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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Mimi Triant and Stavros Triant,

Plaintiffs,

v.

American Medical Systems Inc.,

Defendant.

No. CV-12-00450-PHX-DGC

ORDER

This case was originally filed on March 2, 2012, and was transferred by the Judicial Panel on Multidistrict Litigation ("JPML") to Judge Joseph Goodwin in the Southern District of West Virginia on April 11, 2012, for inclusion in a large multidistrict litigation ("MDL") proceeding. Docs. 1, 8 (MDL No. 2325). On April 1, 2020, Judge Goodwin advised the JPML that consolidated pretrial proceedings had been completed and that remand to this District, as provided in 28 U.S.C. § 1407(a), was appropriate. Doc. 34. The JPML remanded the case to the undersigned judge with the motions addressed in this order already pending.

Plaintiffs Mimi and Stavros Triant allege that Ms. Triant was injured by three of Defendant American Medical Systems, Inc.'s ("AMS") medical devices which were implanted to treat her pelvic organ prolapse ("POP") and stress urinary incontinence

("SUI"). Docs. 1 at 2, ¶¶ 5-7; 41 at 2.[1] AMS moves for partial summary judgment on Plaintiffs' manufacturing defect, breach of warranty, and punitive damages claims. Doc. 12. The parties have also filed four *Daubert* motions. Docs. 13, 15, 17, 19. The motions are fully briefed, and no party requests oral argument. For reasons stated below, the Court will grant the motions in part and deny them in part.

I. Background.

The following facts are undisputed unless otherwise noted. On March 3, 2010, Ms. Triant underwent a procedure at Banner Good Samaritan Medical Center to treat her SUI and POP. Doc. 1 at 2, ¶¶ 6-7. Dr. Scott Crawford implanted three pelvic mesh products manufactured, marketed, and sold by AMS: Elevate Anterior & Apical Prolapse Repair System and Mesh, Elevate Apical & Posterior Prolapse Repair System and Mesh, and MiniArc Sling (the "Devices"). *Id.*; Doc. 41 at 2. Ms. Triant suffered complications and underwent three additional surgeries to remove portions of the Devices on July 2, 2010, by Dr. Crawford at Phoenix Surgicenter; on December 29, 2011, by Dr. Jeffrey Cornella at the Mayo Clinic; and on March 21, 2012, by Dr. Felicia Lane at the UC Irvine Women's Health Care Center. Doc. 11-1 at 46.

The Devices has been cleared through the Food and Drug Administration's ("FDA") 510(k) clearance process, and AMS voluntarily ceased their manufacture and sale when it ended operation of its women's health business. Docs. 12 at 2, ¶ 5; 41 at 2.[2] Plaintiff alleges that the Devices were defective and have caused her chronic and severe pelvic pain, urinary problems, bowel dysfunction, nerve damage, infections, bleeding, and painful

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[1] Citations to documents filed in the Court's docket are denoted "Doc.," and pin cites are to page numbers placed at the top of each page by the Court's electronic system.

[2] The FDA applies different levels of scrutiny to medical devices before approving or clearing them for market. *See In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2017 WL 5625547, at *2 (D. Ariz. Nov. 22, 2017). A 510(k) review is a premarket submission process made to FDA to demonstrate that the device is substantially equivalent to a legally marketed predicate device already on the market. 21 U.S.C. § 360c(f)(1)(A)). A 510(k) review is less rigorous than the FDA's "premarket approval" process. *See* 21 U.S.C. § 360e(a).

intercourse. Docs. 1 at 3, ¶ 14; 41 at 2. AMS denies that the Devices are defective and that they caused Ms. Triant's injuries. Doc. 41 at 3; *see also* Doc. 292 (MDL No. 2325).

II. *Daubert* Motions.

The parties have filed four *Daubert* motions. Under Rule 702, an expert may offer opinions based on "scientific, technical, or other specialized knowledge" if they "will assist the trier of fact to understand the evidence," provided the opinions rest on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). The proponent of expert testimony has the ultimate burden of showing by a preponderance of the evidence that the requirements of Rule 702 have been satisfied. *See Cooper v. Brown*, 510 F.3d 870, 942 (9th Cir. 2007); Fed. R. Evid. 104(a).[3] The trial court acts as a gatekeeper to assure that the testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993).

A. Dr. Saad Juma.

Dr. Saad Juma, a board-certified urogynecologist, produced a case-specific expert report for AMS that opines on the safety and efficacy of polypropylene mesh, the causes of Ms. Triant's injuries, and her prognosis. Docs. 22 at 1; 13-1. Plaintiffs argue that Dr. Juma improperly opines on (1) general causation, (2) the safety and efficacy of the Devices based on his own clinical practice, (3) the adequacy of AMS's product warnings and instructions for use, (4) the cause of Ms. Triant's injuries, and (5) the oxidative degradation of polypropylene, and provides opinions not adequately contained in his report. Doc. 14.

1. General Causation.

Plaintiffs contend that because AMS failed to designate Dr. Juma as a general causation expert, he is precluded from providing general opinions in his Rule 26 report. *Id.* at 4. Plaintiffs challenge the following opinions:

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[3] Because the *Daubert* motions were filed in the MDL, they cite the federal law of the Fourth Circuit. *See In re Gen. Am. Life Ins. Co. Sales Practices Litig.*, 391 F.3d 907, 911 (8th Cir. 2004). Now that the case has been returned to its original jurisdiction, however, the Court will apply Ninth Circuit law, as it would have originally.

- "in my experience, there are actually fewer adverse events associated with the use of these products[.]" Doc. 13-1 at 9;
- "[t]he safety of polypropylene in the body is beyond reproach . . . These basic facts are proof that oxidative degradation is not clinically relevant when polypropylene is used in humans for indicated surgical procedures." *Id.* at 8-9;
- "[t]he Elevate is a safe and useful device . . . [with] appropriately designed mesh . . . whose benefits far outweigh their risks," and "[t]he MiniArc sling was a highly effective treatment for SUI and its benefits outweigh its risks." *Id.* at 8, 24;
- "the IFUs provide adequate warnings of associated risks . . . [and] present[] an excellent narrative of the risks and potential complications known about the device and provides an adequate warning of associated risks." *Id.*

Plaintiffs argue that Dr. Juma cannot give these general opinions because the MDL court distinguished between general and specific causation experts and AMS did not designate Dr. Juma as a general causation expert. The basis for this argument is not entirely clear. In their motion, Plaintiffs cite MDL Pretrial Order 251 (Doc. 14 at 4), but in their reply they cite MDL Pretrial Order 274 (Docs. 27 at 1). AMS addresses MDL Pretrial Order 274. Doc. 22 at 2.

MDL Pretrial Order 274, which has been placed in the docket in this case (Doc. 10), does mention general and specific causation experts, but it does not state that a single expert is limited to one or the other. To the contrary, it recognizes that a single expert may state general and specific causation opinions. *Id.* at 6. The order does say that parties are limited to five experts per case (*id.* at 4), but Plaintiffs do not contend that AMS has violated this limitation. The Court cannot conclude that AMS violated a pretrial order in the MDL and that Dr. Juma's general causation opinions are inadmissible on this basis.[4]

[4] Nor is the Court persuaded by AMS's argument that Plaintiffs' objection is untimely because it was filed 15 days after the local-rule deadline for raising discovery issues in the Southern District of West Virginia. *See* Doc. 22 at 3. A *Daubert* motion is not clearly a discovery issue. The Court also notes, however, that its practice is to allow

Plaintiffs also argue that Dr. Juma's entire report should be excluded under *Daubert* because it lacks reliable scientific support. Doc. 14 at 5. Without specifically addressing any of the more than 40 articles cited by Dr. Juma (Doc. 13-1 at 66-69), Plaintiffs contend that there "is only one single item on his reliance list total that even specifically discusses prolapse mesh at all and there is merely a press release that doesn't specifically mention Elevate or any data on Elevate" (Doc. 14 at 5). But Dr. Juma's report refers to a number of peer-reviewed articles on mesh degradation and the safety of polypropylene, including articles published in the Journal of Urology, the International Urogynecology Journal, and the American Journal of Obstetrics and Gynecology. *See* Doc. 13-1 at 67, 69. AMS notes this fact in its response (Doc. 22 at 4) and Plaintiffs say nothing in reply.

Plaintiffs further assert that Dr. Juma's opinions should be excluded because, "[f]rom reading his report, it doesn't even appear Dr. Juma used both the Elevate devices at issue in this case in his practice." Doc. 14 at 5. AMS responds that "Dr. Juma has ample experience both implanting and explanting transvaginal mesh devices, including MiniArc and Elevate" (Doc. 22 at 4-5), and Plaintiffs do not address this issue in their reply. Dr. Juma specifically states that he is familiar with both the benefits and the risks of the MiniArc and Elevate products (Doc. 13-1 at 7-8), and his report establishes that he has substantial experience in female pelvic medicine and reconstructive surgery, and how the Devices work in practice.

The Court finds that Dr. Juma is qualified to render opinions in this case. He is a board-certified urologist with clinical and research interests in female pelvic medicine and pelvic reconstructive surgery, including minimally invasive treatment for urinary incontinence. Doc. 13-1 at 3. Dr. Juma founded the Incontinence Research Institute in Encinitas, California, and has served as its director since 2002. *Id.* The Institute "advances health care for women through research in diseases including urinary incontinence and pelvic organ prolapse" – the conditions from which Ms. Triant suffered. *Id.* Dr. Juma is

only one expert per issue per side at trial. If the parties disagree and intend on presenting more than one expert per issue, they should raise this matter with the Court at the final pretrial conference.

also a member of several urological associations, has served as an expert reviewer for a number of urological journals, and serves on the American Urological Association Guidelines Update Panel for the "surgical Management of Female Stress Urinary Incontinence." *Id.*

Dr. Juma provides six pages of treatment options for SUI and POP – including descriptions of the MiniArc and Elevate devices – with explanations of the procedures and their risks based on his experience. Doc. 13-1 at 4-9. Plaintiffs present no evidence that he is unqualified to opine on the efficacy of the Devices in treating SUI and POP – areas in which he clearly is an expert. *See* Fed. R. Evid. 702.[5]

2. Safety and Efficacy.

Plaintiffs argue that Dr. Juma should not be permitted to opine on the basis of his personal clinical experience related to the safety and efficacy of the Devices because they have no way of testing such an opinion. Doc. 14 at 6. Plaintiffs note, correctly, that Dr. Juma does not include in his report any information about his personal safety or efficacy rates. *Id.*

In response, AMS asserts that the MDL court has repeatedly held that experts are entitled to opine on the basis of their clinical experience, and that Dr. Juma's opinions are not based solely on his clinical experience. Doc. 22 at 5. The Court agrees with the second half of AMS's argument – Dr. Juma's opinions are not based solely on his clinical experience. He relies on his "education, training and experience as a medical researcher, educator, physician, and surgeon, as well as [his] ongoing review of medical literature and participation on medical expert panels and committees . . . and other sources of medical and scientific information obtained throughout the course of [his] career." Doc. 13-1 at 3. Dr. Juma's report provides general opinions on the safety of the Devices:

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[5] Plaintiffs assert that "several of Dr. Juma's opinions do not relate to any case-specific issue and address conditions and complications that are not reflected in [Ms. Triant's] records," but they never identify those opinions. Doc. 14 at 5.

> The Monarc and Miniarc products were FDA-cleared, appropriately-designed [mid-urethral slings ("MUS")] indicated for the treatment of SUI. MUS techniques in which polypropylene mesh is used are the most commonly-used techniques for the surgical management of stress incontinence and continue to be the standard of care. I am familiar with both the benefits and the risks of the Monarc and the Miniarc products. These products are highly effective treatment for SUI whose benefits far outweigh its risks.
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> * * *
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> The Elevate Apical and Posterior Prolapse Repair System was an FDA-cleared, appropriately designed mesh indicated for the treatment of pelvic organ prolapse in the posterior area of the pelvis. The Elevate is a safe and useful device for the treatment of pelvic organ prolapse.
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> * * *
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> These products are highly effective treatment for POP whose benefits far outweigh their risks.
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> The Elevate and the Miniarc products consist of polypropylene mesh. The safety of polypropylene in the body is beyond reproach . . . Its long track record for safety is well established. . . . This extensive record of safety is unique among the many synthetic materials that are used in surgical procedures daily worldwide. With that record of safety, polypropylene has proven its safety in humans in clinical practice.

Doc. 13-1 at 7-9. The Court concludes that these general opinions are admissible under Rule 702.

But the Court cannot conclude that Dr. Juma should be permitted to testify about outcomes from his own clinical experience. Rule 26 requires an expert's report to contain a "complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). Dr. Juma's report provides no information about his own clinical experience with the Devices. He does not describe the extent to which he has used them, his complication rates, or any other information to support opinions based on his own clinical experience. Because such information is not provided in his report, he

cannot testify about it at trial. As a result, he cannot provided a basis for the Court to conclude by a preponderance of the evidence that Rule 702 is satisfied. *See* Fed. R. Evid. 104(a); s*ee also In re: Ethicon, Inc.*, No. 2327, 2016 WL 4958312, at *3 (S.D.W. Va. Aug. 25, 2016) (holding that defense expert could not discuss personal complication rates or compare those rates to the complication rates found in medical literature because he failed to include those rates in his expert report). Plaintiffs' motion is granted on this issue.[6]

3. Product Warnings.

Plaintiffs argue that Dr. Juma has no expertise in the area of warnings and instructions and it is not clear whether he has used the Devices in his practice. Doc. 14 at 7-8. Plaintiffs also argue the he does not explain the basis for the opinions he renders on AMS's warnings. *Id.* AMS contends that Dr. Juma has decades of clinical experience and training in the surgical repair of pelvic floor disorders and the treatment of patients with SUI, and "knows whether the information necessary to obtain proper patient informed consent is contained in relevant IFUs." Doc. 22 at 7.

Dr. Juma states in his report that the "Instructions for Use (IFU) which accompany the [Devices] presents excellent narrative of, among other things, how to properly place and tension the products (where appropriate) and the risks and potential complications known about the devices; the IFUs provide adequate warnings of associated risks." Doc. 13-1 at 7-8. He provides a similar one-sentence opinion later in his report. *Id.* at 24. Dr. Juma does not address the content of the IFUs or the risks they address, and he does not explain why he thinks the IFUs provide adequate warnings of relevant risks. Nor does he say anything about the kinds of warnings expected by physicians or the standards he applied in concluding that the warnings in this case were adequate. Because Dr. Juma will not be permitted to provide explanations at trial that are not in his report (unless, as noted

[6] Plaintiffs filed their *Daubert* motion before they deposed Dr. Juma. The Court's practice is to limit an expert's testimony to information disclosed in the expert's report (consistent with Rule 26(a)(2)) *and* information elicited by the opposing party in the expert's deposition. If Plaintiffs elicited testimony in Dr. Juma's deposition about his clinical experience with the Devices, that information may provide a basis for a different outcome on this issue. AMS can raise this issue in a motion in limine, if warranted.

above, those explanations were elicited by Plaintiffs' counsel in his deposition), he has provided no evidence to satisfy the requirements of Rule 702 by a preponderance of the evidence with respect to his warning opinions. *See* Fed. R. Evid. 104(a). Further, "[w]ithout additional expertise in the specific area of product warnings, a doctor, such as an urogynecologist, is not qualified to opine on the adequacy of a product warning IFU merely because he is familiar with the products in question in his own practice." *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2187, 2018 WL 605064, at *4 (S.D.W. Va. Jan. 29, 2018), *reconsideration denied in part*, No. MDL 2187, 2018 WL 774068 (S.D.W. Va. Feb. 7, 2018). Plaintiffs' motion will be granted with respect to Dr. Juma's adequacy-of-warning opinions.

4. Specific Causation.

Plaintiffs move to exclude Dr. Juma's opinion as to the cause of Ms. Triant's injuries because he purportedly failed to perform a reliable differential diagnosis. Doc. 14 at 8. Plaintiffs contend that Dr. Juma reached his opinion that Ms. Triant's injuries were caused by irritable bowel syndrome without considering the Devices as a cause. *Id.*

"A differential diagnosis [or etiology] is 'a patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes.'" *Stanley v. Novartis Pharm. Corp.*, 11 F. Supp. 3d 987, 1000 (C.D. Cal. 2014) (quoting *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005)). To perform such a diagnosis, an expert must identify "all of the potential hypotheses that might explain a patient's symptoms, [and] must then engage in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case." *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1058 (9th Cir. 2003). Plaintiffs claim that Dr. Juma did not rule out the Devices or the subsequent surgeries they allegedly made necessary as causes of Ms. Triant's injuries. The Court does not agree. Dr. Juma addressed the various conditions from which Ms. Triant suffers, and ruled out the Devices as a cause of each.

For dyspareunia, which is difficult or painful sexual intercourse, Dr. Juma reviewed various studies and Ms. Triant's medical history and then stated this opinion:

> Taking into account the totality of Ms. Triant's history, and the reviewed medical records, it is clear that she has multiple causes of dyspareunia. One cannot simply blame the mesh and exclude all the numerous other cases of dyspareunia that she has. In fact, when one looks at the chronology of her symptoms, it is clear that the removal of the different mesh components did not contribute in any significant or durable way to the resolution of her stated symptoms of dyspareunia and pelvic pain. This evidence suggests that other causes of dyspareunia that she has, are significant contributing factors to her dyspareunia. It is my opinion that the mesh, particularly after its removal, is not the cause nor a substantial contributing factor to her dyspareunia.

Doc. 13-1 at 27.

Similarly, Dr. Juma ruled out the MiniArc as a contributing cause of Ms. Triant's dyspareunia based on Dr. Dionysios Veronikis's physical exam:

> [Dr. Veronikis's exam] documents the absence of tenderness over the bladder and urethra, and no evidence of erosion or extrusion of the sling was noted. Despite the absence of objective evidence of extrusion, erosion, tenderness over the urethra, and SUI, Dr. Veronikis removed the right arm of the MiniArc sling. The lack of tenderness over the MiniArc indicates it is not the cause, nor is it contributing to her dyspareunia.

Id. at 27.

Dr. Juma next addressed Ms. Triant's bowel dysfunction, fistula, and perineal abscess. He noted that a known cause of each of these conditions is inflammatory bowel disease ("IBD"), a condition from which Ms. Triant suffers. He stated that "[t]here is no credible scientific evidence to suggest that the mesh cause[s] inflammatory bowel disease." *Id.* at 28. He also noted that Ms. Triant's conditions are associated with the J-pouch surgery she underwent. *Id.*

Dr. Juma next addressed Ms. Triant's pain and pudendal neuralgia. He noted that she underwent a pudendal block to reduce or eliminate the pain, and that it actually increased her pelvic pain. He concluded: "This pattern of increased pelvic pain after

pudendal nerve block . . . , and in association with recurrent pouchitis indicates the pain is caused by the pouch/pouchitis and not caused by the pudendal nerve." *Id.* at 29. He found it "more likely that the IBD and the J-pouch are the source of her pelvic pain[.]" *Id.* He noted that a subsequent examination by a pain specialist, after the mesh was removed, identified pain in various points, but that "none of the points of tenderness are in the vicinity of the previously placed mesh[.]" *Id.*

Finally, Dr, Juma addressed Ms. Triant's autoimmune dysfunction. He reviewed a large study of patients who suffer from various conditions, including patients who underwent mesh-based POP surgery. The study found no association between pelvic mesh surgery and autoimmune dysfunction. *Id.* at 30. Based on the study, Dr. Juma opined that Ms. Triant's pelvic mesh implants were not the cause of her autoimmune dysfunction. *Id.*

In short, Dr. Juma provided a basis for his conclusion that the mesh did not cause Ms. Triant's conditions. He did not phrase his report in terms of a differential diagnosis, but he provided a basis for ruling out the Devices as a cause of each condition he addressed. Plaintiffs do not contend that he omitted any of Ms. Triant's conditions.

The Court finds by a preponderance of the evidence that each of the Rule 702 factors is satisfied in Dr. Juma's specific causation opinions. As a trained and experienced urologist who regularly diagnoses and treats SUI and POP, he is qualified to opine on factors that caused Ms. Triant's injuries.

5. Oxidative Degradation.

Plaintiffs move to exclude Dr. Juma's opinion that he has "not seen clinical evidence that polypropylene degrades in the human body nor is there any reliable evidence in support of this position." Doc. 13-1 at 9; *see* Doc. 14 at 10-11. Plaintiffs contend that because Dr. Juma "does not have a background in chemical engineering, has never studied biomaterials, and has never done any bench research or lab research with respect to polypropylene," he cannot provide this opinion. Doc. 14 at 10.

Plaintiffs' factors are neither exclusive nor dispositive in a Rule 702 inquiry, *see Daubert*, 509 U.S. at 593-94, and "may not be pertinent in assessing reliability, depending

on the nature of the issue, the expert's particular expertise, and the subject of his testimony," *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) (quoting *White v. Ford Motor Co.*, 312 F.3d 998, 1007 (9th Cir. 2002)). As the Supreme Court has explained, although some expert testimony "rests upon scientific foundations," in other cases "the relevant reliability concerns may focus upon personal knowledge or experience. *Daubert* makes clear that the factors it mentions *do not* constitute a definitive checklist or test." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (emphasis in original; citations omitted). The Ninth Circuit likewise holds that "[t]he *Daubert* factors (peer review, publication, potential error rate, etc.) simply are not applicable to [testimony] whose reliability depends heavily on the knowledge and experience of the expert, rather than the methodology or theory behind it." *United States v. Hankey*, 203 F.3d 1160, 1169 (9th Cir. 2000).

Dr. Juma has decades of experience treating urological conditions and has specific clinical and research interests in female pelvic reconstructive surgery, including minimally invasive treatment for urinary incontinence. Doc. 13-1 at 3. Dr. Juma has also provided a number of peer-reviewed articles upon which he bases his opinions on mesh degradation and the safety of polypropylene, including those published in the Journal of Urology, the International Urogynecology Journal, and the American Journal of Obstetrics and Gynecology. *See* Doc. 13-1 at 67, 69.

The Court concludes that Dr. Juma's opinions on oxidative degradation "rest[] on a reliable foundation and [are] relevant to the task at hand." *Daubert*, 509 U.S. at 597; *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va. 2013) (ruling that a urogynecologist was qualified to opine on product design and biomaterials because he had "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders").

B. Dr. Brian Raybon.

Dr. Brian Raybon is a board-certified female pelvic specialist and reconstructive surgeon, and Plaintiffs' expert on the cause of Ms. Triant's injuries. Doc. 15-1 at 2. He

has produced an expert report opining, among other things, that the Devices are responsible for Ms. Triant's gastrointestinal surgeries and colorectal problems, that polypropylene degrades and shrinks in the human body, that Ms. Triant's injuries were caused by the Devices, and that Ms. Triant will need ongoing medical care for the rest of her life. *See* Doc. 15-1. AMS contends that Dr. Raybon's opinions are unreliable, he is unqualified to opine on polypropylene, and that his prognosis opinion is speculative. Doc. 15 at 1.

1. Gastrointestinal Health.

Dr. Raybon opines that the Devices are responsible for Ms. Triant's alleged injuries and that "her doctors began to consider the mesh devices and the reaction to them as causes of her colorectal symptoms." Doc. 15-1 at 18-19. AMS contends that there is no reliable basis for this conclusion and that Ms. Triant's "treating physicians have actually rejected this theory of mesh-related gastrointestinal issues." Doc. 16 at 4. AMS points to Dr. Cornella's deposition, where he testified "there is no literature suggesting that polypropylene results in a systemic immune reaction that would be responsible for her symptoms related to inflammatory bowel disease," and that Ms. Triant's husband "agreed that currently there is no scientific evidence of the relationship between polypropylene and immune disease." Doc. 15-1 at 35-36. Dr. Lane, one of Ms. Triant's explanting physicians, similarly testified that there "is no level 1 evidence that supports the claim that vaginal mesh can cause colitis," and Dr. Raybon himself noted that there is no "smoking gun" in the medical literature that supports his position. *Id.* at 39, 43. AMS further contends that "Dr. Raybon has not performed any tests or experiments to confirm that pelvic mesh causes these conditions, nor can he point to any level 1 scientific literature documenting the same[.]" Doc. 30 at 3.

In reaching his conclusion, Dr. Raybon conducted a differential diagnosis, incorporating his experience, peer-reviewed scientific literature, corporate documents, testimony from corporate officials and treating physicians, his review of the medical records, and his examination of Ms. Triant. As required in a differential diagnosis, Dr. Raybon explained that "it is necessary to 'rule in' potential causes of the injury, and then

by process of elimination, to 'rule out' the least likely causes to arrive at the most likely cause." Doc. 15-1 at 17. Dr. Raybon ruled in mesh as a possible cause of Ms. Triant's injuries and ruled out a host of other possible causes, including inflammatory bowel disease, Crohn's disease, ulcerative colitis, auto accident, pre-existing prolapse, pre-existing pressure, and pre-existing stiff neck and back as the cause of her injuries. *See id.* at 18. He explained how he reached these conclusions:

> I considered each of the conditions listed in Mrs. Triant's past medical history and concluded that they were not the cause of her listed injuries as they would not present so severely and so related to the unique mesh complications of mesh shrinkage, mesh contract and severe and chronic pelvic pain (secondary to the tender mesh areas and mesh attachment points). I specifically ruled out GI disorders including IBD, Chron's, ulcerative colitis. The chronicity and severity of her symptomatology are not consistent with these potential causes and are similar to the complications reported in the medical literature and that I see in my own practice that are caused by transvaginal mesh devices that are life-long and not subject to complete resolution. In fact, there are reports in the medical literature of these conditions being caused by mesh. I was also able to rule these out due in part to the refractory nature of her complications – simply put, treatments offered by her GI doctors and colorectal surgeons that would treat these conditions have not resolved her complications. If any of these conditions were the sole cause of her symptoms she would have seen resolution of her underlying symptoms with her treatments. Moreover, the response noted repeatedly in her chart that relates to her pelvic, vaginal, rectovaginal and colorectal area is consistent in the nature, severity and timing of the chronic inflammation, dense scarring and granulation, bleeding, infections, foreign body response, bleeding, drainage, discharge and chronic/severe pain – they are all consistent in that they occurred after the implantation of her three AMS transvaginal mesh devices and were not present prior to her implants – they are all consistently noted in her chart as being associated with a chronic and persistent inflammatory response and mesh related responses by her body as described more below and throughout my report. Moreover, the lack of any definitive diagnoses by her GI doctors and inconsistent findings by her GI doctors support a differential that the GI related physicians were effectively ruling out these causes over time and shown through the lack of a clear etiology and lack of efficacy of treatments for these proposed and potential causes. Eventually, her doctors began to consider the mesh devices and the reaction to them as causes of her colorectal symptoms.

Doc. 15-1 at 18-19.

Dr. Raybon additionally refers to a number of peer-reviewed journals as support for his conclusions, including the conclusion that Ms. Triant's "tissue and body were under attack and constantly trying to fight back against the inflammation and foreign body reaction caused by the three mesh devices, and, as such, Mrs. Triant's vagina, pelvis and colorectal area was consistently in a state of chronic inflammation and scarring and subject to acute, chronic and subclinical infections." *Id.* at 20.[7]

The Court finds by a preponderance of the evidence that Dr. Raybon is qualified to opine on the causes of Ms. Triant's injuries, that his opinions are based on sufficient facts and data, that differential diagnosis is a reliable principle and method for determining cause, and that he has applied the method reliably to the facts of this case. Fed. R. Evid. 104(a), 702. The Court will deny AMS's motion to exclude his specific causation opinion.[8]

2. Mesh Shrinkage, Contraction, and Degradation.

AMS contends that because Dr. Raybon is a urogynecologist and not a biomaterials expert or pathologist, he cannot provide opinions on polypropylene as a possible cause of Ms. Triant's injuries. Doc. 16 at 5. Among other things, AMS challenges Dr. Raybon's conclusions that there "is a correlation between the shrinkage and contraction documented in Mrs. Triant's medical records and the shrinkage and contraction documented by" AMS

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[7] AMS points to a case from 2014 where the court excluded Dr. Raybon's general causation opinions as not meeting *Daubert*'s reliability requirement. *See* Doc. 30 at 3 (citing *Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 701 (S.D.W. Va. 2014)). But in that case Dr. Raybon based his opinion solely on his personal experience, and conceded that he did not reference any articles in reaching his opinion. *See id.* Dr. Raybon's report in this case does not rely on the same basis.

[8] At times it appears that AMS conflates Dr. Raybon's qualification with the reliability of his conclusions. *See* Doc. 30 at 3 ("Dr. Raybon is simply *not qualified* to opine that [AMS's] mesh devices caused Ms. Triant's gastrointestinal, colorectal, and immunologic issues[.]") (emphasis added). Dr. Raybon is qualified as an expert in female pelvic medicine and reconstructive surgery to offer expert opinions on potential causes of Ms. Triant's injuries. He has extensive experience implanting pelvic floor mesh products, including AMS's Elevate devices, and has been retained by AMS as a consultant in product development.

in its internal documents, that the "uneven stretching, pulling and tightening across the arms and central portion of the Elevate mesh due to the contraction and shrinkage . . . caused extreme pain in Mrs. Triant," and that "[d]egredation of the mesh material in the [Devices] caused additional inflammation and foreign body reaction and has contributed to [Ms. Triant's] injuries." Doc. 15-1 at 21, 23-24. AMS argues that Dr. Raybon "has no basis for concluding the Plaintiff's mesh actually degraded, shrunk, or contracted." *Id.* The Court does not agree.

An expert may be qualified "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Dr. Raybon has extensive experience with polypropylene used in pelvic reconstructive surgery. Docs. 15-1 at 2, 23-1 at 85. He also has extensive experience with POP – one of Ms. Triant's conditions – and the use of mesh to treat it. *See Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *1 (S.D.W. Va. Feb. 7, 2015) (finding Dr. Raybon qualified to opine on product design based on his vast experience with mesh in treatment and his background in testing and training on such products).

AMS argues that Dr. Raybon never personally examined Ms. Triant and therefore "cannot opine as to the 'mechanisms' of mesh complications purportedly related to mesh characteristics, such as shrinkage, contraction, and degradation." Doc. 30 at 4. But Dr. Raybon relied on Ms. Triant's medical records, and AMS does not dispute that explanting physicians concluded that the mesh in Ms. Triant had contracted. *See* Doc. 23 at 8-9. Dr. Raybon also cites medical literature and AMS's own documents in support of the proposition that polypropylene shrinks and contracts in the body. Doc. 23-1 at 48. The Court concludes that Dr. Raybon has provided adequate foundation for his opinions. His opinions are based on his "education, training, and experience in treating patients with incontinence/prolapse with or without mesh, educating physicians on prolapse surgery and mesh use, and reviewing mesh related legal cases, as well as [his] familiarity with published medical and scientific literature relating to mesh complications." Doc. 15-1 at 24.

3. Specific Causation.

AMS asserts that because Dr. Raybon is a clinician, "his understanding of certain 'clinical properties of mesh' does not qualify him to speculate about supposed 'mechanisms' about which he has no expertise. Doc. 16 at 6. As the Court concluded above, however, Dr. Raybon provided a sufficient basis for his opinion on the effects of mesh shrinkage in Ms. Triant, and his differential diagnosis provides a sufficient basis for his opinion regarding the cause of her conditions. AMS presents no other colorable argument that Dr. Raybon's specific-causation opinions are unreliable, and does not further address this argument in reply. *See* Doc. 30.

4. Future Complications.

AMS challenges Dr. Raybon's opinion that Ms. Triant's prognosis is poor and that she will need medical treatment "for the rest of her life." Doc. 16 at 6; *see* Doc. 15-1 at 25. AMS's sole basis for challenging this opinion is that it is speculative. *Id.* Plaintiffs contend that because Ms. Triant has continued to receive treatment and has suffered additional complications, Dr. Raybon's opinion is not speculative. Doc. 23 at 11.

Dr. Raybon's prognosis opinion is based on his examination of Ms. Triant, her medical records, his substantial experience treating similar patients and conditions, and medical literature cited in his report. The Court finds his general prognosis opinion admissible under Rule 702. Dr. Raybon also opines that Ms. Triant will need future surgery and plastic surgery, but he provides no explanation for this opinion. Doc. 23-1 at 52. Because he provides no basis for this opinion that satisfies Rule 702, and he cannot testify beyond his report (unless AMS elicited such testimony in his deposition), the Court will exclude his opinions about the need for future surgeries.

C. Dr. Richard Trepeta.

Dr. Trepeta, a board-certified pathologist, has produced a seven-page report concluding that mesh caused and will continue to cause Ms. Triant physical and emotional injuries. *See* Doc. 17-1. AMS contends that Dr. Trepeta is unqualified and that his opinions are unreliable. Doc. 18 at 3-6.

1. Qualification.

AMS contends that as a pathologist, Dr. Trepeta is not qualified to opine about Ms. Triant's current and future physical and emotional injuries. Doc. 18 at 3. AMS argues that Dr. Trepeta's work is done in a lab, examining tissue and other specimens under a microscope, and that he is not qualified to opine on current and future conditions experienced by patients. *Id*. at 4. The Court agrees in part.

"A pathologist is a clinician who provides diagnoses for patient care based on the examination of specimens they receive and relevant clinical information." *Heinrich v. Ethicon, Inc.*, No. 2:20-cv-00166-APG-VCF, 2020 WL 1914812, at *2 (D. Nev. Apr. 17, 2020) (citing *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 712 (S.D.W. Va. 2014)). Dr. Trepeta has more than three decades of experience as a pathologist, and has reviewed hundreds of mesh and non-mesh pathological specimens from every organ and tissue in the body. Doc. 25-1 at 22-23. He serves on the Pathology Committee of the International Society for the Study of Vulvovaginal Disease, which establishes the criteria and terminology for the diagnosis of vulvar and vaginal diseases. Doc. 17-1 at 3. He also has specific experience with the pathology and injuries related to the implantation of polypropylene mesh to treat prolapse and SUI among women. *Id.* Dr. Trepeta is qualified to opine on the basis of his experience and knowledge as a pathologist, and the results of his pathology examination of specimens from Ms. Triant, about what the specimens show regarding her physical conditions, including those caused by her mesh implants.[9]

[9] AMS's reply highlights a number of statements by Dr. Trepeta from another case that, among other things, he has never studied or published on mesh, has never published on the foreign body reaction to biomaterials, and does not diagnose pain disorders in his clinical practice. Doc. 28 at 2-3. Even if these statements are true, Dr. Trepeta based his conclusions in this case on a review of Ms. Triant's medical records and pathology reports, including Ms. Triant's pathological specimen taken from her December 2011 revision surgery. He concluded that the implantation of the polypropylene mesh directly resulted in significant physical damage to Ms. Triant, and that "the body's reaction to the implanted mesh was predictable and the resulting complications expected." Doc. 17-1 at 6; *see* Doc. 25 at 5. These opinions about what he observed as a pathologist have a sufficiently reliable basis to be admissible under Rule 702.

The Court does not find, however, that Dr. Trepeta is qualified to provide expert opinion on the emotional harm suffered by Ms. Triant. When asked what emotional damage he attributed to the mesh, he testified:

> The emotional damage that would seem to be self-evident. That a woman who is of sexual activity age is no longer able to have sexual activity in the routine degree that she once did, and she has a husband who would be interested, unless there's some problem, with having relationships with her and her ability to have relationships. A sexual relationship has been altered. To think that there isn't emotional damage going on between her and her husband or her husband and her due to that absence in their life would be unreasonable. But there is [sic] just certain things in life that you know to be true. Like the sun will come up tomorrow.

Doc. 28 at 7. Dr. Trepeta provides no additional support for his opinion that Ms. Triant has suffered and will suffer emotional damage.

Dr. Trepeta will not be permitted to provide expert testimony based on what he views as self-evident. Such testimony would not be helpful to the jury – which can make its own assessment of what is self-evident – and would not be based on expertise. *See In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 495187, at *4 (D. Ariz. Jan. 22, 2018); *see also Stephenson v. Caterpillar, Inc.*, No. 2:16-CV-00071-JRG-RSP, 2018 WL 5831314, at *4 (E.D. Tex. Nov. 7, 2018) ("Common sense testimony falls within the common knowledge of the jury, and, without more, this testimony is neither reliable nor helpful to the trier of fact.").

The Court will grant AMS's motion with respect to Dr. Trepeta's testimony on emotional injury, and deny it on his opinions about physical injury caused by AMS's products.

2. Alleged Sample Selection Bias.

AMS argues that because Dr. Trepeta's opinions were based on pathology specimens and reports provided by Plaintiffs' attorneys, the opinions must be excluded as unreliable because he provides no explanation of the standards used to select the specimens and does not explain how the specimens correlate to the Devices implanted in this case.

Doc. 18 at 4. AMS's argument, Plaintiffs' response, and Dr. Trepeta's report create confusion on this issue, which the Court has attempted to sort out.

There are at least three different sets of pathology reports discussed in Dr. Trepeta's report. First, he notes that he has reviewed over 100 pathology samples confirming that polypropylene mesh causes injuries in women. Doc. 17-1 at 3. His report does not identify the source of these samples, but he testified in his deposition that they all came from surgeries performed at St. Joseph's Hospital in Phoenix, Arizona, where Dr. Trepeta practices as a pathologist. Doc. 25-1 at 16 (page 52). He states in his report that he has seen an alarming increase in these injuries during the last eight years of his practice. Doc. 17-1 at 3. The Court does not find Dr. Trepeta's reliance on these samples to be problematic. They were generated in the course of his medical practice, rather than being selected by Plaintiffs' counsel, and his clinical experience provides a reliable basis for him to develop expertise in and testify about the effects of polypropylene mesh in women.

Second, Dr. Trepeta states that "pathology reports of AMS mesh" were "provided for review," and that they are consistent with the disease processes addressed in his report. *Id.* Again, his report provides no description of the source of these pathology reports, but he testified in his deposition that they all came from Ms. Triant's mesh-removal surgeries. Doc. 25-1 at 17 (page 54). Reliance on these plaintiff-specific reports is appropriate. Dr. Trepeta reviewed the pathology reports from Ms. Triant to determine whether she suffers from conditions he has observed in other mesh-implant patients in his clinical practice. It is appropriate and consistent with Rule 702 for a doctor who has developed expertise in his clinical practice to examine samples from the plaintiff and opine on the conditions revealed by the samples. AMS cites no case law indicating otherwise, and does not argue that Dr. Trepeta's review of Ms. Triant's pathology reports is unreliable. *See Daubert*, 509 U.S. at 597; *see also Kumho*, 526 U.S. at 152 ("[W]e conclude that the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable."). Because this second category of samples all came from Ms. Triant, there is no concern about selection bias.

Third, Dr. Trepeta's report states – several pages later on page 7 – that he "was provided pathology reports from the Wagstaff and Cartmell, LLP law firm," and that "these reports correlate to AMS products MiniArc and Elevate" and "are consistent with the medical knowledge and reports of tissue interactions, injury, deformation and degradation related to polypropylene mesh implants." Doc. 17-1 at 7. This same opinion has been excluded by Judge Goodwin because the reports on which Dr. Trepeta relied were provided by plaintiffs' counsel and Dr. Trepeta appeared to be using them as the basis for a general causation opinion that AMS mesh products cause injuries, and yet he could provide no assurance that they were selected properly and did not suffer from selection bias. *See In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2326, 2018 WL 8131708, at *2 (S.D.W. Va. May 30, 2018) ("Dr. Trepeta's review of the pathology reports has a fatal deficiency – it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated."); *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *22 (S.D.W. Va. Sept. 29, 2014) (excluding Dr. Trepeta's opinions because there is "no way to ensure that the plaintiffs' counsel did not provide Dr. Trepeta with only those pathology reports that tended to strengthen, rather than refute, Dr. Trepeta's opinions."); *Frankum v. Bos. Sci. Corp.*, No. 2:12-CV-00904, 2015 WL 1976952, at *26 (S.D.W. Va. May 1, 2015) (excluding Dr. Trepeta's opinions because his report "lacked standards to govern the process of selecting the sample of pathology reports to be evaluated').

The Court agrees with these cases. To the extent Dr. Trepeta is relying in this case on pathology reports selected by Plaintiffs' counsel to form opinions about the general effect of AMS products once implanted, the Court will exclude those opinions because the Court cannot rule out selection bias. Although the language from Dr. Trepeta's report tracks the language of his opinions that have been excluded in other cases, Dr. Trepeta testified in his deposition that the third category of reports all came from the explant surgeries of Ms. Triant. *See* Doc. 25-1 at 22 (page 76). If this is true, then it appears Dr. Trepeta's testimony at page 7 of his report is nothing more than a restatement of his earlier

plaintiff-specific testimony, which the Court finds admissible. Thus, to be clear, Dr. Trepeta will not be permitted to give a general causation opinion with respect to AMS products based on a sampling of pathology reports selected by Plaintiffs' counsel, but he will be permitted to give plaintiff-specific causation testimony based on his review of pathology reports from Ms. Triant's explant surgeries and his general clinical experience at St. Joseph's Hospital.[10]

D. Dr. Colleen Fitzgerald.

Dr. Fitzgerald is a board-certified physical medicine and rehabilitation doctor specializing in the etiology and treatment of female pelvic pain. Doc. 19-1 at 16. She conducted an independent medical evaluation of Ms. Triant on May 28, 2019, and prepared a report in which she opines, among other things, on the cause of Ms. Triant's injuries. AMS makes two arguments: (1) there is no reliable foundation for her specific causation opinion, and (2) she failed to employ a reliable methodology. *See* Doc. 20.

1. Specific Causation.

Dr. Fitzgerald opines that Ms. Triant has developed pelvic peripheral sensitization and chronic central sensitization, which are lifelong conditions "requiring ongoing pain medication management and surgical/GI management." Doc. 19-1 at 43. She further concludes that "these diagnoses occurred as a result of multiple ongoing vaginal mesh complications[.]" *Id.* AMS argues that this conclusion is unreliable because Dr. Fitzgerald "could not point to any research at all on mesh-related pelvic pain and quantitative sensory testing" and she failed to provide a list of literature in her report upon which she relied. Doc. 20 at 4.

Rule 26 requires that an expert disclose "the facts or data considered by the witness in forming" his or her opinions (Fed. R. Civ. P. 26(a)(2)(B)(ii)), and Rule 702 requires that

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[10] AMS also argues that Dr. Trepeta's opinions should be excluded because he did not conduct a differential diagnosis. As noted above, however, it is appropriate and consistent with Rule 702 for a doctor who has developed expertise in his clinical practice to examine samples from the plaintiff and opine on the conditions revealed by those samples.

the opinions be "based on sufficient facts or data" (Fed. R. Evid. 702(b)). Dr. Fitzgerald's report does not contain a list of articles or other publications she relied on in reaching her opinions, even though her report states that she plans to use "[e]xcerpts from medical articles and learned treatises" to support her opinions. Doc. 19-1 at 44. When asked during her deposition to identify the specific literature she relied on, Dr. Fitzgerald was unable to identify any specific articles, stating only that she relied on "[t]he entire body of literature that I look at really that's pelvic pain, including the mesh related items." Doc. 24-1 at 13 (page 40).

Plaintiffs make no attempt in their reply to explain why they did not have Dr. Fitzgerald disclose the literature she relied on in forming her opinions as required by Rule 26. They do, for the first time with their reply brief, provide an exhibit titled "List of Mesh-Related Literature" which contains 41 articles with no indication of whether Dr. Fitzgerald relied on them in forming her opinions for this case. Doc. 24-1 at 32-34. This is a wholly inadequate effort to comply with Rule 26, and, more importantly, it has deprived AMS of the opportunity to learn the literature-related basis for Dr. Fitzgerald's opinions. The Court will not preclude Dr. Fitzgerald from testifying entirely because of this failure – the Court concludes that she is qualified by training and experience to render her opinions[11] – but she will not be permitted to testify about medical literature before the jury. She will not be permitted to testify that she relied on medical literature or that medical literature supports her opinions, and she will not be permitted to identify any specific article or other literature source during her testimony before the jury. Having deprived AMS of the opportunity to prepare for such testimony, Dr. Fitzgerald will not be permitted to give it.[12]

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[11] Dr. Fitzgerald's knowledge, training, and experience as a board-certified physical medicine and rehabilitation doctor specializing in the etiology and treatment of female pelvic pain, her examination of Ms. Triant, and her review of Ms. Triant's medical history and ongoing symptoms show by a preponderance of the evidence that her opinion on the cause of Ms. Triant's injuries is sufficiently reliable to be admissible under Rule 702.

[12] Nor will Dr. Fitzgerald be permitted to testify about future surgeries Ms. Triant might need in the absence of a clear explanation, in her report or her deposition, as to how

2. Methodology.

AMS argues that Dr. Fitzgerald's differential diagnosis is flawed because she failed to give serious consideration to inflammatory bowel disease as a potential cause of Ms. Triant's injuries. Docs. 20 at 5-6, 29 at 3. Plaintiffs contend that because there was no definitive diagnosis of this condition in the record, Dr. Fitzgerald was not required to consider it. Doc. 24 at 10. Plaintiffs further contend that Dr. Fitzgerald's review "of the documentary evidence, her familiarity with relevant published medical and scientific literature, the depositions of treating physicians, as well as her own clinical experience," make her differential diagnosis reliable. *Id.* at 10-11.

The first step in a proper differential diagnosis "is to compile a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration." *Clausen*, 339 F.3d at 1057. To perform such a diagnosis, Dr. Fitzgerald must identify "all of the *potential hypotheses* that might explain [Ms. Triant's] symptoms, [and] must then engage in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in [this] case." *Id.* at 1058 (emphasis added).

Dr. Fitzgerald failed to account for an important aspect of Ms. Triant's medical history in conducting her differential diagnosis. Inflammatory bowel disease can be a significant cause of pelvic pain, and yet she did not consider it. *See* Doc. 24-1 at 14-15. Plaintiffs highlight the fact that Ms. Triant had not been conclusively diagnosed with inflammatory bowel disease (Doc. 24 at 10; *see* Doc. 24-1 at 14-15), but, as noted above, Ninth Circuit law requires her to consider all "potential hypotheses" that could reasonably cause her condition. *Clausen*, 339 F.3d at 1058. There was evidence in Ms. Triant's medical record suggesting that inflammatory bowel disease could be a contributing factor to her condition. In fact, there were at least three instances in which Ms. Triant's treating physicians stated that they could not rule our inflammatory bowel disease as the cause of her issues. *See* Doc. 15-1 at 7-8 (Dr. Heigh Russel), 9 (Dr. Anitha Yadav), 10 (emergency

she can conclude that specific surgeries will be required.

room physician at Gilbert Mercy Medical Center and Dr. Elisabeth McLemore). Looking at the same medical record, Dr. Juma reached the conclusion that "Ms. Triant was diagnosed with inflammatory bowel disease." Doc. 13-1 at 25. Likewise, Dr. Raybon, also a specialist in women's pelvic issues, specifically considered inflammatory bowel disease and ulcerative colitis in his differential diagnosis. *See* Doc. 15-1 at 18. Yet Dr. Fitzgerald failed to consider inflammatory bowel disease because it was "not within the scope of [her] own specialty." Doc. 24-1 at 14.

A reliable differential diagnosis "must provide reasons for rejecting alternative hypotheses 'using scientific methods and procedures' and the elimination of those hypotheses must be founded on more than 'subjective beliefs or unsupported speculation.'" *Clausen*, 339 F.3d at 1058 (quoting *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994)). Dr. Fitzgerald has not done so. As a result, Plaintiffs have not shown by a preponderance of the evidence that Dr. Fitzgerald's causation opinions are based on sufficient facts or data to which reliable principles and methods have been applied reliably. Dr. Fitzgerald's opinions on AMS's mesh products as the specific cause of Ms. Triant's injuries are not admissible under Rule 702(b)-(d). *See* Doc. 19-1 at 43 ("It is my medical opinion that these diagnoses occurred as a result of multiple ongoing vaginal mesh complications as delineated above.").

III. Summary Judgment.

AMS moves for summary judgment on Plaintiffs' claims for manufacturing defect, breach of express and implied warranty, and punitive damages. Doc. 11. Plaintiffs state in response that they no longer intend to pursue the manufacturing defect and breach of warranty claims. Doc. 21 at 3-4. The only issue, therefore, is whether AMS is entitled to summary judgment on punitive damages.

Under Arizona law, punitive damages are available when the plaintiff proves by clear and convincing evidence that the defendant engaged in reprehensible conduct and acted with an "evil mind." *Rawlings v. Apodaca*, 726 P.2d 565, 578 (Ariz. 1986); *see Anderson*, 477 U.S. at 254 (the substantive evidentiary burden of proof – including the

heightened clear and convincing burden – applies on summary judgment). An evil mind is established with evidence that the defendant: (1) intended to cause injury; (2) engaged in wrongful conduct motivated by spite or ill will; or (3) acted to serve its own interests, having reason to know and consciously disregarding a substantial risk that its conduct might significantly injure the rights of others, even though defendant had neither desire nor motive to injure. *Bradshaw v. State Farm Mut. Auto. Ins. Co.*, 758 P.2d 1313, 1324 (1988).

A. A.R.S. § 12-689.

The Court must first determine whether A.R.S. § 12-689 bars punitive damages in this case. The statute provides that "[a] manufacturer, service provider or seller is not liable for exemplary or punitive damages if . . . [t]he product alleged to have caused the harm was designed, manufactured, packaged, labeled, sold, or represented in relevant and material respects according to the terms of an approval, conditional approval, clearance, license or similar determination of a government agency." A.R.S. § 12-689(A)(1). AMS contends that the FDA cleared the Devices for manufacturing and sale, making punitive damages unavailable under the statute. Docs. 12 at 6-7, 26 at 1-3. Plaintiffs argue that the statute did not go into effect until August 2, 2012, five months after this action was filed, and therefore does not apply to this case. Doc. 44. The Court agrees.[13]

Under Arizona law, "[n]o statute is retroactive unless expressly declared therein," A.R.S. § 1-244, and a statute "will have prospective operation only, unless it plainly indicates an intent that it have retrospective effect," *Rodriquez v. Terry*, 290 P.2d 248, 249 (Ariz. 1955) (citation omitted). The Arizona Legislature passed § 12-689 in May 2012, and it went into effect on August 2, 2012. *See* A.R.S. § 12-689; Arizona Legislature, General Effective Dates, https://www.azleg.gov/general-effective-dates (last visited

[13] Plaintiffs initially argued that § 12-689 did not apply because AMS intentionally withheld information from the FDA. Doc. 21 at 6-7; *see* A.R.S. § 12-689(B)(2). Plaintiffs later learned that § 12-689 became effective five months after their action was filed and sought leave to file a supplemental brief. Doc. 31. The Court permitted the supplemental brief (Doc. 43) and a response (Doc. 45).

June 23, 2020). Plaintiffs filed this action on March 2, 2012 (Doc. 1), five months before § 12-689 became effective.

AMS contends that the prohibition on retroactive statutes found in § 1-244 is not absolute, and that courts allow for an exception where statutes are "merely procedural." Doc. 45 at 2. But AMS makes no argument that § 12-689 is merely procedural, and the Arizona Supreme Court has held that a rule affecting the measure of damages is substantive. *Hall v. A.N.R. Freight Sys., Inc.*, 717 P.2d 434, 442, 444 (Ariz. 1986). Nor does AMS point to anything in § 12-689 suggesting that the Arizona Legislature intended it to apply retroactively. Because this case was filed before the statute became effective, and the Court cannot conclude that the statute applies retroactively, it does not bar punitive damages in this case.[14]

B. Availability of Punitive Damages.

Plaintiffs argue that AMS acted with an "evil mind" because it knew the Devices "would pose an unjustifiable significant risk of harm to others but chose to consciously disregard those risks for its own economic benefit." Doc. 21 at 6. Plaintiffs contend that they have "produced evidence showing that [AMS] either withheld or intentionally misrepresented information that is directly relevant to the harm Plaintiffs suffered and would be material to the FDA's clearance of its" Devices. *Id.* at 7. AMS argues that Plaintiffs cannot satisfy the high standard for punitive damages, but does not directly address the evidence Plaintiffs cite. Because AMS fails to address Plaintiffs' evidence, the Court finds the evidence sufficient to create a genuine dispute of material fact, even under a clear and convincing standard, on whether AMS acted with an evil mind.

Plaintiffs assert that AMS knew polypropylene was unsuitable for use in human implants and disregarded that fact for its own economic gain. Doc. 21 at 8. They present evidence that decades of medical literature provided notice to AMS about issues related to the use of polypropylene in implantable medical devices. Doc. 21-1 at 22. Plaintiffs also

[14] AMS cites several cases discussing § 12-689, but none discusses whether the statute is retroactive. *See* Doc. 45 at 2-4.

assert that as early as 2004, AMS knew of a potential 30% complication rate for POP mesh products, and that it was warned of polymer degradation related to oxidation in 2005 by Dr. Duane Priddy and Norber Maecker of Polymer Failure Lab. *Id.* at 24, 144.

Plaintiffs assert that Total Petrochemical – the supplier of AMS's polypropylene – did not know its polypropylene was being used to manufacture AMS's pelvic mesh products, and that AMS was concerned it would stop providing the materials if it learned of that use. Doc. 21 at 8; *see* Doc. 21-1 at 19. Plaintiffs highlight Total Petrochemical's material safety data sheet, which did not indicate that the polypropylene was suitable or intended for use in permanently implantable medical devices. Doc. 21-1 at 19. Rather, the data sheet recommended that the polypropylene be used for carpet backing and ropes. Total Petrochemical specifically disclaimed warranties regarding the safety of the material in implantable medical devices. *Id.* at 19. In fact, Total Petrochemical sent out warnings against the use of its polypropylene in medically implantable devices, stating: "Under no circumstances are any products sold by Total Petrochemicals suitable for human or animal implants." *Id.* at 20. Plaintiffs contend that the "FDA likely would not have cleared [AMS's] mesh devices had it known about [AMS's] decision to use the polypropylene material in its products without conducting the appropriate clinical studies despite having knowledge of the substantial risk of harm that polypropylene poses when implanted in the human body." Doc. 21 at 10.[15]

Plaintiffs also present evidence that AMS's management disregarded concerns about the use of polypropylene and sought to go to market without adequately studying or warning physicians of its substantial risks. As Dr. Raybon testified:

> I remember the president or the VP of the division asked me, you know, what would you think if we went ahead and got it on the market and didn't study

[15] In 2012 the FDA issued "522 Orders" to all pelvic mesh manufacturers requiring companies either to conduct additional safety studies to support the use of their product, or to withdraw the product from the market, and later banned transvaginal mesh POP kits from the market. *See* FDA's Activities: Urogynecologic Surgical Mesh, https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/fdas-activities-urogynecologic-surgical-mesh (last visited June 24, 2020).

> it, and I'm, like, are you serious, and he goes yeah. I said, you want my honest opinion, and he said yeah, and I said, you're – you'd be a blanking idiot if you did that because we need some – none of these meshes have had appropriate research on them, you know, to get to the market in my opinion at that point.

Doc. 21-1 at 187.

Plaintiffs further note that AMS was working on a so-called "Truth-Seeking Project" before Ms. Triant's implant, and yet failed to warn her implanting physician. Doc. 21-1 at 197-98. The Project concluded that there was a biomechanical mismatch between the Devices and the pelvic anatomy and that the Devices shrunk, contracted, and deformed in the patients' bodies, resulting in chronic dyspareunia, vaginal scarring, chronic foreign body response, and other complication – the precise injuries Ms. Triant sustained. *Id.*

Construing this evidence in the light most favorable to Plaintiffs, the Court concludes that a reasonably jury could find the requisite evil mind by clear and convincing evidence. "While any single piece of evidence, taken alone, might not be clear and convincing evidence of an 'evil mind,' several such pieces of evidence, taken together, might clear the evidentiary hurdle." *Thompson v. Better-Bilt Aluminum Prod. Co.*, 832 P.2d 203, 211 (Ariz. 1992); *Quintero v. Rogers*, 212 P.3d 874, 879 (Ariz. Ct. App. 2009) ("A court will allow a jury to consider a punitive damages award if sufficient 'circumstantial' evidence exists" (citation omitted)). The Court will deny AMS's motion for summary judgment on punitive damages.

IT IS ORDERED:

1. Plaintiffs' motion to exclude the opinion of Dr. Saad Juma (Doc. 13) is **granted in part and denied in part** as set forth above.
2. Defendant's motion to exclude the opinion of Dr. Brian Raybon (Doc. 15) is **granted in part and denied in part** as set forth above.

3. Defendant's motion to exclude the opinion of Dr. Richard Trepeta (Doc. 17) is **granted in part and denied in part** as set forth above.

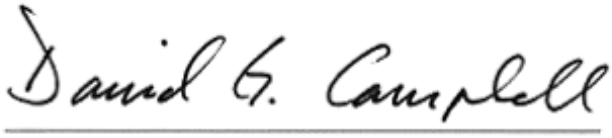
4. Defendant's motion to exclude the opinion of Dr. Colleen Fitzgerald (Doc. 19) is **granted** as set forth above.

5. Defendant's motion for summary judgment (Doc. 11) is **denied** as to the punitive damages claim, and **granted** as to the manufacturing defect and breach of express and implied warranty claims.

6. The Court has scheduled the trial in this case for January 2021. Doc. 21. The Court will issue a separate order setting the final pretrial conference and the motions deadlines that will precede the final pretrial conference.

7. The Court will rule on the Rosenzweig expert issues in a separate order.

Dated this 20th day of July, 2020.



David G. Campbell
Senior United States District Judge