IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

VERONICA MADSEN AND JAMES MADSEN Plaintiffs, v. C.R. BARD, INC. Defendant.	Case No. 20-CV-02345 Judge John Robert Blakey

MEMORANDUM OPINION AND ORDER

In this product liability action, Plaintiff Veronica Madsen claims that she suffered injuries from Defendant C.R. Bard's Align transobturator mesh product implanted in her during a February 2016 surgery to treat urinary stress incontinence and other conditions. She sues Defendant C.R. Bard for negligence (Count I); strict liability design defect, manufacturing defect and failure to warn (Counts II–IV); breach of express and implied warranty (Counts V, VI); and punitive damages (Count VIII). Her husband, Plaintiff James Madsen, also sues for loss of consortium (Count VII). Before the Court is Defendant C.R. Bard's motion for summary judgment [151] and motions to exclude the opinion and testimony of general causation experts Alan Garely [82] and Anthony Brennan [84], and specific causation expert Michael Margolis [86]. For the reasons explained below, the Court grants in part, and denies in part, the motions [82], [84], [86], and [151].

I. Background

A. Procedural History

This case originated from one of the many pelvic mesh multidistrict litigations in Southern District of West Virginia (MDL 2187) each involving thousands of cases. The Court begins with a summary of this case's procedural history in MDL 2187 because it proves relevant to some of Defendant's motions.

Given the number of cases in each pelvic mesh MDL, the MDL Court separated the cases into multiple waves based upon the product at issue, the defendants sued, each case's timeline, and other considerations. The MDL Court initially placed this case in Wave 4 of the Bard MDL (MDL 2187) and then, after the parties' unsuccessful settlement attempts, moved it to Wave 9 of the MDL 2187 in February 4, 2019. [50] (Pretrial Order 299). For Wave 9 (as with other waves), the MDL Court set a schedule for expert disclosures, *Daubert* motions, and dispositive motions. *Id.* Before the Wave 9 *Daubert* and dispositive motions deadline arrived, however, the MDL Court moved this case to Wave 13 of the Ethicon MDL.[1] [63]. The MDL Court then transferred this case to this Court before the MDL Court decided any pending *Daubert* or dispositive motions for this case.

B. Medical History

Ms. Madsen began experiencing urinary stress incontinence in 2000 after she gave birth to her first child. [161-5] at 76:1–10. To treat her condition, a surgeon

[1] Ethicon is another manufacturer of mesh products that has been sued in the MDL. Although Plaintiffs' suit here involves a Bard-manufactured product, the MDL Court placed Plaintiffs' case on an Ethicon MDL wave for scheduling reasons. [63].

performed a Burch colosuspension and cystoscopy surgery ("Burch procedure") on April 18, 2005. [161] ¶ 6. The Burch procedure improved her symptoms for about three months but then failed, suddenly and painfully. *Id.* ¶¶ 7–8.

From then on, Ms. Madsen's urinary stress incontinence progressively worsened, and on December 10, 2015 a gynecologist, Dr. Radha Krishna Upputuri, diagnosed her with abnormal uterine bleeding, uterine polyps, anemia, first degree cystocele, first degree uterine prolapse, urethral hypermobility, mild bladder prolapse, and stress urinary incontinence. [161] ¶ 11. Dr. Upputuri offered her multiple treatment options including continued self-management, physical therapy, routine collagen injections, a pessary device, or implanting a mid-urethral mesh sling. *Id.* ¶ 12. As to the mid-urethral mesh sling, Dr. Upputuri discussed with her various risks and showed her videos of the procedure. *Id.* ¶¶40–43. Based upon conversations with Dr. Upputuri and her own research, Ms. Madsen elected to get a mid-urethral mesh sling. *Id.* ¶¶ 13, 44.

Dr. Upputuri performed the implant surgery on February 4, 2016 using a mesh product developed, manufactured, and sold by Defendant C.R. Bard called the Bard Align TO system (hereinafter "Align product"). *Id.* ¶ 48. During the surgery, Dr. Upputuri also performed an operative hysteroscopy, a novasure uterine ablation, and a cystoscopy. *Id.* Ms. Madsen claims that after her February 2016 surgery, she began to experience a myriad of issues including leg pain, pain with intercourse, tightness in the pelvic floor, sciatic nerve pain, nerve pain in the inner thigh, pain when inserting a tampon, leg weakness, stomach issues, abdominal deformity and

numbness, and pelvic floor pain. *Id.* ¶ 55. She also continued to experience stress urinary incontinence that another doctor, Dr. Kimberly Kenton, attempted to treat further by implanting an autologous facial sling (*i.e.*, a sling made of human tissue) on August 22, 2016. *Id.* ¶ 59. Dr. Kenton did not remove any of the Align product; nor did she see signs that it had eroded or become exposed. *Id.* ¶ 60.

Despite this additional procedure, Ms. Madsen's pain continued, and, on December 2, 2016, she filed this lawsuit against Defendant C.R. Bard claiming that the Align product caused her pain and symptoms. *Id.* ¶ 53. On August 20, 2019, while her lawsuit remained pending before the MDL Court, Ms. Madsen underwent surgery by a gynecologist, Dr. Dionysios Veronikis, who removed the Align product to try to relieve her pain. [161] ¶ 63; [153-18] at 54:19–56:2. She also sought treatment from another doctor, Dr. Fitzgerald, for pelvic floor myofascial pain. [169] ¶ 16.

C. Pelvic Mesh Implant Product History

In October 20, 2008, the Federal Drug Administration ("FDA") issued a Public Health Notification regarding possible serious complications associated with transvaginal placement of surgical mesh to repair pelvic organ prolapse and treat stress urinary incontinence. [161] ¶ 14. Among other things, the notification reported complications such as "erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence." *Id.* ¶ 15. It also noted: "In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia." *Id.*

Finally, it recommended that physicians inform patients of "the potential for serious complications and their effect on quality of life, including pain during sexual intercourse and scarring." *Id.* ¶ 16.

Next, on July 13, 2011, the FDA issued an updated notification that focused on the reported complications from use of pelvic mesh products for prolapsed organ repair surgery. *Id.* ¶¶ 17–18. On March 27, 2013, the FDA also updated its Urogynecologic Surgical Mesh Implant website section with additional information about the risks associated with using surgical mesh to treat stress urinary incontinence. *Id.* ¶ 21. Then, on April 29, 2014, the FDA issued two proposed orders regarding urogynecologic surgical mesh procedures. *Id.* ¶ 22.

These Proposed Orders stated, in part, that there exist other risks even without mesh exposure or extrusion including "vaginal scarring, shrinkage, and tightening (possibly caused by mesh/tissue contraction); pelvic pain; infection (including pelvic abscess); de novo dyspareunia; de novo voiding dysfunction (e.g. incontinence); recurrent prolapse; and neuromuscular problems (including groin pain and leg pain)." *Id.* ¶ 23. Overall, the FDA identified the following risks: "Damage to blood vessels, nerves, connective tissue, and other structures. This may be caused by improperly designed and/or misused surgical mesh instrumentation. Clinical sequalae include pelvic pain and neuromuscular problems; adverse tissue reaction. This may be caused by non-biocompatible materials." *Id.* ¶ 24.

On January 5, 2016, the FDA finalized its 2014 Proposed Orders and reclassified surgical mesh for transvaginal repair from a Class II to a Class III

medical device because the "general controls and special controls together are not sufficient to provide reasonable assurance of safety and effectiveness for this device, and these devices present a potential unreasonable risk of illness or injury." [153-12] at 3; *see also* [161] ¶ 25.

As of Ms. Madsen's February 2016 surgery with Dr. Upputuri, Defendant included an Instruction for Use ("IFU") with its Align product that warned of certain complications, including: "Postoperative hematoma, seroma, abscess or fistula formation, or scarring which may occur following the implant procedure; Irritation at the operative wound site which may elicit a foreign body response that leads to wound dehiscence, inflammation and/or infection; Inflammation, sensitization, pain, dyspareunia, scarification, contraction, device migration and failure of the procedure resulting in recurrence of incontinence." [161] ¶ 28.

Dr. Upputuri testified that he was aware of some of these risks at the time of Ms. Madsen's surgery and the IFU's warning remained consistent with his understanding of possible complications associated with implanting the Align product. *Id.* ¶¶ 31–39. Ms. Madsen also agrees that, prior to her surgery, Dr. Upputuri discussed with her various risks with the procedure, *id.* ¶¶ 40–42, and she signed a consent form confirming that she understood the reason for, and risks associated with, the procedure and her other treatment options. *Id.* ¶ 46. According to Plaintiffs, however, Dr. Upputuri did not warn Ms. Madsen of certain significant risks, including chronic pelvic pain, chronic pain with sexual intercourse, chronic vaginal infection, chronic urinary tract infections, chronic groin pain, chronic thigh

pain, chronic leg pain, chronic nerve pain, chronic foreign body reaction, degradation, and shrinkage. [169] ¶ 21. Plaintiffs also claims that, even if Bard's IFU warned of some of these risks, Bard did not warn about—and therefore, Dr. Upputuri was not aware of—the rate and duration of risks associated with the Align product. *Id.* ¶ 23.

Also, as relevant to Plaintiffs' claims and the parties' arguments, the Align product is made from a polypropylene monofilament supplied by Phillips Sumika. [169] ¶ 40. Phillips Sumikia issued an information sheet listing the following suggested uses for this grade of polypropylene: woven industrial fabric and bags, rope and cordage, woven carpet backing, and geotextile fabrics. *Id.* In turn, Phillips Sumika's polypropylene monofilament is made from a raw polypropylene product called Marlex HGX-030-01. Since 2004, the Material Safety Data Sheet ("MSDS") for Marlex HGX-030-01 included the following warnings: (1) "Incompatibility with Other Materials: May react with oxygen and strong oxidizing agents, such as chlorates, nitrates, peroxides, etc." and (2) "Do not use this material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." *Id.* ¶¶ 38–39. According to Plaintiffs, Defendant knew about the information sheet and MSDS. *Id.* ¶ 39.

II. Defendant's Motions to Exclude Plaintiffs' Experts

While this case was part of the MDL 2187, Plaintiffs designated Drs. Garely and Brennan as general causation experts and Dr. Michael Margolis as a specific causation expert. General causation examines whether the product at issue "had *the capacity* to cause the harm alleged," while specific causation considers whether the

product "did, *in* fact, cause the harm alleged." *C.W. ex rel Wood v. Textron, Inc.*, 807 F.3d 827, 831 (7th Cir. 2015) (emphasis in original) (internal citations omitted). Now Defendant Bard seeks to exclude certain testimony and opinions of all three experts pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 593–94 (1993). [82], [84], [86].

A. Legal Standard

Rule 702 permits expert testimony if the expert has the requisite "knowledge, skill, experience, training, or education" to support the opinion offered and (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702.

For the reliability prong, courts consider multiple factors, including whether the methodology has been tested, subject to peer review, and generally accepted in the relevant community. *See Smith v. Ford Motor Co.*, 215 F.3d 713, 719 (7th Cir. 2000) (citing *Daubert*, 509 U.S. at 593–94). Even if an expert is qualified to offer opinions on a subject, the "expert's ultimate opinion must be grounded in the scientific process and may not be merely a subjective belief or unsupported conjecture." *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). In evaluating the relevance prong, a court must ensure that the proposed expert testimony "logically advances a material aspect of the proposing party's case."

Daubert, 43 F.3d at 1315. The party seeking to admit the expert testimony bears the burden of establishing admissibility under Rule 702. *See Lewis*, 561 F.3d at 705.

B. Motion to Exclude Opinions and Testimony of Dr. Anthony Brennan, Ph.D. [85]

Dr. Brennan, Ph.D is a biomedical engineer and Professor of Material Science and Engineering at the University of Florida. Here, Plaintiffs did not produce an expert report for Dr. Brennan specific to this case, but instead adopted his October 9, 2014 expert report produced for the MDL 2187 Wave 1 and 2 cases, [84-1]. The 2014 Report states that Dr. Brennan has expert knowledge in numerous chemical fields and on "the design, manufacture, testing, clinical evaluation and distribution of medical devices for both short-term and long-term implantation." [84-1] at 4. He also has evaluated "numerous explants to determine behavior in the human body." *Id*. In summary, Dr. Brennan opines that, from "a biomechanical viewpoint, the Bard mesh products and female pelvic tissue are not compatible." [84-1] at 4.

In the Wave 1 and 2 cases, the MDL Court already excluded some of Dr. Brennan's opinions based on Bard's motion. *See Wise, et al. v. C.R. Bard*, 12-cv-1378, 2015 WL 521202, at *9 (S.D. W. Va. Feb. 7, 2015). But the MDL Court also rejected many of Bard's arguments. *Id*. Overall, the MDL Court ruled in *Wise* that Dr. Brennan could: (1) opine on the effect of polypropylene mesh on the human body and the effects it may have including inflammation and degradation; (2) rely on third-party testing performed by Polymer Solutions; (3) offer opinions that reference and rely on biocompatibility testing and the Marlex HGX-030-01 MSDS; and (4) opine about mesh pore size and the effect of physical stress on mesh. *Id.* at *9–11. It held,

however, that Dr. Brennan could not opine on how mesh performs inside the female pelvis to the extent he relies on tensile testing because "tensile testing is not intended to represent how mesh performs inside the female pelvis." *Id.* at *11.

Now, Defendant Bard asks this Court to adopt the MDL Court's decision to exclude Dr. Brennan's opinions on tensile testing, [85] at 5–6, but it also asks the Court to reconsider the MDL Court's decision as to every topic about which it held Dr. Brennan could opine, *id.* at 7–22. Namely, it asks the Court to bar Dr. Brennan from: (1) opining on the effects that Bard's Align product has on the human body because he has no expertise in urogynecology, *id.* at 11–13; (2) opining on inflammation responses, *id.* at 13–14; (3) opining on polypropylene, and its degradation and characteristics, *id.* at 14–16; (4) offering any opinion that relies on tests conducted by third-party Polymer Solutions, *id.* at 17–20, or on the Marlex HGX-030-01 MSDS and biocompatibility testing, *id.* at 22–23; and (5) offering an opinion on the mesh's pore size or the effect of tension on mesh, *id.* at 21–22.

After reviewing the MDL Court's *Wise* opinion and Defendant Bard's arguments, the Court finds no basis to revisit the MDL Court's ruling. As a preliminary point, Plaintiffs insist that Defendant Bard violated the MDL Court's scheduling order for Wave 9 by filing this motion rather than just relying on the MDL Court's prior decision. [90] at 1–2. That is not quite right. Rather, as discussed above, this case moved through different waves of the MDL without the MDL Court deciding any *Daubert* or dispositive motions for this case, specifically. Further, although the MDL Court already issued the *Wise* opinion as to Dr. Brennan's 2014

Report, that opinion only expressly applied to certain cases. *See Wise*, 2015 WL 521202, at *9. Thus, Defendant did not violate an order in the MDL by filing a new motion to exclude Dr. Brennan in this Court.

Nonetheless, even if the MDL Court's decision in *Wise* does not control in this case, Defendant offers no compelling reason why this Court should not adopt the MDL Court's *Wise* decision on Dr. Brennan. To the contrary, the *Wise* decision relates to the same 2014 expert report and the parties did not re-depose Dr. Brennan for this case, so the deposition testimony from Dr. Brennan that the MDL Court considered remains unchanged. Further, Dr. Brennan offers only general causation opinions, and Defendant points to nothing *specific to this case* that renders those general causation opinions irrelevant or inapplicable. Defendant's new motion also does not point to any new case law that calls into question the MDL Court's reasoning. Nor does the new motion explain how the MDL Court got it wrong or point to any argument that the MDL failed to consider—instead, it merely asks this Court to reconsider anew the same arguments. One of the main purposes of an MDL is to streamline and resolve issues common to numerous cases. It would frustrate that purpose if a court, in a case remanded out of the MDL, reconsidered, without cause, decisions that the MDL Court already made on common issues.

Accordingly, this Court grants Defendant's motion [84] to the extent that it asks the Court to adopt the MDL Court's *Wise* decision, but otherwise denies it.[2]

[2] Defendant also argues here, [85] at 7, as it did with the MDL Court, that Dr. Brennan "conceded at his depositions" that he would not offer opinions on: (1) whether mesh degradation caused a plaintiff's specific injuries or a plaintiff's mesh had, in fact, degraded; (2) pathology of a plaintiff's explanted mesh; (3) how mesh was implanted in a specific patient; (4) mesh he did not evaluate; (5) the design,

C. Motion to Exclude Opinions of Alan Garely

Dr. Alan Garely is a Clinical Professor of Obstetrics, Gynecology, and Reproductive Medicine at the Icahn School of Medicine at Mount Sinai in New York and board-certified in obstetrics, gynecology, female pelvic medicine, and reconstructive surgery. [82-4]. As with Dr. Brennan, Plaintiffs did not submit a new report for Dr. Garely in this case but rather adopted his May 12, 2017 expert report produced for the MDL 2187 Wave 3 and 4 cases, [82-4]. In his 2017 Report, Dr. Garely opines about device-related complications for patients implanted with Defendant's Align products and further opines that: (1) the Align product is defectively designed; (2) Defendant failed to adequately warn about known problems with the Align product; (3) clinical trials would have shown risks from the Align product; and (4) there exist alternative safer designs for the Align product. *Id.*

As with Dr. Brennan, the MDL Court excluded some of Dr. Garely's opinions based upon a motion that Defendant filed in the Wave 3 and 4 cases. *In re C.R. Bard, Inc. Pelvic Repair Sys. Prods. Liability Litig.*, 2018 WL 4212409 (S.D. W. Va. Sept. 4, 2018). Namely, the MDL Court ruled that Dr. Garely may only testify about his review of internal corporate documents for the purpose of explaining the basis for his opinions and may not opine about Defendant's knowledge, state of mind, or corporate conduct. It also ruled that Dr. Garely could not offer legal conclusions about the

developing, manufacturing, or marketing of pelvic mesh; (6) IFU labeling adequacy on the products he examined; (7) FDA regulations on medical devices; (8) how to interpret the law; (9) Defendant's state of mind or concern for patient safety; or (10) any medical opinions. Plaintiff does not dispute this. Because Dr. Brennan confirmed he will not offer such opinions, the Court denies as moot Defendant's motion to bar Dr. Brennan from offering such opinions. Defendant may raise timely objections at trial should Dr. Brennan attempt to testify on these issues.

adequacy of Defendant's IFU warnings, such as his opinion that certain omissions "rendered the Align TO device not reasonably safe" or the Align product's design was "unreasonably dangerous and defective." *Id.* at *3. Finally, the MDL Court held that, although Dr. Garely's medical expertise qualified him to testify about the risks of implanting the Align product and whether Defendant's IFU outlined those risks, he lacks the expertise and qualifications to opine about whether Defendant's IFU complies with regulatory standards. *Id.* at *4.

Here, Defendant asks this Court to adopt the MDL Court's Wave 3 and 4 ruling as to Dr. Garely. [83] at 7. In addition, it challenges Dr. Garely's qualifications to opine about the alleged design defects of the Align product. *Id.* at 18–21. In response, Plaintiffs adopt the opposition brief filed by the other plaintiffs in Wave 3 and 4 of MDL. [91], [91-1] (attaching their prior-filed response as an exhibit). But, in doing so, Plaintiffs also acknowledge the MDL Court's prior ruling and only state that this Court should deny Defendant's motion to the extent it "has attempted to inject new arguments at this late stage of these proceedings that it failed or chose not to raise previously with respect to" Dr. Garely. *Id.* at 2. As such, and for the reasons the Court discussed above as to Dr. Brennan, this Court adopts the MDL Court's Wave 4 and 5 rulings as to Dr. Garely.

That still leaves Defendant's argument to exclude Dr. Garely's design defect opinions. As a preliminary point, Plaintiffs argue that this Court should not permit Defendant to "inject new arguments" that it failed to raise with the MDL Court. [91] at 1–2. But Defendant did raise this argument. *See in re Bard Pelvic Support Sys.*

Prods. Liab. Litig., Case No. 2:10-MD-2187, [4562] at 16–19. And although the MDL Court stated it granted Defendant's motion in full, *see* 2018 WL 4212409, its opinion did not address or discuss this argument. Accordingly, the Court will address it on the merits.

According to Defendant, Dr. Garely opines that the Align product design was defective based upon: (1) his review of Bard internal documents and communications; (2) the fact that the mesh was not medical grade and became brittle and hardened; (3) problems patients have experienced after he and other surgeons implanted it; (4) problems with the device's sheath getting stuck in patients' obturator canal; and (5) comparisons to other products. *Id.* at 18. Defendant argues that Dr. Garely is not a biomaterials engineer and his general experience as a urogynecologist does not render him qualified to evaluate the adequacy of the mesh used in the Align product. *Id.* at 18–21.

In response, Plaintiffs—adopting the response filed by other plaintiffs in the MDL Court—argue that Dr. Garely is qualified to offer opinions on the Align product design based upon his extensive experience using pelvic repair devices and treating patients who experienced complications from those devices. [91-1] at 20. Plaintiffs also argue that he has published and presented articles on pelvic repair mesh devices; performed one of the first transvaginal mesh sling operations in the United States; taught other surgeons on how to perform such surgeries; and worked with manufacturers in developing pelvic mesh products. *Id.* In addition, Plaintiffs argue that Dr. Garely would not testify about whether the Align product poses greater risks

than other products, but instead he will focus on the Align product's design for transobturator implantation compared to retropubic implantation. *Id.* at 21.

The Court agrees with Plaintiffs that Dr. Garely's experience performing transvaginal mesh operations and treating patients who experienced complications after such surgeries qualifies him to opine on the Align product's design *from a clinical perspective*. But the same cannot be said to the extent Dr. Garely intends to opine on the biomechanics or engineering of the mesh or how it may react physiologically within a human body. In fact, Dr. Garely agreed in his deposition that he did not consider himself "an expert in how polypropylene is absorbed and used by the human body" and he is "not a physiological expert in how polypropylene reacts in a woman's body." [83] at 18 (quoting [82-2] at 271:6–12).

That being said, the current record fails to provide clear definition as to which opinions cross this requisite line on a pretrial basis. Accordingly, Dr. Garely may opine about the Align product's design to the extent he can tie his opinions to his clinical expertise. But the Court grants Defendant's motion [82] to the extent Dr. Garely seeks to opine about the general biomechanics or physiology of how polypropylene mesh behaves in the human body. Defendant will need to raise timely objections at trial if it believes Dr. Garely offers design opinions that extend beyond a clinical perspective.

D. Motion to Exclude Specific Causation Opinions of Dr. Michael Margolis

Dr. Margolis is a pelvic surgeon and urogynecologist who is board certified in female pelvic medicine and reconstructive surgery. [157-4]. He has observed many

transvaginal surgeries involving mesh products, and extensively studied these procedures. *Id.* He also has performed hundreds of procedures to explant (*i.e.* remove) mesh products, including the Align product. *Id.* He has been offered as both a specific and general causation expert in numerous transvaginal mesh cases.

Here, Plaintiffs designated Dr. Margolis as a specific-causation expert to opine on whether Defendant's Align product caused Ms. Madsen's alleged injuries. [157-2] at 2. Dr. Margolis submitted his first specific causation report in May 2017 before Ms. Madsen had her 2019 mesh explant surgery with Dr. Veronikas. [157-3]. In this 2017 report, Dr. Margolis opines that: (1) Defendant failed to warn Dr. Upputuri about known problems with the Align product, *id*. at 15–16; (2) Defendant should have known about characteristics of the Align product—including mesh degradation, chronic foreign body reaction, fraying and particle loss, mesh roping and curling, loss of pore size, shrinkage/contraction, and scar tissue formation—that made it not suitable for permanent implantation into the pelvic floor, *id*. at 18; (3) Ms. Madsen developed de novo conditions after her Align product implantation, which could only have been caused by "the polypropylene Align TO product and its effects, including shrinkage/contraction as well as others, on Mrs. Madsen's surrounding tissues," *id*. at 18–22; and (4) Dr. Upputuri's treatment of Ms. Madsen met the standard of care, *id.*, at 20.

Dr. Margolis also submitted a supplemental causation report in 2021 after Dr. Veronikas performed the surgery to explant Ms. Madsen's Align mesh. [157-4]. In it, he adds that Dr. Veronikis' findings and the post-explant pathology report for the

explanted mesh confirm his initial opinions. *Id.* at 20–21. Namely, Dr. Margolis opines that Dr. Veronikis found urethral scarification, and the pathology report shows that the Align product contracted 50–80 percent while implanted in Ms. Madsen, and the explanted mesh and surrounding tissue showed "surrounding fibrosis, chronic inflammation and foreign body giant cell reaction." *Id.* Overall, Dr. Margolis concludes that "contraction/shrinkage of the Align TO product was the cause of Mrs. Madsen's de novo" symptoms and, despite Dr. Veronikis' removal of the mesh, some of Ms. Madsen's symptoms and pain "will likely be permanent." *Id.* at 21.

Defendant now moves to exclude Dr. Margolis' opinions, [86], detailing numerous arguments that the Court addresses below.

1. General Causation Opinions

First, Defendant argues that Dr. Margolis impermissibly offers general causation opinions when Plaintiffs only designated him as a specific-causation expert. [157] at 10–11. Defendant argues that the MDL Court already addressed this issue with respect to Dr. Margolis for other cases in Wave 4 and 5 of MDL 2187 (in which this case belonged for some time), holding that "because the plaintiffs disclosed Dr. Margolis as a specific causation expert only, he may not offer general causation testimony." *In re C.R. Bard, Inc.*, MDL No. 2187, 2018 WL 4215636 (S.D. W. Vir. Sept. 4, 2018); *see also id.* at 6 n.5; [168] at 2–3.

In response, Plaintiffs state that they do not intend to elicit general causation opinions from Dr. Margolis. But, they argue, Dr. Margolis relied upon Plaintiffs' general causation experts' opinions in rendering his specific causation opinions and

he should be permitted to testify about his review of and reliance on those general causation opinions. [163] at 2–3.

A specific causation opinion (*i.e,* whether a product caused plaintiff's injuries) necessarily rests in part on general causation (*i.e.* whether the product can cause such injuries) since something can only cause an injury if it has the capacity, generally, to cause such an injury. Thus, to an extent, Plaintiffs' argument appears reasonable. Yet, Dr. Margolis' expert report does much more than reference Plaintiffs' general causation experts' opinions to explain the basis for his specific causation opinion. For example, he opines: (1) about "common complications associated with polypropylene mesh implants," [157-4] at 16; (2) that, based on Defendant's internal documents, Defendant likely knew that its Align product "could cause" various complications, *id*. at 18–19; and (3) that "C.R. Bard's Inc.'s Align TO product is not suitable for the intended use as an implant for pelvic organ prolapse in patients," *id*. at 19. In doing so, he discusses general complications with Align mesh implantation that he agrees Ms. Madsen did not suffer. Further, he states that, in formulating his specific causation opinions, he relied upon Plaintiffs' general causation experts' opinions *as well as* "materials listed in my previously disclosed general expert report" in MDL 2187, Defendant's internal documents, scientific literature and depositions. *Id*. at 16. Thus, Dr. Margolis' report ostensibly offers his own broad-sweeping general causation opinions beyond those of Plaintiffs' general causation experts.

Because Plaintiffs did not designate Dr. Margolis as a general causation expert, consistent with the MDL Court's ruling in Wave 4 and 5, he may not offer his

own broad general causation opinions. Instead, Plaintiffs must establish general causation through their general causation experts. Dr. Margolis may rely on those general causation opinions to reach his specific causation opinions, however, and Dr. Margolis may reference those opinions to the extent he relied upon them in reaching his specific causation opinions. But his testimony must remain focused on specific causation. Defendant will need to raise timely objections at trial if it believes that Dr. Margolis' testimony crosses the line.

2. Dr. Margolis' Specific Causation Opinions

Defendant also attacks the reliability of Dr. Margolis' specific causation opinions, arguing that he failed to conduct a reliable differential diagnosis on causation. [157] at 13–19.

A differential diagnosis is a method whereby a physician "systematically compares and contrasts clinical findings from a patient's medical history to determine which of two or more diseases with similar symptoms is the one from which the patient is suffering." *Myers v. Ill. Central R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). A differential diagnosis remains a reliable method under *Daubert*. *See Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904–05 (7th Cir. 2007). A court should not exclude a specific causation conclusion just because an expert failed to rule out every possible cause and flaws "typically go to the weight of the testimony, not its admissibility." *Wheeler v. C.R. Bard, Inc.*, 19-cv-8273, 2022 WL 971394, at *12 (N.D. Ill. Mar. 31, 2022). Nonetheless, if a differential diagnosis wholly "fails to take serious account of other potential causes," then a court may exclude it for lacking reliability.

Id. (quoting *Sanchez v. Boston Sci. Corp.*, 12-cv-5762, 2014 WL 4851989, at *3 (S.D. W. Va. Sept. 29, 2014)).

Defendant argues that Dr. Margolis' initial 2017 Report, issued before Ms. Madsen's explant surgery, "fails to take serious account of other potential causes" of Ms. Madsen's pain, focuses upon a "perceived temporal relationship" between her reported symptoms and implantation of the Align mesh, and then merely assumes that the mesh caused her symptoms. [157] at 13–14. Defendant also faults Dr. Margolis for not personally examining Ms. Madsen or the Align product implanted in her. *Id.* Defendant further insists that Dr. Margolis' 2021 Supplemental Report constitutes an impermissible post hoc attempt to justify an unreliable opinion and, regardless, Dr. Margolis lacks qualifications to opine about the pathology report on the explanted mesh, *id.* at 17–19.

As a preliminary point, Defendant's focus on Dr. Margolis' 2017 Report is misplaced since Dr. Margolis supplemented his Report in response to developments in Ms. Madsen's medical history and treatment. The Court must assess whether Dr. Margolis' opinions and testimony, as currently formulated and supported, have sufficient reliability for a jury to hear.

Focusing on the Supplemental Report, Dr. Margolis discusses the new symptoms that Ms. Madsen experienced after her Align product implant surgery, including sudden, sharp vaginal pain when inserting a tampon and during intercourse, bilateral groin and pelvic nerve pain, numbness and pain in the medial aspect of both thighs, and bilateral obturator internus pain. [157-4] at 20. He further

explains why mesh shrinkage, inflammation, and scar tissue buildup causes such pain. *Id*. at 20–21. His written report does not specifically detail all the alternative causes that he considered and rejected, but he explained in more detail during his deposition the other causes that he ruled out and why. [157-6]. For example, he explained why he ruled out her other surgeries, myofascial pelvic floor pain syndrome, and prior pelvic floor dysfunction. *Id*. at 116:3–117:5, 118:20–24, 120:10–21.

Further, Defendant's argument about Dr. Margolis' reliance of the 2019 pathology report lacks merit. Defendant argues that Dr. Margolis lacks qualifications to analyze a pathology report's findings on the explanted mesh because he is not a biomedical/biomechanical engineer or a material scientist. [157] at 18. But Dr. Margolis' opinions about the pathology report focus on the mesh from a clinical perspective—*i.e.,* that it was physically smaller than when initially implanted and showed tissue with "surrounding fibrosis, chronic inflammation and foreign body giant cell reaction," and what symptoms he believes such conditions can cause, based on his clinical expertise. [157-4] at 14. Defendant fails to explain why such opinions would require engineering expertise.

Defendant also argues that Dr. Margolis' opinion that the mesh contracted lacks reliability because he did not personally view the explanted mesh and does not know how it was handled after removal, but instead just read a few lines of the pathology report and glanced at a photograph of the mesh included in that report. Defendant insists that a jury remains just as capable as Dr. Margolis to read those

lines and look at the photograph. [157] at 19. These arguments may make good fodder for cross-examination, but they do not establish that Dr. Margolis' opinion lack reliability under FRE 702. Further, even if a jury could read mesh size measurements on the report, Dr. Margolis' opinion is not merely about the size of the mesh after explant, but the *clinical significance* of those measurements from a specific causation perspective.

Dr. Margolis' Supplemental Report and deposition testimony show that he engaged in a sufficiently thorough differential diagnosis to pass muster under *Daubert* and FRE 702.

3. Dr. Margolis' Standard-of-Care Opinions

Next, Defendant asks the Court to bar Dr. Margolis from opining on whether Ms. Madsen's treating physicians met standards of care because he lacks knowledge on the standards of care applicable in Illinois and Missouri (where Ms. Madsen had her relevant surgeries). [157] at 16–17. In response, Plaintiffs state that they do not intend to elicit standard-of-care opinions from Dr. Margolis but reserve the right to do so if Defendant attempts to argue that the implanting or explanting provider breached the standard of care. [163] at 12. Further, they argue that Dr. Margolis is qualified to offer such opinions because he is a board-certified surgeon licensed in four states. *Id*. at 11.

Dr. Margolis has not established that his board-certification in four states other than Illinois and Missouri renders him qualified to opine on the standard of care applicable to physicians in Illinois and Missouri. As Defendant emphasizes and

Plaintiffs acknowledge, [157] at 17, [168] at 7, Illinois applies a "similar locality" standard of care rule and only permits an out-of-state physician to opine on standard of care if he or she establishes: (1) familiarity with the standards of care applicable to qualified physician in the same or similar locality of treatment; or (2) that there exists an applicable nationally uniform standard. *See Jackson v. Graham*, 753 N.E.2d 525, 532–33 (Ill. App. Ct. 2001). Dr. Margolis' report establishes neither.

Nonetheless, Defendant's motion remains moot at this stage since Plaintiffs represent that they do not intend to elicit a standard-of-care opinion from Dr. Margolis.

4. Other Opinions

Fourth, and finally, Defendant asks the Court to bar Dr. Margolis from opining on the following topics because, according to Defendant, Dr. Margolis testified at his deposition that he would not opine on them: (1) IFU labeling; (2) human factors; (3) engineering; (4) material science/biomaterials; (5) chemistry or biomechanics of pelvic mesh design; (6) FDA regulations; (7) Defendant's quality assurance and complaint handling; (8) Defendant's conduct; (9) Ms. Madsen's medical bills; (10) life care planning; (11) Ms. Madsen's future medical care; and (12) other topics "outside the margins" of his report. [157] at 8.

Plaintiffs do respond to this request or dispute that Dr. Margolis testified he would not offer such opinions. [163]. Thus, the Court grants Defendant's motion as agreed as to topics (1)–(11), although Defendant will bear the responsibility to raise timely objections during trial if it believes questions to Dr. Margolis call for such

testimony. The Court denies, however, Defendant's motion as to topic (12) since other topics "outside the margins" of his report lacks sufficient clarity for a pretrial ruling. Instead, Defendant must raise timely objections at trial if it believes that Dr. Margolis attempts to opine on topics beyond those properly disclosed in discovery.

In sum, the Court grants in part, and denies in part, Defendant's motion to exclude Dr. Margolis' opinions and testimony [86]. Dr. Margolis may not offer broad general causation opinions but may offer his specific causation opinions that Defendant's Align product caused Ms. Madsen's alleged injuries. Further, the Court denies as moot Defendant's motion to bar Dr. Margolis' standard-of-care opinions, and grants as agreed Defendant's motion to bar Dr. Margolis from opining about (1) IFU labeling; (2) human factors; (3) engineering; (4) material science/biomaterials; (5) chemistry or biomechanics of pelvic mesh design; (6) FDA regulations; (7) Defendant's quality assurance and complaint handling; (8) Defendant's conduct; (9) Ms. Madsen's medical bills; (10) life care planning; and (11) Ms. Madsen's future medical care.

III. Defendant's Motion for Summary Judgment

A. Legal Standard

Summary judgment is appropriate where the movant shows through "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. In

resolving a motion for summary judgment, the court has "one task and one task only: to decide, based on the evidence of record, whether there is any material dispute of fact that requires a trial." *Waldridge v. Am. Hoechst Corp.*, 24 F.3d 918, 920 (7th Cir. 1994) (citations omitted).

To withstand a motion for summary judgment, the nonmovant must "set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). The Court must construe the record "in the light most favorable to the nonmovant" and avoid the "temptation to decide which party's version of the facts is more likely true." *Payne v. Pauley*, 337 F.3d 767, 770 (7th Cir. 2003). If the evidence is "merely colorable, or is not significantly probative," *Anderson*, 477 U.S. at 249 (citations omitted), or merely raises "some metaphysical doubt as to the material facts," summary judgment may be granted, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

B. Analysis

First, Defendant asks the Court to grant summary judgment on Plaintiffs' claims for strict liability and negligent manufacturing defect, breach of express or implied warranties, and negligent inspecting, marketing, packaging, and selling because Plaintiffs previously conceded them. [152] at 6. In response, Plaintiffs agree, [161] ¶ 56 (response). Thus, the Court grants as agreed Defendant's motion for summary judgment on: (1) negligence (Count I) based on a manufacturing defect, or negligent inspecting, marketing, packaging, and selling; (2) strict liability

manufacturing defect (Count III); (3) breach of express warranty (Count V); and (4) breach of implied warranty (Count VI).

That leaves negligent and strict liability design defect (Counts I and II); negligent and strict liability failure to warn (Counts I and IV), loss of consortium (Count VII), and punitive damages (Count VIII). Defendant argues that these fail as well, because Plaintiffs cannot establish that any alleged defect in the Align product proximately caused Ms. Madsen's alleged injuries. Defendant also argues that the failure to warn claims fail as a matter of law because the implanting surgeon, Dr. Upputuri, knew of the potential risks of which Plaintiffs complain. Finally, Defendant argues that Plaintiffs cannot satisfy the heightened culpability standard required under Illinois law for punitive damages.

1. Causation

Under Illinois law, which the parties agree applies,[3] a plaintiff bringing a product liability claim under either a negligence or strict liability theory must prove that the defendant's product proximately caused the alleged harm. *See Clark v. River Metals Recycling, LLC*, 929 F.3d 434, 439 (7th Cir. 2019) (strict liability); *Malen v. MTD Prod., Inc.*, 628 F.3d 296, 307 (7th Cir. 2010) (negligence). Further, when the action involves "specialized knowledge or expertise outside the layman's knowledge,"

[3] In actions filed directly into MDLs, courts apply the choice-of-law rule of the "originating jurisdiction." *Dobbs v. Depuy Orthopedics, Inc.*, 842 F.3d 1045, 1048–49 (7th Cir. 2016). Here, the parties agree that the "originating jurisdiction" is Illinois because Ms. Madsen had her Align implant surgery in Illinois. [152] at 9; [161] ¶ 49. Illinois' choice-of-law rule applies the "most significant relationship" test from the Restatement (Second) of Conflicts of Torts. *See Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 899–902 (Ill. 2007). Under this test, a court applies the laws of the state where the injury occurred unless a party can show "a more or greater significant relationship to another state." *Id.* at 903. Again, the parties agree that, under this test, Illinois law applies. [161] ¶¶ 1, 4, 49.

Illinois law requires a plaintiff to present expert testimony to establish causation. *Baltus v. Weaver Div. of Kidd & Co.*, 557 N.E.2d 580, 586 (Ill. App. Ct. 1990).

At times, parties dispute whether the product at issue is sufficiently complex or specialized to require expert testimony on causation. *See Clark*, 929 F.3d at 440 (discussing when a product may be "so simple that no expert is needed to tell people how to use them"). This case presents no such issue, however, since a polypropylene mesh product used for a transvaginal mesh procedure indisputably falls "outside the layman's knowledge." *Baltus*, 557 N.E.2d at 586. Instead, the parties dispute whether Dr. Margolis' expert opinions on specific causation suffice to create a disputed issue of fact to overcome summary judgment.

Defendant asserts two arguments in support of its position. First, it points to its motion to exclude Dr. Margolis' specific causation opinions. [152] at 11–12. The Court, however, already addressed and rejected those arguments above. Second, Defendant argues that, even if the Court does not exclude Dr. Margolis' specific causation opinions, Plaintiffs still fail to create a triable issue of fact on proximate causation. *Id.* at 12. According to Defendant, Dr. Margolis only offers broad generalized opinions that the Align product caused Ms. Madsen's pain and symptoms and fails to "link" her "pain and symptoms to the alleged defects" in the Align product. *Id.* at 13.

In so arguing, Defendant relies on *Johnson & Johnson & Ethicon, Inc. v. Batiste*, another transvaginal mesh case in which Dr. Margolis testified as a specific causation expert. *See* 05-14-00864-CV, 2015 WL 6751063 (Tex. App. Nov. 5, 2015).

In *Batiste*, a Texas appellate court reversed a jury verdict against the defendant-manufacturer, finding that the plaintiff "failed to offer legally sufficient evidence that any alleged defect" in the transvaginal mesh product "was the producing cause of her injuries." *Id.* at *1. It emphasized that, although the plaintiff offered evidence of general causation—namely that the mesh product could rope, curl, fray, or degrade causing erosions, infections, obstructions, contractions, damage to adjacent organs, inflammation, scarring, pain, and loss of function—Dr. Margolis' opinion did not establish that any of those things happened in her case. *Id.* at *7–10.

Defendant insists that here, just as in *Batiste*, Dr. Margolis only opines that the Align mesh can curl, fray, rope or break down, but does not opine that it did in Mrs. Madsen's case. *Id.* Further, even though Defendant concedes (as it must) that Dr. Margolis opined that the mesh contracted while implanted in Ms. Madsen, it argues that this does not suffice because Dr. Margolis does not establish "that fibrotic bridging"—*i.e.*, excessive scarring—caused any of Mrs. Madsen's pelvic pain or other symptoms." *Id.* at 13.

Based upon the record, this Court disagrees. As a preliminary point, the *Batiste* decision came after the benefit of a trial in which the defendant presented its own competing witnesses and evidence. Further, the Texas appellate court's decision turned on the specifics of that plaintiff's procedure, and her pre-existing conditions and post-procedure symptoms. Thus, even if Dr. Margolis' specific causation opinions in that case failed to establish proximate cause or overcome the competing evidence that the defendant offered at trial, that does not mean that his specific causation

opinions in this case fail to create a disputed issue of fact to survive summary judgment.

In addition, contrary to Defendant's insistence and as discussed above, Dr. Margolis opines that the mesh explanted from Ms. Madsen in 2019 not only showed shrinkage/contraction, but also showed evidence of tissue inflammation and excessive scarring. He also opined that Ms. Madsen's symptoms pointed to mesh contraction and excessive scarring and discussed why he excluded other potential causes. While Defendant's critiques of Dr. Margolis remain valid points for cross examination, Dr. Margolis's testimony more than suffices to create a disputed issue of fact on proximate causation.

Further distinguishing this case from *Batiste*, Plaintiffs also provide additional causation evidence through Ms. Madsen's explanting surgeon, Dr. Veronikis, and pelvic floor specialist, Dr. Fitzgerald. [169] ¶¶ 9–15. The parties dispute the substance and legal significance of Dr. Veronikis' and Dr. Fitzgerald's deposition testimony, *see id.*, but Dr. Veronikis' deposition transcript confirms that he believes, based upon his examination of Ms. Madsen, that her Align implantation procedure likely caused at least some of her reported symptoms and pain, *see* [153-18] at 58:11–66:9. Likewise, Dr. Fitzgerald's deposition transcript confirms that she believes, based on her examination of Ms. Madsen, that Ms. Madsen's pelvic floor myofascial pain and dysfunction was related to the Align implantation procedure.[4] *See* [161-3]

[4] Defendant also argues that Plaintiffs may not rely on Dr. Veronikis or Dr. Fitzgerald to provide causation opinions because Plaintiff failed to properly disclose them as causation experts in accordance with Fed. R. Civ. P. 26(a)(2)(B). [152] at 14. As Defendant correctly notes, the Seventh Circuit has emphasized that treating physicians may only testify about causation to the extent they made those

at 40:1–13, 41:14–19, 43:17–22, 57:19–60:1. As Defendant notes, these physicians' treatment opinions may not suffice to establish that the Align product's *design* caused Mrs. Madsen's injuries, [152] at 14, but their treatment opinions still provide evidence that the Align implant procedure, rather than one of Ms. Madsen's pre-existing conditions or other procedures, caused some of her post-implant pain and symptoms.

Plaintiffs have offered sufficient evidence on causation through Dr. Margolis and her treating physicians to withstand Defendant's motion for summary judgment on this basis.

2. Failure to Warn

Next, Defendant argues that Plaintiffs' failure to warn claims fail as a matter of law because, according to Defendant, Ms. Madsen's implanting physician, Dr. Upputuri, knew of the potential risks. [152] at 15–18.

Under the learned intermediary doctrine, medical device manufacturers must warn physicians, not patients, about a prescription medical device's "known dangerous propensities." *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002). In addition, manufacturers have no obligation to warn of risks "already known

determinations "in the course of providing treatment." *Meyers v. Nat'l R.R. Pass. Corp.*, 619 F.3d 729, 735 (7th Cir. 2010). Here, Defendant does not dispute that Drs. Veronikis and Fitzgerald treated Ms. Madsen. [169] ¶¶ 15–16. But it insists that neither determined, as part of their treatment, "that the design of the Align caused the injuries" and thus they cannot offer causation opinions. [152] at 14. Not so. While neither formed opinions about the Align product's design, per se, they both testified that, in treating Ms. Madsen, they determined that the Align product procedure likely caused at least some of her symptoms and pain. They may testify as to those opinions without running afoul of Rule 26(a)(2)(B). *See id.* If Defendant believes that they offer causation opinions at trial that they did not form while treating Ms. Madsen, then it must raise timely objections.

to the medical community." *Id.* But the learned intermediary doctrine does not shield a manufacturer "if the warnings it gave to physicians are inadequate." *Id.*

Defendant maintains that Dr. Upputuri knew of the risks of using the Align product because he reviewed the product's IFU, and read the FDA's communications that, according to Defendant, adequately warned of risks. [152] at 16–17 (citing [153] ¶¶ 22–39). Plaintiffs disagree and contend that Dr. Upputuri only knew of some of the risks, reviewed the IFU, and may have reviewed some of the FDA publications. [160] at 7–8. But, they argue, Dr. Upputuri did not know about, and the IFU did not disclose, "several significant risks including the risk of chronic pelvic pain, chronic pain with sexual intercourse, chronic vaginal infection, chronic urinary tract infections, chronic groin pain, chronic thigh pain, chronic leg pain, chronic nerve pain, chronic foreign body reaction, degradation, and shrinkage." [160] at 7–8 (citing [161] SAMF ¶ 21). They also argue that the IFU failed to warn of the "the rate and duration of risks," which was as high as 30–50 percent. *Id.* at 8 (citing [161] SAMF ¶ 122). According to Plaintiffs, Dr. Upputuri testified that, if he had known that any risk was higher than 3 percent, he may not have used the Align product. *Id.* (citing [161] SAMF ¶ 24).

As Defendant correctly notes in reply, Illinois law does not require a manufacturer "to provide a warning listing every possible risk imaginable associated with the product." [167] at 7. But Illinois does require manufactures to *reasonably* warn about any "dangerous condition" and potential injuries. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 742 (S. D. W. Va. 2014) (citing *Happel v. Wal-Mart Stores, Inc.*,

766 N.E.2d 1118, 1123 (Ill. 2002) and *Kennedy v. Metronic, Inc.*, 851 N.E.2d 778, 783 (Ill. 2006)) (applying Illinois law in another transvaginal mesh case alleging failure to warn). In general, the adequacy of warnings remains a fact question that a jury (not a court) should resolve, "unless the movant demonstrates conclusively that there remains no triable issue." *Wheeler*, 2022 WL 971394, at *5 (quoting *Werckenthein v. Bucher Petrochemical Co.*, 618 N.E.2d 902, 908 (Ill. App. Ct. 1993)) (denying summary judgment on a failure to warn claim in another transvaginal mesh case against Defendant Bard because there existed disputed issues of fact on the adequacy of its warnings).

Here, the record confirms that Defendant has not demonstrated conclusively that there remains no triable issue on the adequacy of its warnings. First, while the IFU lists some complications with implantation including "scarring which may occur following the implant procedure", "inflammation, sensitization, pain, dyspareunia, scarification, contraction, device migration and failure of the procedure resulting in recurrence of incontinence," [161] ¶ 161, it does not list all of the injuries of which Ms. Madsen complains, nor does it discuss the rate or severity of possible complications. Thus, a disputed issue of fact remains as to whether it adequately disclosed the likelihood of a risk or potential severity of the possible complications. Further, while Defendant argues that the FDA's communications provided further warnings, [17] at 7, it remains in dispute which FDA publications Dr. Upputuri reviewed prior to Ms. Madsen's surgery and whether the FDA's publications absolved Defendant from having to also warn of such risks. [161] ¶¶ 14–25 (response).

Accordingly, the Court denies Defendant's motion for summary judgment on the failure to warn claims.

3. Punitive Damages

Finally, Defendant seeks summary judgment on Plaintiffs' claim for punitive damages, arguing that Plaintiffs cannot establish that it acted with the heightened culpability required under Illinois law. [152] at 19–20.

Under Illinois law, a plaintiff may seek punitive damages for torts "committed with fraud, actual malice, deliberate violence or oppression, or when the defendant acts willfully or with such gross negligence as to indicate a wanton disregard for the rights of others, or for conduct involving some element of outrage similar to that found in crime." *Homewood Fishing Club. v. Archer Daniels Midland Co.*, 605 N.E.2d 1103, 1110 (Ill. App. Ct. 1993).

Here, in support of their punitive damages claim, Plaintiffs point to Phillips Sumika's information sheet recommending non-medical uses for the grade of polypropylene that Defendant used, such as "Woven industrial fabric and bags, rope and cordage, woven carpet backing, and geotextile fabric." [160] at 11 (citing [161] SAMF ¶ 40). Plaintiffs also point to the Marlex HGX-030-01 MSDS for the raw polypropylene material that Phillips Sumika used, which warned about degradation and incompatibility with other materials and cautioned against use "in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." *Id.* (citing [161] SAMF ¶ 39). Plaintiffs contend that Defendant was aware of the information sheet and MSDS yet

disregarded them and even attempted to conceal the source of the raw polypropylene. *Id.* They argue that these facts, if proven at trial, establish "such gross negligence as to indicate a wanton disregard of the rights of others." *Id.*

In response, Defendant insists that the MSDS and information sheet "do not speak to whether a raw material is appropriate for a particular use in a finished product." [167] at 8. It also argues that the MSDS remains irrelevant because the Occupational Safety and Health Administration regulates MSDSs, which shows that their "purpose is to assure safe and healthful working conditions for employees in the workplace." *Id.* It also attacks the validity of the MSDS warning, contending it has no scientific basis. *Id.* In making such arguments, however, Defendant fails to cite to anything in the record. Instead, it relies merely upon a Fifth Circuit decision in another transvaginal mesh case that upheld a district court's exclusion of the MSDS because the plaintiffs in that case "did not provide any science behind the MSDS." *Id.* (citing *Johnson v. Arkema, Inc.*, 685 F.3d 452, 462–63 (5th Cir. 2012)).

Initially, even though the *Johnson* court excluded the MSDS, the first bellweather transvaginal mesh case, *Cisson v. C.R. Bard, Inc.,* allowed the plaintiff to offer the MSDS "for the limited purpose of showing that the statement was made and that Bard was aware of it," 11-CV-00195, 2013 WL 5700513 (S.D. W. Va. Oct. 18, 2013), *aff'd sub nom. in re C.R. Bard, Inc., MDL No. 2187, Pelvic Repair Sys. Prods. Liab. Litig.*, 810 F.3d 913 (4th Cir. 2016). And the MSDS remains at issue in this case.

Additionally, Plaintiffs' claim for punitive damages does not rely on the truth of the MSDS, but instead focuses on how Defendant allegedly disregarded it and attempted to conceal it. Construing the evidence in the light most favorable to Plaintiffs, a reasonable jury could find that, regardless of whether the MSDS warnings were true, Defendant disregarded public safety by ignoring the polypropylene's MSDS and attempting to conceal it, rather than evaluating the underlying bases of its warnings. This, in turn, could support a viable claim for punitive damages. *See Wheeler*, 2022 WL 971394, at *10 (denying, for similar reasons, a summary judgment on a plaintiff's punitive damages claim against Defendant Bard in a transvaginal mesh case).

IV. Conclusion

For the foregoing reasons, the Court grants in part, and denies in part, Defendant's motions to exclude the expert opinions and testimony of Dr. Brennan [84], Dr. Garely [82], and Dr. Margolis [86], and motion for summary judgment [151]. Plaintiffs may proceed to trial on negligence (Count I) based on design defect and failure to warn; strict liability design defect (Counts II); strict liability failure to warn (Count IV); loss of consortium (Count VII); and punitive damages (Count VIII).

Dated: September 27, 2022 Entered:

John Robert Blakey
United States District Judge