IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Southern Division

CHARLOTTE MORRIS,	*	
Plaintiff,	*	
v.		**Case No.: GJH-18-2440**
	*	
BIOMET, INC., *et al.*,	*	
Defendant.	*	

* * * * * * * * * * * * *

MEMORANDUM OPINION

Plaintiff Charlotte Morris brought this products liability action against Defendants Biomet Orthopedics, LLC, Biomet, Inc. Biomet Manufacturing LLC f/k/a Biomet Manufacturing Corps., and Biomet U.S. Reconstruction, LLC (collectively, "Biomet") based on injuries related to an artificial hip implant manufactured by Biomet that was used during Plaintiff's February 2008 right total hip replacement surgery. ECF No. 1. Specifically, Plaintiff alleges claims of manufacturing defect, failure to warn, negligence, design defect, fraudulent concealment, breach of implied warranties, breach of express warranty, and punitive damages. *Id.* Currently pending before the Court are Biomet's Motion to Exclude Plaintiff's Expert John I. Waldrop, M.D. ("Motion to Exclude Expert Testimony"), ECF No. 226, and Biomet's Motion for Summary Judgment, ECF No. 228.[1] No hearing is necessary to resolve the pending motions. *See* Loc. R. 105.6 (D. Md. 2018). For the following reasons, Biomet's Motion to Exclude Expert Testimony

[1] Also pending before the Court are Plaintiff's Motions to Compel Discovery, ECF Nos. 235, 239, and Biomet's Motion to Strike Certification of Conference or in the Alternative Motion to Narrow Issues, ECF No. 240. On August 14, 2020, the parties filed a Joint Notice of Potential Mootness of Pending Motions informing the Court that, on August 10, 2020, the MDL Court entered an order addressing the issues raised by these Motions, thus potentially rendering them moot, and asking the Court to withhold any ruling on the Motions. ECF No. 246. Subsequently, the parties filed a status report requesting that the motions be withdrawn. ECF No. 24. The Court will find that the Motions are rendered Moot.

is granted, in part, and denied, in part, and Biomet's Motion for Summary Judgment is granted, in part, and denied, in part.

I. BACKGROUND[2]

A. Total Right Hip Replacement Surgery

On March 19, 2002, Plaintiff sought treatment from Dr. Michael A. Jacobs for left hip, knee, and back pain. ECF No. 228-3 at 2–3.[3] Dr. Jacobs diagnosed Plaintiff with significant degenerative joint disease of the left hip and degenerative disc disease in the L-spine, and he recommended a left total hip replacement. *Id.* at 3. On June 19, 2002, at MedStar Good Samaritan Hospital, Dr. Jacobs performed a total left hip replacement on Plaintiff, for which he chose a DePuy metal-on-metal hip implant. *Id.* at 4–6.

On November 8, 2005, Plaintiff sought treatment from Dr. Jacobs for right lower back and buttock pain, *id.* at 7, and in November 2007, Dr. Jacobs observed end-stage osteoarthritis in Plaintiff's right hip and symptoms of spinal stenosis and stiffness in her back, and he recommended surgery, *id.* at 8. On February 6, 2008, at MedStar Good Samaritan Hospital, Dr. Jacobs performed a right hip replacement on Plaintiff for which he chose a Biomet M2a Magnum metal-on-metal hip implant (the "Biomet Device"). *Id.* at 9–10. Plaintiff did not participate in the selection of her implant and trusted Dr. Jacobs to choose the device. ECF No. 228-4 at 3.

B. The Biomet Device

The Biomet Device is a metal-on-metal hip joint replacement. *See* ECF No. 228-7 at 2. It contains three components: a femoral head, a taper insert, and an acetabular cup. *Id.* The head

[2] These facts are either undisputed or viewed in the light most favorable to Plaintiff as the non-moving party.
[3] Pin cites to documents filed on the Court's electronic filing system (CM/ECF) refer to the page numbers generated by that system.

and acetabular cup components are made from cobalt chrome molybdenum (CoCrMo) alloy, and the taper insert is made of a titanium alloy. *See id.* The acetabular cup, which is seated in the hip, is treated with a porous coating of titanium alloy. *Id.*

Biomet included a package insert, or Instructions for Use ("IFU"), with the Biomet Device. *See* ECF No. 228-7. The IFU for Plaintiff's Biomet Device included possible adverse effects of using the device, including:

> 1. Material sensitivity reactions. Implantation of foreign material in tissues may result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and dislocation from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant. Further, there has been a report regarding an association between articulating surfaces of: 1) CoCrMo alloy on CoCrMo alow, 2) CoCrMo alloy on polyethylene, and 3) Titanium alloy on polyethylene in hip replacements and increased genotoxicity. This report, however, did not assess either the clinical relevance of the data or make any definite conclusions as to which metal ions or interactions between metal ions or particulate metals might be responsible for the observed data. The report further cautioned that an association does not necessarily mean a causal relationship, and that any potentially increased risk associated with metal ions needs to be balanced against the benefits resulting from the hip replacement. A low incidence of metal hypersensitivity has been reported with failed metal-on-metal implants. The clinical relevance of these findings is unclear, and it is not known whether metal hypersensitivity causes implant failure.
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> 2. Early or late postoperative infection and allergic reaction.
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> 4. Loosening or migration of the implants may occur due to loss of fixation, trauma, malalignment, bone resorption, or excessive activity.
>
> 10. Fretting and crevice corrosion may occur at interfaces between components.
>
> 11. Wear and/or deformation of articulating surfaces.
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> 15. Elevated metal ion levels have been reported with metal-on-metal articulating surfaces. Although mechanical testing demonstrates that metal-on-metal articulating surfaces produce a relatively low amount of particles, the total

> amount of particulate produced in vivo throughout the service life of the implants remains undetermined. The long-term biological effects of the particulate and metal ions are unknown.

ECF No. 228-7 at 2. Dr. Jacobs does not specifically recall whether he read the IFU prior to Plaintiff's implantation surgery, ECF No. 228-8 at 7–8, but it was his standard practice to familiarize himself generally with the indications received from the manufacturer, such as the surgical technique, which would include reviewing the IFU, *id.* at 4.

C. Revision Surgery

After Plaintiff's right hip surgery, Dr. Jacobs continued to see her once a year for routine follow-up appointments. ECF No. 228-8 at 5. On September 9, 2010, approximately two and a half years after her surgery, Plaintiff complained of right hip clicking, which Dr. Jacobs was able to reproduce upon examination. ECF No. 228-3 at 14. At the time of his examination, Dr. Jacobs suspected that the clicking was a soft tissue band catching. *Id.* The treatment plan involved seeing Plaintiff in a year if she was asymptomatic, but if the clicking became a problem or she developed any further symptoms, she was to have Dr. Jacobs evaluate her sooner. *Id.*

On September 19, 2011, Dr. Davis Hahn, Plaintiff's oncologist, ordered her to undergo a CT scan of her abdomen and pelvis, which showed a low-density fluid collection, or pseudotumor, near her right iliopsoas muscle. *Id.* at 15–16. Dr. Hahn noted that "it seems fairly clear that Mr. Morris does not have a malignancy in her right pelvis causing the iliopsoas mass but simply has a degenerating right hip metal-on-metal prosthesis which is releasing cobalt and also causing a marked bursal reaction…" *Id.* at 17. He also noted that her "cobalt level came back 41 which is in the toxic range." *Id.* Dr. Jacobs also suspected that the pseudotumor was related to a metal-metal hypersensitivity. *Id.* at 18. Based on his concern that Plaintiff was

experiencing a reaction to metal ions, Dr. Jacobs recommended revision surgery. ECF No. 228-8 at 6.

On November 15, 2011, at MedStar Good Samaritan Hospital, Dr. Jacobs performed revision surgery on Plaintiff's right hip. ECF No. 228-3 at 19–20. Before her surgery, Plaintiff had a cobalt level elevated at 58 and a chromium level at 19.6—both in the toxic range. ECF No. 229-5 at 2. During revision surgery, Dr. Jacobs discovered damage to Plaintiff's abductor muscle, noting that "the anterior half of the abductor was off and in a kind of thick fibrous membrane" and that "[i]t looked like the posterior abductor was also off and it was adherent to the fascia." ECF No. 228-3 at 19. Dr. Jacobs also noted that there was "marked metalosis [sic] of the entire hip" and that the acetabulum "was black from metalosis [sic]." *Id.* Dr. Jacobs removed the damaged tissue and the Biomet Device's femoral head and acetabular cup. *Id.* at 20. Upon dislocation, the femoral head was "not visibly damaged" and the acetabular cup was "not visibly loose." *Id.* Dr. Jacobs found "excellent bone behind the cup" and implanted a new Zimmer shell polyethylene liner and a new head. *Id.* at 19–20. No complications were reported during surgery. *See* ECF No. 228-3 at 19–20. Tests performed on January 20, 2012, a couple months after Plaintiff's surgery, showed that her cobalt level had decreased to 9.2 and her chromium level had decreased to 10.1. ECF No. 229-7 at 2.

D. Post-Revision Treatment

After her initial right hip revision surgery, Plaintiff suffered a series of right hip dislocations for which Dr. Jacobs performed close reductions on February 13, 2012 and May 19, 2012. *Id.* at 21–24. On August 21, 2012, at MedStar Samaritan Hospital, Dr. Jacobs performed a second right hip revision surgery on Plaintiff. *Id.* at 25–26. After her second revision surgery, Plaintiff developed an infection and subsequently underwent several irrigation and debridement

("I&D") procedures, temporary implantation of an antibiotic spacer, and wound vacuum-assisted closure ("V.A.C.") to cure the infection. *Id.* at 27–43. In May 2013, Dr. Jacobs evaluated Plaintiff, noting that she "look[ed] fantastic" and that he "aspirated about 3 mL of what looked to be benign fluid," suggesting that her infection was resolved. *Id.* at 44.

On July 2, 2013, Dr. Jacobs performed another right hip revision surgery to remove the antibiotic spacer and re-implant a total hip arthroplasty. *Id.* at 45–27. Plaintiff subsequently developed another right hip infection and underwent additional I&D procedures and another revision surgery between December 2015 and February 2016. *Id.* at 48–53. As of December 6, 2018, Plaintiff was still receiving suppressive treatment for her chronic right hip infection. *Id.* at 54–55.

E. Present Action

On July 29, 2013, Plaintiff sued Biomet in the United States District Court for the Northern District of Indiana. ECF No. 1. On September 6, 2018, Plaintiff's case was transferred to this Court. ECF No. 201. She alleges eight claims based on the Biomet Device: (1) Strict Liability – Manufacturing Defect (Count I); (2) Strict Liability – Failure to Warn (Count II); (3) Negligence (Count III); (4) Negligence – Design Defect (Count IV); (5) Fraudulent Concealment (Count V); (6) Breach of Implied Warranties (Count VI); (7) Breach of Express Warranty (Count VII); and (8) Punitive Damages (Count VIII).

On January 29, 2020, Biomet filed a Motion to Exclude Expert Testimony, ECF No. 226, and a Motion for Summary Judgment, ECF No. 228. Plaintiff filed a response to each motion on February 12, 2020, ECF Nos. 229, 230, and Biomet filed a reply in support of each motion on February 26, 2020, ECF Nos. 233, 234.

II. MOTION TO EXCLUDE EXPERT TESTIMONY

A. Standard of Review

Federal Rule of Evidence 702, which governs the admissibility of expert testimony, provides that:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) The expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) The testimony is based on sufficient facts or data;
> (c) The testimony is the product of reliable principles and methods; and
> (d) The expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. *Daubert v. Merrell Dow Pharm., Inc.* requires the trial court to act as a "gatekeeper" of expert testimony, ensuring that the proposed testimony "both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. 579, 597 (1993). In applying Rule 702, the court balances "two guiding, and sometimes competing, principles." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). On one hand, "Rule 702 is intended to liberalize the introduction of relevant expert evidence." *Id.* On the other hand, "expert witnesses have the potential to 'be both powerful and quite misleading'… [and] proffered evidence that has a greater potential to mislead than to enlighten should be excluded." *Id.* (internal citations omitted).

The proponent of the expert testimony bears the burden of establishing its admissibility, that is, "the burden of coming forward with evidence from which the trial court could determine that the evidence is admissible under *Daubert*." *Main St. Am. Grp. v. Sears, Roebuck, & Co.*, No. JFM-08-3292, 2010 WL 956178, at *3 (D. Md. Mar. 11, 2010) (citing *Daubert*, 509 U.S. at 592 n.10 (1993)). The court "must assess the proffered evidence using a two-pronged analysis," *Main*

St. Am. Grp., 2010 WL 956178, at *3 (citing *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 772 (D. Md. 2002)), and determine whether the testimony is "reliable" and whether it is "relevant." *Id.* (citing *United States v. Barnette*, 211 F.3d 803, 815 (4th Cir. 2000)).

In assessing whether the testimony is reliable, the court may consider a variety of factors, including (1) "whether the theory or technique in question can be (and has been) tested," (2) "whether [the theory or technique] has been subjected to peer review and publication," (3) "its known or potential error rate," and (4) "whether it has attracted widespread acceptance within a relevant scientific community." *Daubert*, 509 U.S. at 580. "The inquiry is a flexible one, and its focus must be solely on principles and methodology, not on the conclusions that they generate." *Id.* Additionally, "although experiential expert testimony does not rely on anything like a scientific method, such testimony is admissible … so long as an experiential witness explains how his experience leads to the conclusion reached, why his experience is a sufficient basis for the opinion, and how his experience is reliably applied to the facts." *United States v. Bynum*, 604 F.3d 161, 167 (4th Cir. 2010) (internal alterations and citations omitted).

Expert testimony is relevant where it is "sufficiently tied to the facts of the case [so] that it will aid the jury in resolving a factual dispute." *Casey v. Geek Squad Subsidiary Best Buy Stores, L.P.*, 823 F. Supp. 2d 334, 341 (D. Md. 2011) (citing *Daubert*, 509 U.S. at 591)). Expert testimony "is presumed to be helpful unless it concerns matters within the everyday knowledge and experience of a lay juror." *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993). Thus, "Rule 702 makes inadmissible expert testimony as to a matter which obviously is within the common knowledge of jurors because such a testimony, almost by definition, can be of no assistance." *Scott v. Sears, Roebuck & Co.*, 789 F.2d 1052, 1055 (4th Cir. 1986); *see, e.g.*, *Page v. Supervalue, Inc.*, No. WGC-14-1508, 2015 WL 1439572, at *16 (D. Md. Mar. 26, 2015) (finding

"[i]t is common knowledge that a grape on the floor creates a dangerously slippery condition" and "placing mats on the floor to prevent dangerously slippery conditions clearly lies within the range of a jury's common knowledge and experience.").

B. Discussion

Plaintiff has retained Dr. John I. Waldrop, an orthopedic surgeon, as a case-specific expert to support various elements of her products liability claims. Dr. Waldrop will testify about five phenomena he has observed during metal-on-metal hip revision surgeries that he has not observed in metal-on-poly or ceramic hip revisions. ECF No. 227-1 at 2–20. He believes these phenomena are the result of metallosis caused by metal particles from the weight-bearing surfaces of the metal-on-metal devices, and are thus the result of the failure of the devices to function properly and effectively. *Id.* He will testify further that the failure of Plaintiff's Biomet Device was due to metallosis, corrosion, and bone and tissue destruction associated with metal-on-metal hip failures, that he performed a differential diagnosis and ruled out any other potential cause for Plaintiff's condition, that Plaintiff's symptoms were consistent with his clinical findings on defective metal-on-metal devices, that Plaintiff's treatment was medically necessary, and that the amount billed for the treatment was reasonable. *Id.* at 24–25.

In its Motion to Exclude Expert Testimony, Biomet contends that certain portions of Dr. Waldrop's testimony are inadmissible. ECF No. 227 at 3. First, it contends that Dr. Waldrop's general opinions concerning metal-on-metal devices lack sufficient specificity to "fit" the case. *Id.* Next, it contends that Dr. Waldrop lacks an adequate methodology to identify a defect in the Biomet Device as the cause of Plaintiff's need for revision surgery and her subsequent difficulties. *Id.* Finally, it contends that Dr. Waldrop offers no reliable methodology for

determining the reasonableness of the amount Plaintiff was billed for her medical treatment. *Id.* The Court will address each challenged portion of testimony separately.

First, Biomet objects to Dr. Waldrop's "general opinions" regarding metal-on-metal revision surgeries that are based on generalized observations. Specifically, it contends that his "general opinions about causes of failure of [metal-on-metal] devices do not provide an adequate 'fit' for this case" because they do not relate specifically to the Biomet Device. ECF No. 227 at 5. Although Biomet is correct that Dr. Waldrop's observations regarding metal-on-metal revision surgeries are not tied to the Biomet Device in particular, Biomet's purported "particularization" requirement appears to be specific to *United States v. Ancient Coin Collectors Guild*, 899 F.3d 295 (4th Cir. 2018), the sole case that Biomet cites in support of its position. In *Ancient Coin*, the Fourth Circuit affirmed the district court's application of a "particularization" requirement for expert testimony in a civil forfeiture case involving ancient coins under the Cultural Property Implementation Act ("CPIA"). *See* 899 F.3d at 318–19. The Fourth Circuit explained that "the CPIA requires an importer to establish the importability of designated archaeological material by reference to the 'article in question,'" and so it was therefore not an abuse of discretion for the district court to require that expert testimony be tailored to the specific ancient coins that the defendant sought to import. *See id.* This "particularization" requirement thus appears to be specific to the CPIA's requirement that importability be established with respect to the specific article in question; it is not rooted in *Daubert* and the Court has not located a similar requirement in any non-CPIA case. The Court will therefore decline to apply it to expert testimony in this products liability action.

Having rejected Biomet's "particularization" requirement, Dr. Waldrop's general opinions are otherwise admissible. Plaintiff's primary allegation in this case appears to be that

the Biomet Device's metal-on-metal design is a design defect, and Dr. Waldrop, an experienced orthopedic surgeon who has performed numerous metal-on-metal revision surgeries, will testify about what he has observed in metal-on-metal hip revisions. "[Dr.] Waldrop's expert testimony is [thus] sufficiently reliable, and [it] will assist the trier of fact in understanding the evidence in this case and to determine the issue of causation," *see In re Wright Med. Tech. Inc., Conserve Hip Implant Prods. Liab. Litig.*, 127 F. Supp. 3d 1306, 1337 (N.D. Ga. 2015) (admitting Dr. Waldrop's testimony in hip implant products liability litigation), and Biomet can challenge Dr. Waldrop's credibility or the content of his testimony on cross-examination or during the presentation of its case. Thus, Dr. Waldrop's general opinions need not be excluded under *Daubert*.

Next, Biomet objects to Dr. Waldrop's differential diagnosis. Specifically, it contends that Dr. Waldrop "employed an unreliable methodology in concluding that [Plaintiff's] right hip was revised due to 'metallosis, corrosion, and bone and tissue destruction associated with metal-on-metal hip failures,'" ECF No. 227 at 7, and that he employed no methodology with respect to his conclusion that all of Plaintiff's subsequent dislocations and infections were directly or indirectly caused by the failure of the Biomet Device, *id.* at 11. "[D]ifferential diagnosis is a standard scientific technique of identifying the cause of a medical problem … by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is most likely." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200 (4th Cir. 2001) (citing *Westberry*, 178 F.3d at 262) (internal quotation marks omitted). "A medical expert's opinion based upon differential diagnosis should not be excluded because the expert has failed to rule out every possible alternative cause of a plaintiff's illness. In such cases, the alternative causes

suggested by a defendant normally affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony. However, a differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation. Thus, if an expert utterly fails to consider alternative causes or fails to offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert's testimony." *Id.* at 202 (internal citations quotation marks omitted).

Here, Dr. Waldrop's expert report demonstrates that he conducted a sufficient differential diagnosis with respect to Plaintiff's first revision surgery. Dr. Waldrop's differential diagnosis is based on the experience, training, and knowledge he has acquired from practicing orthopedics for over forty years, his observations of surgeries for removal of cobalt and chromium metal on metal-on-metal hip implants and revisions of cobalt and chromium hip implants, conversations and presentations by other orthopedic surgeons, his examination of Plaintiff's medical records, and the deposition testimony from Plaintiff and Dr. Jacobs. *See* ECF No. 227-1 at 24–25. He concludes that "[t]he failure of [Plaintiff's Biomet Device] was due to metallosis, corrosion, and bone and tissue destruction associated with metal-on-metal hip failures," *id.* at 25, and, contrary to Biomet's assertion, he appears to have considered and eliminated several alternative causes, including the positioning and placement of the Biomet Device by Dr. Jacobs, *id.*; ECF No. 230-3; infection, ECF No. 230-10 at 8; procedural and post-operative complications, ECF No. 227-1 at 25; Plaintiff's medical history, *id.*; and metal sensitivity, ECF No. 227-3 at 6. Thus, the Court sees no reason to exclude Dr. Waldrop's testimony with respect to specific causation for Plaintiff's first revision surgery. *See Cooper*, 259 F.3d at 200.

The same cannot be said with respect to Dr. Waldrop's conclusion that Plaintiff's subsequent revisions, dislocations, and infections were all the result of a defect in the original Biomet Device that was removed during the first revision surgery. Dr. Waldrop's expert report states in conclusory fashion that "[t]he injuries after the revision surgery including the multiple procedures for dislocations and infections and ongoing pain and loss of mobility were the result of the defective metal-on-metal prosthesis and/or secondarily caused by the necessary surgery of the defective metal-on-metal prosthesis." ECF No. 227-1 at 25. This conclusion does not appear to involve the same rigorous differential analysis that Dr. Waldrop conducted for the first revision surgery and instead seems to be based upon his speculation and subjective belief. *See* ECF No. 227-3 at 6. Dr. Waldrop has therefore provided little basis for testimony regarding causation with respect to Plaintiff's injuries after the first revision surgery, and because the Court need not "admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert," *see Pugh v. Louisville Ladder, Inc.*, 361 F. App'x 448, 454 n.4 (4th Cir. 2010), the Court will exclude Dr. Waldrop's testimony on this issue, *see Zuckerman v. Wal-Mart Stores East, L.P.*, 611 F. App'x 138, 138 (4th Cir. 2015) ("Expert testimony rooted in 'subjective belief or unsupported speculation' does not suffice.").

Finally, Biomet objects to Dr. Waldrop testifying about the reasonableness of the amount that Plaintiff was billed for her medical treatment. In determining whether an expert's testimony is relevant and reliable, a court must aim "to prevent the fact-finder from being unduly swayed by opinions, presented as expert judgments, that in fact amount to no more than informed speculation." *Fireman's Fund Ins. Co. v. Tecumseh Prods. Co.*, 767 F. Supp. 2d 549, 553 (D. Md. 2011).

Here, Dr. Waldrop stated at his deposition that he is "not a biller," but instead just "looked" at Plaintiff's medical bills and determined that they "looked reasonable to [him]." ECF No. 227-3 at 7. He also stated that he does not issue invoices or bills to patients and he does not routinely look at his patients' medical bills. *Id.* at 8. Thus, there is no basis for the Court to conclude that he has "specialized knowledge" regarding medical billing practices that will help the fact-finder determine whether Plaintiff was billed a reasonable amount for her medical treatment or that his testimony is the result of reliable principles and methods. *See* Fed. R. Evid. 702. Because Dr. Waldrop's testimony regarding the reasonableness of Plaintiff's medical bills would amount to no more than speculation, it must be excluded.[4]

In sum, the Court will permit Dr. Waldrop to testify about his general observations regarding metal-on-metal revisions and his conclusions regarding specific causation for Plaintiff's first revision surgery. Dr. Waldrop's testimony regarding causation for Plaintiff's subsequent injuries and the reasonableness of the amount Plaintiff was billed for her medical treatment is excluded. Accordingly, Biomet's Motion to Exclude Expert Testimony is granted, in part, and denied, in part.

Plaintiff's ability to create a genuine issue of material fact, however, is not necessarily vitiated by the Court's conclusions regarding Dr. Waldrop's expert testimony—an inquiry to which the Court now turns.

[4] In her opposition, Plaintiff states, "To the extent [Biomet] argues, Good Samaritan's billing was not reasonable or any such care unnecessary, is grounds for cross-examination but not means for exclusion." ECF No. 230 at 11. However, she does not provide any legal authority to support her assertion, so the Court will disregard this argument.

III. MOTION FOR SUMMARY JUDGMENT

A. Standard of Review

"Under [Federal Rule of Civil Procedure] 56(c), summary judgment is proper 'if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (quoting Fed. R. Civ. P. 56(c)). The party moving for summary judgment bears the burden of demonstrating that no genuine dispute exists as to material facts. *Pulliam Inv. Co. v. Cameo Props.*, 810 F.2d 1282, 1286 (4th Cir. 1987). If the moving party demonstrates that there is no evidence to support the non-moving party's case, the burden shifts to the non-moving party to identify specific facts showing that there is a genuine issue for trial. *See Celotex*, 477 U.S. at 322–23. Importantly, at the summary judgment stage, it is not the Court's function to weigh the evidence but simply to decide if there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). A dispute of material fact is genuine if the conflicting evidence creates "fair doubt," *Cox v. Cty. of Prince William*, 249 F.3d 295, 299 (4th Cir. 2001), such that "a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248.

When ruling on a motion for summary judgment, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255. Nevertheless, a "mere scintilla of proof" is not enough to defeat a motion for summary judgment. *Peters v. Jenney*, 327 F.3d 307, 314 (4th Cir. 2003) (citing *Anderson*, 477 U.S. at 252). To defeat the motion, the party opposing summary judgment must submit evidentiary materials showing facts on the basis of which the finder of fact could reasonably decide the case in its favor. *Anderson*, 477 U.S. at 252. If a party fails to make a showing sufficient to establish the existence of an

essential element on which that party will bear the burden of proof at trial, summary judgment is proper. *Id.*

B. Discussion

In her Complaint, Plaintiff asserts claims for (1) Strict Liability – Manufacturing Defect (Count I); (2) Strict Liability – Failure to Warn (Count II); (3) Negligence (Count III); (4) Negligence – Design Defect (Count IV); (5) Fraudulent Concealment (Count V); (6) Breach of Implied Warranties (Count VI); (7) Breach of Express Warranty (Count VII); and (8) Punitive Damages (Count VIII). ECF No. 1. She also requests attorney's fees. *Id.* In her response to Biomet's Motion for Summary Judgment, Plaintiff states that she withdraws any claims related to "manufacturing defect," but maintains claims as to "design defect" in negligence and strict liability. ECF No. 229 at 12. She also states that she does not assert any freestanding negligence claims, but only asserts negligent failure to warn and negligent design defect claims. *Id.* at 16. Thus, Counts I and III are dismissed to the extent that they allege a manufacturing defect.[5]

Biomet contends that (1) Plaintiff's claims fail for lack of medical causation because she has no expert evidence linking a defect in the Biomet Device to Plaintiff's injuries and because Biomet's experts disprove Plaintiff's claims; (2) Plaintiff's failure to warn claims fails as a matter of law because Biomet discharged its duty to warn under the learned intermediary doctrine, because the Biomet Device's IFU is adequate, and for lack of causation; (3) Plaintiff's fraudulent concealment claims fail for lack of particularity and lack of reliance; (4) Plaintiff's claim for breach of implied warranties fails because she did not give notice to Biomet; (5) Plaintiff's claim for breach of express warranty fails because Biomet did not make any express

[5] In the Complaint, Count I is labeled as alleging only manufacturing defect, but it contains language that could also allege design defect. Because Plaintiff states that she alleges design defect in negligence and strict liability, and Biomet does not appear to object, the Court will interpret Count I as alleging strict liability – design defect.

warranties to Plaintiff; (6) Plaintiff's claim for punitive damages fails because she cannot establish that Biomet acted with actual malice; and (7) Plaintiff is not entitled to attorney's fees because no statute, contract, or exception allows her to claim attorney's fees.

For the reasons that follow, the Court concludes that Biomet is entitled to summary judgment on Plaintiff's failure to warn, fraudulent concealment, breach of implied warranties, and breach of express warranty claims and on Plaintiff's claims for design defect, to the extent that they are based on harms that occurred after the first revision surgery. Plaintiff's design defect claims survive to the extent they pertain to her first revision surgery. The Court also concludes that Plaintiff's claims for punitive damages and attorney's fees must be dismissed.

1. Design Defect (Counts I and IV)

Plaintiff alleges that Biomet is liable in negligence and strict liability for defectively designing a metal-on-metal device. A products liability design defect claim "focuses upon the specifications for the construction of the product and the risks and benefits associated with that design." *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 411 (D. Md. 2001). "The negligence theory of product liability focuses on the conduct of the defendant, while the strict liability theory of products liability focuses primarily on the *product* (and whether or not it can be deemed defective)," but under both negligence and strict liability design defect theories of recovery, a plaintiff must show three product litigation basics: defect, attribution of defect to the seller, and a causal relationship between the defect and the injury. *Parker v. Allentown, Inc.*, 891 F. Supp. 2d 773, 780 (D. Md. 2012). Here, Biomet contends that it is entitled to summary judgment because Plaintiff has presented no evidence establishing a causal relationship between a design defect in the Biomet Device and Plaintiff's injury. The Court disagrees.

As the Court has explained, Dr. Waldrop will provide expert testimony that the Biomet Device's metal-on-metal design was defective and that his differential diagnosis shows that Plaintiff's injuries associated with the first revision surgery were caused by this defective design. *See* ECF No. 228-12. And, as the Court has already determined, Dr. Waldrop's testimony regarding metal-on-metal implants and his differential diagnosis are admissible under the *Daubert* standard. Biomet is certainly permitted to present its own expert testimony to contradict Dr. Waldrop's testimony, proffer alternative causes for Plaintiff's injuries associated with her first revision surgery, and challenge Dr. Waldrop's methodology and conclusions, but that does not change the fact that Plaintiff has presented evidence to create a dispute of material fact with respect to causation for injuries associated with Plaintiff's first revision surgery. This dispute is a issue for the fact-finder to resolve and not a matter for the Court to resolve on summary judgment. *See Anderson*, 477 U.S. at 249. Accordingly, Biomet is not entitled to summary judgment on Plaintiff's design defect claim with respect to the first revision surgery.

However, as the Court has explained, Dr. Waldrop's testimony is not admissible with respect to harms that occurred after the first revision surgery. Plaintiff has cited no other causation evidence with respect to those harms, so Biomet is entitled to summary judgment on Counts I and IV to the extent that those counts allege a design defect with respect to harms that occurred after Plaintiff's first revision surgery.

2. Failure to Warn (Counts II and III)

Plaintiff alleges that Biomet is liable in negligence and strict liability for failure to warn of the risks of the Biomet Device. "Products liability law imposes on a manufacturer a duty to warn if the item produced has an inherent and hidden danger that the producer knows or should know could be a substantial factor in causing an injury." *Shreve*, 166 F. Supp. 2d at 413 (internal

quotation marks omitted). Under Maryland law, "negligence concepts and those of strict liability have 'morphed together'" in failure to warn cases. *Gourdine v. Crews*, 405 Md. 722, 743 (2008). Thus, the traditional concepts of duty, breach, causation, and damage are required for both causes of action. *Id.*; *see also Mazda Motor of Am., Inc. v. Rogowski*, 659 A.2d 391, 394 (1995) ("[I]t is true that a strict liability claim based on failure to warn bears a strong resemblance to a claim of negligence. Concepts of duty, breach, causation, and damages are present in both.").

Maryland courts apply the learned intermediary doctrine in failure to warn cases involving medical devices. *See, e.g.*, *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231–32 (4th Cir. 1984); *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831, 838 (D. Md. 2000). "Under the learned intermediary doctrine, the manufacturer of medical devices … has no duty to warn the patient of the risks associated with products used under the supervision of a doctor." *See Miller*, 121 F. Supp. 2d at 838. Rather, "[t]he manufacturer's duty to warn is limited to adequately informing the patients' doctor of any risks associated with the product's use." *Id.* "A warning is legally adequate when it explains the risk which the plaintiff alleges has caused the injury." *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 95 (D. Md. 1989). "The warning must only be reasonable, not the best possible one." *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 572 (D. Md. 2006); *see also Hartford Mut. Ins. Co. v. Apria Healthcare, Inc.*, 159 F. App'x 479, 483 (4th Cir. 2005) ("Maryland does not require an encyclopedic warning."). But even where a warning is inadequate, a failure to warn claim fails where the doctor was already aware of the risk the allegedly deficient warning should have communicated. *See McClure v. Scientific Spinal*, 11 F. App'x 154, 159 (4th Cir. 2001); *see also Gourdine*, 405 Md. at 743 (stating that "causation" is required for failure to warn claims alleged in strict liability and negligence).

Here, as a manufacturer of a medical device, Biomet's duty to warn was owed to Dr. Jacobs, Plaintiff's treating physician. *See Miller*, 121 F. Supp. 2d at 838. In her response to Biomet's Motion for Summary Judgment, Plaintiff states that "the severity and prevalence of the risks of metal hips and the secondary consequences of long-term exposure to toxic metals in the blood" are "the very risks [Plaintiff claims] caused her injuries." ECF No. 229 at 14. But even if Plaintiff could prove that Biomet's warnings were inadequate with respect to these risks,[6] Dr. Jacobs was already independently aware of the risks that Plaintiff identifies. Dr. Jacobs testified that as of early 2008, he was aware of the "well-documented phenomenon" that metal-on-metal devices would cause elevated metal ion levels. ECF No. 228-8 at 10. He was also aware that metal-on-metal devices can cause a metal sensitivity reaction. *See id.* at 8, 10. Regarding the role that Biomet's warnings played in his selection of the Biomet Device, although Dr. Jacobs testified that it is his standard practice to familiarize himself with the indications received from the manufacturer, *id.* at 4, he did not specifically recall whether he read the IFU prior to Plaintiff's surgery, *id.* at 7–8. And perhaps most notably, Dr. Jacobs testified, "I make my own decisions. I research it in peer-reviewed literature. I, by and large, don't rely on representatives of companies to give me information," *id.* at 7, "I get my information independently as opposed to from manufacturers," *id.* at 11, and "I would glean most of my information from the metal-metal world in general," *id.* at 12. Thus, the evidence overwhelmingly shows that Dr. Jacobs placed little weight on Biomet's warnings, indicating that different warnings would not have

[6] The Court is not prepared to conclude that Biomet's warnings were adequate as a matter of law, particularly with respect to the magnitude of the risks associated with metallosis and pseudotumors. *See In re DuPuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 773 (5th Cir. 2018) (denying summary judgment to defendant where "the warning fail[ed] to put surgeons on notice as to the distinctive risks that arise from [metal-on-metal devices]—'metallosis,' pseudotumors,' and 'tissue necrosis'—*or the magnitude of those risks*." (emphasis added)).

altered his decision-making.[7] Because Plaintiff cannot establish that Dr. Jacobs would have relied on more adequate warnings, she cannot prove her failure to warn claims. Accordingly, Biomet is entitled to summary judgment on Counts II and III.

3. Fraudulent Concealment (Count V)

Plaintiff alleges that Biomet is liable for fraudulent concealment based on omissions and misrepresentations it made to Dr. Jacobs about the Biomet Device. To establish a claim for fraudulent concealment, a plaintiff must prove that the defendant owed a duty to the plaintiff to disclose a material fact, the defendant failed to disclose that fact, the defendant intended to defraud or deceive the plaintiff, the plaintiff took action in justifiable reliance on the concealment, and the plaintiff suffered damages as a result of the defendant's concealment. *Hill v. Brush Engineered Materials, Inc.*, 383 F. Supp. 2d 814, 823 (D. Md. 2005).

Here, Plaintiff has failed to cite any evidence demonstrating that she or Dr. Jacobs relied on any misleading information provided by Biomet. Plaintiff alleges that Biomet made three categories of misrepresentations: (1) falsely stating that the Biomet Device does not suffer from the same defects as the DePuy ASR implants, which cause metallosis and increased revision rates; (2) falsely stating that the Biomet Device has a 99.2% survivor rate over three years; and (3) generally downplaying and understating the serious risks associated with the use of the Biomet Device and the unacceptably high rate of failure and release of metal ion debris. ECF No.

[7] Dr. Jacobs testified that he was independently aware of the risks associated with metal-on-metal devices, but if Biomet had been aware that the Biomet Device in particular had a higher incidence rate of local adverse reactions when compared to metal-on-metal devices in general, that would have been relevant to him. *See* ECF No. 228-8 at 11. But a legally adequate warning need not include the incidence rate or prevalence of a particular adverse reaction. *See Ames*, 431 F. Supp. 2d at 573; *see also McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 405 (S.D.N.Y. 2014); *Ocasio v. C.R. Bard, Inc.*, No. 8:13-CV-1962-T-36AEP, 2015 WL 3496062, at *5 (M.D. Fla. June 3, 2015); *Hurley v. Lederle Labs., Div. of Am. Cyanamid Co.*, 651 F. Supp. 993, 1002 (E.D. Tex. 1986), *rev'd on other grounds*, 863 F.2d 1173 (5th Cir. 1988). Thus, Biomet was not obligated to include incidence rates, even if that information would have been relevant to Dr. Jacobs, and so such evidence does not bar summary judgment on Plaintiff's failure to warn claims.

1 ¶¶ 39, 76, 77. But Plaintiff cites to no evidence demonstrating that she relied on these statements in selecting the Biomet Device. She did not view any marketing materials or other information about Biomet hip replacements prior to her surgery, *see* ECF No. 228-4 at 45, 5, and she trusted Dr. Jacobs to choose the device for her hip replacement, *see id.* at 3, 5. And although Plaintiff correctly notes that misrepresentations made to third-parties, such as Dr. Jacobs, are actionable, *see Md. Nat'l Bank v. Resolution Trust Corp.*, 895 F. Supp. 762, 772 (D. Md. 1995), she must still demonstrate that Dr. Jacobs relied on those misrepresentations. She has not cited sufficient evidence to do so.

With regard to his clinical decisions, Dr. Jacobs testified, "I make my own decisions. I research it in peer-reviewed literature. I, by and large, don't rely on representatives of companies to give me information." ECF No. 228-8 at 7. Further, although he testified that it is his general practice to familiarize himself with the indications provided by the manufacturer, *see id.* at 4; *see also id.* at 7 ("[I]f they had provided me with adverse information, I certainly would have looked into it."), he does not specifically recollect doing so with the Biomet Device in this case, *see id.* at 8. Finally, although Dr. Jacobs did explain that the Biomet Device's stability was a factor in his decision to use that device, *id.* at 5, there is no evidence that he specifically relied on any misrepresentations by Biomet about the device's stability in making his selection. Because Plaintiff has cited to no evidence suggesting that she or Dr. Jacobs specifically relied on the three identified misrepresentations by Biomet in their decision to select the Biomet Device, she cannot prove her claim for fraudulent concealment. Accordingly, Biomet is entitled to summary judgment on Count V.

4. Breach of Implied Warranties (Count VI)

Plaintiff alleges that Biomet breached the implied warranties of merchantability and fitness because the Biomet Device was neither safe for its intended use nor of merchantable quality. A warranty of merchantability is implied in any contract for the sale of goods "if the seller is a merchant with respect to goods of that kind." MD. CODE ANN., COM. LAW § 2-314(1). A warranty of fitness for a particular purpose is implied in the sale of goods when "the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods." *Id.* § 2-315(1). Relevant here, "[t]he Uniform Commercial Code adopted in Maryland requires a buyer to give notice to the seller for a breach of implied warranty." *Doll v. Ford Motor Co.*, 814 F. Supp. 2d 526, 542 (D. Md. 2011) (citing MD. CODE ANN., COM. LAW § 2-607(3)(a)); *see also* MD. CODE ANN., COM. LAW § 2-714(1). "The Maryland Court of Appeals has interpreted this provision to require the buyer to inform the seller of the breach, the particular goods that have been impaired, and set forth the nature of the nonconformity." *Doll*, 814 F. Supp. 2d at 542. "[A] notification to a seller within a reasonable time is a 'prerequisite' for claiming a breach of implied warranty." *Id.* (citing *Lynx, Inc. v. Ordnance Prods.*, 273 Md. 1, 16 (1974)).

Here, Plaintiff claims that she provided proper notice because she was "unaware of any defect in the product until after her revision surgery in December 2011" and her Complaint "filed on July 29, 2013 served to timely notify [Biomet] of the breach of goods and the nature of the non-conformity." ECF No. 229 at 18. However, "a lawsuit cannot constitute notice of a breach" under Maryland law. *See Stanley v. Central Garden and Pet Corp.*, 891 F. Supp. 2d 757, 772 (D. Md. 2012). Because Plaintiff has cited no other evidence of notice to Biomet, there is no

evidence that she has met the prerequisite for filing a claim for breach of implied warranties. *See Doll*, 814 F. Supp. 2d at 542. Accordingly, Biomet is entitled to summary judgment on Count VI.

5. Breach of Express Warranty (Count VII)

Plaintiff alleges that Biomet is liable for breach of express warranty because it marketed the Biomet Device as a "pain free" hip implant that would permit an active lifestyle, even though it was actually unsafe for permanent implantation in the human body, and because it omitted from the IFU multiple known risks of using the device. In order to prevail on a claim for breach of express warranty, the plaintiff must prove that the seller created an express warranty, the product did not conform to the warranty, and the lack of conformity caused the injury suffered. *Shreve*, 166 F. Supp. 2d at 420. A seller creates an express warranty in any of the following ways:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

MD. CODE ANN., COM. LAW § 2-313(1). "[A]n affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." *Id.* § 2-313(2). But a seller need not have a specific intention to create a warranty so long as a representation "is made part of the basis of the bargain. In actual practice affirmations of fact made by the seller about the goods during a bargain are regarded as part of the description of those goods; hence no particular reliance on such statements need be shown in order to weave them into the fabric of the agreement. Rather, any fact which is to take such affirmations, once made, out of the agreement requires clear affirmative proof. The issue

normally is one of fact." *Id.* § 2-313 cmt. 3; *see also Rite Aid Corp. v. Levy-Gray*, 391 Md. 608, 623 (2006). Relying on *Rite Aid*, Plaintiff argues that its breach of express warranty claim survives despite a lack of evidence that Plaintiff was ever made aware of any claim made by Biomet that the device was pain free. The Court disagrees.

Rite-Aid involved a breach of express warranty claim against a pharmacy based on a package insert it generated for a certain medication that read "take with food or milk if upset stomach occurs." *Id*. at 611. Rite-Aid argued that Plaintiff could not prevail on its breach of express warranty claim because Plaintiff was unaware this warranty existed at the time she purchased the medication.[8] The Court of Appeals for Maryland rejected that argument, holding that an express warranty can be formed "even after the sale has been consummated." *Id*. at 625-626. But the Court did not find that a plaintiff could bring a claim without *ever* having been aware of the existence of the warranty, rather, the court determined that a jury could have inferred that Plaintiff "relied on the veracity of Rite Aid's affirmation each time she took the dose of doxcylcline with milk," regardless of whether she had relied on the express warranty in making the original purchase. *Id*. at 635. Here, there is no evidence from which a jury could determine Plaintiff ever saw any express warranty from Biomet that the product was "pain-free."[9] Instead, she relied on the expertise of her doctor, who as discussed above, relied primarily on his own independent research. Thus, even assuming there was an express claim by Biomet that the product was "pain-free," it never became a basis of the bargain and, therefore, was not an express warranty.

[8] The Court determined that the statement at issue was sufficient to establish that Rite-Aid was representing to the plaintiff that the medication was compatible with milk consumption. *Rite Aid*, 391 Md. at 624.

[9] With respect to Biomet marketing the Biomet Device as a "pain free" hip implant that would permit an active lifestyle, Plaintiff cites only to a deposition in which the questioning attorney references an advertisement for the Biomet Device that depicts gymnast Mary Lou Retton and states, "Mary Lou lives pain-free and so should you." *See* ECF No. 229 at 21; ECF No. 229-24 at 8.

Although Plaintiff is correct in stating that whether the seller creates an express warranty is typically a question of fact, *see* MD. CODE ANN., COM. LAW § 2-313 cmt. 3, she must still provide sufficient evidence from which the fact-finder could find in her favor. Because she does not do so with respect to a warranty regarding a "pain free" device, this cannot serve as the basis for a breach of express warranty claim.

Plaintiff's claim based on the risks of using the Biomet Device also fails. She states that "[t]he IFU of the [Biomet Device] omitted multiple known risks, including risks of severe metallosis, pseudotumor, and bone and tissue destruction from metal ions." ECF No. 229 at 19. Under Maryland law, "in order to have an express warranty there must be an affirmative statement of fact by the seller about the goods." *Rite Aid Corp. v. Levy-Gray*, 162 Md. App. 673, 692 (Md. Ct. Spec. App. 2005) (citing MD. CODE ANN., COM. LAW § 2-313). Here, Plaintiff does not complain about affirmative representations made by Biomet about the risks of using the Biomet Device, but instead complains about Biomet's alleged omissions. "[W]arranty by omission," however, would be at odds with the Maryland definition of an express warranty, which requires an "affirmative statement." *See id.* (citing *Witherspoon v. Philip Morris Inc.*, 964 F. Supp. 455, 465 (D.D.C. 1997)). Because this claim appears to simply be a repackaging of Plaintiff's failure to warn claims, which the Court has already addressed, any omissions in the Biomet Device's IFU cannot serve as the basis for Plaintiff's breach of express warranty claim. Accordingly, Biomet is entitled to summary judgment on Count VII.

6. Punitive Damages (Count VIII)

Plaintiff claims she is entitled to punitive damages based on Biomet's conduct with respect to the Biomet Device. A plaintiff may be awarded punitive damages where she "has established that the defendant's conduct was characterized by evil motive, intent to injure, ill

will, or fraud, *i.e.*, "actual malice." *Owens-Illinois, Inc. v. Zenobia*, 32 Md. 420, 460 (1992). "[I]n order for actual malice to be found in a products liability case, regardless of whether the cause of action for compensatory damages is based on negligence or strict liability, the plaintiff must prove (1) actual knowledge of the defect on the part of the defendant, and (2) the defendant's conscious or deliberate disregard of the foreseeable harm resulting from the defect." *Id.* at 462. "In either case, the evidence must show malicious conduct and not simply the supplying of a defective product or negligence." *Id.* at 465. A plaintiff must prove punitive damages by clear and convincing evidence, a "heightened standard." *Id.* at 469. "Clear and convincing evidence" is defined as "evidence … of such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established." *Jimenez v. DaimlerChrysler Corp.*, 269 F.3d 439, 450 (4th Cir. 2001) (internal quotation marks omitted).

Here, Plaintiff simply has not cited to sufficient evidence from which a trier of fact could reasonably conclude that Biomet acted with actual malice with respect to the Biomet Device. Although Plaintiff's response to Biomet's Motion for Summary Judgment includes a three-page list of evidence she states demonstrates Biomet's actual malice, *see* ECF No. 229 at 20–22, this evidence falls short of meeting the "clear and convincing" standard. First, Plaintiff describes much of her evidence as demonstrating that Biomet willfully and intentionally ignored or misrepresented risks related to metal-on-metal devices or made false statements about the Biomet Device, but the Court's review of this evidence reveals that it simply shows that Biomet made certain statements about the Biomet Device that Plaintiff believes to be false, without actually demonstrating that the statements are false or that Biomet acted with any ill-intent. *See* ECF Nos. 229-17, 229-23, 229-24, 229-25. Plaintiff also provides evidence that shows Biomet

entered into a settlement agreement related to paying surgeons to use metal-on-metal devices, *see* ECF No. 229-29, that Dr. John Cuckler, an orthopedic surgeon, consulted with Biomet on metal-on-metal devices and generally advocated in support of metal-on-metal devices in the public without disclosing his association with Biomet, *see* ECF Nos. 229-19, 229-20, 229-21, and that Dr. Hahn attempted to contact Biomet to ask about how to best treat Plaintiff's pseudotumor, but Biomet did not return his calls, *see* ECF Nos. 229-26, 229-27, but none of this evidence establishes that Biomet acted with actual knowledge of any defects in the Biomet Device or that it deliberately disregarded those defects. As far as the Court can tell, the only relevant evidence to the question of actual malice is evidence that, in 1995, a Philadelphia doctor notified Biomet that he had concerns about the potential long-term systemic effects of metal ion release from metal-on-metal devices, ECF No. 229-16, and in 2015, the Australian government released a hazard alert that metal-on-metal hip replacement implants had a higher than expected revision rate, ECF No. 229-30. This evidence does not clearly and convincingly show that Biomet had actual knowledge of a defect in the Biomet Device and that it deliberately disregarded that defect. *See Owens-Illinois, Inc.*, 32 Md. at 462. Accordingly, Plaintiff has not put forth sufficient evidence from which a factfinder could determine she is entitled to punitive damages, and Biomet is therefore entitled to summary judgment on Count VIII.

7. Attorney's Fees

Plaintiff also requests attorney's fees. "Maryland follows the common law 'American Rule,' which states that, generally, a prevailing party is not awarded attorney's fees 'unless (1) the parties to a contract have an agreement to that effect, (2) there is a statute that allows the imposition of such fees, (3) the wrongful conduct of a defendant forces a plaintiff into litigation

with a third party, or (4) a plaintiff is forced to defend against a malicious prosecution." *Nova Research, Inc. v. Penske Truck Leasing Co.*, 405 Md. 435, 445 (2008).

Here, the parties do not have an agreement that provides for an award of attorney's fees, no statutory authority provides for the imposition of attorney's fees, Plaintiff has not been forced into litigation with a third party as a result of Biomet's wrongful conduct, and Plaintiff has not been forced to defend against malicious prosecution. Thus, even if Plaintiff were to prevail on her remaining claims, there would be no ground for awarding attorney's fees. Accordingly, this claim is dismissed.

IV. CONCLUSION

For the foregoing reasons, Biomet's Motion to Exclude Expert Testimony is granted, in part, and denied, in part and Biomet's Motion for Summary Judgment is granted, in part, and denied, in part. A separate Order shall issue.

Date: September 30, 2020

/s/
GEORGE J. HAZEL
United States District Judge