UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

COLEMAN JARRETT, et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 1:12-cv-00064-SEB-DML
	)	
WRIGHT MEDICAL TECHNOLOGY, INC.,	)	
	)	
Defendant.	)	

ORDER

This cause is before the Court on the Motion for Summary Judgment [Dkt. 84] filed by Defendant Wright Medical Technology, Inc. ("Wright Medical"). Plaintiffs Coleman and Paula Jarrett commenced this action in 2012 and it was transferred to the United States District Court for the Northern District of Georgia as part of a multidistrict litigation styled "CONSERVE® Hip Implant Product Liability Litigation, MDL 2329" ("the MDL"). This case was remanded and transferred to our court to proceed individually on July 6, 2018.

On October 1, 2018, Plaintiffs filed their Second Amended Complaint in this individual action, setting forth claims against Wright Medical under the Indiana Products Liability Act, IND. CODE § 34-20-1-1, *et seq.* ("the IPLA") relating to Mr. Jarrett's receipt of hip implant components from Wright Medical's CONSERVE® product line during a July 17, 2006 left total hip arthroplasty. Plaintiffs allege that, based on purported defects in the CONSERVE® devices, generally relating to alleged design defects that allegedly caused excessive metal ion release and loosening of the CONSERVE® Cup device, Mr.

Jarrett was forced to undergo a second "revision" surgery on July 12, 2010 to remove the CONSERVE® devices. In addition to the IPLA claim, Plaintiffs also allege a loss consortium claim as well as a request for punitive damages. Wright Medical has moved for summary judgment on each of Plaintiffs' claims.

For the reasons detailed below, we GRANT Defendant's Motion for Summary Judgment as to Plaintiffs' manufacturing defect, failure-to-warn, and fraud theories under the IPLA as well as Plaintiffs' punitive damages request and DENY the motion as to Plaintiffs' IPLA claim based on a design defect theory and the loss of consortium claim.

Factual Background

I. Wright Medical's CONSERVE® Devices

Hip arthroplasty is a surgical procedure that involves replacing the failed natural hip joint with a fabricated replacement, which is intended to improve mobility and relieve pain associated with degenerative hip disease and other bone quality conditions. Exh. A. at 5; Exh. D at 1–3; Exh. E at 1. Wright Medical's CONSERVE® line of products, which belong to a category of hip prostheses referred to as metal-on-metal ("MoM"), is one type of fabricated replacement used in such procedures. The components of a MoM prostheses include a linerless, high carbon, cobalt-chrome cup, and a large diameter high carbon, cobalt-chrome femoral head. *See* FDA Publication, Effectiveness of Metal-on-Metal Hip Implants, *available at* https://www.fda.gov/medical-devices/metal-metal-hip-implants/effectiveness-metal-metal-hip-implants (last updated March 15, 2019); *see also* Exh. F. Wright Medical began moving into the MoM hip prosthesis market in the early

1990s and strove to be the first company to market such products in the United States. Exh. 1 at WMTMDL0068460.

II. Wright Medical's Knowledge of Risks Related to CONSERVE® Devices

In November 1995, two Wright Medical employees, including the Vice President of Development & Technology, attended a four-day conference on MoM technology at which questions were raised regarding whether MoM devices were a good alternative to poly devices and attendees were informed that more needed to be learned and studied regarding the risks associated with metal-metal bearing surfaces. Exh. 2. That same year, Wright Medical was notified by several surgeons and medical product designers of several significant risks regarding MoM devices that required further testing, including concerns regarding metal toxicity, inflammation, bone loss, allergic reaction, local tumor formation, systemic effects, soft tissue necrosis, osteolysis, and blood-born metal ions. Carroll Dep. at 106–111, 134–35. Wright Medical was also aware at that time that the McKee-Farrar device, a MoM design first used in 1960, was removed from the market in the 1970s because of problems with osteolysis, inflammation, cystic responses, cytoxic metal ions, and tissue reactions in implant patients, which conditions necessitated revisions in 50% of the implants. *Id.* at 113–14.

Wright Medical knew, both when it designed its CONSERVE® devices and throughout the time it was developing, manufacturing, marketing, and selling those devices, of the principles and concerns associated with MoM devices generating wear debris and releasing toxic cobalt and chromium heavy metal ions. *Id.* at 106–110, 114–16, 164–66; Fisher Dep. at 170–71, 173–74, 176, 326–27; Batts Dep. at 101–105;

Timmerman Dep. at 76, 85. Wright Medical was also aware prior to Mr. Jarrett's hip replacement surgery that cobalt and chromium ions can cause metallosis, necrosis, inflammation, bone loss, cup loosening, ALVAL, and pseudotumors, and that such ions can have toxic effects, cytotoxicity, indirect sensitization, and carcinogenicity, but was unaware of the long-term consequences to patients of exposure to such ions. Carroll Dep. at 97–99, 113–15, 134–35, 169–70, 238; Exh. 5 and Exh. 9 to Mosely Dep.; Timmerman Dep. at 85. Wright Medical's biggest concern in selling its CONSERVE® devices was the issue of metal ion release; the "number one concern" of surgeons "was the metal ions." Fisher Dep. at 173; Jerome Dep. at 95. At least as early as 2003, Wright Medical understood that, because "metallic particulate debris is approximately an order of magnitude smaller than PE debris, … even low rates of volumetric wear can lead to a large number of particles." Exh. 8.

Prior to marketing and selling the CONSERVE® devices, including the device implanted in Mr. Jarrett in 2006, Wright Medical did not conduct any studies to investigate the risks associated with metal ion release or other "hot-button" issues that led surgeons to reject MoM implants in the 1970s. Moseley Dep. at 80; Exh. 11 at 20–26. Nor did Wright Medical perform any biocompatibility or other testing to determine whether metal-ion release from the CONSERVE® devices was safe. Fisher Dep. at 190–93; Svarczkopf Dep. at 157–63; Moseley Dep. at 80.

III. Wright Medical's Marketing of the CONSERVE® Devices

Wright Medical marketed its CONSERVE® devices and components under the tagline: "Tested, Trusted." Exh. 13. The company's marketing materials included the following testimonials from patients and surgeons:

- "Before the surgery, I couldn't run. I couldn't play soccer. Now, there's no pain in the joint at all. Hip replacement gave me my life back." Exh. 15.
- "Because the procedure allows him to be as aggressive as we wanted to be, there – there was no reason for me to tell him to hold back." Exh. 16.
- "Some patients have been able to pursue more vigorous activities, including martial arts, hockey, running marathons, even climbing Mount Kilimanjaro." Exh. 17.
- "Wright Medical, which makes the Conserve Total hip said hip replacement lasts 25 to 30 years." Exh. 18.

In marketing its CONSERVE® devices, Wright Medical determined in 2004 that it needed to "address the metal ion issue in order to convince surgeons … that metal ions are not an issue with [its] system." Exh. 40 to Timmerman Dep.; *accord* Batts Dep. at 114. In line with this strategy, at a 2002 meeting, Wright Medical instructed its sales representatives, who acted as the company's direct contact with surgeons, that "[t]he effects of metal ion release are known and have been demonstrated to be safe" and that "[t]he effects of polyethylene debris are known, and have been demonstrated to lead to revision surgery." Exh. 29 to Watson Dep.

Wright Medical represented in its marketing materials that MoM hips had a long clinical use but did not provide information regarding the failure rates of either MoM or poly devices. Smith Dep. at 51. Wright Medical's marketing materials also stated that it

was widely believed that less than one percent of patients have MoM hypersensitivity reactions and that, in a clinical trial with 1800 patients, none suffered a pseudotumor following surgery, but did not provide information regarding whether that study applied to total hip replacements. *Id.* at 52–53.

IV. Mr. Jarrett's Original Hip Surgery

In 2006, Mr. Jarrett experienced increasing hip pain exacerbated by a fall and ultimately underwent a left total hip replacement performed by Andrew Parr, M.D. on July 17, 2006 for bone-on-bone degenerative joint disease. Parr Dep. at 7; 47; C. Jarrett Dep. at 65–66. At the time of the surgery, Mr. Jarrett was 47 years of age and had a medical history that included other concurrent conditions including obesity, degenerative lumbar disease and radiating pain, enlarged prostate, and diabetes, among others, although he reported that, before his fall, he was still able to remain relatively active. Parr Dep. at 42, 45–46; C. Jarrett Dep. at 42, 50, 52, 72. Based on Mr. Jarrett's condition, Dr. Parr chose to implant CONSERVE® MoM devices. Parr Dep. at 22, 28.

Prior to the surgery, Mr. Jarrett did not have any specific discussions with Dr. Parr regarding the devices that would be used, beyond a general conversation in which Dr. Parr explained that, based on Mr. Jarrett's relatively young age and activity level, the implanted devices would be MoM. Jarrett Dep. at 79–80. Mr. Jarrett did not conduct any research regarding Wright Medical or the CONSERVE® devices or speak with anyone from Wright Medical prior to his hip replacement surgery and does not recall receiving any brochures or materials from Wright Medical. *Id.* at 11–12, 92. According to Mr. Jarrett, he did not know that he was being implanted with Wright Medical products at the

time of his surgery and only learned that fact after initially incorrectly filing a lawsuit against a different device manufacturer, Zimmer. *Id.* at 90, 92.

V. Dr. Parr's Decision to Use a CONSERVE® Implant

Mr. Jarrett's physician, Dr. Parr, testified that orthopedic doctors like himself "deal with the state of the art as it exists at the time," meaning that they select "the best treatment to [their] knowledge at that time." Parr Dep. at 20. Dr. Parr selected the CONSERVE® MoM devices for Mr. Jarrett in 2006 based on certain benefits of those devices as compared to other alternatives, including metal-on-plastic and ceramic-on-ceramic devices, available at that time. *Id.* at 24–29. Dr. Parr testified that metal-on-plastic devices had traditionally been used for hip replacements but that "plastic [] traditionally wor[e] out relatively quickly" and MoM bearings had emerged as an alternative to potentially "improve the wear characteristics over metal on plastic" devices. *Id.* at 27. MoM devices also "had less propensity for squeaking" as compared to the ceramic-on-ceramic devices, which devices Dr. Parr testified were known to potentially "fracture and break into pieces." *Id.* at 26–27.

With regard to the CONSERVE® MoM devices in particular, Dr. Parr testified that one significant risk of hip replacement surgery is the risk of dislocation, and the CONSERVE® device had a larger head that resulted in a reduced risk of dislocation. *Id.* at 23–25. The CONSERVE® devices were also "modular," meaning that the device could more easily be positioned to resemble the patient's natural anatomy, improving stability. *Id.* According to Dr. Parr, because of these characteristics, patients like Mr. Jarrett, who wanted "the potential benefit of decreasing the wear rate" from plastic

devices, and who were "younger, [and] more active" and wanted to "improve on dislocation rates," were "candidates" for MoM hip replacement. *Id.* at 27, 29, 41–42, 45–46.

Dr. Parr testified that, prior to Mr. Jarrett's surgery, the CONSERVE® total hip system had been utilized for only a short period of time and Dr. Parr knew that there was a possibility of "wear to the bearing surfaces" and that "patients who were implanted with metal-on-metal total hips would be expected to show … some metal ions both around the hip and measurable in laboratory studies." *Id.* at 25, 28. However, at the time of Mr. Jarrett's surgery, Dr. Parr was unaware of the extent of metallosis that could occur with MoM devices and he had not been informed of issues related to pseudotumors or that physicians using MoM devices were experiencing higher revision rates in their patient populations. *Id.* at 104–105. Dr. Parr testified that, in fact, "nobody was aware of" the prevalence of issues related to metal ions "early on," in 2006. *Id.* at 98. Mr. Jarrett's orthopedic surgeon expert, John Waldrop, M.D., likewise testified that the extent of issues related to MoM devices was not known in the orthopedic community until years after Mr. Jarrett's first surgery. Waldrop Dep. at 50.

Dr. Parr testified that he had "a general knowledge of" Wright Medical's instructions for use, but he could not say for sure whether he saw any Wright Medical product brochures. Parr Dep. at 95, 104. Rather, he based his decision to use the CONSERVE® devices "more off of just the actual research data and those things more so than the marketing." *Id.* at 95. According to Dr. Parr, if he had been aware of the problems associated with MoM devices at the time of Mr. Jarrett's surgery, he would not

have used the CONSERVE® device, but that "nobody was aware of those issues early on []." *Id.* at 98, 99. Dr. Parr discontinued using large diameter MoM hips in 2010 or 2011 based on "published issues with metallosis and early failure with large-diameter metal-on-metal hips …." *Id.* at 98.

VI. Product Warnings and Dr. Parr's Independent Knowledge of Risks

The CONSERVE® devices were accompanied by Wright Medical's product inserts, commonly known as instructions for use ("IFU"). Exh. J. The IFUs were available to Dr. Parr prior to Mr. Jarrett's surgery and outlined certain risks, contraindications, and other instructions for the prescription and implantation of the components. *Id.*; Parr Dep. at 32. As relevant here, the IFU for the CONSERVE® products contains the following warnings:

> **Metal Components.** Some of the alloys used to produce orthopedic prostheses may contain some elements that may be carcinogenic in tissue cultures or intact organisms. Questions have been raised in scientific literature as to whether or not these alloys may be carcinogenic to actual prosthetic recipients. Studies conducted to evaluate these questions have not produced convincing evidence of such phenomenon.

Exh. J at WMTMDL0006703.

The IFU contains additional warnings concerning various "Adverse Effects," including the following:

> 2. With all joint replacements, asymptomatic localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign body reaction to particulate matter. Particulate is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondarily, particles can also be generated by third-body wear. Osteolysis can lead to future complications necessitating

> removal and replacement of prosthetic components. See Important Physician Information section for more information.
>
> 3. Although rare, metal sensitivity reactions in patients following joint replacement have been reported. Implantation of foreign material in tissue can result in histological reactions involving macrophages and fibroblasts.
>
> …
>
> 10. Allergic reactions to the prosthetic component materials can occur.

Id. at WMTMDL0006708-09.

With regard to patient selection, the IFU provides in relevant part as follows:

> 2. **Patient's weight.** An overweight or obese patient can produce high loads on the prothesis, which can lead to failure of the prothesis.

Id. at WTMDL0006700.

Apart from the IFU, Dr. Parr testified that he was independently aware of potential risks of metal wear from the bearing surface and potential release of metal ions in MoM implants, including the CONSERVE® devices at issue here. Parr Dep. at 24, 25, 98. Dr. Parr's knowledge was in part based on his participation in an investigational study using Wright Medical hip systems, including the CONSERVE® Cup, that was conducted from 2004 to 2006, in order to "evaluat[e] a strategy to decrease … metal ion" wear particles from the MoM bearing surfaces. *Id.* at 14–16, 21–22; Exh. 3 to Parr Dep. According to Dr. Parr, at the time of Mr. Jarrett's surgery in July 2006, he would have told patients, and did inform Mr. Jarrett, of these specific risks of metal wear, metal ions, and the potential for loosening prior to performing the hip replacement. Parr Dep. at 35, 37, 47–48. However, at the time of Mr. Jarrett's surgery, Dr. Parr did not know that metal levels

could continue to increase throughout the duration of an implant and thus was not aware of the extent of metallosis that could occur. *Id.* at 104, 121.

Dr. Parr discussed the risk-benefit information of which he was aware with Mr. Jarrett in recommending a MoM articulation. *Id.* at 29–30; Jarrett Dep. at 84–85. Mr. Jarrett acknowledges that he understood at the time of his surgery that any surface, whether metal, ceramic, or plastic, will eventually wear. C. Jarrett Dep. at 85.

VII. Mr. Jarrett's Recovery from Left Hip Replacement and Revision Surgery

Following his July 2006 left hip replacement, Mr. Jarrett recovered well. *Id.* at 93. Mr. Jarrett's medical records indicate that he did not consult his orthopedic surgeon, Dr. Parr, until May 2009, approximately three years after his initial surgery, when he reported experiencing pain and hearing clicking and other noises coming from his left hip. Parr Dep. at 64, 65. At that time, Mr. Jarrett also reported having fallen on a few occasions in the prior year. *Id.* at 66–67. Mr. Jarrett underwent x-rays which showed a slight area of lucency around the components as well as basic lab testing to rule out infection, but he received no other treatment. *Id.* at 67–70.

Mr. Jarrett's symptoms continued and approximately one year later, in June 2010, he fell while stepping down off a curb. Jarrett Dep. at 101–102. He felt a sharp pain when he fell and went to the emergency room where he was diagnosed with a fracture of the acetabulum, the socket of his natural hip joint. *Id.* at 102; Parr Dep. at 71–72. The x-ray indicated that the metal acetabular shell component of the CONVERSE® implant had completely loosened and rotated vertically within the acetabulum. Parr Dep. at 75, 78. On July 12, 2010, Mr. Jarrett underwent revision surgery on his left hip performed by Dr.

Parr. *Id.* at 70. The CONSERVE® devices were not retained and there are no metal ion tests to confirm the presence of metal ions in serum. Exh. A at vii, No. 3; Waldrop Dep. at 64; Jarrett Dep. at 109. The only available physical evidence from the revision surgery are pathology tissue samples which did not show the presence of metallic particles. Exh. D at 4.

In Dr. Parr's revision operative report, he noted that Mr. Jarrett had suffered a "[f]ailed [loose] left acetabular component" with "left hip pseudotumor related to metal on metal articulation with paraprosthetic osteolysis and major osseous defect." Dkt. 93-28; Parr Dep. at 78. Dr. Parr described encountering during the surgery a build-up of a yellow-brown fluid as well as a large amount of brown and grayish tissue surrounding the acetabular component of Mr. Jarrett's hip, which Dr. Parr believed to be a pseudotumor. Dkt. 93-28; Parr Dep. at 88. Following the revision surgery, Dr. Parr sent some of that tissue to pathology, where it was determined to be a hematoma, not a pseudotumor. Parr Dep. at 88–89.

Mr. Jarrett recovered well from the left hip revision surgery and his last appointment with Dr. Parr was in January 2011. Parr Dep. at 81. Mr. Jarrett is not currently seeing an orthopedic doctor for his left hip. Jarrett Dep. at 57.

VIII. Expert Testimony of John I. Waldrop, M.D.

John I. Waldrop, M.D., is an orthopedic surgeon whom Plaintiffs have identified as an expert to offer opinions concerning "the implantation and failure of the Wright Medical CONSERVE® Total Hip Implant Device associated with" Mr. Jarrett. Dkt. 87-1 at 1. Dr. Dr. Waldrop has been practicing medicine for 40 years, maintaining an active

practice performing hip and knee arthroplasties. He estimates that he has performed more than 5,000 to 6,000 total hip procedures and, since 2010, has revised 64 hips, many of which were metal-on-metal implants, including five to ten CONSERVE® devices. *Id.* In his practice, Dr. Waldrop has observed five general "characteristics" of metallosis[1] caused by MoM hip implants: (1) discolored fluid in the joint; (2) "death or necrosis of local tissue in the hip area"; (3) "cystic responses" or pseudotumors; (4) other tissue reactions including inflammation, discoloration, and staining; and (5) elevated cobalt and chromium levels. Dkt. 87-2.

With regard to Mr. Jarrett's case specifically, Dr. Waldrop testified that he "examined the medical records of Coleman Jarrett including digital x-rays of his prothesis," and based on his review of these materials and his education, training, and experience, he has formed the opinion that the failure of Mr. Jarrett's CONSERVE® total hip implant "was due to the pain associated with metallosis, corrosion, and component loosening associated with metal-on-metal hip failures," that the findings during Mr. Jarrett's revision surgery "including the noted pseudotumor, corrosion, and other indicative findings of a metallosis reaction are consistent with [his] own clinical findings on revision of metal-on-metal prosthesis," and that Mr. Jarrett's "pain prior to the revision, necessity of the revision, and injuries after the revision are the result of the defective metal-on-metal prosthesis." Dkt. 87-1 at 2.

[1] Metallosis is a blood poisoning condition that develops as a result of having high levels of toxic metals in the blood.

IX. Expert Testimony of John D. Jarrell, Ph.D, PE

Plaintiffs have also identified as an expert John D. Jarrell, Ph.D., PE, a licensed Professional Mechanical Engineer since 1996 who is actively involved in engineering analysis, design, product development, and research. He graduated from Brown University with a B.S. and M.S. in Materials Science and Engineering and a Ph.D. in Biology, Medical Science and Engineering and has received medical training in histology, physiology, microbiology, and pathology. Dkt. 88-1.

In his report, based on his experience, training, education, review of Wright Medical Technology documents, FDA documents, published scientific literature and inspection and testing of over 100 Wright Medical hip implant components, Dr. Jarrell opines that Wright Medical's CONSERVE® hip system design is defective. Dr. Jarrell identifies Wright Medical's use of a large metal cup against a large metal ball for the articulating bearing surfaces as the major defect in the CONSERVE® hip system, which in his opinion results in metal wear and the release of metal ions into surrounding tissues that can cause injury, or metallosis, as well as eventual cup loosening and device failure.

Dr. Jarrell also opines that Wright Medical's wear testing was inadequate in that it was performed "under ideal circumstances, which does not replicate patient use and clinical results" and failed to "identify the risks associated with exposure to cobalt and chromium metal wear debris, metal ions and corrosive products of [the] Conserve® product line in comparison to the traditional small metal head on poly design." *Id.* at 5. To support these conclusions, Dr. Jarrell's report sets forth results from wear testing he

performed on CONSERVE® devices, from which he determined that 25% of the thirty-three (33) CONSERVE® hips he tested exhibited more wear than advertised, specifically 14 times more wear than anticipated. *Id.* at 21.

X. The Instant Litigation

On January 17, 2012, Mr. Jarrett filed his complaint in this action. The case was transferred to the Northern District of Georgia on February 27, 2012 as part of Multi-District Litigation ("MDL") No. 2329, *In re: Wright Medical Technology, Inc., Conserve Hip Implant Products Liability Litigation* and remanded from the MDL to our court on July 6, 2018. Mr. Jarrett amended his complaint a few months later, on October 1, 2018. Now before the Court is the motion for summary judgment filed by Wright Medical. The motion has been fully briefed and is ripe for ruling.

Legal Analysis

I. Summary Judgment Standard

Summary judgment is appropriate where there are no genuine disputes of material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). A court must grant a motion for summary judgment if it appears that no reasonable trier of fact could find in favor of the nonmovant on the basis of the designated admissible evidence. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). We neither weigh the evidence nor evaluate the credibility of witnesses, *id.* at 255, but view the facts and the reasonable inferences

flowing from them in the light most favorable to the nonmovant. *McConnell v. McKillip*, 573 F. Supp. 2d 1090, 1097 (S.D. Ind. 2008).

II. Discussion

Plaintiffs have alleged in this litigation a cause of action under the IPLA, asserting design defect, failure to warn, and fraud theories, as well as claims for loss of consortium and punitive damages.[2] Wright Medical has moved for summary judgment on each of these claims, which we address in turn below.

A. IPLA Claim

Under Indiana law, the IPLA "governs all actions that are (1) brought by a user or consumer; (2) against a manufacturer or seller; and (3) for physical harm caused by the product," regardless of the legal theory upon which the action is brought. IND. CODE § 34-20-1-1. "Under the Act, a manufacturer who places 'into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer … is subject to liability for physical harm caused by that product.'" *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1007 (7th Cir. 2020) (quoting IND. CODE § 34-20-2-1). To succeed on a claim under the IPLA, the plaintiff must establish that "(1) he or she was harmed by the product; (2) the product was sold 'in a defective condition unreasonably dangerous to any user or consumer'; (3) the plaintiff was a foreseeable user or consumer; (4) the defendant was in the business of selling the product; and (5) the product reached

[2] Plaintiffs originally also asserted a manufacturing defect theory under the IPLA but abandoned that claim in their response in opposition to Defendant's motion for summary judgment. Accordingly, Defendant is entitled to summary judgment as to that theory of defect under the IPLA.

the consumer or user in the condition it was sold." *Bourne v. Marty Gilman, Inc.*, 452 F.3d 632, 635 (7th Cir. 2006).

A medical device falls within the IPLA definition of a product. *See* IND. CODE § 34-6-2-114 (defining "product" as "any item or good that is personalty at the time it is conveyed by the seller to another party" in a transaction not "wholly or predominantly the sale of a service rather than a product"). A plaintiff can establish that a product, such as the CONSERVE® device, was defective "by showing one of the following: a design defect, a manufacturing defect, or a failure to warn." *Ritchie v. Glidden Co.*, 242 F.3d 713, 720 (7th Cir. 2001); *see also Brewer v. PACCAR, Inc.*, 124 N.E.3d 616, 621 (Ind. 2019) ("A product may be defective under the IPLA if it is defectively designed, if it has a manufacturing flaw, or if it lacks adequate warnings about dangers associated with its use.").

In this case, Plaintiffs allege that the Wright Medical CONSERVE® device that was implanted in Mr. Jarrett was defective under the first and third of these theories, to wit, design defect and failure to warn. The IPLA "grounds design-defect and failure-to-warn liability in negligence: a plaintiff must 'establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product or in providing the warnings or instructions.'" *Kaiser*, 947 F.3d at 1008 (quoting IND. CODE § 34-20-2-2). "Under either theory, a plaintiff must prove that the defendant breached the duty of reasonable care owed to him—whether in the product's design or in its warnings—and the breach proximately caused his injury." *Id.*

There is a rebuttable presumption under the IPLA that the product that caused a plaintiff's physical harm was not defective, and the manufacturer or seller was not negligent, if, before the sale by the manufacturer, the product "was in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, and labeled" or "complied with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana." IND. CODE § 34-20-5-1; *see also Kaiser*, 947 F.3d at 1017. This presumption applies to all product liability claims, regardless of theory. *See Indianapolis Athletic Club, Inc. v. Alco Standard Corp.*, 709 N.E.2d 1070, 1075 (Ind. Ct. App. 1999). Once established, the opposing party has a burden of producing evidence to overcome the presumption and avoid dismissal. *See Cansler v. Mills*, 765 N.E.2d 698, 705 (Ind. Ct. App. 2002), *overruled on other grounds by Schultz v. Ford Motor Co.*, 857 N.E.2d 977 (Ind. 2006)).

1. Design Defect

We turn first to address Plaintiffs' design defect claim under the IPLA. As discussed above, to succeed on such a claim, a plaintiff "must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product…." IND. CODE § 34-20-2-2. Thus, a plaintiff must prove that "(1) the defendant owed a duty to the plaintiff; (2) the defendant breached that duty; and (3) the breach proximately caused an injury to the plaintiff." *Simpson v. Gen. Dynamics*

Ordnance and Tactical Systems-Simunition Operations, Inc., 429 F. Supp. 3d 566, 577 (N.D. Ind. 2019) (citation omitted). Additionally, "[e]xpert testimony is needed under Indiana law to establish both defect and causation when 'the issue is not within the understanding of a lay person.'" *Lyons v. Leatt Corp.*, No. 4:15-CV-17-PRC, 2017 WL 4117775, at *8 (N.D. Ind. Sept. 14, 2017); *accord Owens v. Ford Motor Co.*, 297 F. Supp. 2d 1099, 1103–04 (S.D. Ind. 2003) (requiring expert testimony where the existence of a defect depends on matters beyond the understanding of a lay person). We find in this complex products liability scenario that the nature of the alleged design defects and the cause of Mr. Jarrett's injuries are both matters that exceed the understanding of a lay person; thus, expert testimony is required to establish both that the CONSERVE® device implanted in Mr. Jarrett was defectively designed and causation.

We turn first to address whether Plaintiffs have adduced sufficient evidence to raise a genuine issue of material fact regarding whether the CONSERVE® device was defectively designed. Upon a careful review of the record, we find that they have. Plaintiffs' expert, Dr. Jarrell, opines in his report that the cobalt chromium components used in the CONSERVE® device generate excessive toxic wear, that the design of the CONSERVE® device, namely, its use of a large metal ball and cup component, results in inadequate lubrication between the metal components of the device, further exacerbating the wear issues, and finally, that Wright Medical's *in vitro* testing of the wear rate of the CONSERVE® device's metal components was inadequate because it did not accurately replicate the conditions encountered when the hip is implanted in a live patient, resulting

in data that significantly underestimated the actual wear levels associated with the device. This testimony, if believed by the jury, would be sufficient to support a finding that the design of the CONSERVE® device was defective, rendering the device unreasonably dangerous.

Wright Medical, of course, has its own experts who disagree with Dr. Jarrell's conclusions and are expected to testify to the contrary. However, it is well-established that "[t]he question of whether the expert is credible or whether his [] theories are correct given the circumstances of a particular case is a factual one that is left for the jury to determine after opposing counsel has been provided the opportunity to cross-examine the expert regarding his conclusions and the facts on which they are based. … It is not the trial court's role to decide whether an expert's opinion is correct." *Smith v. Ford Motor Co.*, 215 F.3d 713, 719 (7th Cir. 2000) (internal citation omitted). Accordingly, the question of whether the CONSERVE® device was defectively designed must go to the jury.

We turn next to address whether Plaintiff has adduced sufficient evidence to raise a genuine issue of material fact regarding causation, which is a closer question. Because the CONSERVE® device implanted in Mr. Jarrett was not retained after his revision surgery, no tests were performed on the device itself to measure its wear levels. There are also no metal ion laboratory values available indicating the presence of metal ions in Mr. Jarrett's blood; rather, we understand the uncontested testimony of Wright Medical's expert, Edward DiCarlo, M.D., to be that "[p]articles of metallic debris [were] *not*

present" in Mr. Jarrett's tissue following the revision surgery. DiCarlo Rep. at 4 (emphasis added).

In the absence of laboratory evidence showing the presence of metal ions in Mr. Jarrett's blood, Plaintiffs rely solely on what they characterize as Mr. Jarrett's "clearly observable and distinctive injuries from metallosis" as proof of causation.[3] Pls.' Resp. at 13. In support of this claim, Plaintiffs point to Dr. Parr's revision operative report which notes as a post-operative diagnosis "pseudotumor related to metal-on-metal articulation." Exh. 28. In that report, Dr. Parr also described that the "posterior wall and superior part of the acetabulum eroded away by pseudotumor or loose component" and observed a "yellowish-brown fluid" in the joint. *Id.* Dr. Parr testified that these findings are indicative of metal-on-metal failures, which "present a very distinctive appearance." Parr Dep. at 116. Likewise, Plaintiffs' expert, Dr. Waldrop, opined that the failure of Mr. Jarrett's CONSERVE® total hip implant "was due to the pain associated with metallosis, corrosion, and component loosening associated with metal-on-metal hip failures," observing that the findings during Mr. Jarrett's revision surgery "including the noted pseudotumor, corrosion, and other indicative findings of metallosis reaction are consistent with [his] own clinical findings on revision of metal-on-metal prosthesis." Waldrop Rep. at 2.

[3] We previously granted Wright Medical's motion to exclude Dr. Jarrell's specific causation testimony in this case. Accordingly, Plaintiffs' arguments in opposition to Wright Medical's motion for summary judgment that rely on that excluded testimony are not addressed here.

Wright Medical rejoins that Plaintiffs' evidence is insufficient to raise a genuine issue of material fact regarding causation because the primary indicator of metallosis in Mr. Jarrett's case that was cited by both Dr. Parr and Dr. Waldrop is the existence of a pseudotumor, yet when that mass was sent for microscopic examination, it was determined to be a hematoma, not a pseudotumor. Parr Dep. at 88–89. Wright Medical argues that, because hematomas, unlike pseudotumors, are indicative of traumatic injuries, such as a fall, as opposed to injuries from metal wear, (DiCarlo Rep. at 4), Plaintiffs' design defect claim fails for lack of evidence of causation. While the significance of this distinction is certainly an issue that Wright Medical can pursue with Plaintiffs' witnesses on cross-examination, it is not a sufficient basis on which to grant summary judgment in Wright Medical's favor on Plaintiffs' design defect claim. In addition to the pseudotumor, Dr. Parr and Dr. Waldrop both testified regarding other hallmark signs of metallosis that Mr. Jarrett exhibited, which in their view establish that metal wear was the cause of Mr. Jarrett's injuries. Wright Medical's experts not surprisingly opine otherwise, but as discussed above it is not within our purview to determine which of the parties' experts espouse the factually correct view; that is the jury's province. *See Smith*, 215 F.3d at 719 ("It is not the trial court's role to decide whether an expert's opinion is correct."). Accordingly, Wright Medical is not entitled to summary judgment on Plaintiffs' design defect claim.

2. Failure to Warn

A failure to warn claim under Indiana law requires proof "that the manufacturer or seller failed to exercise reasonable care under the circumstances … in providing warnings or instructions." IND. CODE § 34-20-2-2. A product is defective for failure to warn "if the seller fails to: (1) properly package or label the product to give reasonable warnings of danger about the product; or (2) give reasonably complete instructions on proper use of the product." IND. CODE § 34-20-4-2. When assessing the adequacy of a warning in the context of a medical device, Indiana law applies the "learned-intermediary doctrine," meaning that "a medical-device manufacturer can discharge [its] duty by providing adequate warnings to physicians." *Kaiser*, 947 F.3d at 1015, regardless of whether such warnings reach the patient. Under this doctrine, the plaintiff "must not only show that a manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff." *Minisan v. Danek Med. Inc.*, 79 F. Supp. 2d 970, 978–79 (N.D. Ind. 1999). In other words, the relevant inquiry is whether the plaintiff can show that supplemental warnings would have caused his physician to take a different course of action. *Kaiser*, 947 F.3d at 1016.

Here, Plaintiffs allege that Mr. Jarrett was forced to undergo a revision surgery because of alleged defects in the CONSERVE® components, namely, the generation of wear between the metal components of the devices resulting in metallosis and acetabular loosening. The IFU that accompanied the CONSERVE® devices at issue included specific warnings about these potential risks, including the wear of metal components, the

potential of a reaction to wear particle release, and the loosening of prosthetic components. Specifically, the IFU provides that "[s]ome of the alloys used to produce orthopedic prostheses may contain some elements that may be carcinogenic in tissue cultures or intact organisms," and that, while studies had not provided any convincing evidence of such, "[q]uestions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic to actual prosthetic recipients." Exh. J at WMTMDL0006703. The IFU further warns that "[p]articulate is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue." *Id.* at WMTMDL0006708. Warnings that rare "metal sensitivity reactions in patients following joint replacement have been reported," including "histological reactions involving macrophages and fibroblasts," were also included in the applicable IFU. *Id.* Finally, regarding acetabular loosening, the IFU warns generally that "[p]rosthetic components can loosen or migrate due to trauma or loss of fixation." *Id.* The law is well-established that "[w]here the manufacturer warns of the precise adverse effect of which the plaintiff complains, the warning may be deemed adequate as a matter of law." *Tucker v. SmithKline Beecham Corp.*, 701 F. Supp. 2d 1040, 1066 (S.D. Ind. 2010) (citing *Ziliak v. AstraZeneca LP*, 324 F.3d 518, 521 (7th Cir. 2003); *Crisostomo v. Stanley*, 857 F.2d 1146, 1153 (7th Cir. 1988)).

Even assuming that Wright Medical's warnings regarding the CONSERVE® devices at issue were inadequate in some way, Defendant is entitled to summary

judgment on Plaintiffs' failure to warn claim because the evidence establishes both that Dr. Parr was independently aware of the risks of which Plaintiffs complain and that stronger warnings would not have caused him to take a different course of action with regard to Mr. Jarrett's care because the extent of the risks associated with MoM devices were not known at the time of Mr. Jarrett's surgery and Dr. Parr did not rely on Wright Medical's marketing materials in deciding to implant the CONSERVE® devices in Mr. Jarrett.

Dr. Parr's deposition testimony demonstrates that he was aware in 2006 of various potential risks associated with MoM implants, including those alleged in this litigation to have caused Mr. Jarrett's injuries. Specifically, Dr. Parr testified that he was aware, prior to Mr. Jarrett's initial surgery, of the possibility of wear to the metal bearing surfaces and that patients implanted with MoM devices would likely have a measurable amount of metal ions around the hip. He also knew that the CONSERVE® devices had only recently come on the market at the time of Mr. Jarrett's surgery and understood that the full scope of potential issues related to the release of metal ions was at that time unknown. Prior to Mr. Jarrett's surgery, Dr. Parr had been involved in an investigational study of Wright Medical's CONSERVE® devices to "evaluate serum ion concentrations in patients" with "metal-on-metal bearings," in part in response to "concerns" from "some clinicians … over elevated metal ion exposure." Exh. K at 2–3; Parr Dep. at 15–17. Given Dr. Parr's intimate knowledge of the then-known potential risks associated with MoM devices at the time he recommended the CONSERVE® devices to Mr. Jarrett by

virtue of his involvement with Wright Medical to research those risks, Wright Medical cannot be held liable for failing to inform or actively misleading Dr. Parr under a failure to warn theory.

Plaintiffs rejoin that Dr. Parr was not made aware of the extent of the dangers associated with the CONSERVE® devices, including the risk of pseudotumors, metallosis, and metal sensitivity, as well as other information including high failure rates reported by other physicians and poor registry performance of the devices, and that Dr. Parr testified that, had he known such information in 2006, he may not have recommended the CONSERVE® devices to Mr. Jarrett. However, it is axiomatic that manufacturers do not have a duty to warn of risks not yet known. *See Meharg v. I-Flow Corp.*, No. 1:08-cv-184-WTL-TAB, 2010 WL 711317, at *3 (S.D. Ind. Mar. 1, 2010) (granting summary judgment on failure to warn claim in favor of the defendant on grounds that such a claim is premised on risks that were known or should have been known at the time of the plaintiff's surgery, not on risks only discovered later). Here, Dr. Parr testified that "*nobody* was aware of" the full scope of risks associated with metal ions and metallosis "early on" in 2006, a fact confirmed by Plaintiffs' own expert, Dr. Waldrop, who testified that he and other orthopedic surgeons were the ones who were discovering the issues with MoM devices that led to metallosis as they performed surgeries using those devices, but that he had not become aware of the extent of the issues until 2008 or 2009. Parr Dep. at 98 (emphasis added); Waldrop Dep. at 50. Likewise, the data cited by Plaintiffs in support of their failure to warn claim showing

poor registry performance of the CONSERVE® devices is dated 2011, five years after Mr. Jarrett's surgery. Accordingly, the fact that Wright Medical's warnings may not have contained this information does not alter our conclusion that Plaintiffs' failure to warn claim cannot survive summary judgment. Likewise, Dr. Parr's decision in 2010 or 2011—at least four years *after* Mr. Jarrett's surgery—to discontinue using MoM devices once the full extent of the issues related to such devices was known is irrelevant to our analysis.

Finally, although Dr. Parr testified that he had a general understanding of the warnings contained in the IFU applicable to the CONSERVE® devices and agreed that it was important to be able to rely on the accuracy and completeness of the warnings contained therein, he stated that he did not utilize Wright Medical's marketing materials in deciding which devices to implant and instead relied on his own orthopedic experience and the "actual research data." Parr Dep. at 94–95. Thus, Plaintiffs' claim that Wright Medical sales representatives were actively misleading physicians regarding the safety of the CONSERVE® devices is irrelevant to our analysis because no evidence has been adduced to establish that Dr. Parr relied on any statements by Wright Medical's sales representatives or other marketing materials in making treatment decisions for Mr. Jarrett such that stronger warnings from those sources would have altered Dr. Parr's decision to use the CONSERVE® devices. For these reasons, Wright Medical is entitled to summary judgment in its favor on Plaintiffs' failure to warn claim.

3. Fraud

The elements of common-law fraud in Indiana are: "(1) a material misrepresentation of past or existing fact which (2) was untrue, (3) was made with knowledge of or in reckless ignorance of its falsity, (4) was made with the intent to deceive, (5) was rightfully relied upon by the complaining party, and (6) which proximately caused the injury or damage complained of." *Kesling v. Hubler Nissan, Inc.*, 997 N.E.2d 327, 335 (Ind. 2013) (quotation marks and citation omitted). Fraud is not limited only to affirmative representations; rather, "[t]he failure to disclose all material facts by one on whom the law imposes a duty to disclose constitutes actionable fraud." *First Bank of Whiting v. Schuyler*, 692 N.E.2d 1370, 1372 (Ind. Ct. App. 1998).

Here, the primary basis of Plaintiffs' fraud claim mirrors their failure-to-warn claim. Plaintiff has presented no evidence identifying any particular fraudulent statements upon which Mr. Jarrett himself relied, which "indicates that the gravamen" of the fraud claim is Wright Medical's failure to warn about particular risks or dangers associated with the CONSERVE® devices. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 744 (S.D.W.V. 2014) (observing that the plaintiffs' "'fraud-based claims' … are simply repackaged failure-to-warn claims."). To the extent that Plaintiffs' fraud claim is premised on the same allegations as their failure-to-warn claim, it fails for the same reasons. Accordingly, Plaintiffs' claim for fraud insofar as it is based on Wright Medical's alleged failure to disclose known risks and its active misrepresentation and concealment of such risks cannot survive summary judgment.

The only other basis for Plaintiffs' fraud claim is their allegation that Wright Medical promoted, marketed, and sold the Thin Shell, a component used in the CONSERVE® devices, with no regulatory clearance of that component for use in any device. Plaintiffs claim that Wright Medical's active promotion of this component constituted a fraud against Mr. Jarrett and the entire medical community that is a distinct injury from any failure to warn. It is not entirely clear from the briefing the exact basis for this theory of fraud. To the extent that this claim is based on alleged misrepresentations to the FDA during the regulatory process, it is well established that "it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions…." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001); *see also Lautzenhiser v. Coloplast A/S*, No. 4:11-cv-86-RLY-WGH, 2012 WL 4530804, at *7 (S.D. Ind. Sept. 29, 2012) (recognizing that the Supreme Court held in *Buckman* that "'fraud on the FDA' claims could not be the subject of federal litigation").

If, however, Plaintiffs are claiming that, in marketing and promoting the Thin Shell, Wright Medical made false and misleading statements regarding the regulatory process or its outcome to the medical community and the public, any such fraud claim still fails because Plaintiffs have adduced no evidence to establish that either Mr. Jarrett or Dr. Parr reviewed or were even aware of any such undefined statements or information pertaining to regulatory clearance, much less that either relied upon those statements in making treatment decisions. As discussed above, Dr. Parr testified that he did not review

or rely on marketing materials in deciding to implant the CONSERVE® device and Mr. Jarrett stated that he did not conduct any independent research or review any brochures, documents, or statements from Wright Medical prior to his surgery. In fact, Mr. Jarrett was not even aware at the time of his surgery that the device that would be implanted was Wright Medical's. Accordingly, because the undisputed evidence establishes that neither Mr. Jarrett nor Dr. Parr relied on any allegedly false or misleading statements related to the regulatory clearance issues, Wright Medical is entitled to summary judgment on Plaintiffs' fraud claim based on this theory.

B. Loss of Consortium

Plaintiff Paula Jarrett has alleged a claim for loss of consortium based on injuries she allegedly suffered in relation to her husband's underlying product defect claims. In Indiana, a loss of consortium claim is derivative of the injured spouse's personal injury claim. *Price v. Kuchaes*, 950 N.E.2d 1218, 1231 (Ind. Ct. App. 2011). Here, beyond arguing that, if the Plaintiffs' IPLA claim is dismissed in its entirety, the loss of consortium claim must also be dismissed, Wright Medical has presented no independent argument in support of dismissal of Mrs. Jarrett's claim. Because we have found, for the reasons detailed above, that Plaintiffs' IPLA claim based on a design defect theory survives summary judgment, we hold that Mrs. Jarrett is likewise entitled to proceed on her loss of consortium claim.

C. Punitive Damages

To recover punitive damages under Tennessee law,[4] a plaintiff must prove that the defendant acted "maliciously, intentionally, fraudulently, or recklessly." TENN. CODE ANN. § 29-39-104(a)(1). Tennessee law provides that punitive damages may "be awarded only in the most egregious of cases" and must be proved by "clear and convincing evidence" so as to restrict punitive damages to only those cases of "truly reprehensible" conduct." *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896, 901 (Tenn. 1992).

Here, Plaintiffs claim that they are entitled to punitive damages on grounds that Wright Medical not only failed to provide sufficient warnings of the risks of the CONSERVE® devices to surgeons such as Dr. Parr, but also actively misled physicians regarding known risks associated with the devices. However, we have granted summary judgment in Wright Medical's favor on Plaintiffs' failure-to-warn and fraud claims. For those same reasons, Wright Medical is entitled to summary judgment on Plaintiffs' punitive damages request.

III. Conclusion

For the reasons detailed above, Defendants' Motion for Summary Judgment [Dkt. 84] is GRANTED as to Plaintiffs' manufacturing defect, failure-to-warn, and fraud theories under the IPLA as well as Plaintiffs' punitive damages request and DENIED as

[4] Both parties agree that, because Plaintiffs' claim that they are entitled to punitive damages is based on allegations that Wright Medical downplayed or disregarded risks associated with the CONSERVE® devices and failed to provide adequate warnings to dissuade surgeons from using the devices, and Wright Medical's determination of relevant warnings and creation of its IFUs and other marketing materials occurred in Tennessee, Tennessee law governs punitive damages in this case.

to Plaintiffs' IPLA claim based on a design defect theory and the loss of consortium claim. The case will proceed accordingly.

IT IS SO ORDERED.

Date: 9/22/2021

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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