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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 transferred from a large multidistrict litigation proceeding ("MDL") in the United States District Court for the Southern District of West Virginia. Doc. 34. The Court held a conference on July 6, 2020, and the parties stated that a number of disputes remained surrounding Plaintiffs' expert Dr. Bruce Rosenzweig. Doc. 49.[1] At the Court's request, the parties filed a joint memorandum identifying the issues in dispute and the relevant briefing. Doc. 50. This order resolves those disputes. The Court will not repeat the factual background contained in its previous *Daubert* order. *See* Doc. 51 at 2-3.

I. Legal Standard.

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

[1] The parties agreed that there are no *Daubert* issues with respect to J. Matthew Sims, Adam Kozak, and Drs. Duane Priddy, James Coad, Karen Becker, and Stephen Badylak. Doc. 49.

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). 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).

II. Discussion.

Dr. Bruce Rosenzweig, Plaintiffs' general causation expert, produced four Rule 26 expert reports in the MDL. Doc. 50-1 at 2; *See* Doc. 50-3 at 37, 101, 171, 237.[2] AMS filed a motion in the MDL to exclude his opinions under *Daubert* and Rules 702 and 703. Doc. 50-1. AMS made six arguments: (1) he is not permitted to opine on AMS's knowledge or state of mind; (2) his legal conclusions are not proper expert testimony; (3) no cancer opinion is permitted; (4) he is not qualified to opine about the design or testing of medical devices or the adequacy of medical device warnings; (5) his opinions regarding alternative designs are not admissible; and (6) his opinions regarding the material safety data sheet ("MSDS") are irrelevant and exceed his expertise. Doc. 50.

The parties acknowledge that the first three issues have been resolved. *See id.* at 3-4, 15-16, 20-21. Accordingly, Dr. Rosenzweig will not be permitted to opine on AMS's knowledge or state of mind, to offer legal opinions, or to opine that mesh causes cancer. *See id.* The Court will address the remaining issues.

A. Product Design and Failure to Warn.

In his four reports, Dr. Rosenzweig opines that AMS "failed to conduct adequate safety tests" on the mesh used in its devices, including testing to determine if mesh

[2] Dr. Rosenzweig's reports cover various AMS products, including its Apogee and Perigree (Doc. 50-3 at 37), Elevate (*id.* at 101), MiniArc (*id.* at 171), and Sparc and Monarc (*id.* at 237) devices. The Elevate and MiniArc devices are at issue in this case. Docs. 1 at 2, 41 at 2.

degrades in the body and clinical trials prior to marketing its products. *See* Doc. 50-3 at 48, 111, 189, 250. The parties agree that Dr. Rosenzweig is not permitted to testify about the adequacy of AMS's testing, but disagree on whether he is qualified to opine about product design and warnings. *See* Doc. 50 at 4-9.

1. Design.

AMS contends that because "Dr. Rosenzweig is a practicing urogynecologist" and not a "biomaterials expert or pathologist," he is unqualified to opine on the design of AMS products. Doc. 50-1 at 6-7. AMS argues that "Dr. Rosenzweig admitted that he is not trained in polymer chemistry, does not have a degree in engineering, and has not designed a medical device to treat stress urinary incontinence or pelvic organ prolapse." Doc. 50-2 at 4.

The Court does not find this argument persuasive. As the Supreme Court has explained, some expert testimony "rests upon scientific foundations," but 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). In some cases, such as this one, "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. Rosenzweig has decades of experience treating female urological conditions. Doc. 50-6 at 3. He has performed over 1,000 pelvic floor surgical procedures using numerous synthetic pelvis mesh products, including both pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI") products. *Id.* He has performed over 300 surgeries dealing with complications related to synthetic mesh, including the removal of numerous AMS devices. Doc. 50-7 at 27 (pages 95-96). Dr. Rosenzweig testified that his general opinions are based on this clinical experience, review of the relevant literature, years of explanting mesh in women with mesh-related complications, and AMS internal documents. Doc. 50-7 at 36 (page 132).

AMS does not meaningfully address this experience, but appears to argue that because Dr. Rosenzweig has never *implanted* any AMS device, he is unqualified to provide opinions on its devices. Doc. 50 at 7-8. But Judge Goodwin made clear in the MDL that a physician's "experience *removing* polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him [to testify on product design]." *Heatherly v. Bos. Sci. Corp.*, No. 2:13-CV-00702, 2018 WL 3797507, at *4 (S.D. W. Va. Aug. 9, 2018) (emphasis in original). AMS's attempt to differentiate between implanting and explanting its medical devices are matters for cross-examination and not a valid basis for exclusion under *Daubert* or Rule 702.

The Court concludes that Dr. Rosenzweig's opinions on AMS's design defect "rest[] on a reliable foundation and [are] relevant to the task at hand." *Daubert*, 509 U.S. at 597; *see Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 565 (S.D. W. Va. 2014) ("I have considered Dr. Rosenzweig as a general causation expert three times in the past, and on each occasion, I have admitted his general causation testimony on the properties of polypropylene mesh"); *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").

2. Warnings.

The Court reaches the same conclusion on Dr. Rosenzweig's opinions about product warnings. Plaintiffs make clear that he will not be asked to opine on the regulatory aspects of product warning:

> [H]e is not proffered to render opinions on how AMS developed the warning in the IFUs that accompanied AMS' mesh devices. In addition, he is not offered to render opinions on the regulatory requirements or the method or process that is used to develop and approve warnings. Rather, Dr. Rosenzweig is opining as to the completeness and accuracy of the warnings and labels in the clinical setting of surgical treatment for incontinence and pelvic organ prolapse.

Doc. 50-3 at 6.

As a physician who has counseled with patients in more than a thousand pelvic floor surgeries, who understands the risks of mesh products from more than 300 surgeries treating complications of synthetic mesh, and as a urogynecologist with years of experience in reading warning labels and counseling patients, Dr. Rosenzweig is qualified to opine on the completeness and accuracy of warnings and labels in a clinical setting of surgical treatment for SUI and POP. *See Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *8 (S.D. W. Va. July 8, 2014) (Goodwin, J.) (finding Dr. Rosenzweig "qualified to testify generally on the adequacy of the TVT-O's product warnings and marketing materials").

B. Alternative Designs.

The parties disagree on whether Dr. Rosenzweig's opinions regarding alternative designs are admissible. Doc. 50 at 9. He opines that there are a number of feasible alternatives that are as effective as, and safer than, AMS's polypropylene mesh products. These include the Burch procedure; autologous fascia slings; an allograft sling; a lighter weight, larger pore mesh material; a midurethral sling device; and a mesh sling with less polypropylene and sealed edges. Doc. 50-3 at 225. AMS does not challenge Dr. Rosenzweig's qualifications to give these opinions, but contends instead that they are irrelevant because the proposed alternatives either are unavailable in the United States or are surgical techniques and not products at all. Docs. 50-1 at 8-10, 50-2 at 5. AMS argues that "the MDL court has embraced the general rule that an alternative design for the product in issue cannot be a different product altogether or a different surgical procedure." Doc. 50 at 13. The Court concludes that the parties have not provide sufficient briefing to rule on this issue, and will defer the issue to a motion in limine or trial.

Whether this alternative design testimony is relevant will depend on the claims asserted by Plaintiffs under Arizona law – a topic to which the parties give scant attention. In *Golonka v. General Motors Corporation*, 65 P.3d 956 (Ariz. Ct. App. 2003), the Arizona Court of Appeals noted that a risk/benefit analysis may be used in design defect and strict

liability cases, and that the factors to be considered by the jury include the usefulness and desirability of the product and the availability of other and safer products to meet the same need. *Id.* at 962 & n.2. The Court is inclined to agree with Judge Goodwin that an alternative surgical procedure cannot be used to show a defective design of a product. *See Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942-43 (S.D. W. Va. 2017) (alternative designs "must be examined in the context of products – not surgeries or procedures"). But Plaintiffs have also asserted strict liability claims (Doc. 11-1 at 3), and it is possible that alternative procedures may be admitted to show that a product is unreasonably dangerous. The parties do not address this distinction or its treatment under Arizona law.

Nor can the Court conclude at this stage that an alternative product cannot be cited unless it is licensed in the United States. The parties do little to brief this issue, but it seems the relevant question is whether a safer design was available for AMS to use in this product (whether or not it had been placed in another product being marketed), not whether a safer product was available on the market for consumers. AMS's motion will be denied and these issues will be deferred for later consideration.

C. Material Safety Data Sheet.

Dr. Rosenzweig opines that AMS should not have used polypropylene mesh in its products because the manufacturer of the resin used in the mesh issued a "medical application caution" in its MSDS stating that the material should not be permanently implanted in the human body. Doc. 50-3 at 50, 113, 191, 252. Specifically, Dr. Rosenzweig noted that MSDS warnings are:

> especially important when considering permanent implantation of the material in the pelvis, and thus are of special importance to physicians like myself and patients considering pelvic mesh, as the applicable MSDSs state in a section entitled "Stability and Reactivity" and under the heading entitled "Incompatibility with Various Substances" that Total 3365 is "[i]ncompatible or reactive with… oxidizing agents." It is well known that the vagina is naturally occurring oxidizing agents, like peroxides in a woman's pelvis.

Id. at 51, 114, 192, 253. Dr. Rosenzweig further suggests that the MSDS should have led AMS to do additional product testing. *Id.* at 52, 115, 193, 254. The parties agree that Dr. Rosenzweig is not permitted to testify that AMS should have performed additional testing based on the MSDS, but disagree about whether he may use the MSDS as the basis for his opinion that polypropylene mesh should not be used in humans. Doc. 50 at 16-17.

AMS argues that Judge Goodwin excluded Dr. Rosenzweig's opinions related to the MSDS because it is a subject on which he is not qualified to testify. Doc. 50 at 18 (citing *Griffin v. Bos. Sci. Corp.*, No. 2:13-cv-11876, 2016 WL 3031700, at *12 (S.D. W. Va. May 25, 2016)). But Judge Goodwin excluded Dr. Rosenzweig's opinion only as it relates to whether AMS should have done additional testing, finding that "Dr. Rosenzweig lacks the experience and knowledge necessary to opine on what testing a manufacturer should perform on his products." *Id.* Judge Goodwin did not address Dr. Rosenzweig's concerns about the use of polypropylene mesh in the vagina.

The Court does not find that Dr. Rosenzweig is unqualified to provide testimony using the MSDS – specifically the MSDS' statement that polypropylene is incompatible with oxidizers – to support his opinion that the mesh at issue should not be used in the vagina. *See In re Ethicon Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2327, 2016 WL 8788207, at *4 (S.D. W. Va. Aug. 26, 2016) ("A urogynecologist does not need to be an expert in crafting MSDS warnings to use the substance of such warnings in forming opinions about how mesh reacts in the human body."). AMS otherwise presents no argument that Dr. Rosenzweig is unqualified to provide opinions about how mesh reacts in the human body, or that his opinions are unreliable under Rule 702.

IT IS ORDERED:

1. Dr. Rosenzweig **will not** be permitted to testify on AMS's knowledge or state of mind, to offer legal conclusions, or to opine that mesh causes cancer.
2. Dr. Rosenzweig **will** be permitted to testify on AMS's design defect and failure to warn, insofar as his testimony is premised on the characteristics of

polypropylene and the injures that can result from its implantation in humans. He **will not** be permitted to testify about the adequacy of AMS's testing.

3. The Court will defer ruling on Dr. Rosenzweig's alternative design testimony.

4. Dr. Rosenzweig **will** be permitted to rely on the MSDS for his opinion that that polypropylene mesh should not be used in humans, but **will not** be permitted to testify that AMS should have performed additional testing based on the MSDS.

Dated this 28th day of July, 2020.

David G. Campbell
Senior United States District Judge