IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PAULA M. DONALDS,	*	
Plaintiff,	*	
v.	*	Civil Action No. GLR-20-1659
ETHICON, INC., et al.,	*	
Defendants.	*	

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MEMORANDUM OPINION

THIS MATTER is before the Court on Defendants Ethicon, Inc. and Johnson & Johnson's (collectively, "Ethicon") Motion for Summary Judgment (ECF No. 63). 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 Ethicon's Motion for Summary Judgment.

I. BACKGROUND

A. Donalds' Treatment

Plaintiff Paula Donalds began to struggle with urinary incontinence in late 2012 or early 2013. (Paula Donalds Dep. ["Donalds Dep."] at 50:3–9, ECF No. 63-1). On July 17, 2014, Dr. Christine O'Connor implanted her with a TVT Abbrevo device, a type of mesh product produced by Ethicon, to help treat her condition. (Medical Rs. ["Med. Rs."] at 9,[1] ECF No. 63-2). After the surgery, Donalds suffered from bladder spasms, pain, and burning

[1] Citations to exhibit page numbers refer to the pagination assigned by the Court's Case Management/Electronic Case Files ("CM/ECF") system.

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sensations. (Donalds Dep. at 18:2–17, 21:17–23, 22:2–10). She also experienced continued symptoms of her stress urinary incontinence, including leaking. (Id. at 20:20–22). On July 25, 2016, Dr. Richard Ellerkmann performed surgery to remove portions of the TVT mesh product which had eroded. (Id. at 21:11–20; July 25, 2016 Operative Rep. at 1, ECF No. 64-1). During the revision procedure, Ellerkmann identified "two areas of discrete vaginal mesh exposure, one area suburethrally in the midline" and a larger, two-centimeter area of mesh erosion in the "right distal vaginal sulcus." (July 25, 2016 Operative Rep. at 1). Ellerkmann noted that upon examination at the end of this procedure, "there was no evidence of any further mesh exposure." (Id. at 2).

On October 3, 2016, Ellerkmann implanted Donalds with a different mesh device also produced by Ethicon, the TVT Exact, to treat her "[r]ecurrent stress incontinence" and pain. (Oct. 3, 2016 Operative Rep. at 1, ECF No. 64-2). Donalds complains of complications connected to the TVT Abbrevo only. (See Donalds Dep. at 13:14–21).

B. O'Connor's Testimony

During her deposition, O'Connor reviewed an exhibit prepared by Ethicon outlining the risks of "non-mesh" and mesh stress urinary incontinence surgeries ("Risk Chart"). (Dr. Christine O'Connor Dep. ["O'Connor Dep."] at 28:17–19, ECF No. 63-5; Risk Chart at 2–3, ECF No. 63-6). She testified that she was familiar with the potential risks identified in the Risk Chart related to surgeries utilizing mesh, including pain with intercourse, vaginal scarring, infection, urinary problems, organ/nerve damage, bleeding, wound complications, inflammation, recurrence, failure, foreign body response, erosion, contraction, and shrinkage. (O'Connor Dep. at 30:3–6; Risk Chart at 3). She learned of the

risks related to use of mesh from publications and practice statements from the American College of Obstetricians and Gynecologists and the American Urogynecologic Society as well as from her training and education. (O'Connor Dep. at 32:15–22). Further, she was familiar with the risks identified in the Risk Chart at the time of Donalds' surgery in 2014, (id. at 30:7–10), calling them "typical risks that we would quote to patients for these types of surgeries," (id. at 36:2–4).

O'Connor indicated that she relied on the instructions for use ("IFU") affiliated with the TVT Abbrevo as "a reminder of step-by-step instructions." (Id. at 35:3–9). O'Connor did not rely on the IFU in recommending the product to Donalds. (Id. at 36:5–7). She only relied on the IFU to inform her of the risks "[i]n part," as she also relied on her training, education, and review of medical literature. (Id. at 35:10–25). She indicated that even if Ethicon had included all the risks identified in the Risk Chart in the IFU, she would not have changed her decision to prescribe Donalds the device. (Id. at 35:15–25). She testified that she stood by her decision to recommend the TVT Abbrevo to Donalds despite the risks because "[i]t was a good option for her." (Id. at 71:16–20).

C. Summary of Expert Opinions

Donalds designated four expert witnesses: (1) Jerry Blaivas, M.D. (general); (2) Uwe Kling, M.D., Ph.D. (general); (3) Vladimir Iakovlev, M.D. (general); and (4) Richard L. Luciani, M.D. (case-specific causation). (Pl.'s Am. Designation Disclosure Case-Specific Expert Witnesses at 1–2, ECF No. 63-7). Ethicon, on the other hand, designated Nina Bhatia, M.D. (N. Bhatia Expert Report ["Bhatia Rep."] at 2, ECF No. 63-9).

Dr. Richard Luciani is a board-certified gynecologist in New Jersey and Donalds' only case-specific expert. Luciani provided a two-page opinion indicating "that the complications Donalds endured following implantation of the TVT [Abbrevo] mesh product . . . were proximately caused by the erosion of the mesh product." (R. Luciani Expert Report ["Luciani Rep."] at 2, ECF No. 64-3). He opines that the complications include pain, vaginal bleeding, bladder spasms, headaches, and urinary leakage and that the treatment of the mesh erosion was reasonable and necessary. (Id.).

Dr. Jerry Blaivas is a board-certified urologist based in New York. (J. Blaivas Expert Report at 1, ECF No. 64-5). He opines that the "TVT Abbrevo causes serious and life-style altering complications," including chronic pelvic pain syndrome, chronic dyspareunia, nerve injuries, and de novo urinary symptoms. (Id. at 4). Blaivas outlines the problems with the mesh used in Donalds' implant that make it unsuitable for permanent implantation, including: "(1) excessive rigidity of laser-cut mesh; (2) degradation of the mesh; (3) chronic foreign body reaction; (4) infections and bio-films; (5) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (6) shrinkage/contraction of the encapsulated mesh." (Id. at 13). Blaivas explains that the mesh is "laser cut" in the manufacturing process as opposed to mechanically cut, which he contends leads the mesh to be more rigid, stiff, and prone to erode. (Id.). Blaivas opines that slings using biologic materials and polypropylene sutures are safer than synthetic slings. (Id. at 7, 11).

Dr. Uwe Klinge is a general and abdominal surgeon. (U. Klinge Expert Report at 1, ECF No. 64-4). Klinge outlines several qualities of the TVT mesh that make it dangerous. For example, he describes how TVT mesh creates a chronic inflammatory response that

leads to scarring around the mesh. (Id.). Further, the weight of the mesh increases the risk of injury to a patient, as lighter mesh causes fewer complications. (Id. at 2). Klinge also opines that the smaller the distance between the fibers of the mesh, the greater the risk of scar tissue forming in the pores. (Id.). Additionally, Klinge explains that the pores of the mesh "deform and collapse," which increases the risk of injury to patients. (Id.). Finally, Klinge describes the TVT mesh's propensity to contract or shrink thirty to fifty percent after implantation and otherwise deform, fray, and rope, causing injury. (Id. at 3).

Dr. Vladimir Iakovlev is an anatomical pathologist based in Toronto, Canada. (V. Iakovlev Expert Report at 1, ECF No. 64-6). Iakovlev opines that the TVT mesh acts as a foreign object in the body, which causes the body to attempt "to degrade and isolate the mesh." (Id. at 13). The mesh and the body's reaction to the mesh cause damage to the body's tissues, which Iakovlev opines occurs in all patients to varying degrees. (Id.). Iakovlev further opines that the mesh can migrate in the body, which he describes as "one of the mechanisms for mesh erosion through vaginal mucosa." (Id. at 12). Mesh can also deform, or move from its original or intended position, leading to wrinkling, folding, curling, or "roping" of the mesh. (Id.). The mesh can also contract or shrink and stiffen in the body, causing harm. (Id. at 12–13).

Bhatia provided an opinion for Ethicon. Bhatia is a board-certified obstetrician and gynecologist in New Jersey. (Bhatia Rep. at 2). Bhatia opines that Donalds' TVT Abbrevo implant was successful and that her recurrence of symptoms was caused by an unrelated workplace accident on August 9, 2014. (Id. at 10–11). She contends that "it is likely that the forces that acted on her during this accident affected the healing of her surgical site[]

and contributed to the development of recurrent leakage." (Id. at 10). She further opines that the primary contributor to Donalds' mesh exposure was a scissor puncture that occurred during the implantation procedure. (Id.). Bhatia also indicates that the Abbrevo included warnings regarding mesh extrusion and erosion and that O'Connor warned Donalds of that risk as documented in her operative note. (Id. at 11).

D. Procedural History

On April 3, 2017, Donalds filed a short-form Complaint in the ongoing multi-district litigation in the United States District Court for the Southern District of West Virginia regarding pelvic mesh. (ECF No. 1). On April 7, 2017, Donalds amended her Complaint. (ECF No. 4). Donalds alleges claims against both Defendants for: negligence (Count I); strict liability – manufacturing defect (Count II); strict liability – failure to warn (Count III); strict liability – defective product (Count IV); strict liability – design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); unjust enrichment (Count XV); punitive damages (XVII); and discovery rule and tolling (Count XVIII).[2] (Am. Compl. at 4–5). The Amended Complaint does not specify the precise damages Donalds seeks. (See id.).

[2] The Amended Complaint omits Count XVI. (See generally Am. Compl.).

The court issued a Pretrial Order setting the trial schedule on January 30, 2018 (ECF No. 10) and an amended Pretrial Order on June 13, 2018 (ECF No. 16). On October 12, 2018, Ethicon filed a Motion for Partial Summary Judgment. (ECF No. 20). On October 29, 2018, Donalds filed her Opposition. (ECF No. 22). On June 8, 2020, the Southern District of West Virginia transferred the case to this Court after finding that it would be more expeditiously concluded in the venue in which it arose. (Transfer Order at 1, ECF No. 30).

On September 10, 2020, this Court referred the case for settlement and denied Ethicon's Motion for Partial Summary Judgment without prejudice, indicating that Ethicon could reinstate its motion should settlement negotiations fail. (ECF No. 53). On March 4, 2021, the parties filed a Joint Status Report indicating that they were unable to resolve the case during the settlement conference. (Joint Status Rep. at 1, ECF No. 55). Ethicon included a request to supplement its original summary judgment briefing, which Donalds opposed. (Id. at 2–3). On April 9, 2021, the Court convened a teleconference with the parties and issued an Order finding that supplemental briefing was appropriate. (ECF No. 56).

On May 7, 2021, the Court approved the parties' Joint Stipulation of Partial Voluntary Dismissal dismissing Donalds' claims for manufacturing defect under the negligence theory and strict liability (Count II; Count I, in part; Count XIV, in part),[3] strict

[3] As explained more fully below, Donalds raises products liability claims under strict liability and negligence. As such, her claims for failure to warn and design defect are raised through individual strict liability counts (Count III & Count V, respectively) and general negligence counts (Count I, negligence & Count XIV, gross negligence).

liability – defective product (Count IV), negligent infliction of emotional distress (Count X), and unjust enrichment (Count XV) with prejudice. (ECF No. 59).

On June 23, 2021, Ethicon filed its renewed and supplemental Motion for Summary Judgment. (ECF No. 63). On July 15, 2021, Donalds filed her Opposition contesting many of Ethicon's arguments but agreeing to voluntarily withdraw her standalone claims for punitive damages (Count XVII) and discovery rule and tolling (Count XVIII).[4] (ECF No. 64). Ethicon filed a Reply on July 30, 2021. (ECF No. 65).

On November 17, 2021, the Court issued an Order directing the parties to file supplemental briefing regarding the admissibility of Luciani's expert opinion. (Nov. 17, 2021 Letter Order at 1, ECF No. 66).[5] Donalds submitted her Supplemental Brief in Further Opposition on November 29, 2021. (ECF No. 67). Ethicon filed its Supplemental Brief in Support of its Motion for Summary Judgment on December 6, 2021. (ECF No. 68).

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

[4] The Court will accordingly grant Ethicon's Motion as to Counts XVII and XVIII.

[5] The Order explains that Ethicon's Motion "questions the admissibility" of Luciani's opinion and asks that the parties more fully address the admissibility of his opinion under Federal Rule of Evidence 702. (Nov. 17, 2021 Letter Order at 1).

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 "must set forth specific facts, either by affidavit or other evidentiary showing, demonstrating a genuine dispute for trial." Sanchez Carrera v. EMD Sales, Inc., 402 F.Supp.3d 128, 144 (D.Md. 2019). 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) (quoting Fed.R.Civ.P. 56(c)). Thus, summary judgment is warranted if the nonmovant does not provide evidence to establish an essential element of the case. Brocious v. U.S. Steel Corp., 429 F.Supp.3d 82, 86 (D.Md. 2019).

B. Analysis[6]

1. Design Defect

Donalds raises claims premised in whole or in part on an alleged design defect. Specifically, Donalds' design defect claims form part of her negligence claims (Count I & Count XIV) and all of her strict liability – design defect claim (Count V). Ethicon's arguments regarding Donalds' design defect claims center around the inadmissibility of

[6] The parties correctly agree that Maryland law applies. 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))). Donalds' implant procedure was performed in Maryland, so Maryland law applies. (See Med. Rs. at 9).

Donalds' one case-specific expert's causation opinions. Accordingly, the Court will briefly summarize the rules regarding admissibility of expert testimony.

Rule 104(a) of the Federal Rules of Evidence provides that the Court "must decide any preliminary question about whether a witness is qualified . . . or evidence is admissible." This assessment includes a requirement that the Court determine admissibility of expert testimony under Rule 702. McCoy v. Biomet Orthopedics, LLC, No. ELH-12-1436, 2021 WL 252556, at *9 (D.Md. Jan. 25, 2021). The party seeking to present the expert testimony is responsible for establishing its admissibility by a preponderance of the evidence. Id. Here, that party is Donalds.

Rule 702 states:

> 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.

(emphasis added). Under the Rule, "a properly qualified expert witness may testify regarding technical, scientific, or other specialized knowledge in a given field if the testimony would assist the trier of fact in understanding the evidence or to determine a fact in issue, and the testimony is both reliable and relevant." McCoy, 2021 WL 252556, at *10. The Court's "gatekeeping role" requires it to make determinations "of whether the

reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. (quoting Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 592–93, 597 (1993)).

In order for evidence to be reliable, "the testimony must be grounded 'in the methods and procedures of science,' and it must be something more than subjective belief or unsupported assumptions." Id. (quoting Daubert, 579 U.S. at 590). To be relevant, the testimony must have "a valid scientific connection to the pertinent inquiry." Id. (quoting Belville v. Ford Motor Co., 919 F.3d 224, 232 (4th Cir. 2019)). Daubert provides the following, non-exhaustive factors for reviewing the reliability of an expert opinion:

> (1) whether the particular scientific theory has been or can be tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; (4) whether there are standards controlling the method; and (5) whether the technique has gained general acceptance in the relevant scientific community.

Id. at *11 (citing Daubert, 509 U.S. at 593–94).

This Court will not "admit opinion evidence that is connected to existing data only by the ipse dixit of the expert [where there is] simply too great an analytical gap between the data and the opinion proffered." JFJ Toys, Inc. v. Sears Holdings Corp., 237 F.Supp.3d 311, 322 (D.Md. 2017) (quoting Pugh v. Louisville Ladder, Inc., 361 F.App'x 448, 454 n.4 (4th Cir. 2010)). "Expert testimony rooted in subjective belief or unsupported speculation does not suffice." Id. (quoting Zuckerman v. Wal-Mart Stores E., LLP, 611 F.App'x 138, 138 (4th Cir. 2015)).

Ethicon contends that Donalds' one case-specific expert, Luciani, provided an unreliable ipse dixit because he did not explain the methodology he used in reaching his conclusions. (Mot. Summ. J. Mem. Supp. ["Mot."] at 10–16, ECF No. 63; Suppl. Brief Further Supp. Defs.' Mot. Summ. J. ["Suppl. Mot."] at 2–7, ECF No. 68). Further, Ethicon argues that if Luciani performed a differential diagnosis, he did so improperly. As Luciani is Donalds' only case-specific expert, Ethicon contends that without his opinion, she cannot establish the necessary element of causation and therefore her design defect claims must fail. Donalds responds that Luciani's opinion is sufficiently grounded and that if Ethicon "wanted to dive deeper into how Dr. Luciani formed his opinion . . . , they should have taken his deposition." (Pl.'s Opp'n Defs.' Mot. Summ. J. ["Opp'n"] at 10, ECF No. 64). At bottom, the Court agrees that Luciani's opinions are inadmissible and will grant Ethicon's Motion as to Donalds' design defect claims (Count I – in part; Count V; Count XIV – in part).

Here, Luciani issued a two-page report addressing specific causation. The report, dated June 4, 2018, includes the following conclusion:

> It is my opinion to a reasonable degree of medical probability that the complications Ms. Donalds endured following implantation of the TVT ABBREVO mesh product, as described above, were proximately caused by the erosion of the mesh product. These complications include pain (during intercourse and otherwise), vaginal bleeding, bladder spasms, headaches, and urinary leakage. The medical procedures Ms. Donalds underwent to treat the mesh erosion and continued stress incontinence, and the related costs, were reasonable and necessary.

(Luciani Rep. at 2). But Luciani does not explain how he reached this conclusion. Instead, he provides only a brief recitation of the documents he reviewed and offers a short summary of Donalds' surgical history. (Id. at 1). He does not explain how the alleged erosion caused her complications or why he reached that outcome. (See id. at 1–2).

Federal Rule of Civil Procedure 26 requires that an expert's report include "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed.R.Civ.P. 26(a)(2)(B)(i) (emphasis added). The short summary of Donalds' medical records, without more, is insufficient to demonstrate that Luciani applied a reliable methodology in reaching his conclusion that Donalds' complications "were proximately caused by the erosion of the mesh product." (Luciani Rep. at 2). See JFJ Toys, 237 F.Supp.3d at 323–24 (holding that an expert witness' opinion was unreliable and inadmissible where it "[fell] short of reliably applying any alleged expertise . . . in reaching his conclusion"); see also Zenith Elecs. Corp. v. WH-TV Broad. Corp., 395 F.3d 416, 419 (7th Cir. 2005) ("An expert must offer good reason to think that his approach produces an accurate estimate using professional methods."). As Luciani offers no explanation of his methods, his opinion does not rise above the level of "belief or speculation" and is ipse dixit. McCoy, 2021 WL 252556, at *11 (quoting Oglesby v. Gen. Motors Corp., 190 F.3d 244, 250 (4th. Cir. 1999)). Further, under Rule 26, Luciani needed to supply the basis and reasons for his opinions in his written report. The two-page report includes neither. Accordingly, his opinions are inadmissible under Rule 702.

As stated above, this Court gave the parties an opportunity to submit supplemental briefing on the admissibility of Luciani's opinions. (See generally Suppl. Mot.; Suppl.

Brief Further Opp'n Defs.' Mot. Summ. J. ["Suppl. Opp'n"], ECF No. 67). This was primarily to offer Donalds the chance to address Ethicon's broader admissibility arguments in addition to the differential diagnosis argument that formed most of Ethicon's initial briefing. In her Supplemental Opposition, Donalds attempts to stitch together a rationale for Luciani's opinions, pulling together information from the medical records to suggest that Luciani relied on aspects of those records as the basis for his opinions. (Suppl. Opp'n at 4).[7] But Donalds cannot append Luciani's unsupported opinions with her own rationale and turn an insufficient methodology into a sufficient one.

Donalds next argues that the unsupported report is justifiable because Ethicon had the opportunity to depose Luciani during discovery "to further elucidate the completeness of his opinions and the basis for them." (Suppl. Opp'n at 4–5; see also Opp'n at 10). Donalds points out that Ethicon declined to do so, implying that Ethicon cannot now complain that it does not have more information on Luciani's methodology. This, too,

[7] Donalds explains that Luciani reviewed her operative reports and she outlines in detail her complaints listed in those reports. (Suppl. Opp'n at 3–4). She then clips Ellerkmann's factual synopsis included in his October 3, 2016 report, and concludes:

> Based upon Dr. Luciani's review of Ms. Donalds' medical records, he concluded that her complaints of pain, incontinence, and vaginal bleeding were proximately caused by the erosion of the TVT mesh that was implanted in her. Dr. Luciani's opinion is consistent with Dr. Ellerkmann's impressions as set forth in the medical records. [] Luciani's opinions are also consistent with the complications that Doctors Klinge, Blaivas, and Iakovlev explained would likely occur in women implanted with the defectively designed mesh.

(Suppl. Opp'n at 4).

misses the mark. As the party seeking to enter this expert testimony, it is Donalds' burden to show by a preponderance of the evidence that it is admissible. McCoy, 2021 WL 252556, at *9. Donalds cannot point the finger at Ethicon for its failure to draw out the grounds for her expert's opinions in a deposition. The obligation to provide a well-supported, reliable expert report is hers, and the failure to do so is hers as well. See Fed.R.Civ.P. 26(B)(i).

Further, the Court notes that Donalds attached an affidavit by Luciani to her Supplemental Opposition offering a previously undisclosed explanation of his methodology. (See Aff. Richard L. Luciani, M.D. at 1, ECF No. 67-1). The affidavit, dated November 24, 2021, was not produced during discovery. Indeed, it appears that it was created solely for purposes of Donalds' Supplemental Opposition to Ethicon's Motion for Summary Judgment. The affidavit has been submitted far too late to be fairly considered. As Ethicon notes, Donalds had until July 13, 2018 to submit her expert disclosures and reports. That date has long passed. And a party that does not provide information required under Rule 26(a) may not later use that information to supply evidence on a motion unless the failure to timely turn it over "was substantially justified or is harmless." Fed.R.Civ.P. 37(c)(1). Donalds offers no explanation for why her last-minute affidavit is justified or harmless here, and the Court will not consider it.

As Luciani's opinions are unreliable and inadmissible, Donalds' design defect claims must fail. Design defect claims, whether under strict liability or negligence, require a showing of three elements, "defect, attribution of defect to the seller, and a causal relationship between the defect and the injury." Morris v. Biomet, Inc., 491 F.Supp.3d 87, 103 (D.Md. 2020) (emphasis added). "For specific causation, the plaintiff must

demonstrate that the substance actually caused injury in her particular case." See McCoy, 2021 WL 252556, at *8 (internal quotation marks omitted). Proof of a defect "must arise above surmise, conjecture or speculation." Parker v. Allentown, Inc., 891 F.Supp.2d 773, 780 (D.Md. 2012) (quoting Virgil v. Kash N' Karry Serv. Corp., 484 A.2d 652, 657 (Md.Ct.Spec.App. 2005)). Luciani was Donalds' only case-specific expert linking the alleged defects in the TVT Abbrevo to Donalds' injuries. Without his opinion, Donalds has no evidence on specific causation, a necessary element of her design defect claims. Accordingly, Donalds' design defect claims fail as a matter of law and the Court will dismiss Counts I and XIV to the extent they allege a design defect and Count V in its entirety.[8]

2. Failure to Warn

Donalds alleges that Ethicon is liable in negligence and strict liability for failure to warn of the risks of the TVT Abbrevo device. (Count I – in part; Count III; Count XIV –

[8] Ethicon also argues that Donalds' design defect claims fail because the risk-utility test applies and Donalds has failed to offer evidence of a feasible safer alternative design. (Mot. at 17–22). Although the Court need not reach the argument here, Ethicon is incorrect. The consumer expectation test applies, and that standard does not require proof of an alternative design. 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); Halliday v. Sturm, Ruger & Co., 792 A.2d 1145, 1150, 1153 (Md. 2002) ("[T]he risk-utility test does not apply to a design defect unless the product malfunctions in some way.").

in part). Donalds' claims require an understanding of the learned intermediary doctrine and the "heeding presumption" applicable to certain failure-to-warn claims.

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, 491 F.Supp.3d at 103–04 (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).[9] "A warning is

[9] 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

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).

In addition, Maryland courts have recognized a heeding presumption that may assist a plaintiff in establishing the element of causation. Samuel v. Ford Motor Co., 112 F.Supp.2d 460, 463 (D.Md. 2000). The presumption provides that a plaintiff "would have heeded a legally adequate warning had one been given." Id. (quoting U.S. Gypsum Co. v. Mayor & City Council of Balt., 647 A.2d 405, 413 (Md. 1994)). At a minimum, the

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> instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> > (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).

presumption permits jurors to consider the "natural instinct" and "disposition" of an individual to guard himself against danger. Id. (quoting Eagle-Picher Indus., Inc. v. Balbos, 604 A.2d 445, 469 (Md. 1992)). Maryland law, specifically Rule 5-301, governs this presumption. Id. The presumption continues to exist even after evidence is presented to meet or rebut it "unless the Court determines that the rebuttal evidence overcomes the presumption as a matter of law." Id. "The presumption may be rebutted where there is evidence that the personalities or dispositions of the [plaintiffs] were such that they clearly would have ignored the warnings." McCoy, 2021 WL 252556, at *27 (quoting Waterhouse v. R.J. Reynolds Tobacco Co., 162 F.App'x 231, 235 (4th Cir. 2006) (internal quotation marks omitted)). When the heeding presumption and learned intermediary doctrine apply, this Court has looked to the intermediary's conduct to determine whether a defendant has rebutted the presumption. See id. The Court makes its determination regarding the presumption based on the summary judgment record before it. See id. at *27–28.

"To establish causation-in-fact, plaintiff[] must prove not only that [O'Connor] 'would have read, understood, and remembered the warning, but also that [she] would have altered [her] conduct to avoid the injury.'" Id. (quoting Waterhouse, 162 F.App'x at 234) (internal quotation marks omitted). In order to establish causation under the doctrine, the plaintiff must prove that the treating provider, in this case O'Connor, "would have acted differently had [she] received an adequate warning." McCoy, 2021 WL 252556, at *27.

Donalds states in her Opposition that Ethicon failed to warn O'Connor of the TVT Abbrevo's tendency "to deform, fray, lose particles, curl and rope." (Opp'n at 15). Donalds further alleges that Ethicon "[misled] the medical community not only about the specific

complications that the product poses to patients but also as to the permanent nature of those complications and the odds of those complications presenting." (Id.).[10] Ethicon argues that she has failed to produce any evidence on the element of causation. (Mot. at 25). Specifically, Ethicon argues that Donalds obtained no testimony or other evidence that a different, purportedly adequate warning would have changed O'Connor's prescribing decision. (Id.). Donalds does not point to specific evidence but responds that the heeding presumption is sufficient to create a triable issue. (Opp'n at 16). At bottom, the Court agrees with Ethicon.

As an initial matter, Donalds is correct that the heeding presumption applies in this action. Thus, the Court can at least initially conclude that O'Connor, as the learned intermediary, would have heeded an adequate warning if one had been given. This means that under the theories presented by Donalds on summary judgment, Donalds is entitled to a presumption that if O'Connor had been adequately warned of the risk that the TVT Abbrevo had a tendency to deform, fray, lose particles, curl, and rope, or of the risk of permanent complications, that she would have somehow altered her prescription decision.

[10] In her Opposition, Donalds attempts to argue about the general risks of the device without pinpointing which risks Ethicon allegedly omitted from its warnings leading to her injuries. (See Opp'n at 14–18). Her attempts to argue generally place the Court in the position of making specific arguments on her behalf. The Court declines to do so. See United States v. Davis, 622 F.App'x 758, 759 (10th Cir. 2015) ("[I]t is not this court's duty, after all, to make arguments for a litigant that he has not made for himself."); Wootten v. Commonwealth of Virginia, 168 F.Supp.3d 890, 895–96 (W.D.Va. 2016) ("[C]ourts widely agree that parties have the burden to present legal arguments in the first instance." (citing cases)). Accordingly, the Court will conduct its analysis using only the specific risks Donalds mentions in her response to Ethicon's failure to warn arguments, even if those risks were intended only as examples. (See id.).

Under Maryland Rule 5-301, which governs presumptions in civil cases, the heeding presumption offers Donalds the benefit of moving forward with a fact presumed to help satisfy her burden of production on the element of causation. See Rule 5-301; Anderson v. Litzenberg, 694 A.2d 150, 157 (Md. 1997) (interpreting Rule 5-301(a)).

But the presumption alone is not enough to withstand judgment here. As outlined above, Ethicon may rebut the heeding presumption by presenting evidence on the "personalities or dispositions" of the intermediary that would tend to show that the intermediary would have "ignored warnings" even if they had been given. See McCoy, 2021 WL 252556, at *27 (quoting Waterhouse, 162 F.App'x at 234). Here, O'Connor testified in her deposition that she was "pretty sure" that she had seen the IFU affiliated with the TVT Abbrevo before the date of her deposition. (O'Connor Dep. at 33:24–34:1). She did not remember exactly when she reviewed the IFU, though, and she also could not remember the last time she saw it. (Id. at 34:4–7). Further, O'Connor only partially relied on the TVT Abbrevo's IFU to inform her of the risks associated with the device, as she also relied on "everything else," including her "training and literature." (Id. at 35:10–14). O'Connor also specifically did not rely on the IFU in recommending the Abbrevo to Donalds. (Id. at 36:5–7).[11] Moreover, she stood by her decision to recommend the TVT

[11] Additionally, O'Connor testified that she was already aware of a number of the risks tied to the use of mesh at the time of Donalds' surgery, including: acute and/or chronic pain with intercourse, acute and/or chronic pain, vaginal scarring, infection, urinary problems including frequency, urgency, dysuria, retention, obstruction, and incontinence, organ/nerve damage, bleeding, wound complications, inflammation, fistula formation, neuromuscular problems, one or more surgeries to treat an adverse event, recurrence or failure, foreign body response, erosion, exposure, extrusion, contraction, and shrinkage of tissues. (Id. at 29:5–30:15; Risk Chart at 2).

Abbrevo to Donalds because "[i]t was a good option for her." (Id. at 66:4–6, 71:12–20). And O'Connor said that she would not have changed her decision to prescribe the TVT Abbrevo after reviewing the Risk Chart. (Id. at 35:18–25). Taken together, Ethicon has produced evidence showing that O'Connor did not place great weight on Ethicon's IFU. This Court finds that, based on the summary judgment record before it, Ethicon has adequately rebutted the heeding presumption.

Finally, beyond her general reliance on the presumption, Donalds has not presented any evidence on causation regarding her failure-to-warn claims. "[T]he party favored by the presumption is not relieved of the requirement of presenting evidence to establish a prima facie case as to those issues for which [she] bears the burden of proof if the adverse party sufficiently rebuts the presumption." Anderson, 694 A.2d at 158. Here, Ethicon has rebutted the presumption and Donalds elicited no evidence during O'Connor's deposition as to the risks she contends caused her harm—specifically, the tendency of the product to warp and the high risk of permanent complications. Donalds did not ask O'Connor about these alleged risks, nor did she elicit testimony that O'Connor would have changed her prescription decision if she were adequately warned of these risks. Accordingly, her failure-to-warn claims are insufficient to withstand judgment. The Court will dismiss Donalds' negligence claims to the extent they are premised on a failure to warn and her claim for strict liability – failure to warn in its entirety. (Count I – in part; Count III; Count XIV – in part).[12]

[12] The Court notes that it has not reached a determination on the adequacy of Ethicon's warnings regarding the TVT Abbrevo. Ethicon has not argued on summary

3. Breach of Warranty

Ethicon argues next that the Court should dismiss Donalds' claims for breach of express warranty (Count XI) and breach of implied warranty (Count XII) for lack of causation. The Court will dismiss the claims.

To prove that Ethicon breached an express warranty, Donalds 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 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)). 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 421 (citing Md. Code Ann., Com. Law § 2-314). Like Donalds' 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. at 422.

Ethicon argues, among other things, that the Court should dismiss Donalds' breach of express and implied warranty claims for lack of causation, an essential element of both claims. (Mot. at 30). Donalds responds that Ethicon "bear[s] the burden of proof at this stage of the litigation [and it has] failed to present any evidence to suggest [she] cannot meet her burden at trial." (Opp'n at 19). She argues further that she "intends to present

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judgment that its warnings were adequate, and even if the Court wished to consider the issue, the parties have not provided the IFU for the TVT Abbrevo device. Upon review, it appears that Ethicon attached the IFU for a different device, the TVT Exact, to its Motion. (See TVT Exact IFU at 2, ECF No. 63-4).

evidence at trial to sustain her cause[] of action for . . . breaches of express and implied warranties." (Id.). The Court agrees with Ethicon.

As set forth above, without Luciani's expert opinion, Donalds has no admissible evidence on case-specific causation. Therefore, her breach of warranty claims must fail on the same grounds as her design defect claims. Moreover, Donalds does not even attempt in her Opposition to set forth the evidence upon which her claims rely. (See Opp'n at 18–20). Instead, she provides the vague promise that she will offer evidence at trial to support her claims. Such assurances are insufficient to survive a motion for summary judgment. When a motion for summary judgment is properly made and the defendant has argued that the plaintiff is unable to establish an essential element of her claim, the plaintiff must make some showing that she can meet her burden. See Celotex, 477 U.S. at 322–23. She has not even attempted to do so. The Court will therefore dismiss Donalds' claims for breach of express and implied warranty. (Counts XI & XII).

4. Fraud and Negligent Misrepresentation

Ethicon next argues that the Court should also dismiss Donalds' claims for common law fraud, fraudulent concealment, constructive fraud, and negligent misrepresentation for lack of causation. (Counts V, VI, VII, VIII). 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)).

"Constructive fraud occurs when the Defendant breaches 'a legal or equitable duty which, irrespective of the moral guilt of the fraud feasor, the law declares fraudulent because of its tendency to deceive others, to violate public or private confidence, or to injure public interests.'" Dowling v. A.R.T. Ins. of Wash., Inc., 372 F.Supp.3d 274, 295 (D.Md. 2019) (quoting Canaj, Inc. v. Baker & Div. Phase III, LLC, 893 A.2d 1067, 1095 (Md. 2006)). Actual dishonesty of purpose and intent are not essential elements of constructive fraud. SpinCycle, Inc. v. Kalender, 186 F.Supp.2d 585, 590 (D.Md. 2002). The claim "generally arises in a context of trust or confidence, such as a fiduciary duty or confidential relationship." Chassels v. Krepps, 174 A.3d 896, 904 (Md.Ct.Spec.App. 2017).

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).

As with Donalds' other claims and for the reasons provided above, she has no evidence establishing proximate causation. Causation is an essential element to fraud, fraudulent concealment, constructive fraud, and negligent misrepresentation. Accordingly, Donalds' fraud claims will be dismissed. (Counts V, VI, VII, VIII).

5. Violation of Consumer Protection Laws

Finally, Ethicon argues that the Court should dismiss Donalds' claim for violation of consumer protection laws.[13] (Count XIII) (Mot. at 32). The Court will dismiss the claim.

The Maryland Consumer Protection Act ("MCPA") generally prohibits unfair, abusive, or deceptive trade practices in:

> (1) The sale, lease, rental, loan, or bailment of any consumer goods, consumer realty, or consumer services;
> (2) The offer for sale, lease, rental, loan, or bailment of consumer goods, consumer realty, or consumer services;
> (3) The offer for sale of course credit or other educational services;
> (4) The extension of consumer credit;
> (5) The collection of consumer debts; or
> (6) The purchase or offer for purchase of consumer goods or consumer realty from a consumer by a merchant whose business includes paying off consumer debt in connection with

[13] Although she does not specify, the Court assumes that Donalds is referring to the Maryland Consumer Protection Act.

> the purchase of any consumer goods or consumer realty from a consumer.

Md. Code Ann., Com. Law ("CL") § 13-303. The MCPA allows a plaintiff to "bring an action to recover for injury or loss sustained by [her] as a result of a practice prohibited by this title." CL § 13-408(a). Donalds does not provide the grounds for her claim, but the Court presumes that she contends that Ethicon engaged in unfair and deceptive trade practices by releasing the allegedly defective TVT Abbrevo and that those improper practices caused her injury. (See Am. Compl.; Opp'n at 20–21).

As the Court has explained, Donalds has not provided evidence causally linking the TVT Abbrevo to her injuries. Accordingly, her claim for violation of the MCPA must fail because she has not established the essential element of causation. See CL § 13-408(a).[14]

[14] Ethicon specifically argues that the claim must fail because the TVT Abbrevo is a professional medical service and not a consumer good. (Mot. at 32). As the Court explained, Donalds has failed to establish causation as required by CL § 13-408(a). Nonetheless, Ethicon's argument that the TVT Abbrevo is a prescription medical device and explicitly not a consumer good under the MCPA appears convincing. See Hogan v. Md. State Dental Assoc., 843 A.2d 902, 906 (Md.Ct.Spec.App. 2004) (holding that dental fillings are not consumer goods within the context of the MCPA because they "are not purchased by consumers as a good but are selected and used by a practitioner as part of a professional service"); CL § 13-104 ("This title does not apply to: (1) The professional services of a . . . medical or dental practitioner.").

III. CONCLUSION[15]

For the foregoing reasons, the Court will grant Defendants' Motion for Summary Judgment (ECF No. 63). A separate Order follows.

Entered this 28th day of December, 2021.

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

[15] The Court will also dismiss Donalds' claims for negligence (Count I) and gross negligence (Count XIV), as they were premised entirely upon the disposed-of claims of failure to warn and design defect and were included in the Court's analysis of those claims.