively a guarantee that a product is fit for the ordinary purposes for which it is used. C.R.S. § 4-2-314(2)(c). I agree with Stryker's assertion that in this case the breach of warranty claims are essentially identical. Accordingly, they can be discussed together.

Mr. Haffner alleges that Stryker expressly warranted that the Knee System was "safe, effective, fit, and proper for its intended use." Second Amended Complaint [ECF No. 24] at ¶ 58. He also claims that Stryker breached the implied warranty of merchantability. *Id.* at ¶ 53. In both cases, Mr. Haffner contends that the warranties were breached because the Knee System "had dangerous propensities when put to its intended use and would cause severe injuries to the user." *Id.* at ¶¶ 53, 60. However, just because some individuals were allergic to materials in the Knee System does not mean that the product was not merchantable, safe, effective, fit, or proper for its intended use as a knee-replacement device. The express warranty claim must also fail because, as Stryker points out, the inserts expressly indicated that some individuals may have sensitivity to the metal in the product, and that such a reaction may require revisionary surgery. Notably, the inserts included a number of other warnings regarding possible adverse effects accompanying use of the Knee System. *See generally* [ECF Nos. 28-1, 28-2, & 32-1]. An item can be fit for the ordinary purposes for which it is used—here as a knee-replacement device—without being safe for every possible user.

ORDER

For the foregoing reasons, Defendant's Motion to Dismiss [ECF No. 28] is GRANTED IN PART and DENIED IN PART.

DATED this 29th day of September, 2014.

BY THE COURT:

R. Brooke Jackson
United States District Judge