IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Patrick O'Shea,

Plaintiff,

v.

Zimmer Biomet Holdings, Inc., et al.,

Defendants.

_____/

Case No. 1:16-cv-02813

Michael L. Brown
United States District Judge

OPINION AND ORDER

This products-liability case arises from the failure of a replacement knee manufactured by Defendants Zimmer Biomet Holdings, Inc., Zimmer, Inc., and Zimmer U.S., Inc., and implanted in Plaintiff Patrick O'Shea's left leg. For the reasons below, the Court grants Defendants' Motion for Summary Judgment (Dkt. 48) in part and denies it in part. The Court also denies Plaintiff's Motion to Amend Complaint as moot. (Dkt. 55).

I. Background

Plaintiff suffered from chronic knee pain in his left knee. Dkt. 48-2 at ¶ 1-2; Dkt. 51 at ¶¶ 3-4. His left leg was deformed, the result of a gunshot wound sustained in 1978. Dkt. 48-2 at ¶ 3; Dkt. 51 at ¶ 1. His femur bowed forward and to the outside. Dkt. 48-2 at ¶ 4. His left leg was also 1.5 centimeters shorter than his right leg and rotated twenty degrees externally. *Id.* He walked with a gait. *Id.*

In 2007, he decided to have his knee replaced. Dkt. 48-2 at ¶ 6; Dkt. 51 at ¶ 8. He was obese. Dkt. 48-2 at 2. Plaintiff's surgeon, Dr. Diehl, chose to implant a Zimmer Biomet NexGen Complete Knee Solution LPS-Flex Prolong System replacement knee. *Id.* at ¶ 7. Dr. Diehl performed the knee-replacement surgery in June 2007. *Id.* at ¶ 6. Plaintiff recovered well and regained movement. *Id.* at ¶ 10.

Seven years later, Plaintiff's pain returned. Dkt. 48-2 at ¶ 11; Dkt. 51 at ¶ 10-13. Dr. Diehl examined him and recommended another surgery to diagnose the problem. Dkt. 48-2 at ¶ 13; Dkt. 51 at ¶ 14. During that surgery, Dr. Diehl found that the polyethene tibial post of the replacement knee – that is, the portion of the artificial knee attached to the tibia – had broken. Dkt. 48-2 at ¶ 11; Dkt. 51 ¶ 14. Dr. Diehl

replaced the polyethylene liner, still using the Zimmer product. Dkt. 48-2 at ¶ 14. No one kept the broken component after surgery. Dkt. 51 at ¶ 15. Plaintiff filed this action asserting design defect, manufacturing defect, and failure-to-warn claims arising from the broken tibial post. After discovery, Defendants moved for summary judgment on all of Plaintiff's claims. (Dkt. 48).

II. Legal Standard

Summary judgment is appropriate where "the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "No genuine issue of material facts exists if a party has failed to 'make a showing sufficient to establish the existence of an element . . . on which that party will bear the burden of proof at trial.'" *Am. Fed'n of Labor & Cong. Of Indus. Orgs. v. City of Miami*, 637 F.3d 1178, 1186 (11th Cir. 2011) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). An issue is genuine when the evidence is such that a reasonable jury could return a verdict for the nonmovant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986).

The moving party bears the initial responsibility of asserting the basis for its motion. *Id*. at 323. The movant is not, however, required to negate the non-movant's claim. Instead, the moving party may meet its burden by showing that there is "an absence of evidence to support the non-moving party's case." *Id*. at 324. After the moving party has carried its burden, the non-moving party must present competent evidence of a genuine issue for trial. *Id*.

The Court views all evidence and factual inferences in a light most favorable to the non-moving party. *Samples v. City of Atlanta*, 846 F.2d 1328, 1330 (11th Cir. 1988). But the existence of some alleged factual disputes will not defeat an otherwise proper motion for summary judgment. "The requirement is there be no genuine issue of material fact." *Anderson*, 477 U.S. 247-48.

III. Analysis

Plaintiff brings claims of manufacturing defect, design defect, and failure-to-warn arising out of the failure of his Zimmer knee-replacement device. Plaintiff asserts these claims as both strict-liability and negligence claims. Although Georgia recognizes causes of action for products liability sounding in both strict-liability and negligence,

"[b]ecause of the inherent similarity between a negligence and a strict liability action under Georgia law, the analysis of plaintiff's strict liability claims largely applies to an examination of the negligence claim." *Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1251 (N.D. Ga. 2002).

A. Manufacturing Defect

To establish a manufacturing defect under Georgia law, a plaintiff "must prove that defendant is the manufacturer of the property, that the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended (i.e. defective), and that its condition when sold was the proximate cause of the injury sustained." *Williams v. Mast Biosurgery USA, Inc.*, 644 F.3d 1312, 1319 (11th Cir. 2011) (quoting *Chicago Hardware & Fixture Co. v. Letterman*, 610 S.E.2d 875, 877-78 (Ga. App. 1999)). "A manufacturing defect is one where there was a flaw from the manufacturing process not in the design or specifications of the product." *Brazil v. Janssen Research & Dev.*, 196 F. Supp. 3d 1351, 1358 (N.D. Ga. 2016). The flaw must render the product unsuitable for its intended use.

A manufacturing defect is "measurable against a built-in objective standard or norm of proper manufacture." *Banks v. ICI Americas Inc.*,

450 S.E.2d 671, 673 n.2 (Ga. 1994). The "product's defectiveness is determined by measuring the product in question against the benchmark of the manufacturer's designs." *In re Mentor Corp. ObTape Transobturator Sling Prods. Liability Litig.*, 711 F. Supp. 2d 1348, 1365 (M.D. Ga. 2010) (quoting *ACE Fire Underwriters Ins. Co. v. ALC Controls, Inc.*, No. 1:07-cv-606, 2008 WL 2229121, at *2 (N.D. Ga. May 28, 2008)). So to succeed on a manufacturing-defect claim, a plaintiff must show that the defendants' product "was not manufactured in accordance with its design." *Jones v. Amazing Prods. Inc.*, 231 F. Supp. 2d 1228, 1239 (N.D. Ga. 2002). But "[i]t is not necessary for the plaintiff to specify precisely the manner of the defect." *Williams v. American Med. Sys.*, 548 S.E.2d 371, 374 (Ga. App. 2001). To survive summary judgment, the plaintiff must show that the product did not "operate as intended" from which a jury could infer that the product deviated from the manufacturer's design. *Id.*[1]

Defendants contend they are entitled to summary judgment on Plaintiff's manufacturing-defect claim because Plaintiff failed to produce

[1] Of course, the plaintiff must also show that the manufacturing defect proximately caused the injury. *Williams*, 248 S.E.2d at 374.

expert testimony that the replacement knee was defective. Plaintiff contends that he need not provide expert testimony and that his other evidence is enough.

Georgia law does not always require a plaintiff in a manufacturing defect case to present expert testimony. *Mast Biosurgery*, 644 F.3d at 1319. Georgia courts have held that "the existence of a manufacturing defect in a products liability case may be inferred from circumstantial evidence." *Firestone Tire and Rubber Co. v. King*, 244 S.E.2d 905, 909 (Ga. App. 1978). Reliance on circumstantial evidence is particularly appropriate when – as here – the product is destroyed or otherwise unavailable for testing. *Graff v. Baja Marine Corp.*, 310 F. App'x 298, 306 (11th Cir. 2009) (citing *Rose v. Figgie Int'l, Inc.,* 495 S.E.2d 77, 81 (Ga. App. 1997)).

The Eleventh Circuit has explained that expert testimony is necessary to show a manufacturing defect when an evaluation of the alleged defect lies outside the "common experience of a jury" – that is, when a juror would not otherwise understand how the product was intended to perform. *Mast Biosurgery*, 644 F.3d at 1320. In *Mast Biosurgery*, the plaintiff claimed surgical wrap implanted in her abdomen

was defective. *Id*. at 1318-19. She presented testimony from her doctor showing that the wrap broke down into hard plastic pieces, migrated into her colon, and caused severe injuries. *Id*. at 1319. She did not, however, present expert testimony about how the wrap was intended to operate or that it failed to operate appropriately. *Id*.

The Eleventh Circuit affirmed the district court's order granting summary judgment for the defendant, finding that – while Georgia law may not require expert testimony in all manufacturing-defect cases – the proper functioning of the surgical mesh was beyond the ken of the average juror. *Id*. at 1320-1321. Expert testimony was necessary to provide information "about the nature of the product and how it was expected to function when implanted in the human body." *Id.* at 1321. Without this expert testimony, the court found the plaintiff failed to raise an issue of material fact about whether the mesh was defective. *Id*.

In reaching this decision, the Eleventh Circuit distinguished two cases in which Georgia courts ruled that expert testimony was unnecessary. First, the Eleventh Circuit distinguished *McDonald v. Mazda Motors of America, Inc.*, 603 S.E.2d 456 (Ga. App. 2004). In that case, the plaintiff alleged that a new car was defective because it began

making a loud rattling noise right after delivery and the dealership could not fix it. Second, the Eleventh Circuit distinguished *Williams v. American Med. Sys.*, 548 S.E.2d 371, 374 (Ga. App. 2001). In that case, the plaintiff alleged that an inflatable penile implant was defective after it ruptured just one month after implantation.

The Eleventh Circuit held that both cases involved alleged defects "within the common experience of a jury." *Mast Biosurgery*, 644 F.3d at 1320. Expert testimony was unnecessary because the average person would know a new car is not supposed to make loud rattling noises. *Id.* And while an inflatable penile implant may be more complicated, any juror would know the device should not have ruptured within the first month. *Id.* Evidence, therefore, that the engine ran loudly or that the implant broke into pieces was sufficient for the jury to determine that the product did not operate as intended. *Id.*

Like *Williams,* this case involves an implant that simply broke. But, in this case, it did not break within the first month. Plaintiff underwent knee-replacement surgery in 2007. Dkt. 48-2 at ¶ 6; Dkt. 51 at ¶ 8. The Zimmer implant operated perfectly for seven years. Dkt. 48-2 at ¶¶ 6-11; Dkt. 51 at ¶ 8. Plaintiff claims that it was defective for not

lasting eight years or more. A typical juror, however, would not know how long it should last. Also, Plaintiff was obese at the time of his initial surgery and had a pronounced gait because of a previous gunshot wound. The average juror certainly would not know whether the implant failed to function as intended when it wore out and broke after seven years under these circumstances. This is not a case in which an inference of defective manufacturing is "particularly obvious." *Mast Biosurgery*, 644 F.3d at 1320. Put differently, the failure of Plaintiff's replacement knee is not like finding a trout in the milk bottle. *Graff v. Baja Marine Corp.*, 2007 WL 6900363 (N.D. Ga. Dec. 21, 2007) (noting some defects are so obvious that expert testimony is unnecessary as when you "find a trout in the milk bottle").

Because Plaintiff presented no expert testimony, it may seem that Defendants are entitled to summary judgment. But, in *Mast Biosurgery,* the Eleventh Circuit (after finding expert testimony necessary) still considered whether plaintiff's circumstantial evidence was somehow enough to avoid summary judgment. *See id.* at 1321. The court noted that the plaintiff presented testimony from her doctor about his use of the surgical wrap, the fact that he later found pieces of it in her colon,

and that those pieces injured the plaintiff. *Id.* The Eleventh Circuit found this circumstantial evidence insufficient because it did not show that the wrap "performed other than as expected." *Id.* The court explained that the evidence did not "strengthen the inference that it was a manufacturing defect" that caused the injury rather than some other potential cause such as the product being mishandled, having been inserted in a negligent manner, or having been unsuitable for use in this plaintiff. *Id.* The court held that, while a plaintiff need not present circumstantial evidence to disprove all causes other than a manufacturing defect, a plaintiff relying on circumstantial evidence must "provide evidence that would permit a jury to select [his or her] explanation, that of a manufacturing defect, as the most likely cause." *Id.*

The Eleventh Circuit reached a similar conclusion in *Graff v. Baja Marine Corp.*, 310 F. App'x 298 (11th Cir. 2009). In that case, the driver of a speed boat died in a boating accident. His family sued claiming the engine gimble had a manufacturing defect that caused it to break and eject the decedent. *Id.* at 301. The defendant argued that there was no defect and that the decedent hit a wave at an excessively high speed,

causing the gimble to break and leading to the accident. *Id.* The district court excluded the plaintiff's expert witness, and the Eleventh Circuit affirmed. *Id*. at 301-305. As a result, the Eleventh Circuit recognized that the plaintiff was essentially making a circumstantial argument that the gimble housing – a complicated device – would not suddenly fail during operation unless it contained a manufacturing defect. *Id.* at 305. The court found this insufficient, holding that "it would simply be speculation to conclude that plaintiff's theory is the only plausible explanation for the accident." *Id.* at 306. The court held that, without expert testimony, a plaintiff must present circumstantial evidence sufficient to allow the jury to infer that the "plaintiff's theory [of a defect] is the only plausible explanation for the [injury]." *Id.* at 306.[2]

[2] Georgia courts have held that a plaintiff may circumstantially establish a manufacturing defect through evidence that goods manufactured at the same plant at around the same time as the product at issue suffered the same failure. *See Rose,* 495 S.E.2d at 82 ("Circumstantial evidence relevant to prove a manufacturing defect may include evidence of the existence of the defect in goods produced at the same plant at around the same time"). In this case, there is no evidence of problems with other replacement knees manufactured in the same plant and at the same time as the knee implanted in Plaintiff's leg. To the contrary, the undisputed evidence shows that Zimmer's product has an impeccable record for reliability. Dkt. 48-2 at ¶ 20. That theory of liability is thus unavailable here.

As the Eleventh Circuit has done, this Court must consider whether Plaintiff has presented enough circumstantial evidence to avoid summary judgment without expert testimony. Plaintiff argues that an affidavit executed by Dr. Mark Diehl – his surgeon – is sufficient. *See* Dkt. 51-8. Dr. Diehl provided the affidavit before litigation began. In it, he stated that he implanted the knee in the condition he received it from Defendants "without any modification" and that the surgery "went as planned." *Id*. at ¶ 5. Dr. Diehl also stated that "in all [his] years as an orthopedic surgeon performing hundreds of knee surgeries, [he] had not seen such a fracture or failure of this polyethylene insert in this manner, and the insert is not supposed to fail as it did." *Id*. at ¶ 9. He stated that it was his opinion "to a reasonable degree of medical certainty" that Plaintiff's weight and femoral deformity did not cause the fracture. Dkt. 51-8 at ¶¶ 10-11. Finally, he said the implant should have lasted more than fifteen years and "did not perform as [he] would have expected." *Id*.[3]

[3] Although immaterial to this motion, Dr. Diehl testified at his deposition that he believed that Plaintiff's deformities "put some abnormal forces across . . . the post, [which] led to failure." Dkt. 48-3 at 17. Perhaps Dr. Diehl's testimony can be reconciled with his pretrial affidavit, but that is a question for the jury.

Dr. Diehl is not an expert on the design and performance of polyethylene components in replacement knees and was not offered as an expert. As the Eleventh Circuit held in *Mast Biosurgery*, the testimony of a treating physician cannot be enough to show how a manufacturer intended a complicated device to operate when that treating physician is not qualified as an expert in the design and production of the product. *Mast Biosurgery*, 644 F.3d at 1320. So Dr. Diehl's affidavit is insufficient circumstantial evidence to raise a genuine issue of material fact.

But this case involves something else. In support of his claim, Plaintiff points to an internal document, called a complaint-handling form, that Defendants used to gather information about the failure of Plaintiff's replacement knee. *See* Dkt. 51-16. One of Defendants' employees completed the form. Dkt. 51-19 at 2. A question on the form asked: "Does the available information suggest that the device/product has malfunctioned or failed to perform as intended?" Dkt. 51-16 at 26. The employee checked the box for the answer "Yes." *Id*. The form then stated: "If yes, explain circumstance below." The employee wrote: "The articular surface post broke while implanted." *Id*. In a deposition, a Zimmer employee was asked about the question. He explained that "[t]he

articular surface post was not designed to fracture under normal loading and conditions; therefore, a post fracture would be checked off as a yes." Dkt. 51-19 at 2.

The complaint-handling form then asked "Were there any contributing conditions related to the event? (Ex: trauma, illness, previous injury, related non-compliance, patient anatomy)." The employee checked the box for the answer "No." Dkt. 51-16 at 26.

Plaintiff contends that the complaint-handling form creates a genuine issue of material fact about whether the device suffered from a manufacturing defect that caused it to break. The Court agrees. Put together, the answer to these questions establish an admission by Defendants that the knee "malfunctioned or failed to perform as intended" and that there were no other "contributing conditions" like Plaintiff's weight or gait. *Id.* The admission provides both evidence of a defect and evidence that the defect was the most likely cause of the failure.

During oral argument, counsel for Defendants argued that the employee who completed the form had no knowledge of the facts at issue and thus the form has little evidentiary value. That may be true. But no

evidence in the record supports this contention. Indeed, each of these two critical answers allowed Defendants' employee four possible choices: "Yes", "No", "No Information", or "N/A" (not applicable). The employee chose to answer the questions with "Yes" and "No" answers rather than stating that he or she did not have the necessary information. When asked if the device malfunctioned or failed to perform as intended, for example, the employee could have answered "No Information" but said "Yes." Likewise, when asked whether there were any contributing factors (like Plaintiff's anatomy), the employee could have said "No Information" but said "No."

The very next section of the complaint-handling form also includes the following supplemental information: "it was noted that the patient had a verus flexion femoral deformity, but this was corrected by the distal femoral cut." *Id.* at 27. This seems like a reference to Plaintiff's preexisting condition that caused his uneven gait, an indication Defendants' employee was aware of these issues when he or she wrote there were no contributing factors.[4]

[4] It is unclear whether Defendants received the supplemental information after completing the initial answers. But, even so, the employee could have revised the initial answers after receiving the additional

With this one form Plaintiff has accomplished what the plaintiffs in *Mast Biosurgery* and *Graff* failed to do: produce evidence that at once shows that the device did not operate as intended and that – if believed by the jury – would eliminate other plausible explanations for the product's failure. The Court recognizes that Plaintiff's evidence is thin. Defendants may well present evidence to prevent the complaint-handling form from being considered a knowing admission. So Defendants may ultimately obtain judgment as a matter of law. Even so, on this record, Plaintiff has "provide[d] evidence that would permit a jury to select her explanation, that of a manufacturing defect, as the most likely." *Mast Biosurgery*, 644 F.3d at 1321.[5]

For these reasons, the Court denies Defendants' motion for summary judgment on Plaintiff's manufacturing-defect claim.

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information. At any rate, those are also questions for a jury to consider in assessing the strength of the alleged admissions.

[5] If Plaintiff asserts a negligent-manufacturing claim separate from his strict-liability claim, the record lacks any evidence from which a jury could infer that Defendants were negligent in manufacturing the product. *See Williams*, 548 S.E.2d at 374 (granting summary judgment on negligent-manufacturing claim where the plaintiff failed to "demonstrate[] that the defect was the result of any negligence by [the defendants].").

B. Failure to Warn

Under Georgia law, the learned-intermediary doctrine governs failure-to-warn claims involving medical devices. *Lance v. American Edwards Labs.*, 452 S.E.2d 185 (Ga. App. 1994). Under this doctrine, the duty to warn runs not from the manufacturer to the patient, but from the manufacturer to the physician. *See Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272 (11th Cir. 2002) (recognizing that the learned intermediary doctrine applies to failure-to-warn claims involving medical devices). The rationale for the doctrine is that the treating physician is in a better position than the manufacturer to warn the patient. "The decision to employ [a medical device] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular needs and susceptibilities." *McCombs v. Synthes*, 587 S.E.2d 594, 595 (Ga. 2003) (internal quotation omitted).

So "the manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor." *Id.* "In most cases, a court begins its inquiry under this doctrine by determining whether the manufacturer provided the learned intermediary with an adequate

warning. . . . If the warning was adequate, the inquiry ends, and the plaintiff cannot recover." *Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010).

Plaintiff argues that Defendants did not sufficiently warn Dr. Diehl about the risks of breakage or the severity of any injury. The undisputed facts show otherwise. The Instructions for Use included with the Zimmer implant state that a possible adverse effect of the knee implantation is "[l]oosening or fracture/damage of the prosthetic knee components or surrounding tissues." Dkt. 48-8 at 5. And Dr. Diehl testified that he knew of – and explained to Plaintiff – that "the components [of the device] sometimes can fail. They're mechanical parts, just like bearings for your car or tires for your car, and sometimes they don't last like you anticipate they would." Dkt. 51-4 at 16.

Thus, the undisputed facts show that Defendants warned Dr. Diehl about the risk of hardware breakage and Dr. Diehl understood the risk. Because Defendants warned Plaintiff's physician of the exact harm about which Plaintiff complains, its warnings were "adequate and reasonable under the circumstances." *McCombs v. Synthes*, 596 S.E.2d 780, 780 (Ga. App. 2004) (affirming summary judgment on failure-to-warn claim where

medical device's package warned of harm that "occurred in [the plaintiff's] situation.").

The Court grants Defendants' motion for summary judgment on the failure-to-warn claim.[6]

C. Design Defect

"While a 'manufacturing defect' is a fairly straightforward concept, a 'design defect' is a far more diffuse proposition under Georgia Supreme Court precedent, as the latter calls for a finder of fact to employ a loose balancing test to determine whether the manufacturer properly designed the product." *Amazing Prods.*, 231 F. Supp. 2d at 1236. "[A] product design is defective if the risks inherent in a product design outweigh the utility or benefit derived from the product." *In re Mentor Corp*, 711 F. Supp 2d at 1364 (internal quotations omitted). Plaintiff thus must show a genuine issue of material fact that the Zimmer knee was defectively designed. To do this, "[he] must produce evidence from an expert who is qualified to conduct the risk-utility analysis and to opine that the risk

[6] If Plaintiff asserts a negligent failure-to-warn claim, it fails for the same reason.

inherent in the [Zimmer knee's] design outweigh the utility or benefit derived from the product." *Id.* at 1365.

Plaintiff presented no such evidence. He does not even defend his design-defect claim in his response to Zimmer's motion for summary judgment. *See* Dkt. 49. Instead, he asks to amend his complaint and drop the claim. (Dkt. 55). In the light of Plaintiff's failure to present any evidence to show that design of the knee suffered from a defect, summary judgment is appropriate on Plaintiff's design-defect claim. And because the Court grants summary judgment against this claim, the motion to amend the complaint to drop the claim is denied as moot. (Dkt. 55).[7]

IV. Conclusion

The Court **GRANTS IN PART AND DENIES IN PART** Defendants' Motion for Summary Judgment. (Dkt. 48). The Court also **DENIES AS MOOT** Plaintiff's Motion to Amend. (Dkt. 55).

IT IS SO ORDERED.

Dated: September 27, 2018
Atlanta, Georgia

MICHAEL L. BROWN
UNITED STATES DISTRICT JUDGE

[7] If Plaintiff asserts a negligent design defect claim, it fails for the same reason.