UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

RICHARD E. TICE et al.,

Plaintiffs,

v.

ZIMMER HOLDINGS, INC. et al.,

Defendants.
_____/

File No. 1:15-cv-134

HON. ROBERT HOLMES BELL

O P I N I O N

Plaintiff Richard E. Tice and his wife, Sandra Tice, bring this product liability action against Zimmer Holdings, Inc. and its subsidiaries Zimmer, Inc. and Zimmer US, Inc. (collectively, "Zimmer"). Before the Court is Defendants' motion to dismiss Counts I, II, IV and V of the complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, and to dismiss Count VI to the extent that it is derivative of Counts I, II, IV and V. Defendants assert that Counts I, II, IV and V are barred by the statute of limitations, that the failure-to-warn aspect of Counts I, II and V are barred by the "learned intermediary" and the "sophisticated user" doctrines, that any UCC claim in Count IV is barred due to lack of privity, and that Count V has not been sufficiently pleaded. The motion will be granted in part and denied in part.

I.

A complaint may be dismissed for failure to state a claim if "'it fails to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957)). While a complaint need not contain detailed factual allegations, a plaintiff's allegations must include more than labels and conclusions. *Twombly*, 550 U.S. at 555; *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."). The Court must determine whether the complaint contains "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 679. Although the plausibility standard is not equivalent to a "'probability requirement,' . . . it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 678 (quoting *Twombly*, 550 U.S. at 556). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not 'show[n]' – that the pleader is entitled to relief." *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

Although a motion to dismiss under Rule 12(b)(6) is generally not an "'inappropriate vehicle' for dismissing a claim based upon a statute of limitations, . . . dismissal is warranted if 'the allegations in the complaint affirmatively show that the claim is time-barred.'" *Lutz*

v. Chesapeake Appalachia, LLC, 717 F.3d 459, 464 (6th Cir. 2013) (quoting *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 547 (6th Cir. 2012)).

In this diversity action, the Court applies the law of the forum state, Michigan, in accordance with the decisions of its highest court. *Id.* Where the state court has not addressed an issue, this Court must "'predict how the court would rule by looking to all the available data,' including intermediate appellate decisions.'" *Id.* (quoting *Berrington v. Wal–Mart Stores, Inc.*, 696 F.3d 604, 608 (6th Cir. 2012)).

According to the complaint, Defendants designed, manufactured, and sold components for hip replacement surgery, known as: the Zimmer Trilogy Acetabular System Longevity Crosslinked Polyethylene Liner, the Zimmer Versys Hip System Femoral Stem, and the Zimmer Versys Hip System Femoral Head (collectively, the "Devices"). The Devices were implanted into Mr. Tice during a total hip replacement surgery on December 6, 2004. Sometime thereafter, he developed severe and debilitating pain in his hip and "metallosis." (Compl. 2, ECF No. 2.) To treat these complications, he underwent hip revision surgery on June 27, 2013. (*Id.*)

In Count I of the complaint, Plaintiffs claim that Defendants are strictly liable for selling a product that is defective and unreasonably dangerous. The Devices allegedly subject the user to a risk of "increased ion levels," without providing adequate warning of this risk. (*Id.* at 6.) In Count II, Plaintiffs claim that Defendants negligently designed and manufactured the Devices such that they are prone to failure, and negligently failed to warn

the FDA, Mr. Tice, or his physicians about the defective nature of the Devices or their risks. In Count III, Plaintiffs claim that Defendants breached an implied warranty that the Devices were merchantable, fit and safe for their ordinary and intended use. In Count IV, Plaintiffs contend that Defendants breached an express warranty that the Devices were "safe, effective, fit and proper for their intended use." (*Id.* at 10.) In Count V, Plaintiffs assert that Defendants willfully or negligently provided false information to Mr. Tice and his physicians about the quality, safety and effectiveness of the Devices, which induced them to use the Devices. In Count VI, Mrs. Tice seeks damages for loss of consortium. Plaintiffs filed this action on February 12, 2015.

II.

A. Statute of Limitations

Defendants assert that the claims for strict product liability, negligence, breach of express warranty, and fraud/negligent misrepresentation (Counts I, II, IV, and V) are barred by the three-year statutes of limitations for product liability actions, Mich. Comp. Laws § 600.5805(13), and/or for actions to recover damages for injury to a person, Mich. Comp. Laws § 600.5805(10). However, the parties disagree as to when the claims accrued.

Under Michigan law, "the period of limitations runs from the time the claim accrues. The claim accrues at the time . . . the wrong upon which the claim is based was done regardless of the time when damage results." Mich. Comp. Laws § 600.5827. "'The wrong is done when the plaintiff is harmed rather than when the defendant acted.'" *Trentadue v.*

Buckler Automatic Lawn Sprinkler Co., 738 N.W.2d 664, 670 (Mich. 2007) (quoting *Boyle v. Gen. Motors Corp.*, 661 N.W.2d 557, 560 n.5 (Mich. 2003)). In other words,

> [o]nce all of the elements of an action for . . . injury, including the element of damage, are present, the claim accrues and the statute of limitations begins to run. Later damages may result, but they give rise to no new cause of action, nor does the statute of limitations begin to run anew as each item of damage is incurred.

Marilyn Froling Revocable Living Trust v. Bloomfield Hills Country Club, 769 N.W.2d 234, 250 (Mich. Ct. App. 2009) (quoting *Connelly v. Paul Ruddy's Equip. Repair & Serv. Co.*, 200 N.W.2d 70, 72-73 (Mich. 1972)). Moreover, a claim accrues even if the plaintiff is not subjectively aware of an injury or its cause. *See Trentadue*, 738 N.W.2d at 670 (holding that § 600.5827 does not recognize the "discovery rule" from common law, which provides that a claim does not accrue "until a plaintiff knows, or objectively should know, that he has a cause of action and can allege it in a proper complaint").

Defendants assert that, for purposes of Counts I, II, IV and V, the "wrong" occurred on December 6, 2004, when the Devices were implanted into Plaintiff Richard Tice's hip. However, the complaint does not allege that Mr. Tice was harmed by the Devices immediately after they were implanted. Instead, Plaintiffs' allegations are consistent with an injury that occurred at a later time.[1] (*See* Compl. ¶ 21.) As Plaintiffs explain in more detail in response to the motion to dismiss, the Devices

[1]Defendants imply that the Devices were ineffective and caused Plaintiff pain immediately after surgery, but this fact is not alleged in the complaint.

> caused increased pain and put the recipients at risk of metal poisoning, in addition to increased exposure for the development of additional medical problems. Plaintiffs expect to establish [that] . . . over time [the] Devices would corrode and deteriorate to the point that friction would develop due to the metal-on-metal contact between the neck pieces and stem[,] generating miscroscopic metallic debris that are released into the body. This deterioration and metal-on-metal effect causes a breakdown of the tissue around the joint, loosening of the hip replacement, and premature failure of the Devices. These metal ions that enter into the patient's bloodstream also lead to adverse reactions and other medical problems.

(Plfs.' Resp. to Mot. to Dismiss 2-3, ECF No. 10.) This explanation is consistent with Plaintiffs' allegation that the Devices were defective because they were "unreasonably dangerous" and subjected Mr. Tice to a "risk" of harm. (*See* Compl. ¶ 30.) Thus, the complaint can be fairly read as alleging that immediately after surgery Mr. Tice faced a risk of harm, but he did not suffer a physical injury until the Devices deteriorated, some time after he first started using them. In some jurisdictions, being subjected to a *risk* of *future* harm is an injury sufficient to give rise to a tort claim, but that is not the case in Michigan. *See Henry v. Dow Chem. Corp.*, 701 N.W.2d 684, 689 (Mich. 2005) (holding that a plaintiff can pursue a tort claim only if he or she has suffered a present physical injury). In that case, the claims did not accrue at the time of the implant surgery, because absent a "present physical injury," Mr. Tice could not assert a claim. *See Henry*, 701 N.W.2d at 689; *see also Marilyn Froling Revocable Living Trust*, 769 N.W.2d at 250 (noting that a claim does not accrue until all of its elements are met).

In short, although it is not clear when Mr. Tice was injured by the Devices, the complaint does not allege facts indicating that he was injured at the time of his implant

surgery. Consequently, the complaint does not "affirmatively show" that Plaintiffs' claims accrued more than three years before they filed this action. *See Lutz,* 717 F.3d at 464.

Defendants cite *Smith v. Stryker Corp.*, No. 294916, 2011 WL 445646 (Mich. Ct. App. Feb. 8, 2011), in which the plaintiff was injured as a result of the use of the defendants' product, a pain pump. *Id.* at *1. The defendant allegedly marketed the product for use at the site of an injury even though it had not been approved for that use. The plaintiff began using the product in 2003, but she did not file her lawsuit until 2009. She asserted that her claim accrued when her injury "progressed to total destruction" in 2007. *Id.* The court of appeals rejected this argument and held that "the wrong occurred during the use of the product in 2003," even though "she did not manifest the damages until 2007." *Id.* Likewise, Defendants contend that Plaintiffs' claims accrued when Mr. Tice began using the Devices on December 6, 2004, even though he did not require corrective surgery until a later date.

The *Stryker* case is distinguishable from this one. The opinion in *Stryker* does not provide many details about the harm suffered by the plaintiff, but its brief description of the underlying facts suggests that the defendant's product was harmful as soon as the plaintiff started using it. According to the court, she used it at a location where it was not approved for use, and it caused her injury to gradually "progress" to "total destruction." *Id.* In contrast, Plaintiffs' allegations suggest that the Devices were initially beneficial, but then they became harmful after a period of time as a result of corrosion and deterioration in the hip joint.

A more appropriate case for comparison is *Peter v. Stryker Orthopaedics, Inc.*, 581 F. Supp. 2d 813 (E.D. Mich. 2008), in which the plaintiff received a prosthetic knee. For one year after his knee-replacement surgery in 2000, the plaintiff enjoyed improved mobility and decreased pain. *Id.* at 814. In 2001, he started to experience pain and swelling, and in 2004, the prosthesis was removed. *Id.* at 815. After its removal, his physicians determined that one of the components had fractured, causing damage to the surface of the plaintiff's bone. *Id.* The plaintiff brought a product liability action pursuant to Michigan law in 2007. The court noted that, under *Trentadue*,[2] the claim would have accrued *when the prosthesis fractured*, sometime between the date that the plaintiff started to experience pain and swelling and the date that it was removed. *Id.* at 817. Similarly, Plaintiffs' claims accrued when the Devices failed to function as intended and thereby caused an actionable injury, which may have happened at or before the time that Mr. Tice began to experience complications such as "increased pain," "metal poisoning," "breakdown of the tissue" around his hip joint, or other "adverse reactions" and "medical problems." (*See* Plfs. Resp. to Mot. to Dismiss 2-3.)

On the other hand, Plaintiffs are wrong to assert that their claims accrued "at or near June 27, 2013, when . . . Plaintiff required a second surgical procedure for removal of the defective Devices" and that "it was not until this harm was known that all elements of a cause of action were met triggering the statute of limitations." (*Id.* at 5.) *Trentadue* makes

[2]Ultimately, the court decided that *Trentadue* should not apply retroactively to the plaintiff's case. *Stryker Orthopaedics, Inc.*, 581 F. Supp. 2d at 818.

clear that the accrual date for Plaintiffs' claims is not tied to their knowledge of the harm. Likewise, the accrual date is not tied to the date that Mr. Tice's physicians determined that the Devices needed to be removed. Instead, the claims accrued when the alleged defects in the Devices harmed Plaintiff. This must have occurred *before* Mr. Tice or his physicians determined that he needed corrective surgery, and may have occurred before he was even aware that the Devices were causing problems. At this stage of the proceedings, however, it is not clear when the claims accrued; thus, they may have accrued less than three years before the action was filed, in which case they are not time-barred. Consequently, the Court will deny Defendants' motion to dismiss to the extent that it is based on the statute of limitations.

B. Learned Intermediary & Sophisticated User Doctrines

Defendants also contend that the failure-to-warn aspect of the claims in Counts I, II and V are barred by the "learned intermediary" and "sophisticated user" doctrines.

1. Learned Intermediary Doctrine

"[T]he 'learned intermediary' doctrine is an exception to the axiomatic principle that a manufacturer has a duty to warn the user of known dangers inherent to its product." *Mowery v. Crittenton Hosp.*, 400 N.W.2d 633, 637 (Mich. Ct. App. 1986). It applies "to manufacturers of prescription drugs, who are required to warn only the prescribing physician, who acts as a 'learned intermediary' between the manufacturer and consumer." *Id.* Generally speaking, the rationale for the rule is that a physician is in the best position to

weigh the risks of using a prescription drug in a particular case and to convey the appropriate information to the patient. *See id.* at 638 ("To expect the average citizen to know if he or she should take the drug or when to stop taking it, or to understand the technical language so often necessary to explain the dangers of the drug, is unreasonable."). The rule also applies to prescription devices. *Brown v. Drake-Willock Int'l, Ltd.*, 530 N.W.2d 510, 516 (Mich. Ct. App. 1995) (extending the rule to dialysis machines). Thus, Defendants contend that any duty to warn about the risks associated with the Devices extended to Mr. Tice's physicians and not to Plaintiff himself.

First, Plaintiffs argue that the learned intermediary doctrine does not apply because the Devices were not "prescription" devices; that is, they were not devices for which Mr. Tice's physician could "[write] a prescription for him to pick up at a local medical supply or drug store." (Plfs.' Resp. to Mot. to Dismiss 7.) Instead, they were "marketed and sold to hospitals throughout the United States for use in surgically replacing a hip that [is] no longer functional." (*Id.*) Plaintiffs fail to cite any authority to support this distinction. It does not necessarily follow that devices provided by physicians through a hospital are different in kind from devices prescribed by a physician and obtained from a local pharmacy. In both cases, a physician decides whether the device is appropriate for the patient, and the physician is in the best position to evaluate the risks associated with their use. Indeed, Plaintiffs' description might also apply to the dialysis machines in *Brown*, which were only available for purchase by physicians. *See Brown*, 530 N.W.2d at 516. At this stage of the proceedings, the Court

is satisfied that the Devices are prescription devices to which the learned intermediary doctrine applies.

Next, Plaintiffs argue that the learned intermediary doctrine does not bar the failure-to-warn claims because Defendants failed to provide an adequate warning to Mr. Tice's physicians. In other words, even if Defendants did not have a duty to warn Mr. Tice directly, they did have a duty to provide an adequate warning to his physicians, and their failure to do so was a proximate cause of his injury. The Michigan Court of Appeals considered a similar claim in *Nichols v. Clare Community. Hospital*, 476 N.W.2d 493 (Mich. Ct. App. 1991), and stated that causation would be satisfied if the plaintiff could show that "an adequate warning would have prevented the plaintiff's injury by altering the prescribing doctor's conduct or that the doctor might have heeded the warning." *Id.* at 496; *see also Reeder v. Hammond*, 336 N.W.2d 3, 5 (Mich. Ct. App. 1983) (finding that the plaintiff stated an actionable claim against drug manufacturers for failing to provide an adequate warning to the plaintiff's physicians); *Muilenberg v. Upjohn Co.*, 320 N.W.2d 358, 366 (Mich. Ct. App. 1982) ("The drug manufacturer does have a continual duty to warn the medical profession of the side effects of drugs. . . . Where a doctor is not adequately warned, the drug manufacturer may in turn be liable to the patient for a breach of duty[.]"). Thus, even if Defendants did not have a duty to warn Mr. Tice directly, Plaintiffs' assertion that Defendants failed warn his physicians suffices to state a viable claim.

2. Sophisticated User Doctrine

Defendants also invoke the sophisticated user doctrine codified in Michigan law, which provides that "a manufacturer or seller is not liable in a product liability action for failure to provide an adequate warning if the product is provided for use by a sophisticated user." Mich. Comp. Laws § 600.2947(4). Defendants contend that the Devices were prescribed by physicians, who are sophisticated users of that product. *Cf. Brown*, 530 N.W.2d at 516 (holding that physicians are sophisticated users of dialysis machines).

The term "sophisticated user" is expressly defined by statute as:

> . . . a person or entity that, by virtue of training, experience, a profession, or legal obligations, is or is generally expected to be knowledgeable about a product's properties, including a potential hazard or adverse effect. An employee who does not have actual knowledge of the product's potential hazard or adverse effect that caused the injury is not a sophisticated user.

Mich. Comp. Laws § 600.2945(j). The rationale behind the sophisticated user doctrine is that "where a purchaser is a 'sophisticated user' of a manufacturer's product, the purchaser is in the best position to warn the ultimate user of the dangers associated with the product, thereby relieving the sellers and manufacturers from the duty to warn the ultimate user." *Portelli v. I.R. Constr. Prods. Co.*, 554 N.W.2d 591, 599 (Mich. Ct. App. 1996). In other words, "the manufacturer markets a particular product to professionals that are presumed to have experience in using and handling the product, and because of this special knowledge, the sophisticated user will be relied upon by the manufacturer to disseminate information to the ultimate users regarding the dangers associated with the product." *Id.* at 597.

Defendants apparently contend that physicians are always sophisticated users of products that they prescribe and, thus, Mr. Tice's physicians were sophisticated users of the Devices. But whether a user knew or should have known about a product's dangerous characteristics depends on the circumstances of a particular case, including the knowledge and experience of the user and the nature of the risks. *See, e.g.*, *Heaton v. Benton Constr. Co.*, 780 N.W.2d 618, 623 (Mich. Ct. App. 2009) (finding, based on the circumstances of that case, that a general contractor was not a sophisticated user of the product at issue). At this stage of the proceedings, it is not clear whether "by virtue of training, experience, a profession, or legal obligations" a physician could be "generally expected to be" knowledgeable about the properties of Defendants' implants and the risk that they could deteriorate and cause the complications experienced by Mr. Tice. Thus, the Court will deny Defendants' motion to the extent that it relies on the sophisticated user doctrine.

C. Lack of Privity

Defendants further contend that, insofar as Plaintiffs' claims regarding breach of express warranty can be construed as claims brought pursuant to the Uniform Commercial Code (UCC), they should be dismissed because there was no contract between Plaintiffs and Defendants. *See Heritage Res., Inc. v. Caterpillar Fin. Servs. Corp.*, 774 N.W.2d 332, 341 (Mich. Ct. App. 2009). Plaintiffs do not contest Defendants' legal argument, but they assert that they are not bringing any claims pursuant to the UCC; instead, they are bringing tort claims, which do not require privity of contract. Indeed, the Court cannot discern any basis

for a UCC claim in the complaint. There is no allegation that the Plaintiffs and Defendants were parties to an agreement with one another. Plaintiffs do not contend, for instance, that they purchased the Devices directly from Defendants. Thus, to the extent that Plaintiffs' express warranty claims are based on the UCC, they will be dismissed.

D. Fraud and Negligent Misrepresentation

Plaintiffs allege in Count V of the complaint that Defendants willfully or negligently supplied "false information to the public, to Plaintiffs, and to Mr. Tice's physician(s) regarding the high[ ]quality, safety, and effectiveness of the Devices," in order to "induce the public, Plaintiffs and Mr. Tice's physician to purchase and implant the Devices." (Compl. ¶¶ 58, 59.) Defendants assert that these claims are not sufficiently pleaded as required by Rule 9(b) of the Federal Rules of Civil Procedure. This rule provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To satisfy this standard, Plaintiffs' pleadings must "(1) specify the statements the plaintiff contends were fraudulent; (2) identify the speaker; (3) state where and when the statements were made; and (4) explain why the statements were fraudulent." *La. Sch. Employees' Ret. Sys. v. Ernst & Young, LLP*, 662 F.3d 471, 478 (6th Cir. 2010). Defendants contend that Plaintiffs have not identified the time, place or content of any misrepresentations.

In response, Plaintiffs argue that the allegations of the complaint make clear that "Zimmer" (referring to all Defendants) is the speaker, and that it committed fraud when it

"advertised, marketed and promoted" the Devices as a "high-quality, safe and effective product . . . to doctors and hospitals worldwide." (Plfs.' Resp. to Mot. to Dismiss 10.) Plaintiffs contend that the foregoing "statements" were made "each and every time the defective Devices were marketed to the health care community and shipped from Defendant[s'] manufacturing plant and put into the stream of commerce." (*Id.*)

The foregoing allegations are not sufficient to satisfy Rule 9(b). They do not put Defendants on notice of any specific statements that were fraudulent, let alone explain why they are fraudulent, or indicate where and when they were made. Plaintiffs apparently contend that every time Defendants marketed or sold the Devices they were misrepresenting the safety and quality of their products, but in effect, this merely recasts Plaintiffs' implied warranty claim as a fraud claim. The latter requires more than the mere promotion or sale of a defective product; it requires specific misrepresentations of fact, which Plaintiffs have not identified with any specificity.

Plaintiffs assert that they cannot provide the specificity requested by Defendants without further discovery. At the same time, however, they allege that Defendants provided false information to the public and the medical community at large. It is odd that Plaintiffs are not able to find such widely-disseminated information without resort to discovery from Defendants. Moreover, Plaintiffs are presumably aware of the statements that they relied upon when selecting the Devices. Thus, the Court is not persuaded that discovery is necessary to clarify their claim. Indeed, allowing discovery on the matter would defeat

several of the purposes of Rule 9(b), which include protecting Defendants' reputations from fraud allegations, preventing "fishing expeditions" to discover unknown wrongs, and narrowing "potentially wide-ranging discovery to only relevant matters." *Thompson v. Bank of Am. N.A.*, 773 F.3d 741, 751 (6th Cir. 2014).

In their response, Plaintiffs seek leave to amend the complaint under Rule 15, if the Court finds that the complaint is "somehow insufficient to allege notice of the contours" of their claims. (Plfs.' Resp. to Mot. to Dismiss 11.) Leave to amend is to be "freely" given "when justice so requires." Fed. R. Civ P. 15(a)(2). That rule applies especially when a complaint does not allege fraud with particularity. *See Morse v. McWhorter*, 290 F.3d 795, 799-800 (6th Cir. 2002). Consequently, the fraud and negligent misrepresentation claims in Count V of the complaint will be dismissed, but Plaintiffs will be given an opportunity to correct the deficiencies in those claims by filing an amended complaint within 21 days of the Court's order.

III.

In summary, to the extent that Defendants seek dismissal of claims arising under the UCC and dismissal of the fraud and negligent misrepresentation claims in Count V of the complaint, the motion will be granted. Plaintiffs shall have 21 days in which to file an amended complaint to cure the defects in Count V. In all other respects, the motion to dismiss will be denied.

An order will be entered that is consistent with this Opinion.

Dated: July 15, 2015

/s/ Robert Holmes Bell
ROBERT HOLMES BELL
UNITED STATES DISTRICT JUDGE