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

CHRISTINE WHEELER and DOUGLAS WHEELER, Plaintiffs, v. C.R. BARD, INC., Defendant.	)	No. 19-cv-08273 Judge John J. Tharp, Jr.

MEMORANDUM OPINION AND ORDER

Plaintiff Christine Wheeler received a pelvic mesh implant manufactured by the defendant, Bard. She claims that the mesh caused her injuries, necessitating four surgeries to remove it, and that her injuries resulted from Bard's failure to warn of dangers inherent in its product. She brings claims of negligence, design defect, and failure to warn.[1] Her husband, Douglas Wheeler, brings a loss-of-consortium claim.[2] This case was part of the pelvic mesh Multidistrict Litigation (MDL) in the Southern District of West Virginia and has been returned to the Northern District of Illinois. Prior to repatriation, Bard had moved for summary judgment, arguing, among other things, that Mrs. Wheeler's action is barred by Illinois' statute of limitations, that she can't prove Bard's device caused her injuries, and that its warnings of risks associated with its pelvic mesh were adequate as

[1] Mrs. Wheeler has dropped her claims of manufacturing defects; breach of implied and express warranty; and negligent marketing, labeling, packaging and selling. Mr. Wheeler has dropped his claim to recover lost profits. Def.'s Mot. for Sum. J. 12, ECF No. 136.

[2] Mr. Wheeler's loss of consortium claim depends on the success of Mrs. Wheeler's claims. Bard argues in a footnote that Mr. Wheeler's loss-of-consortium claim must fail because all of Mrs. Wheeler's claims fail on summary judgment; because its motion for summary judgment is mostly denied, this argument fails as well. *See* Def.'s MSJ at 15 n.10. Accordingly, this opinion ignores the loss of consortium claim to simplify the discussion.

a matter of law. For the reasons set forth below, the Court denies Bard's motion for summary judgment. The Court also took up the parties' motions to exclude expert witnesses pursuant to *Daubert v. Merrill Dow Pharmaceuticals*, which were also originally filed before the MDL court, and grants in part and denies in part those motions.

BACKGROUND[3]

In November 2009, Christine Wheeler sought treatment for stress urinary incontinence from Dr. Feinstein, a gynecologist in Chicago. Defendant's Statement of Material Facts (DSMF) ¶ 6, ECF No. 137. Dr. Feinstein diagnosed her with urinary incontinence, incompetent mid-urethral sphincter, and severe anterior prolapse/cystocele. *Id.* at ¶ 7. After Mrs. Wheeler signed an informed consent form, *id.* at ¶¶ 8-15, Dr. Feinstein performed a "Mid-Urethral Sling Bladder," using the Coloplast Mentor Aris Tape, and an "anterior pelvic organ prolapse-cystocele repair" using, according to his notes, an "Avaulta Repair System from BARD," specifically, a Bard Avaulta Solo. Plaintiff's Response to DSMF and Plaintiff's Additional Material Facts (PSMF) ¶¶ 23-24, ECF No. 141.

In postoperative visits to Dr. Feinstein between December 2009 and February 2010, Mrs. Wheeler reported that her incontinence had improved. PSMF ¶ 26. However, in January 2010, she complained of a pulling sensation, and in February, reported constant pain. DSMF ¶¶ 33-35. Dr. Feinstein advised her that her pain was likely due to difficulty healing from the November surgery. PSMF ¶ 52. Her pain persisted, and at another follow-up appointment on June 8, 2010, Dr. Feinstein told Mrs. Wheeler that he might need to remove the pelvic mesh that he had implanted the previous November. PSMF ¶ 51. He performed the first procedure to remove the mesh on June

[3] Fact disputes are identified and discussed only where material to the parties' summary judgment arguments.

18, 2010. DSMF ¶ 49. According to Dr. Feinstein, who had implanted two different mesh products, this revision surgery "was to address problems that corresponded exactly to the location of a portion of the Bard Avaulta implant[.]" Ex. 2 to Pl.'s Resp. to Def.'s MSJ, Rosenzweig Expert Report 5 n.2, ECF No. 141-2 (compiling medical history). Ultimately, Mrs. Wheeler underwent four separate procedures to excise the mesh, performed by several surgeons over a period from June 2010 to March 2011. DSMF ¶ 49; Rosenzweig Report 5-11. After each of these procedures, she had a brief respite from the pain, only to suffer a recurrence soon after. Rosenzweig Report 5-11. Throughout this time, she also complained of severe pain during intercourse. DSMF ¶ 35. On December 2014, Mrs. Wheeler was implanted with another mesh product, a TVT Exact, manufactured by Ethicon, to treat her ongoing stress-urinary incontinence and pain; this pelvic mesh remains implanted. DSMF ¶ 50; Rosenzweig Report at 25. According to her medical records, her vaginal pain and inability to engage in intercourse persisted after the Bard mesh was removed and the TVT exact was implanted. Rosenzweig Report at 27. In 2018, Mrs. Wheeler was diagnosed with an ovarian tumor. *Id.* at 27. Her medical records also document some other conditions—among them a history of sarcoidosis (a condition of the lungs and skin), and endometriosis (a condition of the uterus). Rosenzweig Report at 31.

The Food and Drug Administration and the medical community were aware that complications could arise from pelvic mesh implants.. In 2008, the FDA issued a notice entitled "Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence." DSMF ¶ 16. The informed consent form wherein Mrs. Wheeler acknowledged her awareness of risks listed several complications that could result from the surgery and included a "black box" warning that summarized the FDA's assessment of the risks of pelvic mesh products DSMF ¶¶ 13-16. Bard

also warned of risks in the "Instructions for Use" that was directed at physicians implanting the device. DSMF ¶ 21. According to Mrs. Wheeler, these warnings did not adequately apprise physicians of the dangers posed by Bard pelvic mesh, including "permanent, lifelong and debilitating pelvic pain, lifelong sexual complications and dysfunction, difficulty removing the device, lifelong risk of erosions… and the risk of serious complications and effect on a patient's quality of life." PSMF ¶ 54.

Companies that provided raw materials to Bard also demonstrated an awareness of the risks attendant to pelvic mesh products. Bard's implants were manufactured using "Marlex" polypropylene material manufactured by Chevron Phillips. PSMF ¶ 68. In 2004, Chevron Phillips added a statement to the Marlex Material Safety Data Sheet (MSDS) warning against the material's use in medical applications: "Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." PSMF ¶ 70. One of Bard's suppliers of polypropylene monofilament—a more processed version of the polypropylene sold by Chevron—became aware of this warning and decided to stop supplying Bard with polypropylene monofilament, even after Bard offered to indemnify it. Def.'s Resp. to PSMF ¶¶ 71-75, ECF No. 148.

Mrs. Wheeler also claims that Bard was presented with several proposed studies on its pelvic mesh devices, but declined to pursue them, despite knowledge that the product might be risky. A 2002 patent application filed on Bard's behalf for polypropylene mesh products acknowledged a "higher potential for complications such as the occurrence of infection or foreign body reaction around the mesh." PSMF ¶ 77. Some of Bard's marketing and sales employees lamented the lack of testing data, which they attributed to a need to "reduce expenses." PSMF ¶ 80. The President of Bard's Urological Division stated in 2006, "We as a division need to step it

up on these [*sic*] department. We always release products with no data." PSMF ¶ 81. When the FDA, in 2012, directed that the Avaulta product line be subjected to clinical trials, Bard decided to remove those products from the market. PSMF ¶ 87.

I. Bard's Motion for Summary Judgment

Summary judgment is appropriate "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 Court's role is not to "weigh the evidence and determine the truth of the matter" but rather to determine "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255.

Bard has moved for summary judgment on several issues. First, it argues that Mrs. Wheeler's action is time-barred under Illinois' statute of limitations and attendant discovery rule. Second, it argues that, because the Mrs. Wheeler's experts must be excluded, they cannot show that the Bard Avaulta caused Mrs. Wheeler's injuries. Third, Bard argues that she cannot persuade a reasonable jury that Bard failed to warn of the risks posed by the Bard Avaulta. Finally, Bard contends there is no evidence to support compensation for Mrs. Wheeler's lost profits or the imposition of punitive damages. The Court addresses these arguments in turn and denies summary judgment except as to Mrs. Wheeler's claim for lost profits.

A. Statute of Limitations

Product liability actions in Illinois are subject to a two-year statute of limitations that begins to run on "the date on which the claimant knew, or through the use of reasonable diligence should have known, of the existence of the personal injury[.] 735 ILCS 5/13-213(d). This discovery rule "postpone[s] the commencement of the relevant statute of limitations until the injured plaintiff knows or reasonably should have known that he has been injured and that [his] injury was

wrongfully caused." *Mitsias v. I-Flow Corp*., 959 N.E.2d 94, 100 (Ill. 2011). A plaintiff must have more than "a mere suspicion that wrongdoing might have occurred in order to trigger the limitations period." *Id.* at 102. "[T]he time when the injured party knows or should have reasonably known both of her injury and that her injury was wrongfully caused by another person is often a disputed question of fact," unless the facts support only one clear inference. *Stark v. Johnson & Johnson*, 10 F.4th 823, 829 (7th Cir. 2021) (holding that fact issue precluded summary judgment where physicians had discussed the possibility of mesh erosion with the plaintiff, who did not sue until eight years later).

Mrs. Wheeler underwent pelvic mesh implant surgery in November 2009 and filed this action in April 2012. Bard contends that her claim accrued, at the latest, in February 2010, when she began experiencing pain as a complication from her mesh surgery, and that the statute of limitations therefore expired in February 2012. That would mean that Mrs. Wheeler sued about two months too late. Up until June 2010, however, Wheeler attended post-operative visits where Dr. Feinstein advised her the pain was likely due to difficulty healing from the surgery. PSMF ¶ 52. Mrs. Wheeler argues that her claim did not accrue until June 2010, when Dr. Feinstein recommended removing the mesh. *Id.* at ¶ 51.

Thus, the question is whether Mrs. Wheeler's claim accrued when she began experiencing symptoms, in February 2010, or when her physician told her that he might need to remove the mesh, in June 2010. Bard—which elsewhere argues that Mrs. Wheeler has not adduced any evidence that Bard caused her injuries—argues here that the cause of her symptoms was clear enough in February 2010 that she should have concluded Bard wrongfully caused her injuries. The onset of symptoms should have set off an inquiry, it says, which would have led her to the various

warnings of complications that arise from pelvic mesh surgery, such as the FDA black box warning. Def.'s MSJ at 7, ECF No. 136.

Bard finds little support for its position in precedent. Faced with similar circumstances, both the Seventh Circuit and Illinois courts have held that application of the discovery rule is a fact question inappropriate for resolution at the summary judgment stage.

In *Stark v. Johnson & Johnson*, the Seventh Circuit, applying Illinois' discovery rule, reversed a grant of summary judgment for the defendant based on the statute of limitations, on facts that made the case for a timely lawsuit more tenuous than in this case. Ms. Stark had received a pelvic mesh implant in in 2007. 10 F.4th at 826. Her symptoms did not abate after the surgery, and her implanting surgeon suspected that another underlying medical condition, Ehlers-Danlos syndrome, might have been the cause. *Id.* In early 2008, Stark sought a second opinion; the physician she consulted suggested another mesh implantation surgery, to which the plaintiff agreed. During the surgery, this physician found and removed eroded mesh from the first surgery embedded in the plaintiff's urethral wall. This doctor explained that her underlying syndrome might make her prone to mesh erosion but did not suggest that the eroded mesh product itself was defective. *Id.* at 827. In 2010, she again saw this physician and complained of ongoing symptoms, which her doctor chalked up to other conditions, though "the two discussed the possibility of recurrent mesh erosion." *Id.* Stark didn't see another physician for five-and-a-half years, during which her symptoms continued to worsen. That doctor attempted to remove the mesh but was unable. Finally, in March 2018, Stark spoke with a lawyer who suggested the mesh might have been defective, and filed a lawsuit in September 2018. Despite Stark's years of complications and worsening symptoms, the Court held that a reasonable jury could conclude that Stark was not on inquiry notice that the mesh manufacturer might have wrongfully caused her injuries until March

2018, in large part because "none of Ms. Stark's physicians suggested to her that the mesh could be defective." *Id.* at 830. The same is true here. Bard argues that a few weeks of post-operative symptoms, combined with the warnings provided by her physician were sufficient, as a matter of law, to put Mrs. Wheeler on inquiry notice--but even ten years of symptoms and procedures did not dictate that outcome in *Stark*; rather, the Seventh Circuit assessed her diligence by examining her physicians' advice. An "unfortunate outcome, by itself, is not sufficient to start the statute of limitations clock." *Id.* at 836.

The Seventh Circuit's approach is consistent with the Illinois Supreme Court's. In *Nolan v. Johns–Manville Asbestos*, for example, the state Supreme Court was confronted with evidence analogous to that adduced here: the plaintiff began experiencing shortness of breath in 1957 and was diagnosed with pulmonary fibrosis in 1965. 421 N.E.2d 864, 865-66 (Ill. 1981) In 1968, there was information available to asbestos workers to suggest that the material caused lung problems. *Id.* at 866. Finally, in 1973, a physician identified asbestos as the cause of Nolan's injuries. *Id.* The Illinois Supreme Court observed that, on the one hand, the discovery rule does not hold plaintiffs to "knowing the inherently unknowable," but "once it reasonably appears that an injury was wrongfully caused, the party may not slumber on its rights." The Court did not decide when the claim accrued, but rather held that, because of conflicting evidence as to whether the plaintiff had sufficient information for his claim to accrue, "summary judgment… is not an appropriate remedy here." *Id.* at 171-72; *see also Young v. McKiegue*, 708 N.E.2d 493, 499 (Ill. App. 1st Dist. 1999) ("The issue of when a party knew or should have known both of the injury and that it was wrongfully caused is generally one of fact.").

Similarly, in this matter, a reasonable jury could easily conclude that Wheeler was exercising reasonable diligence by attending regular follow-up appointments with her surgeon and

listening to his advice, that she reasonably agreed with him that her symptoms in February were caused by slow healing rather than defective mesh, and that she did not have enough information that Bard's mesh wrongfully caused her injuries until Dr. Feinstein recommended surgery to remove it in June 2010. *See Young*, 708 N.E.2d at 389 (finding that plaintiff knew or should have known that husband's death was wrongfully caused when her lawyer received a physician's report opining that the death was caused by malpractice); *Nair v. Bloom*, 890 N.E.2d 1113, 1116-19 (Ill. App. 1st Dist. 2008) (finding that plaintiff's claim accrued when she had information that prompted her to consult with counsel, not, as defendant argued, when she began to experience symptoms).

B. Causation

Next, Bard argues that Mrs. Wheeler has not adduced evidence that its product caused her injuries. Bard contends she cannot prove that its mesh, rather than her various other medical conditions or other mesh implants, caused her pain and other symptoms.[4] Expert testimony is

[4] The parties also dispute whether a Bard product was even implanted in Mrs. Wheeler. Bard concedes that there is a genuine dispute of material fact here and that it cannot get summary judgment arguing that its product was not used. Def.'s MSJ 10 n.5. The contours of the dispute are as follows: Bard points to Dr. Feinstein's operative report from the implantation surgery, which identifies the product he implanted as "AVAULTA REPAIR SYSTEM FROM BARD." DSMF ¶ 24. He does not identify the specific model of Bard mesh, but Wheeler contends it was the Bard Avaulta Solo. In his deposition, Dr. Feinstein explained that he only used one type of Bard product, but that he did not remember the precise model because he had long since closed his practice. PSMF ¶ 24. Still, he said, Bard should have records that indicate which type of Avaulta Bard supplied him with. *Id.* Indeed, Bard's records, in the form of a "Product Sales History," demonstrate that the Bard Avaulta Solo was the only device Bard shipped to Dr. Feinstein from 2004 to 2012. *Id.*

According to Mrs. Wheeler, this record settles the issue; but the problem is thornier than she acknowledges. Bard's expert, Dr. Clark, points to portions of the operative report that appear to describe a pelvic mesh product made by an entirely different manufacturer—among other things, Dr. Feinstein described in the report that he removed plastic "sheaths" during the operation, but the Bard Avaulta Solo does not have sheaths; furthermore, the surgeon who removed the mesh described it as blue, but the Bard Avaulta Solo is not blue. Clark report at 71, Ex. T to Def.'s Obj. to PSMF, ECF No. 148-2.

required to establish causation in products liability actions. *Salerno v. Innovative Surveillance Tech. Inc.*, 932 N.E.2d. 101, 112 (Ill. App. 1st. Dist. 2010). Mrs. Wheeler's evidence that Bard caused her injuries consists of expert testimony from two physicians, Dr. Fitzgerald and Dr. Rosenzweig. Bard contends these experts must be excluded and refers the Court to the arguments in its *Daubert* motions. Def.'s MSJ at 9; ECF Nos. 90 and 92. As explained in more detail below, the parties' *Daubert* motions are denied, and their respective experts will be permitted to testify as to whether Mrs. Wheeler's injuries can be attributed to the Bard Avaulta Solo. Accordingly, the Court denies Bard summary judgment on this issue.

C. Failure-to-Warn

Bard next argues that no reasonable jury could find that Bard failed to warn of risks posed by the Avaulta Solo, because Bard had a duty to warn only Mrs. Wheeler's physician of risks, and it did so. In Illinois, a medical device manufacturer has a duty to warn physicians—not patients—of the risks attendant to medical devices. *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d. 35, 42 (Ill. 2002). Manufacturers, moreover, need not warn of risks "already known to the medical community." *Id.* at 42. This is known as the learned intermediary doctrine. *Id.* A physician is not a learned intermediary, however, if the warnings given by the manufacturer are inadequate, and the adequacy of a warning is generally a fact question reserved for the jury. *See Mahr v. G. D. Searle & Co.*, 390 N.E.2d 1214, 1230 (Ill. App. 1st Dist. 1979). That general rule applies here, where both parties have adduced evidence going to the adequacy of Bard's warnings to the medical community which could support a jury verdict for either side.

Arguing that it provided adequate warnings to the medical community, Bard relies on the Avaulta Instructions for Use (IFUs), which lists risks of the device, as well as the FDA "black

box" warning."[5] Mrs. Wheeler responds that Bard did not adequately warn physicians because it understated the severity of some risks and omitted others, and that, in any event, the adequacy of warnings is a fact question inappropriate for resolution on summary judgment. Bard disputes the necessity of any additional warnings and avers that the allegedly unwarned-of conditions and symptoms have no basis. According to Bard, medical device manufacturers are not required to "provide a warning listing every possible risk imaginably associated with the product[.]" Reply 6, ECF No. 149.

The IFUs provided to surgeons, which Bard says adequately informed them of the risks of its product, include a section detailing "risks of complication:"

> I am aware of the risks of perforation and erosion of the sling or graft, either through the vaginal incision or through any part of the roof of the vagina, including deep inside the vaginal vault in the far lateral recesses. I am aware of the risk of erosion into the urethra, the bladder neck, the bladder, the contiguous organs surrounding the operative site, and the possibility of erosions, or perforations, into the great blood vessels surrounding the operative site. I understand that these complications, if they occur, will require further surgery to repair.
>
> I am also aware of the specific complications involving the suspension part of the procedure, which range from insufficient suspension to over suspension. Insufficient suspension will result in continued incontinence. Over-suspension of the urethra will result in urinary retention. I may suffer from frequency, urgency, or de novo urgency incontinence. I may suffer from slow stream, hesitancy in the onset of the urinary stream, weak stream, start and stop stream, increased post void residuals, increasing cystitis, repetitive urinary tract infections, urosepsis, and the need to urinate in abnormal positions to help change the angle of the urethra to assist

[5] The "black box" warning was included in the informed consent form Mrs. Wheeler signed before her surgery and is a brief statement that warns of a possibility of "exposures, perforations, or penetrations" which are "usually handled easily by applying hormone cream to the area," among other treatments. DSMF ¶ 14. The parties dispute whether Mrs. Wheeler was given the warnings by Dr. Feinstein, but whether she received and understood them is irrelevant—the question is whether Bard discharged its duty to warn the physician of any risks; if it did, it is not liable on this claim.

> emptying, I may suffer from frank urinary retention and require catheterization.

DSMF ¶ 13. Bard also says that Dr. Feinstein was adequately warned when the FDA released a warning in 2008, part of which is reproduced here:

> The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. There were also reports of bowel, bladder, and blood vessel perforation during insertion. 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.
>
> Treatment of the various types of complications included additional surgical procedures (some of them to remove the mesh), IV therapy, blood transfusions, and drainage of hematomas or abscesses.
>
> Specific characteristics of patients at increased risk for complications have not been determined. Contributing factors may include the overall health of the patient, the mesh material, the size and shape of the mesh, the surgical technique used, concomitant procedures undertaken (e.g. hysterectomy), and possibly estrogen status.

DSMF Ex. H, ECF No. 137-8.

The plaintiffs do not dispute that Dr. Feinstein was aware of these warnings, Pl.'s Resp. to DSMF ¶¶ 16-19, but they argue that the warnings are inadequate because Bard knew of risks that were not communicated in these warnings. *Id.* Mrs. Wheeler relies on her expert, Dr. Rosenzweig, who says that Bard failed to warn of

> permanent, lifelong and debilitating pelvic pain, lifelong sexual complications and dysfunction, lifelong risk of multiple surgeries, need for removal of the device, difficulty removing the device, lifelong risk of erosions, chronic and delayed urinary problems, and the risk of serious complications and effect on a patient's quality of life" and that the mesh "can degrade and shrink; there is a lifelong risk of contraction; and it was never meant to be used in the human body."

PSMF ¶ 54. She also points to the report of a Dr. Raybon, who says that there are additional dangers not disclosed in the IFU or the FDA warnings, including that

> the polypropylene being used was not approved for medical implants; that the pores in the Avaulta mesh were not large enough for proper tissue integration; that the mesh had nearly twice the density of the maximum safe density; that the small pore size in the mesh results in rigid scar plate formation; that the mesh would shrink as much as 30-50% after implantation; that Bard had conducted only limited animal studies, which failed to establish the product's safety in humans; that the uncovered, flat arms of the Avaulta products would cause tissue damage as they were pulled through the smaller, rounder trocar tunnel, causing the mesh to saw through tissue; that the use of trocars inserted blindly presented the unnecessary risk of nerve damage and tissue trauma; and that it is extremely difficult to remove the Avaulta products once they are implanted.

PSMF ¶ 88. The risks which Mrs. Wheeler contends Bard failed to warn about center on the severity and permanence of the complications that can result from mesh implantation. Illinois also requires manufacturers to warn of "dangerous condition[s]" in addition to the injuries that can result from the product, and the Mrs. Wheeler argues that Bard insufficiently warned of the mesh's propensity to degrade and deform inside the human body. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736 (S.D.W. Va. 2014). Dr. Feinstein testified in his deposition that he was unaware of these risks, that he would have expected Bard to warn of them, and that the availability of this information would have influenced his decision to recommend the procedure to Mrs. Wheeler, including consideration of using alternative medical devices. PSMF ¶¶ 59-61.

Thus, there is no dispute as to the content of warnings in the IFU, nor about Dr. Feinstein's awareness of them. Bard asserts that their warnings were adequate without seriously addressing the plaintiff's contention that not all risks were described in the IFU or other documents. The dispute, therefore, centers on whether the warnings adequately informed physicians of the risks of pelvic mesh, which Illinois courts treat as a fact question inappropriate for resolution on a motion for summary judgment. *See Mahr v. G.D. Searle & Co.*, 390 N.E..2d 1214, 1230-31 (1st. Dist. 1979) ("Ultimately, the sufficiency of form, content and intensity is not resolved by pointing to a

single document, but remains a question to be resolved by the trier of fact in the light of all the information provided by the manufacturer and all that was reasonably possible to provide."); *Werckenthein v. Bucher Petrochemical Co.*, 618 N.E.2d 902, 908 (1st Dist. 1993) ("Examples of inadequate warnings include those that do not specify the risk, are inconsistent with use of the product, provide no reason for the warning, or do not reach the user…. [a]dequacy of warnings… is an issue inappropriate for summary judgment unless the movant demonstrates conclusively that there remains no triable question."); *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 327 (applying the same standard in Indiana law: "whether a warning is 'reasonable' is generally a question for the trier of fact to resolve'…. [i]t only becomes a question of law when the facts are undisputed and only a single inference can be drawn from those facts"). Bard has not cited any authority to support its contention that the warnings in the IFU were adequate as a matter of law.

The evidence adduced by the parties does not inexorably lead to one inference; both parties have adduced expert testimony regarding the adequacy of warnings. Bard's expert, Dr. Clark, opines that IFU's need not contain an exhaustive warning of all risks for the intended audience of experienced surgeons, because, among other reasons, surgeons understand the range of complications that can result from the risks stated in the IFU. Dr. Clark report 12, ECF No. 148-2. But, with the information in Dr. Rosenzweig's report and Dr. Feinstein's deposition testimony, there is sufficient evidence here for a reasonable jury to conclude that Bard breached its duty to warn physicians of the Avaulta Solo's risks. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 741-42 (S.D. W. Va. 2014) (applying Illinois law in a pelvic mesh case and concluding that "the TVT-O's potential to rope and fray, polypropylene's propensity to degrade, and complications associated with small pore mesh are all potential dangerous conditions about the TVT-O of which Dr. Byrkit allegedly was not warned."). Therefore, there is a dispute of fact about whether the

TVT-O's warnings were adequate."). Accordingly, the Court denies summary judgment on Mrs. Wheeler's failure-to-warn claim.

D. Lost Profits

Mrs. Wheeler claims that she is entitled to recover profits she lost while complications from pelvic mesh surgery made her unable to work at the business she and her husband own, First Community Insurance. Pl.'s Resp. at 12. Bard argues that Wheeler should not be able to pursue damages in the form of lost profits, both because she did not raise the issue until after discovery and because she has not adduced any evidence that Bard's product proximately caused her to lose profits. The Court need not address the waiver issue because Mrs. Wheeler has clearly not discharged her burden in opposing summary judgment to adduce any evidence in support of her claim that she lost profits.

"Lost profits in a tort action are limited to those damages proximately caused by defendants' wrongful conduct… a plaintiff must present competent proof of damages from which a reasonable basis of computation can be derived." *ABC Trans Nat. Transport, Inc. v. Aeronautics Forwarders, Inc.*, 413 N.E.2d 1299, 1312 (Ill. App. 1st. 1980) (citations omitted) (upholding jury verdict denying lost profits where plaintiff presented data and expert testimony).

Bard contends that Wheeler has failed to produce evidence that she lost profits because of her mesh injuries. The Court agrees. Wheeler's first response to this argument is that it is Bard's burden, as the movant, to produce evidence negating Wheeler's claim, but she misunderstands her task under Rule 56. The rule provides that "a party asserting that a fact cannot be… genuinely disputed" can discharge their burden 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. Proc. 56(c)(1)(B). Rule 56 does not necessarily require the movant to produce evidence, but rather to "***inform*** the court of the basis for the motion and

identify the supporting materials." *Spierer v. Rossman*, 798 F.3d 502, 508 (7th Cir. 2015) (clarifying the requirements of Rule 56 in situations where a movant identifies a lack of evidence) (emphasis in original). "[W]here the nonmoving party will bear the burden of proof at trial on a dispositive issue, the nonmoving party bears the burden of production under Rule 56 to designate specific facts showing that there is a genuine issue for trial." Mrs. Wheeler has the burden of proof at trial to prove lost profits; in the face of a summary judgment motion asserting that she has not adduced evidence sufficient to support an award of lost profits by a jury, she was required to point to evidence that creates a genuine dispute as to her claim. She failed to do so.

The only scraps of evidence Mrs. Wheeler identifies lies in her deposition testimony and that of her husband. Mr. Wheeler testified that Mrs. Wheeler is an owner of First Community insurance, that she managed the entire office during the time of her surgeries, and that the lost profits could be calculated with reference to tax and employment records. PSAMF ¶ 66. Mrs. Wheeler testified that she often could not work while she was experiencing health problems, and that "95 percent" of that time spent not working was due to mesh related injuries. PSMF ¶ 67. Mrs. Wheeler does not point to any tax or payroll records in response to Bard's motion for summary judgment, and her assertion that their business lost money due to her illness does not suffice to create a genuine dispute of material fact. Even assuming that First Community Insurance performed below expectations during the relevant time frame (a fact that has not been established), Mrs. Wheeler provides nothing that would allow a reasonable jury to attribute such a disappointing performance to Mrs. Wheeler's injuries, as opposed to market conditions or business reversals. Mrs. Wheeler bears the burden "of proving those damages to a reasonable degree of certainty," but the Court sees no basis at all upon which to calculate lost profits. *TAS Distrib. Co. v. Cummins Engine Co.*, 491 F.3d 625, 632 (7th Cir. 2007). Bard is entitled to summary judgment on this issue.

E. Punitive Damages

Mrs. Wheeler intends to pursue punitive damages, but Bard contends she has no evidence that shows it acted with the heightened culpability required for such damages. *See Kelsay v. Motorola, Inc.*, 384 N.E.2d 353, 359 (Ill. 1978). In Illinois, punitive damages may be awarded "when torts are 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 1140, 1149 (Ill. App. 4th 1992). In product liability actions, punitive damages are appropriate if "the injury is attributable to conduct that reflects a flagrant indifference to public safety." *Moore v. Remington Arms Co., Inc.*, 427 N.E.2d. 608, 617 (Ill App. 4th 1981); *see also Baier v. Bostitch*, 611 N.E.2d 1103, 1110 (Ill. App. 4th 1993). "While the amount of punitive damages is a question for the jury, the initial decision of whether punitive damages may be awarded in a particular case is a matter of law for the trial judge to decide." *Homewood Fishing Club*, 605 N.E.2d at 1149.

Mrs. Wheeler cites the first bellwether case in the Bard MDL, where the Fourth Circuit upheld an award of punitive damages applying Georgia law, which requires clear and convincing evidence of "willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences," a standard she argues is more demanding than that of Illinois. *In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig.*, 810 F.3d 913 (4th Cir. 2016).[6] While the analysis in the Fourth Circuit's

[6] Wheeler argues that the Georgia standard applied by the *Cisson* court sets a higher bar than Illinois' for proving liability that would support the imposition of punitive damages because a Georgia defendant's conduct must "exceed[] gross negligence." Resp. at 14, citing *Cisson*, 2013 WL 5700513 at *12. The Court does not share Wheeler's confidence that Illinois' standard—

opinion is limited to whether those damages were constitutionally permissible—the only challenge brought against the defendants—Mrs. Wheeler argues that much of the same evidence that supported the jury's award of punitive damages in that matter is present here.

Mrs. Wheeler points first to a Material Safety Data Sheet (MSDS) that lists manufacturer safety warnings for polypropylene, the raw material used to create Bard's pelvic mesh. Chevron Phillips' MSDS for the "Marlex" polypropylene warns: "Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids." PSMF ¶ 70. Emails among Bard employees, and between Bard and its suppliers, she says, indicate that Bard sought to hide its use of Chevron Phillips' polypropylene in medical applications because it feared getting cut off if Chevron and other suppliers discovered Bard's use of the material in medical applications. PSMF ¶ 71-73. Bard offered to indemnify one supplier, a company called Shakespeare, but, citing the MSDS, that company still balked at providing polypropylene for medical implants. PSMF ¶¶ 72-73.

Bard responds with a vigorous attack on the validity of the warning in the MSDS. Without citing to its Rule 56.1 statement, Bard contends the MSDS warning has no scientific basis and that the FDA has "knowingly cleared products made from the material" with full awareness of the MSDS warning. Reply at 13. Furthermore, Bard argues that MSDS are regulated by the Occupational Health and Safety Administration and designed to protect workers who handle raw materials in the workplace, whereas medical devices and their applications are regulated by the Food and Drug Administration. *Id.* They cite various authority from trial courts in other states

"gross negligence as to indicate a wanton disregard for others"—is really much different than Georgia's.

which have ruled the MSDS inadmissible on relevance grounds, and a Fifth Circuit opinion upholding a district judge's decision not to admit MSDS on the grounds that the plaintiffs "did not provide any science behind the MSDS." *Johnson v. Arkema, Inc.*, 685 F.3d 452, 462-63 (5th Cir. 2012).

Bard's point that the MSDS may not be all it's cracked up to be is well-taken—but even if some skepticism is warranted, this does not mean Mrs. Wheeler will not be able to use the MSDS at all. The admissibility of the MSDS was a hard-fought issue in the bellwether case, *Cisson*. There, the trial court allowed the MSDS as non-hearsay "for the limited purpose of showing that the statement was made and that Bard was aware of it"—a ruling affirmed by the Fourth Circuit. *Cisson*, 810 F.3d at 923. The trial court also admitted the MSDS for its truth under Federal Rules of Evidence 803(17) ("Market Reports and Similar Commercial Publications"), 803(18) "(Statements in Learned Treatises, Periodicals, or Pamphlets"), and 807 (the "Residual Exception"), all of which the Court of Appeals found to be an abuse of discretion. The plaintiff was able to use the MSDS evidence for the limited purpose of showing that "Bard received the warning and then responded either by ignoring it or withholding it from other parties." *Id.* at 926.

Thus, while this Court is aware of the obstacles Mrs. Wheeler faces in admitting the MSDS at trial, and intends no prejudice to any pretrial motions Bard might file to exclude it, at this point, drawing all reasonable inferences in favor of the plaintiff, the Court concludes that the MSDS supports the existence of a genuine issue of material fact as to whether Bard flagrantly disregarded public safety. A reasonable jury could conclude that, even if there were no evidence the MSDS warning was true, that Bard's actions—trying to obscure the sources of the material and its intended use instead of investigating Chevron's basis for the warning—are consistent with such indifference to public safety.

Mrs. Wheeler's evidence of heightened culpability, moreover, does not consist solely of the MSDS; she also calls attention to awareness among Bard employees of the dangers posed by Bard mesh and an unwillingness to conduct testing because of the expense involved.[7] An email from one of Bard's marketing professionals laments the lack of clinical data, which she says is "first to be cut when we had to reduce expenses." PSMF ¶ 80. In another email, a Bard employees complains that "[w]e always release products with no data." PSMF ¶ 81.. Mrs. Wheeler also cites the testimony of Dr. Ross, a Bard consultant, who unsuccessfully tried to persuade Bard to conduct animal and human testing of Bard's mesh products. PSMF ¶ 83. Bard attempts to deflect evidence of a lack of premarket testing, citing *Hagen v. Richardson-Merrell, Inc.*, 697 F. Supp. 334, 338 (N.D. Ill. 1988) for the proposition that such testing "is not relevant on the issues of fraud and punitive damages." That statement (which of course is not binding here) can only be understood in context; the plaintiff's evidence of a lack of premarket testing was deemed irrelevant because of "significant testing carried out by Merrell Dow subsequent to the introduction of the drug." *Id.* Here, Bard does not dispute Wheeler's assertion that there was a lack of pre-market testing, rather, it maintains that it nonetheless complied with all regulatory requirements. Additionally, the original patent application filed on Bard's behalf shows the company was aware of serious risks inherent in polypropylene mesh, specifically the possibility that it can "slice through the patient's tissue." PSMF ¶ 77; *cf. Baier*, 611 N.E.2d. at 1107 (finding that patent application indicating awareness of potential for injury was relevant evidence for punitive damages).

Viewing the facts in the light most favorable to the plaintiff, Mrs. Wheeler has adduced evidence upon which a reasonable jury could base a finding that Bard acted with flagrant indifference to public safety by foregoing testing of a product that it knew, or should have known,

[7] Bard does not argue that any of these emails constitute hearsay.

posed a danger to patients. As Mrs. Wheeler points out, other juries have made such a finding, applying similar standards and with similar evidence. Bard is not entitled to summary judgment on this issue.

II. *Daubert* motions

Expert testimony is admissible if the expert is qualified and if the testimony is reliable and relevant. Fed. R. Evid. 702; *Daubert v. Merrill Dow Pharmaceuticals*, 509 U.S. 579, 597 (1993). Under *Daubert*, courts apply a two-step framework. At step one, the proponent of the testimony must establish that "the proposed witness would testify to valid scientific, technical, or other specialized knowledge." *Robinson v. Davol, Inc.*, 913 F.3d 690, 695 (7th Cir. 2019). At step two, the judge evaluates "whether the proposed scientific testimony fits the issue to which the expert is testifying." *Id.* The first step is an inquiry into the reliability of the testimony; the second, an inquiry its relevance. *Ammons v. Aramark Uniform Servs., Inc.*, 368 F.3d 809, 816 (7th Cir. 2004).

Bard has moved to exclude the opinions of both of Mrs. Wheeler's experts, and she has in turn moved to exclude Bard's expert. These motions were filed before the MDL court, and feature argument as to whether experts designated to provide "case specific" causation opinions have impermissibly strayed into offering "general" expert testimony. The Court understands that the parties are tussling over a quirk of MDL procedure—that certain expert opinions apply generally to a group of plaintiffs, while others apply to the facts of a particular plaintiff. Now that this matter has left the MDL, the Court will not consider such arguments—so long as the expert testimony proffered complies with Federal Rule of Civil Procedure 26 (*e.g.*, it was properly disclosed), the Court will consider it procedurally sound. Insofar as the parties' motions seek exclusion based on a failure to comply with MDL procedure, the motions are denied.

A. Mrs. Wheeler's Motion to Exclude Opinions of Dr. Clark

Dr. Clark is a urogynecologist in California with 20 years of experience in the field. He has performed "well over 1300 prolapse surgeries" using various mesh products, including Bard's. Dr. Clark Expert Report 2, ECF No. 96-1. He lectures, teaches surgery skills, and serves as a consultant for medical device manufacturers. *Id.* at 3. Mrs. Wheeler seeks to exclude three categories of opinions: 1) regarding the adequacy of Bard's IFU for the Avaulta Solo, 2) that the Avaulta Solo was reviewed by the FDA "for safety and effectiveness," and 3) that the complication rates of patients in his practice are rare or otherwise uncommon.

1. Instructions For Use

Mrs. Wheeler argues that Dr. Clark is not qualified to offer his opinion that the warnings in the IFU are adequate. While Dr. Clark says that he has participated as a "clinician advisor" in drafting IFUs, he cannot recall whether any of his suggestions were actually published in an IFU. Pl.'s *Daubert* Motion as to Dr. Clark 3-4, ECF No. 88. Apart from that experience, he does not appear to have any expertise with respect to warnings and their contents. Mrs. Wheeler points to several rulings in pelvic mesh cases in which courts have agreed to exclude opinions regarding the adequacy of IFUs from physicians with similar backgrounds. The Court in *In re Ethicon, Inc.*, MDL 2327, 2016 WL 4557036 (S.D. W. Va. 2016), found that an experienced urogynecologist was not qualified to testify "about what an IFU should or should not include" because he was not "an expert in the development of warning labels[.]" *Id.* at *3.[8] In *Wise v. C.R. Bard, Inc.*, 2015 WL 521202 (S.D. W. Va. 2015), the court similarly

[8] Bard cites this case for the proposition that experience as a urogynecologist is sufficient for an expert to be qualified to offer an opinion on labelling; in fact, the Court barred the expert from offering testimony about the adequacy of the IFU absent "additional expertise to offer expert testimony about what information should or should not be included in an IFU."

concluded that the expert's experience reviewing IFUs for mesh products was insufficient, found this expert "unqualified to opine on FDA regulations and whether a product label satisfies those regulations." *Id.* The court nevertheless allowed the expert to testify "about risks he perceives that the Avaulta poses to patients" and that "the Avaulta IFU did not convey these risks." *Id.* at *5.

The path set out in those decisions is appropriate to follow here. Dr. Clark may have participated in drafting some language in IFU's, but the Court finds that this does not provide a reliable basis for his opinions that the Bard Avaulta Solo IFUs "fully complied with what was required of manufacturers in terms of IFUs, and they were consistent with all rules, requirements, and industry standards." Dr. Clark Expert Report at 12-13, ECF No. 96-1. Nothing in Dr. Clark's experience suggests he is qualified to offer such an opinion about Bard's compliance with regulatory requirements as they relate to IFUs. He may, however, offer his opinion of the risk of complications that Bard's product poses to patients and whether the IFUs communicate those risks.

2. FDA compliance

Mrs. Wheeler contends that Dr. Clark should not be permitted to offer opinions regarding Bard's Avaulta receiving "FDA clearance" "for safety and effectiveness," nor his opinion that the device was "properly brought to market in accordance with all applicable rules, requirements, and industry standards." ECF No. 88 at 1. They rely on several decisions from the MDL litigation in the Fourth Circuit in which courts have excluded testimony about manufacturers' compliance with the FDA's § 510(k) process. *See Huskey v. Ethicon, Inc.*, 848 F.3d 151, 160-61 (4th Cir.), cert. denied, 138 S. Ct. 107, 199 L. Ed. 2d 185 (2017); *In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig.*, 810 F.3d 913, 919 (4th Cir. 2016). In *Huskey,* for example, the Fourth Circuit affirmed the district court's ruling excluding testimony regarding the 510(k) process under Rule 403, due to "its limited probative value and the risk of confusing the jury." *Huskey,*

848 F.3d at 921-22. The 510(k) process, the court explained, "focuses mostly on the equivalence between the product in question and an older one, and only 'tangentially' examines the safety of the product going through the process." *Id.* This is consistent with the Supreme Court's characterization of the 510(k) process as a "qualification for an exemption rather than a requirement." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 332 (2008).

The reasoning in those decisions is persuasive, and the Court will similarly bar Dr. Clark from offering opinions about the 510(k) process. That is not to say, however, that any and all testimony that the device "was properly brought to market" will be excluded, as Mrs. Wheeler urges. She assumes that the reasoning behind exclusion of testimony regarding the § 510(k) applies equally to all opinions about industry standards and the FDA, and accordingly, the 510(k) issue is the only point on which Mrs. Wheeler offers any real argument. She expressly declines to argue, for example, that Dr. Clark is unqualified to offer opinions about FDA approval and industry standards, on the basis that "it does not matter whether he is qualified to give opinions that should be excluded for other reasons." Reply at 6, ECF No. 98. Nor does she seriously address the fact that Dr. Clark's opinion that the Avaulta Solo was "properly brought to market in accordance with all applicable rules, requirements, and industry standards" encompasses more than just the 510(k) approval process. For example, Mrs. Wheeler, while focusing her arguments on pre-market approval, does not address Dr. Clark's opinion regarding an FDA document published in 2013, "Considerations about Surgical Mesh for SUI," which discusses some of the literature on the risks of pelvic mesh implantation. Dr. Clark Report 25. This document reports on the findings of a scientific panel regarding pelvic mesh slings.[9] In the absence of more specific argument, the Court

[9] *See* https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/considerations-about-surgical-mesh-sui

will not indiscriminately exclude all opinions regarding the FDA's views on pelvic mesh. Given the lack of argument regarding anything except the 510(k) process, the Court declines to exclude Dr. Clark's opinions about compliance with industry standards and FDA guidance regarding the Avaulta. He may not opine, however, that the Avaulta was "cleared" by the FDA before being brought to market or discuss the 510(k) process.

3. Opinions regarding Dr. Clark's complication rates

Mrs. Wheeler's counsel has sparred with Dr. Clark in other pelvic mesh matters, and anticipates that Dr. Clark will offer testimony, not included in his report, about complication rates in his own practice. She seeks to exclude this opinion testimony on the basis that it was never disclosed pursuant to Rule 26(a)(2)(B)(ii) (providing that a retained expert's report must include "a complete statement of all opinions the witness will express and the basis and reasons for them."). Bard does not respond to the non-disclosure point, instead arguing that Dr. Clark's testimony about his clinical experience is relevant and reliable. Resp. at 13-14, ECF No. 96. That may be, but Bard fails to address the fact that any opinion about complication rates was not disclosed, which naturally means that any data supporting those rates has not been disclosed nor tested by Wheeler during discovery. *See In re: Ethicon, Inc.*, 2016 WL 4958312 (S.D. W. Va. 2016) (excluding undisclosed opinion "comparing complication rates and the complication rates found in medical literature); *In re Ethicon Pelvic Repair Systems Product Liability Litigation*, 2018 WL 3545127 (N.D. Ill. 2018) ("Expert testimony about specific rates is unreliable without more than the expert's assurance that the data is reliable."). Dr. Clark will not be permitted to offer testimony about complication rates in his own practice.

B. Bard's Motion to Exclude Opinions of Dr. Fitzgerald

Dr. Fitzgerald is the Medical Director of the Clinical Research Office of Loyola University of Chicago. Pl.'s Resp. 1-2, ECF No. 95. She has practiced for over a decade, and her clinical work

and research are devoted to "the understanding, diagnosis, etiology and treatment of female pelvic pain." *Id.* at 2. She has previously offered testimony in pelvic mesh matters, and a previous motion by Bard to exclude her as unqualified was rejected as "completely unfounded, given that Dr. Fitzgerald's entire clinical practice is dedicated to understanding, diagnosing, and treating female pelvic pain, as well as pelvic pain-related complications." *Wise v. C.R. Bard*, 2015 WL 521202 *12 (S.D. W. Va. 2015). She physically examined Mrs. Wheeler in preparation for her report. Pl.'s Resp. at 10.

Bard moves to exclude Dr. Fitzgerald's opinions that Bard's product caused Mrs. Wheeler's injuries on the basis that she conducted an improper differential diagnosis. Mot. to Exclude Dr. Fitzgerald 7, ECF No. 90. A physician employing this method "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. Illinois Central R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010) (quotation marks and internal citations omitted) (excluding causation testimony where expert's deposition testimony showed experts knew "little to nothing about Myers's medical history[.]"). It is "an accepted and valid methodology for an expert to render an opinion about the identity of a specific ailment." *Myers v. Illinois Central R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). A differential diagnosis is reliable under *Daubert* when based on "scientifically valid decisions as to which potential causes should be 'ruled in' and 'ruled out.'" *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904-905 (7th Cir. 2007). "A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation," *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989 (S.D. W. Va. 2014), but "a medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a

plaintiff's illness." *Huskey*, 29 F. Supp. 3d 691, 717 (S.D. W. Va. 2014). Flaws in a differential diagnosis typically go to the weight of the testimony, not its admissibility. *Hammer v. Residential Credit Solutions, Inc.*, 2015 WL 7776807 *40 (N.D. Ill. 2015).

Bard highlights several of Mrs. Wheeler's medical conditions and other potential causes of her complaints and argues that Dr. Fitzgerald, in her report, did not consider them, rendering her opinion unreliable. Among those medical conditions are stress urinary incontinence, sarcoidosis, endometriosis, her later mesh implant, and ovarian tumor surgery. They argue that because Dr. Fitzgerald did not mention any of these other potential causes, she did not perform a reliable differential diagnosis. The relevant section of her report is reproduced here:

> It is my medical opinion that these diagnoses occurred as a result of vaginal mesh complications, specifically the Bard Avaulta POP mesh kit implanted. Her chronic pain, the presentation, duration, and severity is [sic] consistent with what I see in my practice treating women have been implanted with transvaginal mesh devices. I have ruled out other potential causes, for example, her intermittent back pain is not the cause of Ms. Wheeler's severe chronic pelvic pain. There is objective evidence of diffuse pelvic floor muscle tenderness, hypertonicity and weakness. While back pain can be a potential cause of episodic pelvic pain in some patients, it is not the cause of Ms. Wheeler's severe chronic pelvic pain because of the objective findings on my exam, the nature and severity of her chronic pelvic pain, the documented findings in her records that necessitated multiple mesh revision surgeries and the timing, severity and duration of her pelvic pain symptoms. Validated pain measures as documented reflect her pain intensity and pain related disability.

Fitzgerald Expert Report 16, ECF No. 95-1. The only other potential cause Dr. Fitzgerald discusses in her report is back pain.

The Court agrees that Dr. Fitzgerald's written description of her differential diagnosis is conclusory, but in her deposition, she responded in detail to questions about what conditions she had ruled in and then ruled out. For example, she explained, without any prompting about the

specific conditions she described, that Wheeler "had this post herpetic neuralgia, unfortunately, so she had shingles about a year prior to me seeing her and it was a region not too far from her pelvis. So that was also in the differential, you can have persistent herpetic neuralgia related to that. Additionally, she had had some recent gynecological surgeries that can sometimes cause ongoing pain. And I ruled that out." Pl.'s Resp. 8, ECF No. 95. She also described in detail why she ruled out Mrs. Wheeler's current mesh implant as a cause of her pain: "Her physical exam wasn't consistent with that, so they often will have pain more at the 12:00 o'clock position and kind of 11:00 and 1:00 versus where she had pain more at the lateral wall." *Id.* at 9.

Any concern on the part of the Court that Dr. Fitzgerald's report evinces a conclusory differential diagnosis is mitigated by her deposition testimony, which shows that she seriously considered other potential causes and had a reasoned basis for ruling them out. This satisfies *Daubert*, and her opinion that the Bard Avaulta caused Mrs. Wheeler's injuries will not be excluded. *See Gayton v. McCoy*, 593 F.3d 610, 618-619 (7th Cir. 2010) (chiding district court for excluding expert testimony where judge "fail[ed] to account for the inefficiencies of requiring an expert to list each and every possible cause of a given outcome").

C. Bard's Motion to Exclude Opinions of Dr. Rosenzweig

Dr. Rosenzweig is a urogynecologist and an assistant professor of obstetrics and gynecology. Dr. Rosenzweig did not physically examine Mrs. Wheeler, Def.'s Motion to Exclude 3, ECF No. 92, but he did review her medical records, including the exam conducted by Dr. Fitzgerald, all of which informed his differential diagnosis. Pl.'s Resp. 5, ECF No. 94.

Bard argues that Dr. Rosenzweig's causation opinions are unreliable because they are based on general inferences rather than information specific to Mrs. Wheeler's medical history.[10]

[10] Bard also argues that Dr. Rosenzweig's opinions in this matter should be excluded in their entirety because "his case-specific opinions derive from his 'general liability reports.'" Mot.

Bard emphasizes that Rosenzweig did not test the Bard mesh that was removed from Mrs. Wheeler. Indeed, no one tested the explanted mesh; what we know of the explanted mesh consists of notations in Wheeler's medical records by the explanting surgeon. In this respect, argues Bard, Dr. Rosenzweig offers opinions like those excluded in *Huskey*, where the Court concluded that his "testimony on degradation, fraying, and particle loss [was] not sufficiently reliable under Rule 702." 29 F. Supp. 3d. at 707. In *Huskey*, Dr. Rosenzweig had physically examined the plaintiff and stated that upon examination, he "fe[lt] a very tender band along the left side of the vagina.

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to Exclude Dr. Rosenzweig 6, ECF No. 92. As mentioned above, in MDL litigation, experts often file both a "general" report, that applies to a set of cases, and a "specific" report, that applies to a particular plaintiff. Bard's *Daubert* motion as to Dr. Rosenzweig, originally filed before the MDL and then refiled here, "incorporates by reference all arguments regarding the exclusion of Dr. Rosenzweig's general opinions and general report, as set forth in Bard's contemporaneously filed Wave 9 motion." *Id.* at 7. Because that motion filed before the MDL should be granted, Bard says, then all of Dr. Rosenzweig's opinions about Mrs. Wheeler's case must fall.

Incorporating by reference its motion to exclude Dr. Rosenzweig's general opinions is not sufficient to bring those arguments before this Court, particularly when Bard fails to explain in the motion filed before this Court how Dr. Rosenzweig's specific opinions improperly rely on his general opinions.At a hearing on February 6, 2020, the Court agreed with counsel that rebriefing the motions for summary judgment filed before the MDL was appropriate. The Court then turned to the pending *Daubert* motions, and asked counsel if the pending motion for summary judgment depended on resolving those motions. Counsel responded that they did not (which turned out to be wrong) and the defendant did not re-file any motions to exclude general opinion testimony, nor did they ask the Court to rule on them.

Nevertheless, the Court reviewed Bard's motion to exclude Dr. Rosenzweig's general causation opinions and attendant briefing, wherein Bard argues that several portions of Dr. Rosenzweig's general opinions should be excluded: 1) testimony regarding Bard's knowledge or state of mind, 2) testimony summarizing or reading corporate documents, 3) testimony giving legal opinions or drawing legal conclusions, 4) testimony regarding the insufficiency of Bard's testing, 5) testimony opining on Bard's failure to provide training, 6) testimony regarding testing of Bard products, and 7) testimony that there is an association between polypropylene and cancer. *In re: C. R. Bard, Inc., Pelvic Repair System Products Liability Litigation*, 2:10-md-02187, Def.'s Mot. to Exclude or Limit Opinions and Testimony of Dr. Rosenzweig 2, ECF No. 7413. That review did not reveal anything in Dr. Rosenzweig's case-specific expert report that is necessarily derived from the general opinions Bard sought to exclude and, again, Bard has not identified the opinions that are the product of such reliance. Accordingly, the Court has addressed only the specific grounds for exclusion of Dr. Rosenzweig's opinions set forth in Bard's "case specific" motion (ECF No. 92).

That could represent mesh that's frayed, pieces of mesh that are still there, or a scar plate that formed… before it was excised." *Id.* at 708. The Court mentioned the fact that he had not tested any explanted mesh but focused on the fact that Rosenzweig also admitted that there were numerous other potential causes of this tenderness other than degraded mesh, but did not make an effort to rule those out. *Id.* Bard argues the same result should obtain here because, as in *Huskey*, Rosenzweig offered opinions about mesh degradation without testing the explanted mesh.

Mrs. Wheeler maintains that testing of explanted mesh is not required to opine on causation; courts in pelvic mesh cases have routinely allowed experts to opine that mesh caused injuries to specific plaintiffs where there has been no testing of explanted mesh or a pathology report regarding the explanted mesh. Pl.'s Resp. 8, ECF No. 94 (gathering cases). On this point, the Court agrees—the exclusion in *Huskey* was warranted because, in that matter, Dr. Rosenzweig simply failed to account for other potential causes while making an inferential leap from "tenderness" to "mesh degradation." Citing the lack of a physical examination, Bard also attacks Rosenzweig's conclusion that Mrs. Wheeler's injuries are attributable to "erosion, banding, scarring, cording, scar plate, chronic inflammation, chronic foreign body reaction, dense, heavy, and frayed, rough edges" of the Avaulta, arguing this was not based on "plaintiff-specific indicia of individual mesh degradation, deformation, shrinkage, or contraction." Mot. to Exclude Dr. Rosenzweig at 15-16, ECF No. 92. By this, Bard means testing of mesh explanted from Mrs. Wheeler. But medical training, examination of medical records, and use of differential diagnosis can be sufficient to support causation opinions. *See Gayton v. McCoy*, 593 F.3d 610, 613 (7th Cir. 2010). Bard's argument really goes to the reliability of Dr. Rosenzweig's differential diagnosis, and there is no requirement that a differential diagnosis be based on tests of an explanted medical device.

1. Dr. Rosenzweig's differential diagnosis

Bard also avers that Dr. Rosenzweig's differential diagnosis is unreliable because he failed to consider some of Mrs. Wheeler's health issues—such as her history of smoking—and because he didn't address the role that other mesh products might have played in her injuries. Mot. at 12-13. The Court finds that Dr. Rosenzweig's differential diagnosis is sufficiently reliable to survive Bard's *Daubert* challenge. Dr. Rosenzweig described Mrs. Wheeler's medical history, acknowledged other conditions, and stated that he had ruled them out, and the analysis set forth in his report is more thorough than Dr. Fitzegerald's, which the Court discussed above and found to be sufficiently reliable. *See* Rosenzweig Expert Report 30-32, ECF No. 141-2. He considered Mrs. Wheeler's history, including "vaginal delivery, sarcoidosis, GERD, asthma, endometriosis, hypothyroid, allergic rhinitis, sinusitis, and HTN," and gave specific explanations as to why he ruled them out—among other reasons, the symptoms Wheeler's pain, dyspareunia and other complaints "all presented within a few months to 5 years after the Avaulta implant procedure." *Id.* at 31. As for the other mesh implants—including the Coloplast Aris sling that was implanted concurrently with the Bard Avaulta, and the Ethicon product that was implanted years later—his ruling out of those as of a source of her injuries is based on details from her medical records, specifically the fact that "the Avaulta was localized as the source of her pain on palpation by her treating physician." *Id.* The problems Bard identifies with Dr. Rosenzweig's differential diagnosis ultimately go to the weight to be accorded to his testimony and will undoubtedly provide fodder for vigorous cross-examination.

2. Opinions regarding standard of care

Bard argues that the Court should exclude Dr. Rosenzweig's opinion that the physicians who treated Mrs. Wheeler met the standard of care. They say that Rosenzweig is licensed in

Illinois, and that since Wheeler's surgeries took place outside of Illinois, he cannot opine on the standard of care offered by a doctor from another state. But the factual premise is incorrect—Wheeler was treated by Illinois doctors, in Illinois. Pl.'s Resp. 14. Bard offers nothing on this point on reply. Dr. Rosenzweig's opinion regarding the quality of care Wheeler received from other physicians, then, will not be excluded.

3. Instructions for Use

Bard argues that Dr. Rosenzweig should not be allowed to offer his opinion that the Avaulta IFU's "failed to include significant adverse events" including "permanent, lifelong and debilitating pelvic pain, lifelong sexual complications and dysfunction, lifelong risk of multiple surgeries, need for removal of the device, difficulty removing the device, lifelong risk of erosions, chronic and delayed urinary problems," among other things. Rep. at 34. Bard is correct that Dr. Rosenzweig does not purport to be a labeling expert. But he does not offer expertise on labeling, but rather lists the risks that he thinks are posed by the Avaulta Solo and states that the IFUs did not warn of those risks. Expert report at 33-34, ECF No. 141-2. Unlike Dr. Clark, he does not offer opinion that the IFU complied with labeling requirements. Of course, Dr. Rosenzweig will be subject to the same limitation as Dr. Clark when it comes to IFUs: that is, he cannot opine that the Avaulta Solo IFU did not "fully compl[y] with what was required of manufacturers in terms of IFUs" nor that they were not "consistent with all rules, requirements, and industry standards." Dr. Clark Expert Report at 12-13, ECF No. 96-1. Like Dr. Clark, he may speak to the risks posed by the Bard Avaulta and offer his opinion as to whether the IFUs warned of those risks. Bard's motion on this point is thus denied.

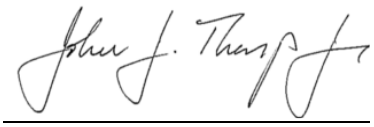
4. Opinion regarding safer alternative designs

Bard moves to exclude Dr. Rosenzweig's opinion regarding "safer alternative designs" of the Bard Avaulta, which, it points out, are not alternative designs but rather alternative procedures. Def.'s Mot. 17-18. Mrs. Wheeler does not dispute that the "designs" proposed by Dr. Rosenzweig, are not designs, but rather procedures other than mesh implantation. Instead, they say that evidence regarding alternatives to mesh is relevant to showing that Bard's product is unreasonably dangerous.

Bard is correct that these alternative procedures are not "safer alternative designs" and are thus irrelevant to Mrs. Wheeler's design defect claim. *See Wiltgen v. Ethicon, Inc.*, 2017 WL 4467465 *2-3 (N.D. Ill. 2017) (gathering cases excluding opinions regarding alternative surgical techniques to support design defect claims). But Mrs. Wheeler's rejoinder is also correct: the availability of alternative procedures can support her negligence claim under Illinois' risk-utility test. *Id.* at *3 (citing *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 346-53 (Ill. 2008); *see also Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 264 (Ill. 2007) (listing factors that inform risk-utility analysis). The availability of alternative procedures is relevant to the first factor Illinois courts consider in risk-utility analysis: "the usefulness and desirability of the product[.]" 864 N.E.2d at 264; *see also Herrera-Nevarez by Springer v. Ethicon, Inc.*, 2017 WL 3381718 *7 (N.D. Ill. 2017) (allowing testimony regarding alternative procedures on this basis). Bard has not identified any other basis to exclude this opinion, accordingly, its motion on this point is denied, with the proviso that Dr. Rosenzweig may not sow confusion by referring to alternative procedures as "alternative designs."

* * *

Bard's motion for summary judgment is granted as to Mrs. Wheeler's claim for lost profits, but otherwise denied. Mrs. Wheeler's motion to exclude Dr. Clark's opinions is granted in part and denied in part, and Bard's motions to exclude opinions of Drs. Fitzgerald and Rosenzweig are denied.



John J. Tharp, Jr.
United States District Judge

Date: March 31, 2022