IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PAULA CONWAY, et al.,	*	
Plaintiffs,	*	
v.	*	Civil Action No. GLR-18-1466
AMERICAN MEDICAL SYSTEMS, INC.,	*	
Defendant.	*	

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MEMORANDUM OPINION

THIS MATTER is before the Court on Defendant American Medical Systems, Inc.'s ("AMS") Motion for Summary Judgment (ECF No. 18-56) and Supplement thereto (ECF No. 32). The Motion is ripe for disposition and no hearing is necessary. See Local Rule 105.6 (D.Md. 2021). For the reasons outlined below, the Court will grant in part and deny in part AMS' Motion for Summary Judgment.[1]

[1] Also pending before the Court are several evidentiary motions and supplements filed by AMS: (1) Motion to Exclude the General Causation Opinions and Testimony of Bruce Rosenzweig, M.D. (ECF Nos. 18-5–6, 33); (2) Motion to Exclude the Specific Causation Opinions and Testimony of Bruce Rosenzweig, M.D. (ECF Nos. 18-64–73, 34); (3) Motion to Exclude the General Causation Opinions and Testimony of Vladimir Iakovlev, M.D. (ECF Nos. 18-18–20, 35); (4) Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. (ECF Nos. 18-9–10, 36); (5) Motion to Exclude the Opinions and Testimony of Erin Carey, M.D., MSCR (ECF Nos. 18-14–15, 37); and (6) Motion to Exclude Opinions and Testimony of Linda Schweiger (ECF Nos. 18-60–63, 38). The parties will be permitted to present arguments to the Court regarding the Motions during the pre-trial conference. As such, the Court will deny the Motions without prejudice at this time. The parties may file a line renewing the Motions and responses thereto before the pre-trial conference.

I. BACKGROUND

A. Conway's Treatment

Plaintiff Paula Conway suffers from stress urinary incontinence. On January 27, 2010, Dr. Virginia Staiman implanted Conway with a Monarc mid-urethral sling designed and produced by AMS to treat her condition. (Dr. Virginia Staiman Dep. ["Staiman Dep."] at 16:21–17:10, ECF Nos. 18-58, 18-79).[2] Conway alleges that her Monarc device failed and she underwent a revision procedure on March 29, 2012. (Compl. ¶ 55, ECF No. 1).[3] She further "required neuro stimulation for bladder control and has had significant complications including additional surgeries and has ongoing pelvic pain and incontinence." (Id.).

The Monarc instructions for use ("IFU") in use at the time of Conway's surgery warned of the following risks: local irritation and/or foreign body response; tissue responses including vaginal extrusion, erosion through the urethra or surrounding tissue, migration of the device from the desired location, fistula formation, and inflammation; potentiation of an existing infection; temporary or permanent lower urinary tract obstruction and retention; pain, infection, erosion, device migration, and complete failure

[2] The electronic document accessible at ECF No. 18-58 contains multiple exhibits to AMS' Motion for Summary Judgment. The Staiman deposition transcript excerpts may be found at pp. 2–23 of ECF No. 18-58, using the pagination assigned by the Court's Case Management and Electronic Case Files ("CM/ECF") system.

[3] The parties did not attach to their briefing any evidence regarding Conway's revision procedure or any other "additional surgeries" she underwent. Accordingly, the Court has pulled some facts from Conway's Complaint. (See Compl. ¶ 55).

of the procedure resulting in "incontinence and mild to moderate urinary incontinence due to incomplete support or overactive bladder." (Monarc IFU at 8, ECF No. 18-58).[4]

B. Dr. Staiman's Testimony

Staiman testified during her deposition that she generally reviews the IFU affiliated with the products she uses in surgery, including the Monarc device. (Staiman Dep. at 11:12–18; 27:11–18). Additionally, Staiman relies on several sources to provide her with information regarding her treatment decisions, including (1) her medical training; (2) information provided by the manufacturer of the medical device; (3) medical literature, including articles, journal studies, and other published information; (4) her own experience with the device; (5) information from colleagues in her large urology practice; and (6) meetings with medical societies like the American Urological Association. (Id. at 72:20–76:19). Staiman generally knew the major risks of the products she used and did her best to communicate those risks to her patients. (Id. at 11:12–12:2).

Staiman's notes from Conway's surgery indicate that she specifically warned Conway of the following risks:

> So I discussed the procedure in great detail, including the risks of the procedure; infection, bleeding, requiring transfusion, injury to the bladder, urethra, nerves or blood vessels, blood clots, persistent urinary incontinence, extrusion of sling, erosion of sling or urinary retention.

(Staiman Dep. at 21:20–22:6). Staiman's notes further state that "[Conway] expressed an understanding of the procedure and wished to proceed." (Id.). According to her notes,

[4] The Monarc IFU may be found at pp. 34–44 of ECF No. 18-58, using the pagination assigned by the Court's CM/ECF system.

Staiman did not warn Conway of the risk of chronic pain or chronic sexual pain. (Id. at 26:6–16). Nonetheless, Staiman believes that she adequately advised Conway of the risks of the device at the time of her surgery. (Id. at 81:5–9).

Although the Monarc device is no longer available, Staiman indicated that she would still use it if it were. (Id. at 68:18–20). Staiman "liked" the Monarc because it was "easy to use" and gave her "very good results." (Id. at 68:22–69:1). Specifically, Staiman had "good results on patients" and found the Monarc to be effective in treating her patients' conditions without "a lot of complications," particularly with erosions. (Id. at 69:2–7; 70:12–71:4). She also found the product to be "safe[]." (Id.). Staiman found the Monarc, like other mid-urethral slings, was easier to use than alternative treatments and created "less of a risk of complication for [the] patient." (Id. at 70:4–9). Additionally, patients had an easier recovery after their surgeries. (Id. 70:8–11). Indeed, Staiman said that if Conway presented to her today with the same symptoms and complaints, she would "[a]bsolutely" still have offered her the Monarc. (Id. at 71:17–72:11). Stairman stated, however, that based on what she knows now about slings, she would change the risk analysis discussion that she offered Conway and would talk to her about the risk of a fistula, pain in the groin, and pain with sexual relations. (Id. at 82:3–7). Staiman further stated that if she knew of a contraindication to the procedure, she would not have moved forward with it. (Id. at 30:15–31:6). She did not indicate, however, that she was aware of any such contraindications. (See id.).

C. Procedural History

On May 22, 2018, Paula Conway and her husband Earl Conway filed a Complaint in this Court. (ECF No. 1). The Complaint alleges: strict liability – failure to warn (Count I); strict liability – design defect (Count II); strict liability – manufacturing defect (Count III); negligence (Count IV); breach of express warranty (Count V); breach of implied warranty (Count VI); fraudulent concealment (Count VII); fraud (Count VIII); equitable tolling (Count IX); negligent misrepresentation (Count X); and loss of consortium (Count XI). (See Compl. at 14–33, ECF No. 1). Earl Conway joins as to the loss of consortium count only.

On June 13, 2018, the case was transferred to the United States District Court for the Southern District of West Virginia as part of the multidistrict litigation regarding mesh products. (See Transfer Order at 1, ECF No. 5). After conducting discovery, AMS filed a Motion for Summary Judgment on May 13, 2019. (ECF No. 18-56). On May 24, 2019, the Conways opposed the Motion. (ECF No. 18-78). In their Opposition, the Conways indicate that they are no longer pursuing a manufacturing defect claim (Count III). (Pls.' Resp. Def. Mot. Summ. J. ["Opp'n"] at 11, ECF No. 18-78).[5] AMS filed a Reply on June 4, 2019. (ECF No. 18-92).

On February 20, 2020, the case was remanded from the Southern District of West Virginia back to this Court with the Motion pending. (Conditional Remand Order at 1, ECF No. 8). On February 21, 2020, the Court directed the parties to file a status report including,

[5] The Court will therefore grant summary judgment as to Count III, strict liability – manufacturing defect.

among other things, whether they wished to participate in a mediation. (ECF No. 11). Although the parties' previous attempts to mediate were unsuccessful, they indicated a willingness to discuss whether an additional mediation would be useful. (ECF No. 12). On February 26, 2020, the Court referred the case for mediation. (ECF No. 23). Mediation took place in November 2020 but was unsuccessful. On January 8, 2021, the parties filed a Joint Motion for Proposed Scheduling Order. (ECF No. 26). On April 1, 2021, the Court held a teleconference with the parties and directed them to re-file their pending motions and any supplemental briefs thereto. (ECF No. 28). The Court also denied the Joint Motion for Proposed Scheduling Order as moot. (Id.).

On May 13, 2021, AMS filed its Supplement to its Motion for Summary Judgment. (ECF No. 32). The Conways supplemented their Opposition on May 27, 2021. (ECF No. 43). Finally, AMS submitted a Reply in Support of its Supplement on June 11, 2021. (ECF No. 54).

II. DISCUSSION

A. Standard of Review

In reviewing a motion for summary judgment, the Court views the facts in a light most favorable to the nonmovant, drawing all justifiable inferences in that party's favor. Ricci v. DeStefano, 557 U.S. 557, 586 (2009); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986) (citing Adickes v. S.H. Kress & Co., 398 U.S. 144, 158–59 (1970)). Summary judgment is proper when the movant demonstrates, through "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . admissions, interrogatory answers,

or other materials," that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a), (c)(1)(A). Significantly, a party must be able to present the materials it cites in "a form that would be admissible in evidence," Fed.R.Civ.P. 56(c)(2), and supporting affidavits and declarations "must be made on personal knowledge" and "set out facts that would be admissible in evidence," Fed.R.Civ.P. 56(c)(4).

Once a motion for summary judgment is properly made and supported, the burden shifts to the nonmovant to identify evidence showing that there is a genuine dispute of material fact. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986). The nonmovant cannot create a genuine dispute of material fact "through mere speculation or the building of one inference upon another." Othentec Ltd. v. Phelan, 526 F.3d 135, 140 (4th Cir. 2008) (quoting Beale v. Hardy, 769 F.2d 213, 214 (4th Cir. 1985)).

A "material fact" is one that might affect the outcome of a party's case. Anderson, 477 U.S. at 248; see also JKC Holding Co. v. Wash. Sports Ventures, Inc., 264 F.3d 459, 465 (4th Cir. 2001). Whether a fact is considered to be "material" is determined by the substantive law, and "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." Anderson, 477 U.S. at 248; accord Hooven-Lewis v. Caldera, 249 F.3d 259, 265 (4th Cir. 2001). A "genuine" dispute concerning a "material" fact arises when the evidence is sufficient to allow a reasonable jury to return a verdict in the nonmoving party's favor. Anderson, 477 U.S. at 248. If the nonmovant has failed to make a sufficient showing on an essential element of his case where he has the burden of proof, "there can be 'no genuine

[dispute] as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Celotex Corp. v. Catrett, 477 U.S. 317, 322–23 (1986).

B. Analysis[6]

1. Failure to Warn

Conway alleges that AMS is liable in negligence and strict liability for failure to warn of the risks of the Monarc device. (Count I; Count IV – in part).[7] In her Opposition, she argues that "Staiman was not aware that the Monarc mesh could lead to chronic pain and permanent pain during sex" and did not warn her of those risks. (Opp'n at 4–5). She further asserts that Staiman "was never warned [that] patients with pre-existing conditions such as prior pain syndromes faced greater risks." (Id.). At bottom, the Court finds that there is no evidence to support Conway's contention that AMS owed a duty to warn Staiman of the risks of chronic pain, permanent pain during sex, or of a contraindication for patients with prior pain syndromes, and therefore, Conway's failure to warn claims will be dismissed.

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[6] AMS asserts that Maryland law applies to the Conways' substantive claims. (See Mem. Law Supp. Mot. Summ. J. ["Mot."] at 3–4, ECF No. 18-59). AMS is correct. See Belanger v. Ethicon, Inc., No. 2:12-MD-02327, 2014 WL 346717, at *7 (S.D.W.Va. Jan. 30, 2014) ("[T]he choice of law that applies is the place where the plaintiff was implanted with the product."); Smith v. MTD Prods., Inc., No. CCB-19-1592, 2019 WL 5538273, at *2 (D.Md. Oct. 24, 2019) ("The lex loci delicti rule provides that 'the substantive tort law of the state where the wrong occur[s]' governs." (quoting Philip Morris v. Angeletti, 752 A.2d 200, 231 (Md. 2000))). As Conway was implanted with the device in Maryland, the Court will apply Maryland law. (See Compl. ¶ 55).

[7] Conway's failure to warn claims constitute part of her negligence claim (Count IV) and all of her strict liability – failure to warn claim (Count I).

In Maryland, "[p]roducts 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." Morris v. Biomet, Inc., 491 F.Supp.3d 87, 103–04 (D.Md. 2020) (quoting Shreve v. Sears, Roebuck & Co., 166 F.Supp.2d 378, 413 (D.Md. 2001)). Negligence and strict liability concepts have "morphed together in failure to warn cases." Id. at 104 (quoting Gourdine v. Crews, 955 A.2d 769, 782 (Md. 2008)) (cleaned up). This is because "traditional concepts of duty, breach, causation, and damage are required for both causes of action." Id.

The learned intermediary doctrine addresses to whom the duty to warn extends. See Gourdine, 955 A.2d at 776. The doctrine provides that a manufacturer need only provide an adequate warning to the patient's prescribing physician of the risks attendant to the product used. Ames v. Apothecon, Inc., 431 F.Supp.2d 566, 572 (D.Md. 2006). The natural corollary, of course, is that the manufacturer has no duty to warn the patient directly. Lee v. Baxter Healthcare Corp., 721 F.Supp. 89, 94–95 (D.Md. 1989). "If the physician has been adequately warned, he is a 'learned intermediary' because he is in the 'best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment.'" Ames, 431 F.Supp.2d at 572 (quoting Lee, 721 F.Supp. at 95).[8] "A warning is

[8] The Restatement Third of Torts provides:

> (d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

legally adequate when it explains the risk which the plaintiff alleges has caused the injury." Lee, 721 F.Supp. at 95. "The warning must only be reasonable, not the best possible one." Ames, 431 F.Supp.2d at 572. Further, even if the 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." Morris, 491 F.Supp.3d at 104. The doctrine takes into account the learned intermediary's "entire field of knowledge" regarding the alleged risks; it is not restricted to the warnings provided by the manufacturer alone. Ames, 431 F.Supp.2d at 572. It is well settled that the learned intermediary doctrine applies in cases involving medical devices, like the TVT Abbrevo device used here. See Morris, 491 F.Supp.3d at 104 (citing cases).

The doctrine takes into account the learned intermediary's "entire field of knowledge" regarding the alleged risks; it is not restricted to the warnings provided by the manufacturer alone. Ames, 431 F.Supp.2d at 572. Maryland courts have recognized the learned intermediary doctrine in the context of prescription drugs, Gourdine, 955 A.2d at 776, and medical devices, Miller v. Bristol-Myers Squibb Co., 121 F.Supp.2d 831, 838 (D.Md. 2000). Indeed, it is well settled that the learned intermediary doctrine applies in

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> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
> (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Restatement (Third) of Torts: Prod. Liab. § 6(d) (1998).

cases involving medical devices, like the Monarc device used here. See Morris, 491 F.Supp.3d at 104 (citing cases).

Conway argues that the learned intermediary doctrine does not apply here because AMS' warnings were inadequate. (Opp'n at 5). She argues further that AMS failed to warn Staiman, Conway's implanting physician, "that the Monarc mesh could lead to chronic pain," "permanent pain during sex," and the greater risks for "patients with pre-existing conditions such as prior pain syndromes." (Id. at 4–5). Conway points to Staiman's testimony indicating that she did not inform Conway of the risk of chronic pain or chronic sexual pain before the implant procedure. (Staiman Dep. at 26:6–16). Conway also points to Staiman's testimony that "if something is contraindicated," and she knew it was contraindicated, she would not move forward with the implant procedure. (Id. at 30:15–31:6).

The Court need not determine how the learned intermediary doctrine would apply here because Conway cannot demonstrate that AMS had a duty to warn Staiman of these particular risks. "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." Morris, 491 F.Supp.3d at 103–04 (emphasis added) (quoting Shreve, 166 F.Supp.2d at 413); see Doe v. Miles Lab'ys, Inc., 927 F.2d 187, 194 (4th Cir. 1991) ("Miles II") (stating in a failure to warn case that a pharmaceutical manufacturer "must warn physicians . . . of risks known or reasonably foreseeable at the time the product is administered"). Here, Conway has not presented sufficient evidence that AMS knew or should have known of the risks of chronic pain,

chronic pain during sex, or that a clinical history of pain syndromes could be a substantial factor in causing injury in patients implanted with the Monarc device. She has offered no expert testimony indicating that AMS knew or should have known of these risks. (See generally Rosenzweig Report, ECF No. 18-83; Noreen Report, ECF No. 18-85). Her only support is drawn from a February 14, 2008 email from Randy Hoyt to Deb Fleetham and Diane Sahr, three otherwise unidentified individuals. (Feb. 14, 2008 Email at 1, ECF No. 18-81). In the email, which is titled "Perigree/Apogee IFU Update for Pain," Hoyt writes:

> I guess the real answer that I need out of the meeting is do we agree that we will add a statement to the IF regarding chronic pain as a risk? I need to respond to MPA (Swedish government) regarding this very soon. The[y] noted in their letter that we do not identify it as a risk and cited several published articles for us to review regarding chronic pain as a result of hernia and pelvic floor repair. In my response I would like to tell them we will add some language to the IFU. Exact wording is TBD.

(Id.). There is no written response to the message. (See id.). This email is unconvincing because (a) it is unclear whether Hoyt, Fleetham, and Sahr work for AMS and (b) the email refers to "Perigree" and "Apogee," but not "Monarc," the relevant device in this action. (See id.). Conway does not provide the Court with any context on the "Perigree" or "Apogee" products and it is not clear whether the unspecified articles regarding "chronic pain" affiliated with those products apply to the Monarc. The mere "possibility" of a risk is insufficient to trigger a duty to warn regardless of whether the duty extends to the physician or the patient. See Miles II, 927 F.2d at 194 ("If pharmaceutical companies were required to warn of every suspected risk that could possibly attend the use of a drug, the consuming public would be so barraged with warnings that it would undermine the

effectiveness of these warnings."). Conway has not provided sufficient evidence that AMS knew or should have known that chronic pain, chronic pain during sex, or a higher incidence of complications in patients with prior pain syndromes could be substantial factors in an injury. As such, she has not demonstrated that AMS owed a duty to warn of said risks.

Even if this Court were to consider the application of the learned intermediary doctrine here, Conway's arguments that it does not apply are unconvincing. Conway argues that the learned intermediary doctrine applies only in cases where the warning is found to be adequate, not in cases where the warning is inadequate. (Opp'n at 5–6). Conway oversimplifies and misconstrues the law in this regard. Maryland courts have indeed applied the learned intermediary doctrine in cases where the warning was found to be inadequate. In Morris v. Biomet, this Court held that "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." 491 F.Supp.3d at 104. Accordingly, the doctrine applies both (a) where a warning is legally adequate and (b) where the warning is inadequate and the doctor was independently aware of the risk which allegedly caused plaintiff's injury. Again, Conway's failure to warn claim does not make it this far because it is premised on several speculative risks, but even if that were not the case, the learned intermediary doctrine appears to apply.

Conway argues next that even if the doctrine applies here, the Court should adopt a new rule in Maryland that if the adequacy of the warning is in question, "then proximate cause can be shown by proof other than the doctor's testimony that an adequate warning

would have altered his or her prescribing behavior." (Opp'n at 6–7).[9] Conway cites only one unpublished case from North Carolina in support of her position. See Fussman v. Novartis Pharms. Corp., No. 1:06CV149, 2011 WL 5836928 (M.D.N.C. Nov. 21, 2011). In Fussman, the court declined to overturn a jury's verdict in favor of the plaintiff on product liability claims, including failure to warn. The court noted that a North Carolina statute provided for an "affirmative defense" "where a prescription drug manufacturer provides an adequate warning to the prescribing physician." Id. at *8 (citing N.C. Gen. Stat. § 99B–5). The court indicated that the jury expressly rejected the defense and, in any event, concluded that the warning given to the plaintiff's physician was inadequate. Id. Fussman is both factually and legally inapposite, and the Court is unpersuaded that it supports Conway's argument that the learned intermediary doctrine should be modified in Maryland.

Accordingly, Conway has failed to demonstrate that AMS had a duty to warn her physician of the risks of chronic pain, chronic pain during sex, and an increased risk of complications associated with the Monarc implant in patients with a history of pain syndromes. The Court will grant judgment in favor of AMS on Conway's failure to warn claims. (Count I & Count IV – in part).

[9] Specifically, Conway seeks to rely on her own testimony that "no one informed her of specific risks and hazards associated with the Monarc and if she had been warned of such as the risk that she could suffer chronic/permanent pain, then she would not have proceeded with the procedure." (Opp'n at 7).

2. Design Defect

Conway brings design defect claims under strict liability and negligence. (Count II; Count IV – in part). AMS argues that Conway's strict liability design defect claim fails because Maryland law precludes it and, alternatively, because she has not presented evidence of a feasible safer alternative design, which it contends is a required element of the claim. (See Def.'s Mem. Law Supp. Mot. Summ. J. ["Mot."] at 8–9, ECF No. 18-59). AMS does not challenge Conway's negligence theory design defect claim.[10] At bottom, the Court disagrees with AMS and will deny AMS' Motion as to Conway's strict liability design defect claim. (Count II).

"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.'" Morris, 491 F.Supp.3d at 103 (quoting Shreve, 166 F.Supp.2d at 411). The negligence theory, on the other hand, "focuses on the conduct of the defendant." Id. (quoting Parker v. Allentown, Inc., 891 F.Supp.2d 773, 780 (D.Md. 2012)). Both theories, however, require a showing of the same three elements, "defect, attribution of defect to the seller, and a causal relationship between the defect and the injury." Id. Accordingly, "the elements of proof are the same whether the claim [is] characterized as one for strict liability or negligence." McCoy v.

[10] AMS argues in its Motion that Conway's negligent design defect claim fails for lack of evidence regarding a safer alternative design. (See Opp'n at 8–9). As the Court will explain, however, AMS' argument relates only to strict liability design defect, as evidence of a safer alternative design is not considered in design defect claims based on the negligence theory. Accordingly, the Court shall only consider AMS' argument as it relates to strict liability design defect (Count II) and not Conway's negligence claim, which is substantively unchallenged. (Count IV – in part).

Biomet Orthopedics, Inc., No. ELH-12-1436, 2021 WL 252556, at *22 (D.Md. Jan. 25, 2021) (quoting Heckman v. Ryder Truck Rental, Inc., 962 F.Supp.2d 792, 802 (D.Md. 2013)).

Proof of a defect "must arise above surmise, conjecture or speculation." Parker, 891 F.Supp.2d at 780 (quoting Virgil v. Kash N' Karry Serv. Corp., 484 A.2d 652, 657 (Md.Ct.Spec.App. 2005)). There is "significant overlap" between negligence theory and strict liability design defect as the claims "share the 'product litigation[] basics,' i.e., a defect attributable to Defendant and a causal relationship between that defect and Plaintiff's injury." Id. (quoting Laing v. Volkswagen of Am., Inc., 949 A.2d 26, 39 (Md.Ct.Spec.App. 2008)).

Despite the overlap, negligence theory design defect and strict liability design defect have distinct elements. See Parker, 891 F.Supp.2d at 780. Negligence theory claims recall the familiar, well-known elements of negligence—duty, breach, proximate cause, and damages. Id. Under the negligence theory, the manufacturer must design and manufacture the product in a way that is safe for all reasonably foreseeable uses. Id. Strict liability design defect diverges from the negligence theory, however, as "duty, breach, and foreseeability are not elements of a strict liability claim." Id. at 781. Instead, the elements of strict liability design defect are:

> (1) the product was in a defective condition at the time that it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause of the injuries, and (4) that the product was expected to and did reach the consumer without substantial change in its condition.

Id. (quoting Phipps v. Gen. Motors Co., 363 A.2d 955, 958 (Md. 1976)). Accordingly, "for a seller or manufacturer to be strictly liable for a design defect, the product must be both in a defective condition, as required in negligence and strict liability alike, and unreasonably dangerous at the time that it is placed on the market by the seller or manufacturer." Id. (quoting Phipps, 363 A.2d at 958) (cleaned up).

When determining whether a product is "defective and unreasonably dangerous, for strict liability purposes," the court will either apply the consumer expectation test[11] or the risk-utility test.[12] Parker, 891 F.Supp.2d at 791 (quoting Halliday v. Sturm, Ruger & Co.,

[11] Under the consumer expectation test, a product is defectively dangerous "if it is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it with the ordinary knowledge common to the community as to the product's characteristics." Halliday v. Sturm, Ruger & Co., 792 A.2d 1145, 1150 (Md. 2002) (quoting W. Page Keeton et al., Prosser and Keeton on the Law of Torts, § 99, at 698 (5th ed. 1984)).

[12] Under the risk-utility test, the court considers:

> (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
> (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
> (3) The availability of a substitute product which would meet the same need and not be as unsafe.
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or the existence of suitable warnings or instructions.
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

792 A.2d 1145, 1150, 1152 (Md. 2002)). "The consumer expectation test asks whether the product was in a defective condition at the time it was sold." Lloyd v. Gen. Motors Corp., 275 F.R.D. 224, 228 (D.Md. 2011). "The risk-utility test asks whether a manufacturer, knowing the risks inherent in the product, acted reasonably in putting it on the market." Id. (citation and internal quotation marks omitted).

AMS argues that Conway's claim fails because she has not presented evidence of a reasonably feasible alternative design, which is an element of the risk-utility test used in some strict liability design defect claims. (Mot. at 8–9). But because the Court finds that the risk-utility test does not apply in this case, Conway need not make such a showing.

The default test that Maryland courts apply in design defect cases is the consumer expectation test. See Simpson v. Standard Container Co., 527 A.2d 1337, 1340 (Md.Ct.Spec.App. 1987) ("To determine whether a product is defective in its design, Maryland cases have generally used the 'consumer expectation' test."); Ruark v. BMW of N. Am., LLC, No. ELH-09-2738, 2014 WL 1668917, at *6 (D.Md. April 24, 2014) (indicating that the Maryland Court of Appeals has adopted the consumer expectation test in all three cases in which it addressed the proper standard in a strict liability design defect case). The risk-utility test is the exception to the rule and "only applies in certain, limited circumstances—those in which a product malfunctions (i.e. performs in a manner other than how it was designed to perform)." Ruark, 2014 WL 1668917, at *8; see also Halliday, 792 A.2d at 1153 ("[T]he risk-utility test does not apply to a design defect unless the

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Parker, 891 F.Supp.2d at 791.

product malfunctions in some way."). In addressing the proper test to apply to a strict liability claim, the Maryland Court of Appeals has explained that a gun "does not malfunction when it shoots a bullet into a person in whose direction it is fired." Halliday, 792 A.2d at 1153. Rather, in that case, the gun is operating as intended and designed and the consumer expectation test should apply. Id.; accord Ruark, 2014 WL 1668917, at *5. Products that courts have found malfunctioned, requiring the application of the risk-utility test, include an unbalanced machine that tipped over, a motor home that exploded, a power press that caught the user's hands, and a rack that tipped over. See Ruark, 2014 WL 1668917, at *5 (quoting Kelley v. R. G. Indus. Inc., 497 A.2d 1143, 1149 (Md. 1985)); Parker, 891 F.Supp.2d at 791. The risk-utility test "cannot be extended to impose liability on the maker or marketer" of a product which has not malfunctioned. Ruark, 2014 WL 1668917, at *5 (quoting Kelley, 497 A.2d at 1149).

Here, Conway does not allege that her specific Monarc device malfunctioned. Instead, she argues that there are problems with the design of the product, such as the stiffness of the mesh and the use of large amounts of polypropylene, which she contends render the product dangerous and prone to cause complications. Put simply, Conway argues that the product should have been designed more safely. AMS does not explicitly assert that the Court should adopt the risk-utility test here or offer any argument on the use of the risk-utility test over the consumer expectation test. Accordingly, the Court finds that the consumer expectation test applies and evidence of a safer alternative design is not required to establish her claim.

AMS raises no substantive argument regarding Conway's strict liability design defect claim under the consumer expectation test. The Court will therefore deny AMS' Motion as to Conway's strict liability design defect claim. (Count II).[13]

3. Breach of Express Warranty

Conway alleges that AMS is liable for breach of express warranty because AMS marketed the Monarc for stress urinary incontinence even though it was unsafe for "permanent implantation in the human body," and because it omitted "multiple known risks" from the Monarc's IFU. (Opp'n at 13). To prove that AMS breached an express warranty, Conway must "establish that 1) a warranty existed, 2) the product did not conform to the warranty, and 3) the breach proximately caused the injury or damage." BnP

[13] AMS argues generally that Maryland law precludes strict liability design defect claim under comment k of the Restatement Second of Torts § 402A and therefore Conway's claim must fail. (Mot. at 8). It contends that comment k "acknowledges that there are some products – like medical devices and prescription drugs – that are 'unavoidably unsafe products,' and that 'the doctrine of strict liability in tort has no application' to those products." (Id. (quoting Miles Lab'ys, Inc. v. Doe, 556 A.2d 1107, 1117 (Md. 1989) ("Miles I"))).

The Maryland Court of Appeals has adopted comment k, which excludes "unavoidably unsafe products" from strict liability. Miles I, 556 A.2d at 1123–24; see also Bruesewitz v. Wyeth LLC, 562 U.S. 223, 234 (2011) ("Comment k exempts from this strict-liability rule 'unavoidably unsafe products.'"). Nonetheless, this Court has never held that all prescription medications and medical devices are unavoidably unsafe, as AMS implies here. Grinage v. Mylan Pharms., Inc, 840 F.Supp.2d 862, 869 n.5 (D.Md. 2011). Instead, a prescription or medical device may be found to be unreasonably unsafe after weighing the risks of the product against its usefulness under several factors. Id.; see also Miles II, 927 F.2d at 191 (referencing the "four common threads" the Court of Appeals used in determining whether blood products specifically were unreasonably dangerous). AMS provides no argument on the weighing process and instead simply asserts that Maryland law precludes strict liability design defect claims. That is not so. See generally, Parker v. Allentown, Inc., 891 F.Supp.2d 773 (D.Md. 2012); Halliday v. Sturm, Ruger & Co., Inc., 792 A.2d 1145 (Md. 2002); Shreve, 166 F.Supp.2d 378 (assessing strict liability design defect claims under Maryland law).

Ventures, LLC v. G-Force Sportfishing, Inc., 499 F.Supp.3d 175, 181 (D.Md. 2020) (quoting Palmer v. CVS Health, No. CCB-17-938, 2019 WL 6529163, at *6 (D.Md. 2002)). A seller can create 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.

Morris, 491 F.Supp.3d at 107 (quoting Md. Code Ann., Com. Law ("CL") § 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. (quoting CL § 2-313(2)). A seller does not need to have the specific intention to create a warranty as 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. (quoting CL § 2-313 cmt. 3).

AMS argues that Conway's breach of express warranty claim fails on the merits because she did not recall the name of the product during her deposition, had never spoken to an AMS representative in the past, and never relied on any representations from AMS

or advertisements in deciding to have the Monarc device implanted. (Mot. at 11). The Court agrees.

Conway testified at her deposition as follows:

> Q: You testified you never contacted AMS and said anything like "hey, I had one of your products, your product was defective?"
>
> A: No.
>
> Q: You never made that call?
>
> A: No.
>
> Q: Did you rely on any advertising from AMS to decide whether you would use the Monarc sling?
>
> A: No.
>
> Q: Did you ever talk to anybody, any representative from AMS at any time?
>
> A: No.
>
> Q: Was any statement made to you by any representative of American Medical Systems at any time?
>
> A: No.
>
> Q: In filing this lawsuit, did you rely on anything that was given to you orally or in writing by an AMS representative?
>
> A: Huh-uh. No.

(Paula Conway Dep. ["Conway Dep."] at 250:4–23, ECF No. 18-58, 18-82).[14] Conway's testimony does not suggest that she was aware of the existence of a warranty. There is no evidence that AMS made an express warranty and further, even if it did, that the warranty "became a basis of the bargain." See Morris, 491 F.Supp.3d at 107–08. Additionally, Conway's argument that AMS omitted known risks from its IFU also fails. "[I]n order to

[14] The Conway deposition transcript excerpts may be found at pp. 25–32 of ECF No. 18-58, using the pagination assigned by the Court's CM/ECF system.

have an express warranty there must be an affirmative statement of fact by the seller about the goods." Id. at 108 (quoting Rite Aid Corp. v. Levy-Gray, 876 A.2d 115, 126 (Md.Ct.Spec.App. 2005)). Conway's complaints about omissions are thus inapplicable to an express warranty claim. See id.

Accordingly, the Court will grant judgment in favor of AMS on Conway's breach of express warranty claim (Count V).

4. Breach of Implied Warranty

Conway alleges that AMS breached the implied warranty of merchantability[15] because the Monarc device was not fit for the ordinary purposes for which such goods are used. (Opp'n at 13). "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.'" Morris, 491 F.Supp.3d at 106 (quoting CL § 2-314(1)). In order to prove an implied warranty of merchantability claim, "a plaintiff must show that the product was not fit for its intended purpose." Shreve, 166 F.Supp.2d at 422; Md. Code Ann., Com. Law § 2-314. Like Conway's design defect claims, breach of implied warranty requires proof of a defect, attribution to the seller, and a causal relationship between the defect and the injury. Id.

AMS argues, among other things, that Conway "has not alleged that she provided the requisite notice of her claim . . . nor has she adduced evidence of any such notice." (Def.'s Suppl. Mot. Summ. J. ["Suppl. Mot."] at 5, ECF No. 32). Conway responds that she "filed the instant action in 2018," and that she also "filed an action in 2012 informing

[15] Conway does not assert in her Opposition that AMS breached the implied warranty of fitness. (See Opp'n at 13–14).

[AMS] of warranty claims." (Pls.' Opp'n Def.'s Suppl. Mot. Summ. J. ["Suppl. Opp'n"] at 6 n.2, ECF No. 43).

The UCC "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). Notably, the buyer must "inform the seller of the breach, the particular goods that have been impaired, and set forth the nature of the nonconformity." Id. "[A] notification to a seller within a reasonable time is a 'prerequisite' for claiming a breach of implied warranty." Id. In Maryland, "a lawsuit cannot constitute notice of a breach." Morris, 491 F.Supp.2d at 106 (quoting Stanley v. Cent. Garden & Pet Corp., 891 F.Supp.2d 757, 772 (D.Md. 2012)). Here, Conway does not attach any documentation regarding her efforts to place AMS on notice and instead only references her lawsuits, which are insufficient to provide notice under Maryland law. Accordingly, AMS is entitled to judgment on Count VI.

5. Fraud

AMS argues that the Court should dismiss Conway's claims for fraud, fraudulent concealment, and negligent misrepresentation (Counts VII, VIII, & X). (Mot. at 13). At bottom, the Court agrees and will dismiss the claims.

To establish fraud, a plaintiff must show that

> (1) the defendant made a false representation to the plaintiff, (2) the falsity of the representation was either known to the defendant or the representation was made with reckless indifference to its truth, (3) the misrepresentation was made for the purpose of defrauding the plaintiff, (4) the plaintiff relied on the misrepresentation and had the right to rely on it, and (5) the plaintiff suffered compensable injury as a result of the misrepresentation.

Dierker v. Eagle Nat. Bank, 888 F.Supp.2d 645, 651 (D.Md. 2012) (quoting Hoffman v. Stamper, 867 A.2d 276, 292 (Md. 2005)). To establish fraudulent concealment, a plaintiff must show

> (1) the defendant owed a duty to the plaintiff to disclose a material fact; (2) the defendant failed to disclose that fact; (3) the defendant intended to defraud or deceive the plaintiff; (4) the plaintiff took action in justifiable reliance on the concealment; and (5) the plaintiff suffered damages as a result of the defendant's concealment.

Lawley v. Northam, No. ELH-10-1074, 2011 WL 6013279, at *9 (D.Md. Dec. 1, 2011) (quoting Lloyd v. Gen. Motors Corp., 916 A.2d 257, 274 (Md. 2007)). Finally, to establish negligent misrepresentation, a plaintiff must show

> (1) the defendant, owing a duty of care to the plaintiff, negligently asserts a false statement; (2) the defendant intends that his statement will be acted upon by the plaintiff; (3) the defendant has knowledge that the plaintiff will probably rely on the statement, which, if erroneous, will cause loss or injury; (4) the plaintiff, justifiably, takes action in reliance on the statement; and (5) the plaintiff suffers damage proximately caused by the defendant's negligence.

Id. (quoting Lloyd, 916 A.2d at 273).

Here, Conway has failed to cite evidence sufficient to demonstrate that she or Staiman relied on any misrepresentations made by AMS. In her Opposition, Conway does not identify AMS' allegedly false statement or statements central to her fraud-based claims. Assuming she relies on the same misrepresentations she used in her failure to warn claims, Conway contends that AMS misrepresented the Monarc's tendency to lead to "chronic pain and permanent pain during sex" and the risk of complications in patients with prior pain syndromes. (Opp'n at 4–5). Conway does not cite any evidence that demonstrates that she

relied on AMS' statements or omissions in this regard. (See Opp'n at 14–15). As outlined supra in Section II.B.3, Conway testified that she did not rely on any advertising from AMS in deciding to use the Monarc device, she never talked to any representative from AMS at any time, she never received any statements made to her by any representatives of AMS at any time, and she did not rely on anything given to her by an AMS representative in filing her lawsuit. (Conway Dep. at 250:10–23).

Further, although Conway correctly indicates that Maryland law recognizes liability for misrepresentations made to third parties, see Md. Nat'l Bank v. Resol. Tr. Corp., 895 F.Supp. 762, 772 (D.Md. 1995), she has not demonstrated that Staiman relied on any misrepresentations, either. See Morris, 491 F.Supp. at 105–06 (noting that the plaintiff "must still demonstrate that [the third party] relied on those misrepresentations"). While Conway argues that Staiman testified that she was not aware of the risks of chronic pain and chronic sexual pain, that mischaracterizes the testimony. Staiman actually said that she did not specifically discuss the risks of chronic pain and chronic pain during sex with Conway, not that she was unaware of those risks altogether:

> Q: Okay. Is it fair to say that you never specifically discussed with Ms. Conway the risk of chronic pain from the mesh?
>
> A: According to my record, I did not.
>
> Q: Okay. Is it fair to say that you never discussed the risk of chronic sexual pain with Ms. Conway?
>
> A: According to my record, I did not.

(Staiman Dep. at 26:6–16 (emphasis added)).[16] Further, although she testified that she would not have performed the surgery if it were contraindicated for the patient, she specifically said that Conway was not contraindicated for the surgery based on what she knew at the time. (Id. at 18:2–11, 30:15–31:6). Moreover, Staiman said that she adequately advised Conway of the risks of the device. (Id. at 81:5–9). Critically, Conway offers no evidence to suggest that she was contraindicated for the procedure or that Staiman has since learned of any such contraindications. At most, Conway offers speculative questions posed by her counsel during Staiman's deposition about how Staiman would react if she were aware of hypothetical contraindications not otherwise supported by the evidence. (See id. at 30:15–31:6, 35:1–9; see generally Rosenzweig Report; Feb. 14, 2008 Email at 1). This evidence is insufficient support for her fraud claims. Accordingly, the Court will dismiss Conway's claims for fraud, fraudulent concealment, and negligent misrepresentation. (Counts VII, VIII, & X).

6. Punitive Damages

Finally, Conway has made a claim for punitive damages. Punitive damages may be awarded where the plaintiff "has established that the defendant's conduct was characterized by evil motive, intent to injure, ill will, or fraud, i.e., 'actual malice.'" Morris, 491 F.Supp.3d at 108 (quoting Owens-Illinois, Inc. v. Zenobia, 601 A.2d 633, 652 (Md. 1992)). Moreover,

> in 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

[16] The Court has omitted objections for clarity and concision.

> 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. (quoting Zenobia, 601 A.2d at 653). "In either case, the evidence must show malicious conduct and not simply the supplying of a defective product or negligence." Id. (quoting Zenobia, 601 A.2d at 655). The plaintiff must prove her claim for punitive damages by clear and convincing evidence. Id.

AMS argues that Conway has failed to present any evidence to show that AMS acted with actual malice. (Mot. at 14). Conway responds by pointing to the following contentions she claims are supported by the evidence: (1) Total Petrochemicals USA, the company that formulated the polypropylene resin used in the Monarc device, "has not given any indication that [the resin] is intended or suitable for use in a permanently implanted medical device"; (2) AMS used the resin "without even knowing what exactly is in it" because AMS did not "investigate what antioxidants and/or stabilizers are added to the polypropylene material until after" Conway's surgery; (3) AMS did not conduct sufficient testing of the device before it was sold; (4) AMS did not adequately warn of the dangers of implanting polypropylene; and (5) AMS did not warn of "chronic pain and pain during sex" in the Monarc IFU. (Opp'n at 16–17). A review of the record, however, provides little to no support for these assertions. For example, Conway identifies nothing in the record about Total Petrochemicals USA's determinations regarding the use of their polypropylene resin in permanent medical devices. Moreover, Conway points to no evidence to support her contention that AMS used the resin "without even knowing what exactly is in it."

(Opp'n at 16). All Conway has offered is a short report created by Allen Noreen, Ph.D., finding that some unspecified polypropylene samples contained "Irganox" 1010, 1076, and 3114, without offering the relevance of those additives. (Noreen Report at 2, ECF No. 18-85). The evidence presented thus does not clearly and convincingly demonstrate that AMS knew the polypropylene used in the Monarc was unsafe for permanent implantation and deliberately disregarded that fact. As such, Conway has failed to set forth sufficient evidence on summary judgment to establish actual malice. Accordingly, AMS is entitled to judgment on Conway's request for punitive damages.[17]

III. CONCLUSION[18]

For the foregoing reasons, the Court will grant in part and deny in part AMS' Motion for Summary Judgment (ECF No. 18-56) and Supplement thereto (ECF No. 32). A separate Order follows.

Entered this 28th day of December, 2021.

/s/
George L. Russell, III
United States District Judge

[17] Although Conway does not include a separate count for punitive damages, she does list it in her separate prayer for relief and at the end of each of her counts. (See Compl. at 16, 18–19, 23–24, 26, 29, 31, 33–34).

[18] AMS argues that Conway cannot establish claims for negligent testing, inspection, marketing, packaging, or selling. (Mot. at 10). Conway responds that she has not made a separate claim on any of these issues and therefore AMS' arguments are moot. (Opp'n at 12). The Court agrees with Conway and will not address AMS' arguments regarding separate claims for negligent testing, inspection, marketing, packaging, or selling, as there are none. (See generally Compl.).