IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ROSARIO GODREAU-RIVERA and JOSE RIVERA-KERCADO, Plaintiffs, v. COLOPLAST CORP., Defendant.	C.A. No. 19-1807-LPS

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MEMORANDUM OPINION

April 14, 2022
Wilmington, Delaware

STARK, U.S. Circuit Judge:

On January 27, 2016, Plaintiffs Rosario Godreau-Rivera and Jose Rivera-Kercado ("Plaintiffs") filed a lawsuit against Defendant Coloplast Corp. ("Defendant" or "Coloplast") in multi-district litigation ("MDL") then pending in the U.S. District Court for the Southern District of West Virginia. (*See* D.I. 1) Plaintiffs asserted 17 counts arising from the injuries allegedly caused by Defendant's Restorelle® DirectFix ("Restorelle") polypropylene surgical mesh device implanted during Ms. Godreau-Rivera's pelvic floor reconstructive surgery. (*See* D.I. 1 ¶ 13; D.I. 102 at 1)

On September 26, 2019, after the time to conduct discovery was complete and the parties had filed motions to exclude expert testimony ("*Daubert* motions") and motions for summary judgment in the MDL (*see* D.I. 80), Plaintiffs' individual case was transferred to this Court. (*See* D.I. 67, 75) This Court denied all then-pending motions without prejudice to renew and set out procedures for the parties to file case-specific *Daubert* and summary judgment motions in this case. (*See* D.I. 87 at 4-5; D.I. 105 at 10-11) Pursuant to these procedures, Defendant filed several *Daubert* and summary judgment motions, which are pending before the Court.[1] (*See* D.I. 101)

[1] After Defendant filed the opening brief in support of its case-specific *Daubert* and summary judgment motions, Plaintiffs filed a motion to strike Defendant's motions, contending that Defendant had violated the Court's procedures for renewing motions and had waived certain issues by failing to raise them in the MDL motions. (*See* D.I. 103, 104, 109, 110) The Court heard argument on the motion to strike and denied the motion. (*See* D.I. 118; D.I. 121 at 20) The Court, however, allowed the parties to address – in additional pages of the then-forthcoming answering and reply briefs of the pending *Daubert* and summary judgment motions – pertinent issues raised in the motion to strike, including the waiver issue. (*See* D.I. 118; D.I. 121 at 20-21)

The Court has reviewed the parties' briefs and other materials submitted in connection with the pending motions. (*See, e.g.*, D.I. 102, 122-24, 126, 128, 129, 132, 134, 136-39)[2] The Court also heard oral argument via teleconference on April 27, 2021. (*See* D.I. 133) ("Tr.")

I. LEGAL STANDARDS

A. *Daubert* Motions

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993), the Supreme Court explained that Federal Rule of Evidence 702 creates "a gatekeeping role for the [trial] judge" in order to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Rule 702(a) requires that permissible expert testimony "help the trier of fact to understand the evidence or to determine a fact in issue." Expert testimony is admissible only if "the testimony is based on sufficient facts or data," "the testimony is the product of reliable principles and methods," and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)-(d). There are three distinct requirements for admissible expert testimony: (1) the expert must be qualified; (2) the opinion must be reliable; and (3) the expert's opinion must relate to the facts. *See generally Elcock v.*

[2] Given the size of the MDL and the numerous remand proceedings that have already occurred in other courts, it is unsurprising that essentially every issue raised in Defendant's motions has been litigated in other courts – usually, quite extensively. The Court directed the parties to prepare a table that, as of May 2021, listed every decision of the MDL court and the remand courts that addressed one or more of the *Daubert* issues raised in Defendant's pending motions. (*See* D.I. 137; *see also* D.I. 138 (Defendant advising Court in February 2022 of supplemental authority granting motions to exclude opinions of Drs. Mays and Pence); D.I. 139 (Plaintiffs advising Court in February 2022 of five opinions permitting Dr. Mays' testimony and seven opinions permitting Dr. Rosenzweig's testimony)) The Court has found this table (as well as the parties' subsequent filings), and the decisions summarized, to be helpful in its analysis. Although none of the opinions listed in the table are binding on this Court, many are persuasive, and the Court has benefited from considering each of them. Many are cited elsewhere in this Memorandum Opinion.

Kmart Corp., 233 F.3d 734, 741-46 (3d Cir. 2000). Rule 702 embodies a "liberal policy of admissibility." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008).

B. Summary Judgment Motion

"The court shall grant summary judgment if the movant shows 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). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). An assertion that a fact cannot be – or, alternatively, is – genuinely disputed must be supported either by citing to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for the purposes of the motion only), admissions, interrogatory answers, or other materials," or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita*, 475 U.S. at 587 (internal quotation marks and emphasis omitted). The Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586; *see also Podohnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment "must present more than just bare assertions, conclusory

allegations or suspicions to show the existence of a genuine issue") (internal quotation marks omitted). However, the "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;" and a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial"). Thus, the "mere existence of a scintilla of evidence" in support of the non-moving party's position is insufficient to defeat a motion for summary judgment; there must be "evidence on which the jury could reasonably find" for the non-moving party. *Anderson*, 477 U.S. at 252.

II. DISCUSSION

A. *Daubert* Motions

1. Rosenzweig

a. Specific Causation

Defendant seeks to exclude Dr. Rosenzweig's specific causation opinions, first contending that Dr. Rosenzweig is not qualified to offer these opinions. (*See* D.I. 102 at 3) The Court disagrees. Dr. Rosenzweig "has performed over 1,000 pelvic floor surgeries," "including more than 300 revision surgeries addressing complications associated with synthetic mesh products, specifically including the removal of numerous Coloplast products." (D.I. 122 at 1; *see also id.* Ex. B at 2) He has also "published numerous articles and given many lectures on the

treatment of urinary incontinence and pelvic organ prolapse." (D.I. 122 at 1; *see id.* Ex. A) Dr. Rosenzweig is well-qualified to offer specific causation opinions on Ms. Godreau-Rivera's Restorelle implant.

Defendant next argues that Dr. Rosenzweig's opinion that "[Ms. Godreau-Rivera's] Restorelle caused her alleged pelvic pain, vaginal pain, dyspareunia, pelvic muscle spasms, urinary dysfunction, and the need for mesh excision" is unreliable because he failed to perform a competent differential diagnosis. (D.I. 102 at 4) According to Defendant, Dr. Rosenzweig "omits critical elements of [Ms. Godreau-Rivera's] medical history" and fails to provide "any explanation for ruling out fibromyalgia as the cause of [Ms. Godreau-Rivera's] complaints." (*Id.* at 4-5) Plaintiffs counter that Dr. Rosenzweig has performed a "thorough and reliable differential diagnosis," adding that "he explicitly states how he arrived at his conclusions regarding [Ms. Godreau-Rivera's] injuries and how he eliminated other potential causes in his deposition." (D.I. 122 at 4)

The Court agrees with Plaintiffs that Dr. Rosenzweig's differential diagnosis is competent and his specific causation opinions are sufficiently reliable. Differential diagnosis "must be properly performed in order to be reliable." *Feit v. Great W. Life & Annuity Ins. Co.*, 271 F. App'x 246, 254 (3d Cir. 2008). A proper differential diagnosis requires that the expert scientifically rule in and then rule out by eliminating alternative causes of a plaintiff's injuries. *See id.*

Dr. Rosenzweig has adequately considered and ruled out the potential alternative causes noted by Defendant. (*See* D.I. 102 at 4) For example, with respect to fibromyalgia, Dr. Rosenzweig explained that Ms. Godreau-Rivera's "pelvic pain and dyspareunia went away after her hysterectomy while she was still having ongoing fibromyalgia." (D.I. 122 Ex. C at 135) Dr.

Rosenzweig also testified that Ms. Godreau-Rivera's pains, which were "temporally related to" the Restorelle implantation, "improved" after the mesh implant was removed. (*Id.* at 150) In addition, contrary to Defendant's contention that Dr. Rosenzweig failed to account for Ms. Godreau-Rivera's medical history between her hysterectomy in 2008 and her visit to Dr. Vakili in 2014, Dr. Rosenzweig explained at deposition that he had considered Ms. Godreau-Rivera's complaints of pelvic pain in her medical records during that period. (*See id.* at 101) ("There were complaints [of pelvic pain] that were associated with her prolapse [after the hysterectomy but before seeing Dr. Vakili]."))[3] Further, the purported inconsistency between Dr. Rosenzweig's testimony and Ms. Godreau-Rivera's pain complaints in her medical records (*see* D.I. 128 at 6; D.I. 129 Ex. 1) goes to the weight of Dr. Rosenzweig's opinions but does not provide a persuasive basis for exclusion.

Accordingly, the Court will deny this portion of Defendant's motion.

b. Ms. Rosario Godreau-Rivera's Continued Complications

Defendant contends that Dr. Rosenzweig should be precluded from testifying that Ms. Godreau-Rivera "will have continued and ongoing complications" because the purported factual predicate of this opinion – that the "majority of Ms. Godreau-Rivera's Direct Fix still remains in her pelvic tissue"[4] – is contradicted by Dr. Vakili's operative notes and deposition testimony that

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[3] Because of the applicable schedule, Dr. Rosenzweig did not have the benefit of Ms. Godreau-Rivera' deposition testimony at the time he prepared his expert report. Defendant, therefore, faults the expert report for purportedly failing to consider her complaints of dyspareunia in 2010, which she testified about in her deposition. (*See* Tr. at 10-11) At his own subsequent deposition, however, Dr. Rosenzweig testified that he had by then been provided with Ms. Godreau-Rivera's deposition testimony (*see* D.I. 122 Ex. C at 9) and it did not change anything in his opinions. (*See* Tr. at 28) Again, Defendant may cross-examine Dr. Rosenzweig on this point, but it does not render his opinion inadmissible.

[4] In his expert report, Dr. Rosenzweig states that "[t]he majority of Ms. Godreau-Rivera's Direct Fix still remains in her pelvic tissue." (D.I. 102 Ex. 6 at 12) However, during his deposition, Dr.

he removed the entire implant. (*See* D.I. 102 at 5-6; *see also id.* Ex. 3 at 92-94 ("I did document in the findings it was removed in its entirety.")) Plaintiffs counter that any conflict between Dr. Rosenzweig's "continued complications" opinions and Dr. Vakili's operative notes and testimony is not ground for exclusion but, instead, cross-examination. (*See* D.I. 122 at 6) This portion of Defendant's motion will be denied.

Dr. Rosenzweig considered Dr. Vakili's operative notes and deposition testimony and concluded, nonetheless, that there were fragments of mesh remaining in Ms. Godreau-Rivera's pelvic tissue, even after Dr. Vakili purportedly removed the mesh "in its entirety." (*See* D.I. 122 Ex. C at 154-55; *see also* Tr. at 32-33) Although Dr. Rosenzweig admitted he did not have "direct evidence" to support his conclusion (*see* D.I. 122 Ex. C at 155), he opined that "there are more likely than not fragments of mesh since it was transected to be removed in two pieces." (*See id.*; *see also* Tr. at 33)

The dispute between the experts' assessment of the existence of mesh fragments remaining in Ms. Godreau-Rivera's pelvic tissue goes to the weight, not the admissibility, of Dr. Rosenzweig's opinions. *See generally United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004) ("*Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct."). It is not, in the Court's view, a basis to exclude Dr. Rosenzweig's opinions.[5]

Rosenzweig clarified that his report should have said a "minority" of Ms. Godreau-Rivera's mesh implant remained in her pelvic tissue. (*See* D.I. 122 Ex. C at 155) ("That should have said a minority of the mesh remains in her body.")

[5] Dr. Rosenzweig's "continued complication" opinions are not based solely on the mesh fragments he believes remain in Ms. Godreau-Rivera's pelvic tissue. (*See* Tr. at 34) In his report, Dr. Rosenzweig also opines that Ms. Godreau-Rivera "will likely continue to suffer other injuries associated with the original implantation of the device." (D.I. 102 Ex. 6 at 13)

c. The "Blind Passage" Procedure

Defendant contends that Dr. Rosenzweig's opinion that the Restorelle implant is "unsafe because the implanting surgeon must perform a 'blind passage'" should be excluded as unsubstantiated. (*See* D.I. 102 at 6) This portion of Defendant's motion will be denied.

The Court agrees with Plaintiffs that Dr. Rosenzweig's opinions on the "blind passage" procedure are well-grounded in his extensive clinical experience with pelvic floor surgery and mesh products. (*See* D.I. 122 at 8) Dr. Rosenzweig sufficiently explains in his expert report that the "blind passage" is unsafe because "[i]t creates an inherently, unreasonably dangerous risk of causing perforated and/or lacerated organs and excessive damage to nerves, vascular structures and other tissues." (*Id.* Ex. E at 43) This opinion is sufficiently grounded in the evidence and will not be excluded as unreliable.

d. Degradation Of Restorelle *In Vivo*

Defendant seeks to exclude Dr. Rosenzweig's opinions on the degradation of polypropylene *in vivo* because he "is not an expert in polymer science nor a chemist" and, hence, "lack[s] expertise in the relevant, specialized disciplines." (D.I. 102 at 7) The Court does not agree. As a surgeon who has performed over 1,000 pelvic floor surgical procedures, including over 300 procedures dealing with complications related to synthetic mesh, Dr. Rosenzweig has sufficient familiarity with the behavior of mesh products in the human body. (*See* D.I. 122 Ex. B at 2) Thus, Dr. Rosenzweig is qualified to offer opinions on the degradation of polypropylene mesh products *in vivo*. "Any gaps in Dr. Rosenzweig's knowledge [concerning mesh degradation] go to his credibility, not his admissibility as an expert." *Wilkerson v. Bos. Sci. Corp.*, 2015 WL 2087048, at *5 (S.D.W. Va. May 5, 2015).

Defendant next contends that Dr. Rosenzweig's opinions about polypropylene degradation are unreliable because he has "never done any type of degradation testing," his opinions are not peer-reviewed, and his review of literature ignored a recent publication showing contrary results. (*See* D.I. 102 at 8-9) The Court disagrees. In reaching his opinions, Dr. Rosenzweig adequately relied on his extensive clinical experience and his review of scientific articles, in which the theory of polypropylene degradation *in vivo* has been tested and reported. (*See* D.I. 122 at 10) The scientific rigor underlying Dr. Rosenzweig's opinions – including his purported failure to account for more recent literature – goes to their persuasiveness, not their admissibility.

Finally, Defendant argues Dr. Rosenzweig's opinions that Ms. Godreau-Rivera's Restorelle implant degraded are unreliable because he did not examine the explanted mesh, and his opinions are contradicted by Dr. Vakili's testimony. (*See* D.I. 102 at 10-11) Although Dr. Rosenzweig did not examine the explanted mesh, he reviewed Ms. Godreau-Rivera's medical record, including Dr. Vakili's operation notes. (*See, e.g.*, *id.* Ex. 7 at 110-12, 139-44) This is sufficient grounding for Dr. Rosenzweig's opinions – and his failures are fruitful areas for cross-examination. Likewise, the purported inconsistency between Dr. Rosenzweig's interpretation of operation notes and Dr. Vakili's deposition testimony goes to the weight the factfinder may accord to the testimony but is not a meritorious basis for excluding the opinions.

Accordingly, the Court will deny this portion of Defendant's motion.

e. Informed Consent

Defendant contends that Dr. Rosenzweig is neither qualified nor has a reliable basis to testify that Defendant's alleged failure to disclose the risks of the Restorelle implant in its Instructions for Use ("IFU") was a "substantial factor and/or cause" of Ms. Godreau-Rivera's

injuries. (*See* D.I. 102 at 11-12) Defendant clarifies that, although other courts have found Dr. Rosenzweig is qualified to opine "generally on the adequacy of the product warnings," here it "challenges the reliability of Dr. Rosenzweig's opinion as it relates to proximate causation" in this specific case. (D.I. 128 at 9-10)[6]

This narrow portion of Defendant's motion will be granted. The Court agrees with Defendant that, since Dr. Rosenzweig cannot attribute personal knowledge or a specific state of mind to either Ms. Godreau-Rivera or her implanting surgeon, Dr. Vakili, his opinions regarding the causal relationship between the purported inadequacy of the Restorelle IFU and Ms. Godreau-Rivera's lack of informed consent should be excluded. *See, e.g.*, *White v. Ethicon, Inc.*, 2021 WL 129818, at *2 (W.D. Wash. Jan. 14, 2021); *Sutton v. Ethicon, Inc.*, 2020 WL 5801049, at *6 (E.D. Mo. Sept. 29, 2020); *Arevalo v. Coloplast Corp.*, 2020 WL 3958505, at *12 (N.D. Fla. July 7, 2020).

f. Insufficiency Of Defendant's Testing

Defendant seeks to exclude Dr. Rosenzweig's opinions on Defendant's alleged insufficient device testing, on the ground that he lacks the specialized training and education to be qualified to offer such an opinion. (*See* D.I. 102 at 12-13) Plaintiffs explain that Dr. Rosenzweig will not opine on the specific nature of the testing that Defendant needed to perform, but will offer only the general opinion that "Coloplast should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene to degrade." (D.I. 122 at 13) The Court will grant this portion of Defendant's motion.

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[6] The Court understands that Defendant does not seek to exclude Dr. Rosenzweig's opinions on the adequacy of the Restorelle IFU in general or on the general effect an inadequate IFU may have on informed consent. To the extent Defendant seeks to do so, its *Daubert* motion on these issues will be denied.

Dr. Rosenzweig's expert report does not reveal any experience, education, or knowledge about the appropriate testing a medical device manufacturer should perform on its mesh products prior to marketing. Although Plaintiffs contend that Dr. Rosenzweig "has substantial experience with testing genitourinary and pelvic medical devices" (*id.*), none of the listed product development projects Dr. Rosenzweig participated in has anything to do with mesh products or clinically relevant testing (*see id.* at 13 n.2). Dr. Rosenzweig is not qualified to provide expert opinions on the adequacy of Defendant's testing of mesh products. *See, e.g.*, *Humleker v. Bos. Sci. Corp.*, 2020 WL 6870852, at *9 (M.D. Fla. Oct. 2, 2020) (excluding Dr. Rosenzweig's opinion that "Defendant should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene used in Defendant's Mesh Products to alter inside the woman's body").

g. Safer Alternative Designs

Defendant contends that the Court should exclude the opinions of Dr. Rosenzweig – and also of Dr. Garely – regarding safer alternative designs for the Restorelle mesh implant, arguing these opinions are "unsupported, speculative, and irrelevant." (D.I. 102 at 19) According to Defendant, the expert opinions on this point are "guesswork" lacking scientific support, and the alternative surgical procedures and non-mesh repair products pointed to by the experts are irrelevant because they are not "alternative product designs." (*Id.* at 19-22) In response, Plaintiffs argue that Drs. Rosenzweig and Garely's experience in the medical profession enables them to reliably opine on comparable design concepts and products, and that their opinions about safer alternative designs – including procedures and non-mesh products – are relevant to Plaintiffs' claims. (*See* D.I. 122 at 14-15)

This portion of Defendant's motion will be denied. Drs. Rosenzweig and Garely's opinions regarding safer alternative designs are relevant and sufficiently reliable. Under Delaware law, "[i]t is legally possible for a plaintiff to prove [a] defective design even if no alternative design has been identified." *Barba v. Carlson*, 2014 WL 1678246, at *5 (Del. Super. Ct. Apr. 8, 2014). This makes the opinions relevant.

Moreover, these opinions are based on these experts' experience with mesh products and their review of medical literature and other product materials (*see, e.g.*, D.I. 102 Ex. 6 at 15; D.I. 123 Ex. I), and on their conclusions that the existing materials and designs of the Restorelle mesh implant have contributed to complications and tissue damages (*see, e.g.*, D.I. 102 Ex. 6 at 15; D.I. 122 Ex. H at 14-16, 29-33). Defendant's contention that injuries might still occur using an alternative procedure or product does not warrant the exclusion of Drs. Rosenzweig and Garely's opinions. (*See* D.I. 102 at 19; *see also Dorgan v. Ethicon, Inc.*, 2020 WL 5367062, at *3 (W.D. Mo. Sept. 8, 2020)) The challenges to the scientific rigor of Drs. Rosenzweig and Garely's opinions (*see* D.I. 102 at 19-20) go to the weight the factfinder may choose to give these opinions, not their admissibility.

2. Garely

a. Defective Design Of Restorelle

Defendant seeks to exclude Dr. Garely's opinions regarding the defective design of the Restorelle mesh implant, first contending that Dr. Garely does not have the requisite qualifications because he "concedes he is not an expert in design and admits he has no knowledge about the design of mesh devices beyond his experience as a urogynecologist." (D.I. 102 at 14) The Court disagrees. Dr. Garely is board certified in obstetrics, gynecology, and female pelvic medicine and reconstructive surgery, and he has significant experience with pelvic

repair surgery. He has personally examined, diagnosed, and treated over 100 patients with mesh complications. He has also authored multiple peer-reviewed articles, including articles relating to mesh products, and four book chapters on pelvic floor disorders. (*See* D.I. 122 Ex. H at 1-5) His experience in pelvic floor surgery and his familiarity with the complications caused by mesh products render him qualified to provide opinions on the design of mesh products.

Defendant next argues Dr. Garely cannot opine that the Restorelle implant has a "defective design" because that opinion "impinges upon the province of the jury to make findings of fact." (D.I. 102 at 14) An expert opinion "is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704. Defendant also insists that Dr. Garely's opinions relating to the design features of the Restorelle implant are unreliable because they are not "based on the methods and procedures of science." (D.I. 102 at 15) The Court, however, finds that Dr. Garely's opinions are well-grounded in both his clinical experience in treating mesh complications (*see* D.I. 122 Ex. H at 1-5), and in his review of Defendant's internal documents on mesh products (*see* D.I. 123 Ex. I).

Hence, this portion of Defendant's motion will be denied.

b. Adequacy Of Defendant's IFUs

Defendant seeks to exclude Dr. Garely's opinions regarding the adequacy of its IFUs. (*See* D.I. 102 at 15-17) According to Defendant, since Dr. Garely, by his own admission, is not an expert in the areas of product warnings, product labeling, or regulation compliance, he cannot offer opinions about "what an IFU should or should not include," or "whether an IFU complies with regulatory standard." *In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 2018 WL 4212409, at *4 (S.D.W. Va. Sept. 4, 2018); *see also In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4582209, at *3 (S.D.W. Va. Sept. 1, 2016).

Plaintiffs counter that Dr. Garely's undisputed expertise in female pelvic health and reconstructive surgery makes him "fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices, & Prods. Liab. Litig.*, 2011 WL 6301625, at *11-13 (S.D. Ill. Dec. 16, 2011); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d, 691, 719 (S.D.W. Va. 2014) (finding urologist qualified to testify about risks of implanting product and whether those risks were adequately expressed on product's IFU).

In the Court's view, the parties' competing positions are not truly conflicting. The Court finds the reasoning in *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015), instructive here:

> I have concluded that although Dr. Ostergard is not qualified to opine on FDA regulations and whether a product label satisfies those regulations, he is qualified to evaluate Bard's warnings based on his knowledge of and experience with the risks of the Avaulta. . . . I reach the same conclusion with respect to Dr. Raybon. Dr. Raybon has no demonstrated experience in the requirements for product labeling, and as such, he may not testify as to what the Avaulta label should or should not have included under the law. However, as an experienced urogynecologist, he may testify about the risks he perceives that the Avaulta poses to patients and then opine that the Avaulta IFU did not convey those risks.

The court in *Arevalo*, 2020 WL 3958505, at *5, embraced the same analysis:

> The Court finds that Dr. Garely is qualified to testify about the risks associated with the device and whether those risks were adequately expressed in the device's IFU, how physicians use IFUs, and the type of information typically included in IFUs, but he is not qualified to opine on whether an IFU complies with regulatory standards.

The Court will adopt the same approach here. Dr. Garely will be permitted to offer opinions as to whether Defendant's IFUs provided adequate information about the risks associated with mesh implants, but he may not offer opinions as to what Defendant was, for example, "obligated" to include in its IFUs. (*See, e.g.*, D.I. 122 Ex. H at 23) ("If Coloplast knew or believed . . . , it was obligated to so advise the physician users of the products.") Accomplishing this result means granting in part and denying part this portion of Defendant's motion.

c. General Causation

Defendant contends that Dr. Garely's general causation opinions should be excluded because they are not based on either "sufficient facts and data" or "reliable principles and methods." (D.I. 102 at 17) According to Defendant, Dr. Garely's "personal experience with the Restorelle is virtually non-existent," adding that the publications on which his opinions rely are not "specific to Restorelle." (*Id.* at 17-18)

This portion of Defendant's motion will be denied because the Court finds Dr. Garely's general causation opinions are sufficiently reliable. In his report, Dr. Garely states that his general causation opinions are based on his personal observation and treatment of "patients that have experienced . . . complications associated to the transvaginal placement of polypropylene pelvic organ prolapse mesh," and "[t]he published medical literature [that] reports these same types of complications." (D.I. 122 Ex. H at 35-36) While Dr. Garely may not have personal experience with the Restorelle product specifically, he has extensive clinical experience with polypropylene-containing pelvic mesh products generally. It is not unreliable for him to extrapolate his observations of the complications associated with polypropylene-containing pelvic mesh products in general to those associated specifically with the Restorelle implant. (*See*

D.I. 122 at 21; *see also* D.I. 123 Ex. J at 299-300 ("I don't know necessarily what [mesh products the patients] have. It doesn't change the approach or the outcome.")) The scientific rigor of Dr. Garely's opinions is a proper subject for cross-examination and presents an issue going to the weight, not the admissibility, of the opinions.

d. FDA's Position On Surgical Mesh Products

Defendant seeks to preclude Dr. Garely from testifying about the FDA's position on surgical mesh products. (*See* D.I. 102 at 18) At deposition, Dr. Garely repeatedly asserted that "the FDA agrees" with his opinions on the use of surgical mesh implants for transvaginal repair of pelvic organ prolapse. (*See, e.g.*, *id.* Ex. 2 at 58) ("I do not believe them to be safe, and this is why I don't, and I have been now validated, I guess, by the FDA, who also does not believe them to be safe.") Defendant contends that Dr. Garely is not qualified to render an opinion on the FDA's position and that his opinions on this topic are irrelevant and unhelpful. (*See id.* at 18-19) Plaintiffs acknowledge Dr. Garely "does not opine that he is an FDA regulatory process expert, nor does he set forth the FDA's position on surgical mesh," but insist that Dr. Garely should be permitted to testify that "he and the FDA are in agreement on the safety of transvaginal mesh products." (D.I. 122 at 22)

This portion of Defendant's motion will be granted. Dr. Garely will be precluded from testifying about the FDA's position on surgical mesh products, including that "he and the FDA are in agreement." He is not qualified to render opinions about the FDA's position.[7]

[7] Whether the jury will hear anything about the FDA's position is not the subject of any pending motion. If Plaintiffs have some other witness through whom they believe they can admit such evidence, this issue may become the subject of a motion *in limine* or an objection at trial.

3. Michaels

Defendant seeks to exclude Dr. Michaels' opinions that Ms. Godreau-Rivera's Restorelle mesh implant caused a fibrotic reaction that resulted in her "pelvic pain, irritative bladder symptoms, and dyspareunia." (D.I. 102 at 22) Defendant first contends that Dr. Michaels is not qualified to offer opinions on the causation of clinical complications because, as a pathologist, he "does not counsel or treat any patients." (*Id.* at 23) The Court concludes, however, that Dr. Michaels possesses sufficiently appropriate qualifications. Dr. Michaels is board certified in anatomic pathology, clinical pathology, and cytopathology, with a "strong subspecialty focus in breast and gynecology pathology, as well as cytopathology." (*Id.* Ex. 17 at 1) "Part of pathology involves reaching a diagnosis through clinical and pathologic correlation." *Sanchez v. Bos. Sci. Corp.*, 2014 WL 4851989, at *20 (S.D.W. Va. Sept. 29, 2014) (internal quotation marks omitted). In the Court's view, Dr. Michaels' understanding and application of clinical pathology "qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response." *Id.*; *see also e.g.*, *Townsend v. Ethicon, Inc.*, 2021 WL 304555, at *1 (D. Nev. Jan 29, 2021) ("Dr. Michaels is qualified as a pathologist to opine that there is no other pathological cause for [the plaintiff's] injuries following a review of her medical records and examination of specimens of the mesh and her tissue."); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 712 (S.D.W. Va. 2014) ("A pathologist is a clinician who provides diagnoses for patient care based on the examination of specimens they receive and relevant clinical information.").

Defendant next contends that Dr. Michaels' causation opinions are unreliable because he "ignores Restorelle's distinct properties, as well as the research showing different tissue response." (D.I. 102 at 24) The Court disagrees. During deposition, Dr. Michaels testified,

contrary to Defendant's contention, that he reviewed literature specifically concerning the Restorelle mesh implant. (*See* D.I. 123 Ex. L at 18-19) Dr. Michaels also explained that his opinions would not differ in a Restorelle case from those in cases involving other polypropylene mesh products. (*See* D.I. 122 at 24; *see also* D.I. 123 Ex. L at 68) Additionally, Dr. Michaels states in his report that he reviewed Ms. Godreau-Rivera's medical records and evaluated slides prepared from her vaginal mesh pathology specimen. (*See* D.I. 102 Ex. 17 at 1) Dr. Michaels also considered and ruled out several alternative causes. (*See* Tr. at 56; *see also* D.I. 102 Ex. 17 at 8) Thus, Dr. Michaels' specific causation opinions are based on reliable pathological methodology.

Defendant's challenges with respect to the scientific soundness of Dr. Michaels' opinions, including the alleged failure to account for the characteristics of Restorelle (*see* D.I. 128 at 14-15), and the purported insufficiency of Dr. Michaels' differential diagnosis (*see* Tr. at 59-62), go to the weight the factfinder may accord to Dr. Michaels' opinions, not their admissibility. *See, e.g.*, *Tucker v. Ethicon, Inc.*, 2021 WL 825921, at *4 (E.D. Mo. Mar. 4, 2021) ("Dr. Michaels' case-specific opinions appear to be grounded on his general opinions and his review of Plaintiff's medical history, tissue samples, and explanted pelvic mesh. These are sufficiently reliable for purposes of *Daubert*, even if Dr. Michaels did not use a control sample."); *Townsend*, 2021 WL 304555, at *1 ("Dr. Michaels reviewed [the plaintiff's] medical records, slides of tissue specimens explanted from [the plaintiff], internal Ethicon documents, scientific literature, and deposition testimony from this case. . . . The defendants' challenges go to the weight of Dr. Michaels' testimony, not its admissibility, and the defendants may cross examine him on these points."). Accordingly, this portion of Defendant's motion will be denied.

4. Mays

a. Polypropylene Degradation *In Vivo*

Defendant contends that Dr. Mays' opinions regarding the degradation of polypropylene *in vivo* should be excluded because he "wholly ignores one of the principal findings of the peer-reviewed published paper." (D.I. 102 at 26) This portion of Defendant's motion will be denied.

Dr. Mays' opinions on polypropylene degradation *in vivo* are sufficiently reliable. Dr. Mays did not "wholly ignore[]" the *Thames* study; instead, he specifically addressed that study in his expert report. (*See* D.I. 123 Ex. M at 25-26) Dr. Mays explained that he did not credit the findings of the *Thames* study because he relied on the *Thompson* study, which criticizes the "extreme procedure" used in the *Thames* study. (*See* D.I. 122 at 27; *see also* D.I. 123 Ex. M at 25-26) This dispute does not provide a basis for excluding Dr. Mays' opinions. *See, e.g.*, *Bayless v. Bos. Sci. Corp.*, 2020 WL 10058191, at *4 (M.D. Fla. Dec. 7, 2020) ("Other scientific literature that may contradict an expert's well-founded opinions is certainly fertile ground for cross-examination.").

b. Degradation of Defendant's Polypropylene Mesh Products

Defendant first contends that Dr. Mays' opinions regarding the degradation of Defendant's polypropylene mesh products *in vivo* are unreliable because he "misstates the literature upon which he relies." (D.I. 102 at 30) In Defendant's view, Dr. Mays' assumption – that "the body continually releases high concentrations of oxidizing agents for the entire duration the implant remains in the body" – is not supported by the literature cited in his report. (*See id.*) In response, Plaintiffs insist that, since the cited studies show the release of oxidizing agents "***only decreases*** over time," and do not suggest "there [are] no oxidizing agents being generated," these studies are not inconsistent with Dr. Mays' opinions regarding the continuous

release of oxidizing agents and persistent foreign body response. (*See* D.I. 122 at 29; *see also* D.I. 123 Ex. N at 233-34) The parties' competing interpretations of scientific studies, as well as their conflicting positions over whether these studies support the factual predicate of Dr. Mays' opinions on polypropylene degradation *in vivo*, present a dispute to be resolved by the factfinder and go to the weight, not the admissibility, of these opinions. *See, e.g.*, *Nunez v. Coloplast Corp.*, 2020 WL 2315077, at *4 (S.D. Fla. May 11, 2020) ("[A]s to the argument that there are authorities that 'flatly contradict' Dr. Mays's opinions, . . . this [is] an issue that goes to weight and credibility.").

Defendant also contends that Dr. Mays' opinions are unreliable because he relied on an article containing the testing data he had included in his expert report submitted in a different MDL, a report which "was excluded on several occasions," and he failed to account for some "key differences" between the polypropylene mesh products made by other manufacturers and the ones made by Defendant. (D.I. 102 at 31) In the Court's view, however, Dr. Mays' opinions – which are based on his experience, training, and education in polymer science, and his review of scientific literature and documents on Defendant's polypropylene mesh products (*see* D.I. 122 at 28) – are sufficiently reliable to meet the requirements of Rule 702. The purported differences between Defendant's polypropylene products and those of other manufacturers do not render Dr. Mays' opinions unreliable. *See In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4958282, at *2 (S.D.W. Va. Aug. 25, 2016) ("I disagree that the supposed distinction between Prolene specifically and polypropylene generally renders studies on the latter unhelpful when discussing the former."). Accordingly, this portion of Defendant's motion will be denied.

c. Linking Degradation To Medical Complaints

Defendant contends Dr. Mays is not qualified to offer opinions regarding the medical complications allegedly caused by the degradation of polypropylene mesh. (*See* D.I. 102 at 32) Plaintiffs counter that Dr. Mays, a polymer expert with expertise in biomaterials, should be allowed to opine on "the clinical significance of [polypropylene] degradation." (D.I. 122 at 31) During oral argument, Plaintiffs clarified that Dr. Mays would only offer "general opinions about . . . the producing of a tissue response to the oxidizing of the polypropylene in the tissue;" he will not testify to "something of clinical significance specifically in [Ms. Godreau-Rivera]" or "what the patient would subjectively experience." (Tr. at 70-71) The Court will deny this portion of Defendant's motion.

Dr. Mays' extensive experience in polymer science, and particularly in biomaterials, renders him qualified to testify generally about tissue responses caused by oxidative degradation of polypropylene mesh products, even though he is not a medical doctor and does not examine or treat patients. *See, e.g.*, *Nunez*, 2020 WL 2315077, at *3; *Wise*, 2015 WL 521202, at *9.

d. Oxidative Degradation Results In Reduction Of Mechanical Properties Of Surgical Mesh Implants

Defendant seeks to exclude Dr. Mays' opinions that oxidative degradation results in a breakdown of mechanical properties of polypropylene mesh products, on the grounds that (1) Dr. Mays is not qualified to quantify the breakdown of mechanical properties, and (2) his opinions are based on an assumption unsupported by any published study. (*See* D.I. 102 at 33) This portion of Defendant's motion will be denied.

The Court agrees with Plaintiffs that Dr. Mays possesses the requisite qualifications and that his opinions are sufficiently reliable. Dr. Mays' inability to quantify the degree of mechanical breakdown does not prevent him from providing opinions, in a qualitative sense, that

reduction in mechanical properties and increase in stiffness of the polypropylene mesh products occur. (*See* D.I. 122 at 32; *see also Arevalo*, 2020 WL 3958505, at *8) Dr. Mays' opinions rest on a reliable foundation as they are based on his extensive experience in polymer science and his review of scientific publications. The fact that he was not able to point to a specific article demonstrating a breakdown in mechanical properties of the polypropylene mesh products goes to the weight, not the admissibility, of his opinions.

e. Medical Safety Data Sheets

Defendant first contends that Dr. Mays should be precluded from giving opinions on the alleged toxicity or irritability of polypropylene resin or antioxidants. (*See* D.I. 102 at 33-34) This portion of Defendant's motion will be granted. The Court agrees with Defendant that since Dr. Mays is not a toxicologist, he is not qualified to offer opinions on the toxicity of materials. *See, e.g.*, *Arevalo*, 2020 WL 3958505, at *8; *Bayless*, 2020 WL 10058191, at *5.

Defendant next seeks to exclude Dr. Mays' opinions on the oxidative degradation of the finished products *in vivo*, arguing that the information on the Medical Safety Data Sheets ("MSDS") for raw materials is not a reliable basis for Dr. Mays' opinions with respect to the finished products. (*See* D.I. 102 at 34) This portion of Defendant's motion will be denied. Dr. Mays has adequately explained the connection between the MSDS for raw materials and his opinions on the oxidative degradation of the finished products. (*See* D.I. 123 Ex. M at 29-34) Thus, his reliance on the raw materials MSDS does not render his opinions regarding the finished products unreliable. *See, e.g.*, *Arevalo*, 2020 WL 3958505, at *8; *Wise*, 2015 WL 521202, at *11. Defendant's criticisms on these points go to the weight and not the admissibility of these opinions.

Defendant also seeks to exclude Dr. Mays' testimony that "impermissibly inject[s] corporate state of mind or intent." (D.I. 102 at 34) Since Plaintiffs agree that Dr. Mays will not testify on Defendant's "state of mind, corporate conduct, and legal conclusions" (D.I. 122 at 33), this portion of Defendant's motion is moot and, therefore, will be denied.

5. Pence

a. Adequacy Of Restorelle IFU

Defendant contends that Dr. Pence's opinions regarding the adequacy of the IFU for Defendant's Restorelle mesh product are unreliable. (*See* D.I. 102 at 35) Plaintiffs fail to address Defendant's challenge in their brief and conceded during oral argument that "[t]hose portions of her opinions have been excluded by other courts, and we would be fine with [the Court] applying those rulings here as well." (Tr. at 85-86) This portion of Defendant's motion will be granted.

b. Adequacy Of Defendant's Premarket Testing

Defendant seeks to exclude Dr. Pence's premarket testing opinions, contending these opinions are unreliable because Dr. Pence failed to support them "with any regulatory requirements or other binding authority." (D.I. 102 at 37) Defendant particularly points out that international bodies – including the Global Harmonization Task Force ("GHTF"), certain French and British authorities, and industry groups – are not responsible for medical device regulation in the United States. (*See id.* at 38) Plaintiffs respond that the non-binding nature of the standards relied on by Dr. Pence does not render her opinions unreliable. (*See* D.I. 122 at 35-37) This portion of Defendant's motion will be denied.

Dr. Pence has extensive experience in the pharmaceutical and medical device industries, and her testing opinions are based on "multiple sources that stress the importance of running

clinical trials before incorporating mesh materials into a surgical product." *Sanchez*, 2014 WL 4851989, at *34. Contrary to Defendant's contention, the non-binding nature of industry standards does not compel a conclusion that Dr. Pence's premarket testing opinions based on them are unreliable. *See Heatherly v. Bos. Sci. Corp.*, 2018 WL 3797507, at *5-6 (S.D.W. Va. Aug. 9, 2018); *see also Lees v. Carthage Coll.*, 714 F.3d 516, 525 (7th Cir. 2013) (finding that whether international guidelines are controlling in industry is not "the relevant question for admissibility purposes").

The Court is further unpersuaded by Defendant's argument that Dr. Pence's opinions are unreliable because she "simply summarizes comments from various sources about clinical testing and then jumps to her opinion that Coloplast's device testing was inadequate." (D.I. 102 at 39) By relying on her review of a voluminous amount of peer-reviewed scientific articles, deposition testimony, government codes and regulations, clinical trial materials, and Defendant's internal documents, Dr. Pence has sufficiently demonstrated that her opinions are a product of a soundly grounded methodology. (*See generally* D.I. 124 Ex. P at 82-113)

c. Adequacy Of Post-Market Surveillance

Plaintiffs do not address this issue in their brief and conceded during oral argument that the Court can apply the rulings of other courts that have excluded Dr. Pence's post-market surveillance opinions. (*See* Tr. at 85-86) The Court will grant this portion of Defendant's motion.

B. Motion For Summary Judgment[8]

1. Claims Based On Specific Causation

This portion of Defendant's motion for summary judgment is based solely on Plaintiffs' supposed inability to adduce expert evidence to establish specific causation. (*See* D.I. 102 at 42) In other words, the motion turns entirely on Defendant's related *Daubert* motions. As the Court has denied the pertinent portions of those *Daubert* motions – and has ruled that Drs. Rosenzweig and Michaels' specific causation opinions are admissible – Defendant's motion for summary judgment with respect to all of Plaintiffs' claims based on specific causation will be denied.

2. Negligent Failure To Warn (Part Of Count I)

The parties agree that Delaware's "learned intermediary" doctrine applies to Plaintiffs' negligent failure to warn claim. (*See* D.I. 102 at 44; D.I. 122 at 42) "The learned intermediary doctrine provides for an exception to the general rule that a manufacturer of a [medical device] owes a duty to warn the consumer directly concerning the risks associated with the [device]." *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 399 (Del. 1989). The doctrine "acts as an affirmative defense." *Hagan v. Bos. Sci. Corp.*, 2021 WL 1921893, at *6 (Del. Super. Ct. May 12, 2021). Hence, a manufacturer of a prescription medical device satisfies its duty to provide an appropriate warning about the device "when it gives the patient's physician the necessary information to be disseminated to the patient." *Lacy*, 567 A.2d at 399. The "learned intermediary" doctrine is inapplicable if a warning is "inadequate as a matter of law." *Evans v.*

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[8] Defendant has moved for summary judgment on "all of Plaintiffs' claims." (D.I. 102 at 40) Plaintiffs indicate in their brief that they will not pursue the following claims: manufacturing defect (Count III and part of Count I), fraudulent concealment (Count VIII), constructive fraud (Count IX), discovery rule, tolling and fraudulent concealment (Count X), negligent infliction of emotional distress (Count XII), unjust enrichment (Count XV), and all strict liability claims (Counts II-V). (*See* D.I. 122 at 40-42) Accordingly, the Court will grant Defendant's motion for summary judgment with respect to these claims.

Johnson & Johnson Co., 2020 WL 616575, at *4 (D. Del. Feb. 10, 2020) (quoting *Barba*, 2014 WL 1678246, at *2). If the warning is not insufficient as a matter of law, the issue proceeds to "whether additional information or warnings would have made a difference to a ***reasonable*** learned intermediary." *Barba*, 2014 WL 1678246, at *3. "If the warnings and information are found to be adequate, ***and*** additional warnings or information would not have affected the medical decisions of a reasonable physician, then the learned intermediary insulates the manufacturer from liability." *Id.*

Defendant contends that its motion for summary judgment should be granted because (1) the warning Defendant provided to Ms. Godreau-Rivera's prescribing and implanting physician, Dr. Vakili, is adequate (*see* D.I. 102 at 44-45); and (2) Plaintiffs cannot establish proximate causation, since Dr. Vakili was "independently aware of the potential risks" for which Plaintiffs now seek recovery and a differently-worded warning would not have changed Dr. Vakili's prescribing decision (*see id.* at 45-47). Plaintiffs dispute both grounds. (*See* D.I. 122 at 43-47) They further contend that Dr. Vakili's "financial bias" creates fact issues precluding summary judgment. (*See id.* at 47-49)

The Court finds there is a genuine dispute of material fact over both the adequacy of the warning and proximate cause. A reasonable juror, taking all the evidence in the light most favorable to Plaintiffs and drawing all reasonable inferences in their favor, could find that the warning Defendant provided to "learned intermediaries" like Dr. Vakili was insufficient and, additionally, could also find that a different warning could have caused Dr. Vakili to act materially differently. Accordingly, and as more fully set out below, Defendant's motion for summary judgment with respect to Plaintiffs' negligent failure to warn claim will be denied.

a. Adequacy Of Warning

Defendant argues "the undisputed record evidence establishes that Coloplast provided accurate, clear, and unambiguous warnings about the potential risks associated with Restorelle in the accompanying IFU." (D.I. 102 at 44) In particular, Defendant insists that the Restorelle IFU warned of each of the risks of developing each of the problems Ms. Godreau-Rivera has allegedly suffered. (*See id.* at 45) Relying primarily on Dr. Rosenzweig's expert report, Plaintiffs counter that Defendant's IFU "did not include sufficient information to advise physicians on the permanency, frequency, and severity of the complications that can arise from the use of its devices," and further that Defendant "significantly downplayed the risks that it actually did list in its IFU." (D.I. 122 at 43-44; *see also id.* Ex. F at 43-48) In its reply brief, Defendant argues that "so long as the manufacturer warned the physician about the injuries plaintiff complained of, the learned intermediary doctrine bars a failure-to-warn claim as a matter of law," citing *Lacy*, 567 A.2d at 401. (D.I. 128 at 22)

Defendant's reliance on *Lacy* is misplaced. *Lacy* does not hold that a medical device provider's obligation to warn a learned intermediary is discharged as long as the label mentions the types of injury of which a plaintiff complains, regardless of the injury's "permanency, frequency, and severity." Moreover, here the Court agrees with Plaintiffs that they have introduced sufficient evidence – including expert opinions the Court has found admissible – to create a genuine dispute of material fact as to whether the warnings provided by the Restorelle IFU are adequate. *See Hagan*, 2021 WL 1921893, at *6 ("The issue of whether adequate warnings were issued is factual and is usually resolved by the trier of fact.").

b. Proximate Cause

Defendant first contends that, prior to Ms. Godreau-Rivera's implantation surgery, Dr. Vakili was independently aware of the "well-publicized" risks associated with Restorelle. (*See* D.I. 102 at 45-46) According to Defendant, this independent knowledge was obtained, at least in part, "through reading medical literature and FDA safety communications." (*Id.* at 46) The record, however, reveals a genuine dispute of material fact as to whether the risks about Restorelle known to Dr. Vakili at the pertinent time would include the risks that Dr. Rosenzweig opines should have been included in the Restorelle IFU.

Defendant further argues that a differently-worded warning would not have changed Dr. Vakili's prescribing decision. (*See id.* at 46-47) The Court finds, however, a genuine dispute of material fact as to whether Dr. Vakili's prescribing decision would have remained the same had he received additional warnings about the fitness of Restorelle for human implantation. Dr. Vakili testified at his deposition:

> Q: Yeah. If the company told you that polypropylene is not meant for human – permanent human implantation, would you continue to use polypropylene mesh?
>
> A: I have to think about the answer to that question because it seems a little leading. So if the company said polypropylene as a material is not meant for human consumption?
>
> Q: Implantation?
>
> A: Implantation. If I was told that by the company, would I not use it?
>
> Q: Yes.
>
> A: ***I would take it into consideration, but I'm not sure it would totally inform my decision.***
>
> Q: Why wouldn't it totally inform your decision?

A: Because I would look at the body of medical literature that exists regarding products of that material before I made a final decision.

(D.I. 124 Ex. Q at 129-30) (emphasis added) Since Dr. Vakili did not unequivocally state that he would not have changed his prescribing decision, a reasonable factfinder could conclude that Dr. Vakili – after taking "into consideration" the hypothesized manufacturer warnings that polypropylene mesh is unfit for human implantation – may have come to a different prescribing decision. *See, e.g.*, *Humleker*, 2020 WL 6870852, at *16 (denying motion for summary judgment when implanting physician suggested that "she would have wanted additional information" regarding the safety of implanting polypropylene in human body).

The situation here is distinguishable from those presented in cases cited by Defendant (*see* D.I. 128 at 25), in which courts granted motions for summary judgment when physicians provided unequivocal testimony that they would not have changed their prescribing decisions – testimony Dr. Vakili did not give in this case.[9] Thus, the genuine factual dispute over proximate cause provide a further basis for denying Defendant's motion for summary judgment with respect to Plaintiffs' negligent failure to warn claim.[10]

[9] In supplemental authority submitted by Defendant (*see* D.I. 136), *Salinero v. Johnson & Johnson*, 995 F.3d 959, 966 (11th Cir. 2021), the Eleventh Circuit affirmed the district court's grant of summary judgment to a defendant based, in part, on the implanting physician being "clear that an IFU containing more information on the risks posed by Artisyn Y-Mesh would not have altered his decision to use the implant in [the plaintiff's] surgery." This authority does not help Defendant because the record is devoid of such a statement by Dr. Vakili.

[10] The Court need not reach Plaintiffs' additional argument that Dr. Vakili's financial bias creates fact issues precluding summary judgment. (*See* D.I. 122 at 47-49)

3. Breach Of Express Warranty (Count VI)

Under Delaware law, to prevail on a breach of express warranty claim, "the buyer must prove: (1) the existence of an express . . . warranty, (2) a breach of the defendant's express . . . warranty, (3) a causal connection between the defendant's breach and the plaintiff's injury or damage, and (4) the extent of loss proximately caused by the defendant's breach." *Driscoll v. Automaxx*, 2016 WL 5107066, at *2 (Del. Com. Pl. Apr. 27, 2016). An express warranty may arise in three 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.

6 Del. C. § 2-313(1). Defendant contends that Plaintiffs' breach of express warranty claim fails because there is "no evidence that Coloplast made any express warranties to [Ms. Godreau-Rivera] as to the safety or effectiveness of Restorelle." (D.I. 102 at 47) The Court agrees with Defendant.

Plaintiffs ground their express warranty theory on Defendant's "assurances to the general public, hospitals, and health care professionals that its mesh products were safe and fit for their intended purpose." (D.I. 122 at 51) However, it is undisputed that Ms. Godreau-Rivera "has never had any contact or conversation with anyone from Coloplast or seen any advertisements, brochures, or websites from Coloplast." (*Compare* D.I. 102 at 41 *with* D.I. 122 at 38; *see also* D.I. 102 at 47, *id.* Ex. 32 at 164, 167, 198) It follows that, therefore, Plaintiffs cannot establish

Ms. Godreau-Rivera's reliance on the purported "assurances" to enter into a bargain with Defendant. *See, e.g., Barba*, 2014 WL 1678246, at *5 (granting summary judgment because plaintiff testified "she neither received nor relied upon any Boston Scientific materials"); *Dilenno v. Libbey Glass Div., Owens-Ill., Inc.*, 668 F. Supp. 373, 376 (D. Del. 1987) (holding that plaintiff's claim for breach of expressed warranty must fail because "[t]here is no evidence in the record to suggest that [the plaintiff] ever saw the [defendant's] catalog let alone relied on it when she purchased the [product]").

Thus, Defendant's motion for summary judgment with respect to Plaintiffs' breach of express warranty claim will be granted.

4. Negligent Misrepresentation (Count XI)

Under Delaware law, to prove negligent misrepresentation, Plaintiffs must establish: "(1) a pecuniary duty to provide accurate information, (2) the supplying of false information, (3) failure to exercise reasonable care in obtaining or communicating information, and (4) a pecuniary loss caused by justifiable reliance upon the false information." *Pa. Emp. Benefit Trust Fund v. Zeneca, Inc.*, 710 F. Supp. 2d 458, 485-86 (D. Del. 2010) (citing *Atwell v. RHIS, Inc.*, 2006 WL 2686532, at *1 (Del. Super. Ct. Aug. 18, 2006)).

Defendant contends summary judgment is warranted because: (1) its "pecuniary duty" was owed to Dr. Vakili, and (2) Plaintiffs cannot prove Dr. Vakili relied on the alleged misrepresentation. (*See* D.I. 102 at 48-49) The Court need not address the first issue, because even assuming the learned intermediary doctrine is applicable to a negligent misrepresentation claim,[11] the Court finds – for the same reasons provided in connection with Plaintiffs' negligent

[11] Although the Delaware Supreme Court has not directly addressed the issue, this Court has applied the learned intermediary doctrine to a negligent misrepresentation claim. *See Evans*, 2020 WL 616575, at *3-4.

failure to warn claim (*see supra* Part II.B.2.b) – there is a genuine dispute of material fact as to whether Dr. Vakili relied on Defendant's alleged misrepresentation regarding the risks of polypropylene mesh implant products. Thus, Defendant's motion for summary judgment with respect to Plaintiffs' negligent misrepresentation claim will be denied.

5. Punitive Damages (Count XVII)

Under Delaware law, the availability of punitive damages turns on whether a plaintiff establishes a *prima facie* case that Defendant exhibited a "willful and wanton disregard for the safety of others." *Porter v. Turner*, 954 A.2d 308, 312 (Del. 2008). "For a defendant's conduct to be found willful or wanton, the conduct must reflect a 'conscious indifference' or 'I don't care' attitude." *Id.* (quoting *Cloroben Chem. Corp. v. Comegys*, 464 A.2d 887, 891 (Del. 1983)). "Where the evidence only supports a negligence claim, summary judgment [of no punitive damages] is appropriate." *Estate of Rae v. Murphy*, 956 A.2d 1266, 1270 (Del. 2008).

Defendant contends that Plaintiffs' claim for punitive damages fails as a matter of law because there is "no record evidence demonstrating that Coloplast's conduct was willful or wanton, thus reflecting a 'conscious indifference' or an 'I don't care attitude' required to support punitive damages" (D.I. 102 at 50) The Court, however, agrees with Plaintiffs that there is sufficient evidence in the record from which a reasonable factfinder could find that Defendant's alleged misconduct was based on a *mens rea* constituting a "conscious indifference" or "I don't care" attitude. (*See* D.I. 122 at 53-54) (citing evidence) For example, Dr. Rosenzweig points out that "as early as 2011 Coloplast was being advised by a third-party polymer company about polypropylene degradation and stiffening. Coloplast was advised to consider abandoning the use of polypropylene in TVM all together." (*Id.* Ex. E at 22) A reasonable factfinder could find that Defendant acted with a state of mind worse than mere negligence, warranting imposition of

punitive damages. Accordingly, the Court will deny Defendant's motion for summary judgment with respect to punitive damages.

C. Waiver

Plaintiffs contend that Defendant failed to raise the following issues in the MDL motions and, thus, has waived them:

> [1] it did not move to exclude the entirety of Dr. Rosenzweig's specific causation opinions; [2] it did not move on Dr. Garely's mesh design opinions or his qualifications to opine on the adequacy of the warnings; [3] it did not challenge Dr. Mays' qualifications on the material safety data sheet.

(D.I. 122 at 55) In response, Defendant shows that it has, in fact, raised the identified issues concerning Drs. Garely and Mays in their MDL motions. (*See* D.I. 128 at 30 (citing D.I. 129 Exs. 9-10)) The parties' dispute with respect to waiver, then, is limited to Dr. Rosenzweig's specific causation opinions. Because the Court has addressed the merits of this portion of Defendant's *Daubert* motion – and, as explained above (*see supra* Part II.A.I.a), is denying this portion of the motion on the merits – the Court need not address the waiver issue.

III. CONCLUSION

An appropriate order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ROSARIO GODREAU-RIVERA and JOSE RIVERA-KERCADO, Plaintiffs, v. COLOPLAST CORP., Defendant.	C.A. No. 19-1807-LPS

ORDER

At Wilmington this **14th** day of **April, 2022**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that:

1. Defendant's motion to exclude opinions and testimony of Bruce Rosenzweig, Alan Garely, Paul Michaels, Jimmy Mays, and Peggy Pence, and its motion for summary judgment (D.I. 101), are **GRANTED IN PART** and **DENIED IN PART**, to the extent and as detailed in the Memorandum Opinion.

2. With respect to the disputed portions of their opinions, the experts addressed in the pending motion will be permitted to offer the following opinions at trial (subject to any subsequent order of this Court):

a. Dr. Rosenzweig will be permitted to provide his opinions on specific causation; Ms. Rosario Godreau-Rivera's continued complications; the "blind passage" procedure; degradation of Restorelle *in vivo*; and safer alternative designs.

b. Dr. Garely will be permitted to provide his opinions on the defective design of Restorelle; the adequacy of Defendant's IFUs (but not the regulatory obligations for IFUs); general causation; and safer alternative designs.

c. Dr. Michaels will be permitted to provide his opinions on specific causation.

d. Dr. Mays will be permitted to provide his opinions on polypropylene degradation *in vivo*; the degradation of Defendant's polypropylene mesh products; general tissue response caused by polypropylene degradation; the reduction of mechanical properties of mesh implants resulting from oxidative degradation; and the degradation of Defendant's finished products based on the MSDS of raw materials.

e. Dr. Pence will be permitted to provide her opinions on the adequacy of Defendant's premarket testing.

3. This case will proceed on the following claims:

a. Negligence (except on the basis of manufacturing defect) (Count I)

b. Breach of implied warranty (Count VII)

c. Negligent misrepresentation (Count XI)

d. Violation of consumer protection laws (Count XIII)

e. Gross negligence (Count XIV)

f. Loss of consortium (Count XVI)

g. Punitive damages (Count XVII)

UNITED STATES DISTRICT COURT