IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

CLEMENTINA ROEDER and
RONALD ROEDER, JR.,

Plaintiffs,

v. Case No. 20-1051-JWB

AMERICAN MEDICAL SYSTEMS, INC.,

Defendant.

MEMORANDUM AND ORDER

This matter comes before the court on Defendant's motion to exclude the opinions of Dr. Rosenzweig. (Doc. 40). Defendant also seeks to exclude the opinions of Drs. Iakovlev, Blaivas, Guelcher, and Mays. (Docs. 55-5, 55-10, 56-2, 56-6.) The motions have been fully briefed and the court is prepared to rule. (Docs. 41, 42, 46, 55-6, 55-7, 55-8, 55-11, 55-12 to 55-18, 56-1, 56-3 to 56-5, 56-7 to 56-10, 57-12, 57-13, 67, 76.)[1] For the reasons stated herein, Defendant's motions are GRANTED IN PART and DENIED IN PART and TAKEN UNDER ADVISEMENT IN PART.

I. Facts and Procedural History

This is a product liability action filed by Plaintiff Clementina Roeder (individually, "Plaintiff") and her husband Ronald Roeder, Jr. (together with Plaintiff, hereinafter referred to as "Plaintiffs") involving injuries allegedly sustained by Plaintiffs due to Defendant's products.

On January 6, 2011, Plaintiff complained to her physician Dr. Darrell Werth of stress incontinence and discomfort. Plaintiff had previously suffered from extensive stress urinary

[1] The parties identified all of the applicable briefs from the MDL record in the pretrial order. (Doc. 66.)

incontinence ("SUI") and pelvic organ prolapse ("POP"). Plaintiff was diagnosed with a large cystocele (bladder prolapse) with associated uterine prolapse and urethral hypermobility. Dr. Werth recommended a hysterectomy with anterior mesh cystocele repair and sling suspension of the bladder neck. The proposed treatment involved implanting two vaginal mesh products ("the products"), the MiniArc Precise ("MiniArc") for SUI and the Elevate Anterior Apical System with IntePro Lite ("Elevate") for POP. Defendant American Medical Systems, Inc., manufactured and sold the products. (Docs. 66 at 2.)

On June 9, 2011, Plaintiff underwent the implant procedure in which the Elevate and MiniArc mesh products were implanted by Dr. Werth to treat Plaintiff's conditions. On July 1, 2015, Plaintiff saw Dr. Brian Flynn and complained of constant vaginal pain and burning, painful sexual intercourse, bleeding, infections, and frequent/urgent urination. (Doc. 91-6.) On October 6, 2016, Plaintiff underwent surgery by Dr. Flynn who removed the MiniArc and a portion of the Elevate. (Doc. 66 at 2.)

Plaintiffs filed this action on September 2, 2015, in the Pelvic Mesh Multidistrict Litigation in the United States District Court for the Southern District of West Virginia. *See In re: American Medical Systems, Inc., Pelvic Repair Systems Products Liability Litigation*, Case No. 12-MD-2325 ("MDL"). In that action and as raised in the pretrial order in this case, Plaintiff seeks damages on the basis that she suffered significant injuries due to the implantation of the products. Plaintiffs have identified several experts who will testify regarding the products. In 2018, while this action remained pending in the MDL, Defendant moved to exclude or limit the testimony of Plaintiffs' experts. (*See* Doc. 66 at 11-15) (listing outstanding *Daubert* motions filed in the MDL action). Prior to resolving those motions, Judge Goodwin transferred this case to this court. (Doc. 48.) After being transferred, a pretrial order was entered. The pretrial order directed the parties

to supplement the briefing in the *Daubert* motions to identify any relevant Tenth Circuit authority. (Doc. 66 at 11.) The parties have now done so. (Docs. 67, 72, 76.) In ruling on these motions, the court has considered the briefing filed in the MDL action as identified in the pretrial order and the supplemental briefs.

II. Standard

Federal Rule of Evidence 702, which controls the admission of expert witness testimony, provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Under this rule, the district court must satisfy itself that the testimony at issue is both reliable and relevant, in that it will assist the trier of fact, before permitting a jury to assess such testimony. *Schulenberg v. BNSF Ry. Co.*, 911 F.3d 1276, 1282 (10th Cir. 2018) (citing *United States v. Nacchio*, 555 F.3d 1234, 1241 (10th Cir. 2009) (en banc)). The district court must first determine whether the witness is qualified by knowledge, skill, training, experience, or education to render an opinion. *Id.* If so, the district court must determine whether the witness's opinion is reliable by assessing the underlying reasoning and methodology. *Id.* at 1283. The court is not required to admit opinion evidence that is "connected to existing data only by the *ipse dixit* of the expert," and may exclude the opinion if "there is simply too great an analytical gap between the data and the opinion offered." *Id.* (quoting *Gen. Elec. Co. v. Joiner,* 522 U.S. 136, 146 (1997)).

But the rejection of expert testimony is the exception rather than the rule, and "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert v. Merrell Dow Pharm., Inc.* 509 U.S. 579, 596 (1993).

"The court has discretion to determine how to perform its gatekeeping function under *Daubert*." *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig*., No. 17-MD-2785-DDC-TJJ, 2020 WL 1164869, at *3 (D. Kan. Mar. 10, 2020) (citing *Bill Barrett Corp. v. YMC Royalty Co*., LP, 918 F.3d 760, 770 (10th Cir. 2019)). The most common method of fulfilling that role is by conducting a *Daubert* hearing, "although such a process is not specifically mandated." *Goebel v. Denver & Rio Grande W. R.R. Co.*, 215 F.3d 1083, 1087 (10th Cir. 2000). In this instance, neither party has requested a *Daubert* hearing. With the exception of Dr. Iakovlev, the court finds that a *Daubert* hearing is not necessary here because of the nature of the opinions expressed, the relative completeness of the expert's reports, and the materials cited in support of and against the challenged opinions, including numerous decisions regarding these experts in other courts. *Ho v. Michelin N. Am., Inc*., 520 F. App'x 658, 664 (10th Cir. 2013) (district court permissibly exercised its discretion in ruling without a formal *Daubert* hearing). Should additional *Daubert* issues arise at trial that require further inquiry, the court will determine at that time how to handle them. *Cf. Bill Barrett Corp. v. YMC Royalty Co., LP*, 918 F.3d 760, 772 (10th Cir. 2019) ("a judge does not abuse his discretion by conducting a *Daubert* hearing in the presence of the jury through direct examination and voir dire.") (citing *Goebel*, 215 F.3d at 1087)

III. Analysis

A. Dr. Guelcher and Dr. Mays

Defendant seeks to exclude the opinions of both Dr. Guelcher and Dr. Mays. Dr. Scott Guelcher has a Ph.D. in chemical engineering and completed post-doctoral training in biomedical engineering. He is currently a professor of chemical and biomolecular engineering at Vanderbilt University. (Doc. 56-8, Exh. A.) Dr. Jimmy Mays has a Ph.D. in polymer science. He is currently a professor of chemistry at the University of Tennessee. (*Id*., Exh. C.) Both of these experts have extensive experience in their field of study and have published numerous peer-reviewed papers. Both experts opine that polypropylene mesh, which is used by Defendant in the products at issue, degrades when inside the body due to oxidation which results in chain scission and diminished mechanical properties. (*Id.*, Exh. A at 4; C. at 5.) Dr. Guelcher further opines that the oxidative degradation can lead to adverse events including inflammation and pain, Defendant knew about the effects of oxidation on polypropylene stability but did not consider the risks to the detriment of the patients, and alternative procedures and materials were available when the mesh was first commercialized. (*Id.*, Exh. A at 4.) Defendants seek to exclude these opinions for the reasons discussed herein.

1. Medical Literature

Defendant argues that Dr. Guelcher and Dr. Mays' general causation opinions are unreliable because they are based on unreliable articles that do not confirm in vivo degradation of AMS pelvic mesh and because the experts have not independently tested AMS's mesh. First, Defendant points to a 2017 peer-reviewed article published in a scientific journal and co-authored by Dr. Guelcher. *See* A.D. Talley, et al., *Oxidation and Degradation of Polypropylene Transvaginal Mesh, J. of Biomaterials Sci.*, Polymer Ed. (2017) ("the Talley study"); Doc. 56-9, Exh. E. The abstract of the Talley study states that the study tested the hypothesis that polypropylene transvaginal mesh oxidizes under *in vitro* conditions simulating the foreign body

reaction, resulting in degradation of the polypropylene mesh. *Id.* at 2. Three slings were evaluated and the specimens were incubated in an oxidative medium for up to five weeks. According to the study, oxidation and degradation of the mesh were evidenced by chemical and physical changes under the simulated in vivo conditions. *Id.*

Defendant argues the Talley study is unreliable because the intentional oxidative testing reported does not form a reliable basis for the degradation opinions, Dr. Iakovlev did not follow a protocol when scraping explanted polypropylene mesh fibers, and the authors did not rule out possible alternative explanations for the presence of oxygen on the mesh fibers. (Docs. 56-7 at 6-7, 67 at 11-12.) In response, Plaintiffs argue that the Talley study was subject to peer review; the article extensively recounts the materials, methods, and procedures that were followed; and their general causation opinions are based on their experience and the literature which has already been admitted in other cases. Plaintiffs argue that Defendant's criticisms of the Talley study go to the weight and not the admissibility of the opinion. The court agrees.

Based on a review of authority, it appears that only one court has determined that Dr. Guelcher's opinions were unreliable to the extent they were based on the Talley study. *See Salinero v. Johnson & Johnson*, No. 1:18-CV-23643-UU, 2019 WL 7753453, at *16 (S.D. Fla. Sept. 5, 2019). In *Salinero*, the court held that the plaintiffs did not respond to the defendant's challenges and therefore had not carried their burden. *Id.* The court did allow Dr. Guelcher to opine on polypropylene oxidation and degradation in the body to the extent it was not based on the Talley study. But, as another district court in this circuit noted, that holding "appears to reflect more the parties' litigation positions in that case, than the objective reliability of the Talley Study." *Wood v. Am. Med. Sys. Inc*., No. 120CV00441DDDKLM, 2021 WL 1178547, at *4 (D. Colo. Mar. 26, 2021). Overall, the majority of courts held that Defendant's arguments here were fodder for

cross-examination and did not result in a finding that the opinions were unreliable. *See id.*; *Gomez v. American Medical Sys., Inc.*, No. CV-20-00393-PHX-ROS, 2021 WL 1163087, *13 (D. Az. Mar. 26, 2021) ("Drs. Guelcher and Mays seek to use [the Talley] study to support their opinion that polypropylene mesh, generally, degrades in vivo. The details of the study go to weight, not admissibility of the opinions."); *McBroom v. Ethicon, Inc*., No. CV-20-02127-PHX-DGC, 2021 WL 2709292, at *22 (D. Ariz. July 1, 2021).

The court agrees. Defendant has not shown that these "relatively minor flaws" fundamentally undermine the Talley study. *Wood,* 2021 WL 1178547, at *4. Moreover, the experts' extensive reports reflect that they do not solely rely on the Talley study as the basis for their opinions.

Next, Defendant challenges one study because it analyzes degradation of eye sutures, including exposure to UV-light which does not happen with pelvic mesh. Again, "these are all legitimate bases for cross examination, but they don't fundamentally undermine the reliability of Dr. Guelcher or Dr. Mays's testimony." *Id.* at *5.

Finally, in supplemental briefing, Defendant moves for exclusion of specific opinions regarding oxidation by Dr. Mays on the basis those opinions were excluded in *Arevalo v. Coloplast Corp.*, No 19-3577, 2020 WL 3958505, at *6 (N.D. Fla. July 7, 2020). In that case, the defendant argued that Dr. Mays' opinions were based on unfounded assumptions, that he was not qualified, his sources contradicted him, and he lacked a reliable basis. Reviewing *Arevalo*, that court was presented with different arguments than the parties raised in the initial briefing in this case. (*See* Doc. 56-6 through 56-10.) While Defendant is not precluded from raising an objection to the testimony at trial, the court declines to address these issues as they were not fully briefed.

The court finds that both Dr. Guelcher and Dr. Mays are qualified to testify regarding polypropylene oxidation and degradation in the body. The court further finds that their general causation opinion regarding the oxidation and degradation of polypropylene in vivo is based on a reliable foundation.

2. Medical Causation Opinions

Defendant moves to exclude any opinions offered by Dr. Guelcher or Dr. Mays regarding medical causation or clinical opinions because they are not medical doctors. In response, Plaintiffs argue that their education and experience on biomaterials and engineering provide a sufficient foundation for opinions regarding the adverse effects that the mesh will have on the human body. Both experts have significant experience in polymer science. However, they are not medical doctors and have not conducted differential diagnoses. Therefore, as the MDL Judge determined in another mesh MDL, they are unqualified to offer an opinion regarding medical complications "resulting from alleged polypropylene degradation." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig*., No. 2327, 2016 WL 4547055, at *3 (S.D.W. Va. Aug. 31, 2016). Therefore, the court finds that they are not qualified to offer opinions regarding medical complications. *Id.*; *see also Gomez*, 2021 WL 1163087, *13.

3. Legal Conclusions and Defendant's State of Mind

Defendant moves to exclude any opinions that state legal conclusions or opine regarding Defendant's state of mind. In response, Plaintiffs argue that they do not intend to offer such opinions and will abide by the previous rulings of the MDL court.

Defendant's motion to exclude such opinions is granted. *Hartzler v. Wiley*, 277 F. Supp. 2d 1114, 1117–18 (D. Kan. 2003) (holding that an expert may "not apply the law to the facts of the case to form legal conclusions" but may refer to the law in expressing his opinion."); *N. Nat.*

Gas Co. v. L.D. Drilling, Inc., 405 F. Supp. 3d 981, 1011 (D. Kan. 2019) (discussing that expert opinions "on the intent, motives, or states of mind of corporations... have no basis in any relevant body of knowledge or expertise.")

4. Alternative Design

Defendant seeks to exclude Dr. Guelcher's opinion regarding alternative designs. Dr. Guelcher has opined that using autologous fascia lata, allograft, sutures, or polyvinylidene fluoride (PVDF) mesh does not present with the same complications and that all of these materials were available when Defendant's meshes were first commercialized. (Doc. 56-8, Exh. A at 25-26.) Defendant argues that these are not alternative designs because they are not medical devices; rather, they are surgical techniques that utilize grafts. In response, Plaintiff cites to authority stating that this is a fact question for the jury. *See Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 946 (S.D.W. Va. 2017). A review of Judge Goodwin's opinion in that case shows the court ruled that the plaintiff "must provide evidence of an alternative, feasible design for the *product* at issue—in this case, the TVT. Once the court determines that the plaintiffs have provided sufficient evidence to identify a comparable product or design concept, whether the *design features* of the comparable product or the *design concept* existing at the time of the TVT's manufacture is an alternative, feasible design for the TVT is a factual question left to the jury." *Id.* at 944. Notably, however, the court held that "a surgical procedure [that] should have been used in place of a device is not an alternative, feasible design in relation to the" product and that a "polypropylene suture is not an alternative, feasible design" to the product. *Id.* at 943, 944.

Although Plaintiff argues that Dr. Guelcher should be able to opine that biologic repairs are safe alternatives to using polypropylene mesh, Plaintiff offers no authority in support of this position from the MDL court or from this circuit. (Doc. 72 at 7.) The Tenth Circuit has recently

held that an expert's failure "to commit to any definitive feasible *design* alternative" renders the testimony inadmissible. *Petersen v. Raymond Corp*., 994 F.3d 1224, 1226 (10th Cir. 2021) (emphasis supplied). Here, Dr. Guelcher has opined that different procedures or sutures should have been used instead of a device. That is not a feasible design alternative for the products at issue. Rather, "alternative surgeries or procedures raise issues wholly within the context of what a treating physician has recommended for patients based on the individual needs and risk factors associated with individual patients." *Mullins*, 236 F. Supp. 3d at 943. This concerns the medical judgment of Plaintiff's prescribing doctor and not whether the design could have been made safer. *Id.* Therefore, any opinions regarding alternative procedures or sutures are not admissible.[2]

5. AMS Testing

Defendant argues that Dr. Guelcher's opinions regarding the adequacy of its testing should be excluded because he is not qualified to opine on this subject. Specifically, Defendant argues that the court should exclude Dr. Guelcher's opinions regarding the testing Defendant should have done to determine the stability of the mesh in an oxidative environment and that Defendant failed to study the effects in the human body. (Doc. 56-7 at 10.) In response, Plaintiffs argue that Dr. Guelcher may properly testify regarding his review of Defendant's internal documents. (Docs. 56-8 at 8-9; 72 at 7-8.) Plaintiff fails to respond to Defendant's arguments regarding Dr. Guelcher's qualifications to opine on adequate testing. Therefore, Defendant's motion is granted. *Gomez*, 2021 WL 1163087, at *14 (excluding this opinion due to the plaintiff's failure to address the arguments).[3]

[2] Dr. Guelcher also opines that Polyvinylidene fluoride (PVDF), an alternative mesh, is an alternative design. (Doc. 67-5 at 26.) This opinion is not admissible as Defendant has shown that this product was not available in the United States and therefore is not a feasible alternative design. *See infra* at 18.

[3] In the supplemental briefing, Defendant argues that Dr. Mays should be precluded from offering his opinion that proper testing would have revealed the oxidative properties of polypropylene mesh. (Doc. 67 at 12.) This was not raised in the initial *Daubert* briefing. Therefore, the court declines to consider this argument.

B. Dr. Iakovlev

Dr. Vladimir Iakovlev is an anatomical pathologist and the director of cytopathology at St. Michael's Hospital in Toronto, Canada. His professional practice includes diagnostic examination of specimens removed surgically or by biopsies and his annual practice volume amounts to 3000-5000 cases. (Doc. 67-1 at 4.) Dr. Iakovlev has offered opinions regarding mesh degradation resulting in clinical conditions. Defendant does not assert a challenge to Dr. Iakovlev's qualifications and Judge Goodwin, in another mesh MDL, has previously found Dr. Iakovlev qualified to testify regarding "mesh design, mesh deformation, and polypropylene degradation." *Tyree v. Bos. Sci. Corp*., 54 F. Supp. 3d 501, 554 (S.D.W. Va. 2014), as amended (Oct. 29, 2014).

Defendant seeks to exclude Dr. Iakovlev's general causation opinions because his methodology is unreliable and his opinion regarding mesh degradation is based on "unreliable scientific literature." (Doc. 55-12 at 2, 5.) In response, Plaintiffs argue that his report is grounded on a reliable methodology and it is based on reliable medical literature. Dr. Iakovlev's report spans more than 150 pages and includes numerous citations to studies and scientific articles. (Docs. 55-10, 55-11.) Defendant's primary argument regarding the exclusion of these opinions is that they are based on an unreliable methodology in his examination of Defendant's mesh specimens that were explanted. (Doc. 67 at 12-16.) In his deposition, Dr. Iakovlev testified that his opinions in this case are based on the medical literature and not the examination of approximately 60 explants that he received in this litigation. (Doc. 67-7 at 17:18-18:12.) He further testified that those explants demonstrate that Defendant's products behave in the way that has been described in the literature and his report. Dr. Iakovlev received the majority of those explants from SteelGate, which is a third party bio repository that is keeping the specimens for the MDL litigation. (*Id.* at 19:1-16.) Defendant makes several arguments regarding Dr. Iakovlev's methodology in

examining these mesh explants, such as choosing certain specimens for his report, his inability to identify the mesh product in the pictures, and the lack of a control in his examination of the explanted mesh. (Doc. 67 at 14-16.) In response, Plaintiffs argue that Dr. Iakovlev employs the same reliable and accepted morphology methodology regardless of the source of the pathology, he did not opportunistically choose samples, his findings include all of the meshes that he reviewed, and that the use of a control sample is not appropriate for diagnostic pathology.

After review of the materials, the court finds that the evaluation of Dr. Iakovlev's testimony is better suited to an evidentiary hearing. Plaintiffs are to notify the court of their intent to call Dr. Iakovlev as a witness at trial at least 60 days prior to trial and provide the court with the parties' availability for a *Daubert* hearing prior to trial after conferring with Defendant.

C. Dr. Blaivas

Dr. Blaivas is a board certified urologist. He has extensive experience with surgical procedures for women suffering with sphincteric incontinence. He has issued an expert report in the MDL action. His report offers opinions concerning the AMS Monarc and the Sparc Sling System. (Doc. 72-3.) In addition to opinions specific to these devices, Dr. Blaivas also opined that "mesh deforms in vivo," "Polypropylene mesh degrades in vivo," and "Polypropylene mesh creates scar plate that can entrap nerves." (*Id.* at 5.) Defendant moved to exclude his opinions in the MDL action. In that motion, Defendant argued that Dr. Blaivas was not qualified to give his opinions regarding mesh degradation, along with other arguments specific to his opinions related to the devices which are not at issue here. (Doc. 55-6.) This court ordered supplemental briefing on the *Daubert* motions. In that supplemental briefing, Defendant argues that the court should exclude Dr. Blaivas' opinions because he did not issue an opinion on the products at issue in this case. (Doc. 67 at 16.) In response, Plaintiffs argue that they intend to offer Dr. Blaivas' opinions

regarding mesh degradation and that Dr. Blaivas is qualified to give such testimony because of his extensive experience treating medical complications. In reply, Defendant now argues that Dr. Blaivas' testimony is cumulative. (Doc. 76 at 10.) Defendant does not raise any further objection to Dr. Blaivas' qualifications. Defendant also does not contend that it is somehow prejudiced or surprised by Plaintiffs' designation of Dr. Blaivas as an expert in this case.

The court will not exclude Dr. Blaivas as an expert in this case on the basis that his report offers opinions on different devices. Dr. Blaivas' report presents several opinions generally regarding the mesh that is also used in the products in this case and those opinions would be relevant to Plaintiffs' claims. Moreover, Defendant has not argued that it would be prejudiced if Dr. Blaivas offered his opinions at trial. That said, the court will not allow cumulative testimony from experts. To the extent that Plaintiff intends to call both Dr. Guelcher and Dr. Mays on the issue of mesh degradation and oxidation, it would be duplicative to have Dr. Blaivas also render an opinion on the same subject. This ruling equally applies to Defendant. The court will not allow more than two defense witnesses to offer the same opinion, i.e. mesh does not degrade in vivo. Given this ruling, if Plaintiff intends to call Dr. Blaivas, Plaintiff must notify Defendant as to the scope of Dr. Blaivas' testimony sixty days prior to trial. Defendant may then renew any specific challenges to that testimony by filing a motion in limine.[4] Such motion must include Plaintiff's notice to Defendant regarding the scope of Dr. Blaivas' testimony at trial.

D. Dr. Rosenzweig

Finally, Defendant moves to exclude the opinions of Dr. Bruce Rosenzweig. (Docs. 40, 56-2.) Dr. Rosenzweig is a urogynecologist and is currently an assistant professor of obstetrics

[4] Although the court will reserve ruling on any challenges regarding Dr. Blaivas' qualifications, the court notes that his report states that he has operated on about 75-100 patients with severe synthetic mesh complications. (Doc. 72-3 at 5.) This clinical and professional experience has been found to be sufficient to offer opinions regarding polypropylene mesh and its complications. *See Gomez*, 2021 WL 1163087, at *11.

and gynecology at Rush University Medical Center in Chicago, Illinois. (Doc. 67-12 at 2.) Over his career, Dr. Rosenzweig has performed over a thousand pelvic floor surgical procedures, including synthetic mesh repairs, and has performed over 350 surgeries dealing with complications related to synthetic mesh. (*Id.* at 3.) Dr. Rosenzweig has been designated as an expert in several mesh MDL actions. In this case, he has authored three different reports: a report pertaining to the MiniArc (Doc. 67-9); a report pertaining to the Elevate (Doc. 67-8); and a case specific report regarding Plaintiff and her injuries (Doc. 67-12). His reports are extensive. He describes Defendant's products, the history of synthetic mesh, medical conditions requiring treatments which led to the use of these products, and the basis for his opinions. Summarily, Dr. Rosenzweig has opined as follows: that the resin used to manufacture the polypropylene mesh should never have been used to manufacture a medical implant; the mesh degrades and deforms; and the implanted mesh results in medical complications including pain, dyspareunia, nerve irritation, and chronic inflammation. (*See, e.g.*, Doc. 67-8 at 12.) Dr. Rosenzweig further opines that the designs of the products are unsafe because it places the patient in an unreasonable risk of nerve damage, pain, and other complications. He has also opined that Defendant failed to conduct adequate safety tests and that Defendant failed to disclose adverse risk information and pertinent information about the defects in the properties of the mesh. (*Id.* at 13; Doc. 67-9 at 20.)

With respect to his specific causation opinions, Dr. Rosenzweig has opined that Plaintiff sustained debilitating injuries that were directly caused by the products. Dr. Rosenzweig further opined that her injuries were caused: by the design of the products; the materials used to manufacture the products; degradation, contraction, shrinkage, deformation, and sharp edges of the products; or a combination of these factors. (Doc. 67-12 at 10.) Dr. Rosenzweig has opined that Plaintiff will continue to have ongoing complications and need additional medical treatment

in the future due to the permanent complications she suffered and because pieces of the products still likely remain in her pelvic tissue. (*Id.*) In forming his opinions, Dr. Rosenzweig relied on scientific literature, Defendant's internal documents, depositions of Defendant's employees, depositions in this case, and Plaintiff's records. (*Id.* at 3-4.)

Defendant moves to exclude various opinions on the basis that Dr. Rosenzweig is not qualified to opine regarding the matter or on the basis that his methodology is unreliable. The court will address Defendant's arguments in turn.

A. Legal Conclusions and State of Mind

Defendant seeks to exclude any opinions that state legal conclusions or offer opinions as to Defendant's state of mind. (Doc. 67 at 16-19.) In response, Plaintiffs state that Dr. Rosenzweig will not offer these opinions. Defendant's motion is granted with respect to these opinions.

Defendant also argues that Dr. Rosenzweig should not be allowed to parrot Defendant's corporate documents. (*Id.* at 16.) In forming his opinions, Dr. Rosenzweig has reviewed and relied on Defendant's documents. Although he will not be allowed to simply recite Defendant's documents while testifying, he will be allowed to discuss those documents to the extent that they form a basis for his opinions (and are otherwise admissible). *See Huskey v. Ethicon, Inc*., 29 F. Supp. 3d 691, 702-03 (S.D.W. Va. 2014); *In re: Ethicon Inc.*, 2016 WL 4547055, at *3 (discussing that the expert may testify as to the review of internal documents to explain the basis of his opinion). Therefore, to the extent Defendant seeks to exclude Dr. Rosenzweig from testifying regarding Defendant's internal documents, the motion is denied.

B. Testing Opinions[5]

[5] In Defendant's motion filed in the MDL, Defendant argued that Dr. Rosenzweig's opinions regarding the adequacy of the warning should be excluded because he is not qualified to opine regarding the sufficiency of the warnings. (Doc. 56-3 at 6.) Defendant does not address this in supplemental briefing. (Doc. 67.) In another mesh MDL, Judge Goodwin found that Dr. Rosenzweig was qualified to opine regarding the sufficiency of the warnings due to his

Defendant seeks to exclude Dr. Rosenzweig's opinion that Defendant failed to conduct adequate safety tests and the tests that it did perform were deficient. (Doc. 67 at 19.) Defendant argues that Dr. Rosenzweig has no specialized training or education that qualifies him to offer opinions about the proper testing of medical devices. In response, Plaintiffs argue that he is qualified from the perspective of a clinician based on his experience. Although Plaintiffs cite numerous cases allowing Dr. Rosenzweig to offer opinions on mesh degradation, inadequate warnings, and clinical complications, Plaintiffs do not cite any authority for the proposition that Dr. Rosenzweig is qualified to opine regarding testing deficiencies. (Docs. 56-4 at 10; 72 at 18-19.)

In another pelvic mesh MDL, Judge Goodwin determined that Dr. Rosenzweig was not qualified to offer any opinions regarding testing deficiencies. *In re Bos. Sci. Corp. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2326, 2018 WL 2426159, at *2 (S.D.W. Va. May 29, 2018) ("Although Dr. Rosenzweig has years of experience operating with polypropylene mesh products, his expert report does not convey any similar experience, education, or knowledge about the appropriate testing that a medical device manufacturer should perform on its products prior to sale. Therefore, I agree with BSC and find Dr. Rosenzweig unqualified to testify on the adequacy or inadequacy of BSC's product testing.") This court agrees that Dr. Rosenzweig is not qualified to opine regarding the adequacy or inadequacy of Defendant's product testing. *See also, Wood,* 2021 WL 1178547, at *9.

C. Design Opinions

experience as a urogynecologist, in which he has reviewed numerous instructions for use (IFU), and he is qualified to opine about the risks of the product, pelvic mesh surgery, and whether the risks have been adequately expressed. *See Huskey*, 29 F. Supp. 3d at 704. For these reasons and because Dr. Rosenzweig's reports here also sufficiently provide a basis for this same experience in this case, the court finds that he is qualified to opine regarding the sufficiency of the warnings.

Next, Defendant argues that Dr. Rosenzweig is unqualified to opine that Defendant should have designed its mesh implants differently because he is not a biomaterials expert or pathologist and lacks training in medical device design. Dr. Rosenzweig's opinions regarding design include an opinion that Defendant should not have used resin to manufacture polypropylene pelvic mesh. As discussed previously, Dr. Rosenzweig has extensive experience in treating female urological conditions including thousands of procedures and hundreds of surgeries dealing with complications relating to devices containing the mesh. He has also designed medical devices previously, including a medical device that was cleared through the FDA. (*See* Doc. 67-11 at 102:2-4.) The court finds that Dr. Rosenzweig is qualified to offer opinions regarding the design of the products. *See Triant v. Am. Med. Sys. Inc.*, No. CV-12-00450-PHX-DGC, 2020 WL 4333645, at *2 (D. Ariz. July 28, 2020) (agreeing with Judge Goodwin that a physician's "experience removing polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him [to testify on product design].") (quoting *Heatherly v. Bos. Sci. Corp*., No. 2:13-CV-00702, 2018 WL 3797507, at *4 (S.D. W. Va. Aug. 9, 2018)). *Wood*, 2021 WL 1178547, at *10 (finding that he "is certainly qualified to testify about the negative effects he has clinically observed from its design and placement.")

Defendant further argues that Dr. Rosenzweig fails to provide a basis for his opinion that the "blind passage" technique to implant the Elevate is unsafe. (Doc. 67 at 20-21.) This argument was not raised in Defendant's briefing filed in the MDL action. (Docs. 56-3, 56-5.) Plaintiffs do not address this argument in their supplemental brief. Because this issue was not raised in the initial briefing and it has not been fully addressed, the court denies Defendant's motion on this issue. *But see Wood*, 2021 WL 1178547, at *10 (finding that Dr. Rosenzweig may offer this opinion.)

Finally, Defendant seeks to exclude Dr. Rosenzweig from testifying regarding alternative procedures and devices. Defendant argues that an alternative procedure is not an alternative design. The court agrees and these opinions are excluded for the reasons previously stated with respect to Dr. Guelcher's opinion. With respect to Dr. Rosenzweig's opinion regarding alternative devices, such as UltraPro and Dynamesh, Defendant argues these devices and the PVDF mesh have not been cleared by the FDA and were not in the market in the United States at the time Defendant designed and manufactured its products. (*See* Doc. 56-3 at 7, 56-5 at 6-7.) Dr. Rosenzweig's deposition supports this argument. (Doc. 56-5 at 6.) Plaintiffs do not address this argument in their response. (Doc. 56-4.)

"Evidence of a reasonable alternative design, if introduced, must consist of more than an expert's proposal; the plaintiff must show that the alternative design is feasible, adequate, and effective." *Griffin v. Suzuki Motor Corp*., 84 P.3d 1047, 2004 WL 375831, *6 (Kan. Ct. App. Feb. 27, 2004), *aff'd sub nom. Griffin ex rel. Green v. Suzuki Motor Corp*., 280 Kan. 447, 124 P.3d 57 (2005). Here, these alternative designs or products are not feasible as the products were not available in the United States. *See id*.; *Wood*, 2021 WL 1178547 at *10.

Therefore, Dr. Rosenzweig cannot offer his opinions regarding alternative procedures or devices.

D. MSDS

Defendant also seeks to exclude Dr. Rosenzweig from testifying regarding the material safety data sheet ("MSDS") for the polypropylene resin used in Defendant's products. The MSDS is discussed in Dr. Rosenzweig's reports, specifically in support of his opinion that the "resin used to manufacture the polypropylene mesh in [the product] should have never been used to manufacture a medical implant." (Doc. 67-8 at 12.) Dr. Rosenzweig goes on to explain that the

MSDS states that the chemical is "incompatible or reactive with ... oxidizing agents." (*Id.* at 15.) He explains that this is significant in that it is "well known that the vagina is [sic] naturally occurring oxidizing agents, like peroxides in a woman's pelvis." (*Id.*) The manufacturer of the polypropylene resin disclaimed any warranties regarding the safety or applicability of the resin in medical devices in the MSDS and later issued a letter regarding its products stating that the products are not suitable for human or animal implants. (*Id.*) Dr. Rosenzweig states that these warnings are important when considering permanent implantation of material in the pelvis and of special importance to physicians like himself. Dr. Rosenzweig further opined that Defendant should have done additional testing due to the MSDS.

Defendant argues that Dr. Rosenzweig is not qualified to opine regarding the MSDS because it is intertwined with his opinions on testing which are inadmissible. (Doc. 67 at 22.) Although the court has determined that he is not qualified to offer opinions on the adequacy of testing, Dr. Rosenzweig's opinion regarding the use of the mesh is based, in part, on the MSDS. Defendant has not sufficiently shown that his opinions regarding testing and the use of the mesh are so intertwined that they cannot be separated.

Defendant further argues that the opinion is irrelevant because Dr. Rosenzweig's premise is incorrect regarding the statements in the MSDS in that the manufacturer does not warn against the use of its products in medical applications. Defendant further argues that an MSDS is for workplace chemical hazards and not for doctors. The court does not find Defendant's arguments persuasive. "The MSDS need not expressly forbid implantation in humans for Dr. Rosenzweig to use its statements about strong oxidizers—which he explains are readily found in the vagina—to support his concerns about mesh use in the vagina." *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2020 WL 774234, at *4 (S.D.W. Va. Feb. 13, 2020). Defendant's

arguments go to the weight of the evidence and not its admissibility. Defendant may address these issues on cross examination.

Defendant's motion to exclude Dr. Rosenzweig from testifying regarding the MSDS is denied.

E. Specific Causation Opinions

As a preliminary matter, Defendant's motion to exclude Dr. Rosenzweig's specific causation opinion -- that Defendant's products caused Plaintiff's injuries -- argues that his general causation opinions are not reliable and cites to its motion to limit Dr. Rosenzweig's general causation opinions in support. (Doc. 46 at 4.) In that motion, Defendant moved to limit Dr. Rosenzweig from testifying regarding the opinions discussed above. Defendant did not seek to exclude Dr. Rosenzweig's general opinions that mesh degrades, contracts, and causes certain medical complications. (*See* Doc. 56-3, 56-5.) Notably, the MDL court has previously held that Dr. Rosenzweig is qualified to testify as to general causation regarding mesh degradation and found the opinions to be reliable on more than one occasion. *See Tyree*, 54 F. Supp. 3d at 565 (citing cases). Based on Dr. Rosenzweig's significant experience as a urogynecologist who treats medical complications that arise from the implantation of pelvic mesh surgical devices, he is qualified to opine on the degradation, shrinkage, and medical complications as a result of the mesh. *Id.* His opinions are also reliable in that they are based on his experience, the medical literature, Defendant's documents, and other materials discussed in his reports.

Turning to the remaining arguments, Defendant asserts that Dr. Rosenzweig's specific causation opinion in this case should be excluded because it is based on his general causation opinion and he did not examine Plaintiff's pathology specimen so he cannot testify as to whether her mesh degraded or contracted. (Doc. 46 at 2-6.) In his deposition, Dr. Rosenzweig testified

that he believed that there was degradation of the MiniArc and Elevate mesh that had been removed from Plaintiff. He based his opinion on his clinical experience, review of the medical literature, internal documents, and deposition testimony. (Doc. 67-13, at 34:20-35:5.) He further explained that he believes that Plaintiff experienced exposure of the Elevate mesh based on Plaintiff's documented medical records, which includes Dr. Flynn's surgery records. (*Id.* at 13:6-15.) Dr. Rosenzweig has opined that Plaintiff's injuries are due to these complications with Defendant's products.

Although Dr. Rosenzweig did not examine Plaintiff or the explanted mesh, his testimony and report provide a sufficient basis to opine regarding the cause of Plaintiff's injuries. *See Tyree*, 54 F. Supp. 3d at 566-67. *Daubert* requires "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid." 509 U.S. at 592. Here, by reviewing Plaintiff's medical history in light of the medical literature and the other records in this case, Dr. Rosenzweig has provided a reliable basis for his opinion. Moreover, he testified that he considered several other potential causes for her source of pain and ruled those out. (Doc. 40-2, Exh. H, Dr. Rosenzweig Depo. at 25:3-26:4.) The court finds that Dr. Rosenzweig's opinions are based on a reliable foundation and methodology.

F. Future Injuries

Finally, Defendant argues that Dr. Rosenzweig's opinion that Plaintiff may suffer potential future complications should be excluded because it is speculative and there is no reliable basis for the opinions. Plaintiff argues that these opinions are well supported and reliable.

Defendant argues that there is no evidence in the medical records that there is any mesh inside of Plaintiff. In his deposition, Dr. Rosenzweig testified that "more likely than not there is Elevate mesh left behind." (Doc. 67-13, at 34:5-13.) Dr. Rosenzweig provides no basis for this

opinion and Plaintiffs essentially ignore this argument. A review of his report also fails to provide a basis for his opinion that Plaintiff continues to have mesh inside of her body. Rather, the report details that the medical records show a "complete removal of the body of anterior Elevate prolapse kit" and a "complete removal of MiniArc mesh sling." (Doc. 67-12 at 6.) The report goes on to opine that she will have further complications and need additional treatments because "despite her physician's efforts, pieces of the Elevate and MiniArc Precise still likely remain in Mrs. Roeder's pelvic tissue." (*Id.* at 9.) Dr. Rosenzweig, however, fails to provide a basis for this opinion.

Therefore, to the extent Dr. Rosenzweig's opinions regarding future harm are based on mesh remaining in Plaintiff's body, those opinions are excluded.

IV. Conclusion

Defendant's motion to exclude the opinions of Dr. Rosenzweig. (Doc. 40) is GRANTED IN PART and DENIED IN PART. Defendant's motions to exclude the opinions of Drs. Iakovlev, Blaivas, Guelcher, and Mays (Docs. 55-5, 55-10, 56-2, 56-6) are GRANTED IN PART and DENIED IN PART and TAKEN UNDER ADVISEMENT IN PART.

IT IS SO ORDERED. Dated this 15th day of October, 2021.

s/ John W. Broomes
JOHN W. BROOMES
UNITED STATES DISTRICT JUDGE