IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

RITA ARMSTEAD and WILLIAM ARMSTEAD,	)	
Plaintiffs,	)	
v.	)	1:19-CV-1000
COLOPLAST CORP.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Catherine C. Eagles, District Judge.

Defendant Coloplast Corp. has moved to exclude or limit the testimony at trial of Bruce Rosenzweig, M.D. Coloplast challenges Dr. Rosenzweig's methodology for generating his opinions in his expert report and asserts they are not supported by a reliable, scientific basis. The Court will deny the motion because Dr. Rosenzweig is qualified and in large part his report and opinions rest on a reliable foundation. The Court reserves ruling on the admissibility of Dr. Rosenzweig's testimony on safer alternatives.

Background

Mrs. Armstead's claims stem from the implantations of an Altis pelvic mesh device during surgery on January 31, 2014, and a Restorelle Y Mesh pelvic mesh device during surgery on April 27, 2015. Doc. 13 at 5; Doc. 10. Both devices are manufactured by Coloplast, Doc. 5 at 2, and contain synthetic mesh made of polypropylene. Doc. 40-1 at 13–14. Mrs. Armstead asserts these devices caused multiple physical injuries. Doc 13

at 6–7, 13–16. Pretrial matters were handled in a multi-district litigation proceeding against Coloplast and other defendants in the Southern District of West Virginia, and the case was recently transferred to this district for trial. *See* Doc. 58.

In support of her products liability claims, Mrs. Armstead proffers the expert report of Dr. Bruce Rosenzweig. Doc. 40-1. Dr. Rosenzweig is an Assistant Professor of Obstetrics and Gynecology at Rush University Medical Center in Chicago, Illinois. *Id.* at 2. He has over thirty years of experience in obstetrics and gynecology and has performed over a thousand pelvic floor surgical procedures. *Id.* at 2–3. He has also performed over 350 surgeries relating to complications with synthetic mesh, including Coloplast mesh products. *Id.* at 3. Dr. Rosenzweig has testified in numerous pelvic mesh cases, including some cases where he offered opinions on the same issues as here.[1]

In his expert report, Dr. Rosenzweig offers his opinions including:

- that the injuries suffered by Mrs. Armstead are the direct result of the Altis and Restorelle devices;
- that the resulting medical treatment necessary to treat the injuries from the implants was foreseeable;
- that the Altis and Restorelle devices are the primary cause of Mrs. Armstead's complications;
- that no cause for her injuries exists apart from the implantation of these devices;
- that safer alternatives were available; and

[1] *See, e.g., Wilkerson v. Boston Sci. Corp.*, No. 2:13-cv-04505, 2015 WL 2087048 (S.D.W. Va. May 5, 2015); *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501 (S.D.W. Va. 2014); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691 (S.D.W. Va. 2014).

- that inadequate warnings accompanying the Altis and Restorelle devices "significantly increased the likelihood of injury."

Doc. 40-1 at 13–14, 24–25.

In arriving at these opinions, Dr. Rosenzweig relied on Mrs. Armstead's medical records and testing results, as well as her medical history. *Id.* at 4–13. After reviewing her record, Dr. Rosenzweig employed a differential diagnosis methodology that involved ruling in possible causes for symptoms and conditions and then eliminating possible causes until reaching one that could not be ruled out or determining one is most likely. *Id.* at 3. Dr. Rosenzweig's methodology involved five steps: (1) reviewing Mrs. Armstead's records and test results; (2) reviewing her medical history; (3) reviewing and applying the scientific literature to determine possible causes of her symptoms; (4) applying clinical experience to determine possible causes; and (5) applying his experience and the literature to eliminate possible causes. *Id.* This is the same method that Dr. Rosenzweig uses in his practice to determine the cause or causes of his patients' medical conditions. *Id.* at 3–4. This methodology "has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999).[2]

Coloplast asks the Court to exclude or limit some of Dr. Rosenzweig's opinions and testimony. Doc. 40. Coloplast does not challenge Dr. Rosenzweig's qualifications

[2] The Court omits internal citations, alterations, and quotation marks throughout this opinion, unless otherwise noted. *See United States v. Marshall*, 872 F.3d 213, 217 n.6 (4th Cir. 2017).

or general opinions but attacks the methodology of his case-specific opinions. Doc. 45 at 1. Specifically, Coloplast seeks to exclude Dr. Rosenzweig's testimony:

- that inadequate information in the Altis and Restorelle Instructions for Use contributed to Mrs. Armstead's injuries;
- that polypropylene in the Altis and Restorelle devices induced a foreign body reaction in Mrs. Armstead, causing them to degrade, shrink, contract, and migrate; and
- that other surgical procedures or non-mesh products are safer alternatives.

Doc. 41 at 2.

Legal Standard

Rule 702 provides that a report from a witness qualified as an expert is admissible if (1) it is "based upon sufficient facts or data," (2) it is "the product of reliable principles and methods," and (3) "the principles and methods have been applied reliably to the facts of the case." *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 123 (4th Cir. 2011); Fed. R. Evid. 702. The testimony is admissible if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

The district court "must act as a gatekeeper," *E.E.O.C. v. Freeman*, 778 F.3d 463, 472 (4th Cir. 2015), and "determine reliability in light of the proposed expert's full range of experience and training as well as the methodology used to arrive at a particular conclusion." *Am. Honda Motor Co. v. Allen*, 600 F.3d 813, 816 (7th Cir. 2010); *see also Westberry*, 178 F.3d at 261. Whether expert evidence is reliable is primarily a question of the validity of the expert's methodology, not the quality of the data used or the conclusions produced. *Manpower, Inc. v. Ins. Co. of Penn.*, 732 F.3d 796, 806 (7th Cir.

2013). "The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact, or, where appropriate, on summary judgment." *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000); *see also United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (noting that a court's focus is "on the principles and methodology employed by the expert, not on the conclusions reached"), *overruled on other grounds by United States v. Evans*, 526 F.3d 155 (4th Cir. 2008).

The Court also "need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Moreland*, 437 F.3d at 431 (quoting *Daubert*, 509 U.S. at 596).

Analysis

A. Dr. Rosenzweig's testimony on the adequacy of the Coloplast IFUs

Coloplast seeks to exclude Dr. Rosenzweig's testimony that the Altis and Restorelle Instructions for Use (IFU) were inadequate and any causal effect they had on Mrs. Armstead's injuries. Doc. 41 at 4–5.

IFUs are provided by the medical device manufacturer and are intended to provide physicians with information about the device, including any adverse reactions and known risks, so that the physician can make an informed decision about whether to use the device and can relay this information to the patient. Doc. 43-3 at 6–7. Dr. Rosenzweig's expert report asserts that Coloplast provided inadequate IFUs about the Altis and

Restorelle devices which "significantly increased the likelihood of . . . and caused or contributed to cause the injuries and damages to Ms. Armstead." Doc. 40-1 at 25. Dr. Rosenzweig also asserts that Coloplast failed to use reasonable care to provide adequate IFUs to users. *Id.* Specifically, he asserts that the IFUs did not include all known risks, downplayed the risks they did list, were misleading and inaccurate, and did not properly inform physicians about the devices and how to implant them. *Id.*; Doc. 43-2 at 5–16; Doc. 43-3 at 6–12; Doc. 54-13 at 23–32.

In forming these opinions, Dr. Rosenzweig drew on his extensive experience, Doc. 43-3 at 7, as well as the medical literature and Coloplast's internal documents. Doc. 40-1 at 25–26. Dr. Rosenzweig has testified on the adequacy of IFUs in past cases involving pelvic mesh devices, *Huskey*, 29 F. Supp. 3d at 703–04; *Wilkerson*, 2015 WL 2087048, at *7–8, and there is no reason to think he has suddenly become unqualified to render an opinion on the topic now. His experience, supported by the literature and Coloplast's own documents, are a sufficient basis for his opinion on the IFUs.

Coloplast does not contend that Dr. Rosenzweig is not qualified to give opinions on the adequacy of the IFUs, nor does it contend that his methodology, conclusions, or facts supporting them are flawed. Instead, Coloplast contends that Dr. Rosenzweig's testimony should be excluded because he could not know what other warnings Mrs. Armstead received from her physician and because he is not qualified to testify about the state of mind of Mrs. Armstead or her treating physician. Doc. 41 at 4–5. These arguments do not undermine the reliability of Dr. Rosenzweig's opinions on the adequacy of the IFUs or their impact but go to the persuasiveness of this testimony.

The motion as to this aspect of Dr. Rosenzweig's testimony will be denied, without prejudice to an objection at trial should Dr. Rosenzweig be asked or offer testimony about Mrs. Armstead's or her physician's state of mind. *See, e.g.*, *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *4 (S.D.W. Va. Sept. 29, 2014).

B. Dr. Rosenzweig's opinion about polypropylene

Dr. Rosenzweig intends to testify that polypropylene mesh, such as that in the Altis and Restorelle implants, causes a strong foreign body response which results in the degradation of the polypropylene and leads to shrinkage, contraction, and migration of the implants. Doc. 40-1 at 14–15. He further intends to testify that Mrs. Armstead's devices degraded and caused the complications and injuries that Mrs. Armstead suffers from. *Id.* at 14. Coloplast contends that Dr. Rosenzweig's opinions on polypropylene degradation are irrelevant and unreliable. Doc. 41 at 6–7.

a. *General Causation*

Coloplast does not challenge the admissibility of Dr. Rosenzweig's opinions on general causation. Dr. Rosenzweig's extensive experience in urogynecology—particularly his experience with mesh implantation products—and his review of the medical and scientific literature more than adequately provide a basis for his testimony on polypropylene degradation. Furthermore, he has extensively detailed his review of the medical literature in his report and assessed how it supports his opinions. Doc. 40-1 at 13–22. Finally, Dr. Rosenzweig has been admitted as an expert to offer general causation testimony in many other cases. *See Tyree*, 54 F. Supp. 3d at 565 (listing cases).

b. *Specific Causation*

Coloplast challenges Dr. Rosenzweig's testimony that Mrs. Armstead's Altis and Restorelle mesh implants have degraded and are causing her injuries. Dr. Rosenzweig arrived at this opinion through the differential diagnosis methodology.

As discussed *supra*, Dr. Rosenzweig began his analysis by extensively reviewing and detailing Mrs. Armstead's medical records and history. Doc. 40-1 at 4–13. The correlation of the onset of Mrs. Armstead's symptoms and the implantation of the pelvic mesh devices suggested the implants had caused the injuries. Furthermore, Mrs. Armstead's injuries were consistent with injuries to other people caused by polypropylene devices, as detailed in his expert report. *Id.* at 15–23. Dr. Rosenzweig then relied on his experience, Mrs. Armstead's records, and the medical literature to identify other potential causes, which he was able to rule out. *Id.* at 23–24. Based upon his review and experience, Dr. Rosenzweig concluded that "[t]o a reasonable degree of medical certainty, no cause for [Mrs. Armstead's injuries] exists other than the polypropylene Altis and Restorelle implants and their effects on surrounding tissue." *Id.* at 14. Dr. Rosenzweig's report was produced using a reliable methodology and based upon reliable facts. *See Westberry*, 178 F.3d at 262. His report is thorough and detailed, and his opinions are within the scope of his qualifications. His testimony is admissible.

Dr. Rosenzweig has never physically examined Mrs. Armstead, nor has he examined her mesh products which are still implanted, and Coloplast contends this makes his opinion inadmissible. While relevant in considering whether to admit Dr. Rosenzweig's testimony, it is not determinative. *See Tyree*, 54 F. Supp. 3d at 565–67

(admitting Dr. Rosenzweig's expert testimony on specific causation absent a physical examination and noting he "thoroughly considered [the patient's] medical history and test results in the light of the applicable publications, thereby establishing medical evidence as to what caused [the patient's'] specific injuries"). Indeed, a physical examination is not required to reach a reliable differential diagnosis so long as the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999)). Dr. Rosenzweig notes that the method employed in his report is the same he uses in his medical practice. Doc. 40-1 at 4. ON this record, that Dr. Rosenzweig has not examined Mrs. Armstead's implants does not render his report irrelevant or unreliable. Coloplast is free to raise this criticism on cross-examination. *Westberry*, 178 F.3d at 261.

In support of its argument, Coloplast relies almost exclusively upon *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691 (S.D.W. Va. 2014). In *Huskey*¸ the district court excluded Dr. Rosenzweig's testimony that the plaintiff's mesh implant (similar to the ones implanted in Mrs. Armstead) had degraded and caused injury to the plaintiff. *Huskey*, 29 F. Supp. 3d at 707–08. The court found Dr. Rosenzweig's testimony to be unreliable because he had not examined the plaintiff's mesh, he did not explain how the plaintiff's symptoms indicated the mesh had degraded, he did not attempt to rule out other potential causes for the symptoms, and he did not say precisely how often he found degradation in similar situations. *Id.* at 708.

Thus, it was a combination of factors not present here which led to the exclusion of Dr. Rosenzweig's testimony in *Huskey*, and it is therefore distinguishable. As discussed *supra*, Dr. Rosenzweig provided a detailed and thorough explanation of how Mrs. Armstead's symptoms and their timing indicate the Altis and Restorelle polypropylene mesh induced a foreign body reaction that degraded and shrank the implants, causing them to migrate. Doc. 40-1 at 4–23. He cites to numerous reports and medical studies which indicate that polypropylene products induce foreign body responses and lead to injuries like those suffered by Mrs. Armstead. *Id.* at 15–23. Additionally he employed a differential diagnosis methodology which entailed considering and eliminating other potential causes. *Id.* at 23–24.

Because Dr. Rosenzweig's testimony that the Altis and Restorelle implant devices caused Mrs. Armstead's injuries is reliable and based upon reliable scientific principles and because Coloplast's other concerns "implicated not the reliability of [Dr. Rosenzweig's] methodology but the conclusions that it generated," *Manpower*, 732 F.3d at 807, the Court will deny Coloplast's motion to exclude Dr. Rosenzweig's testimony on polypropylene degradation..

C. Dr. Rosenzweig's opinion on safer alternatives

Dr. Rosenzweig intends to testify that safer alternatives to the Altis and Restorelle mesh devices were available for treatment of Mrs. Armstead's conditions. Doc. 40-1 at 24–25. In his report, Dr. Rosenzweig does not directly compare other methods or products. *Id.* at 24–25. Apart from listing some examples, he does not explicitly explain why or how the proposed alternatives would be safer. *Id.* Nor does he provide a specific

analysis of his proposed alternatives. He cites no studies or research in direct support of this opinion. His opinion that the Altis and Restorelle devices are flawed and caused Mrs. Armstead's injuries does not on its own support the separate opinion that safer alternatives were available.

That said, Dr. Rosenzweig has decades of experience in the field and has used many different surgical mesh implants, including those at issue here, as well as other techniques, both surgical and non-surgical, to treat problems like Ms. Armstead experienced. While experience may form the basis for expert testimony on its own, "the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702 advisory committee's note to 2000 amendment. Dr. Rosenzweig's report states generally that he has "experience with many of these safer alternatives," Doc. 40-1 at 24, but provides no information as to how his experience supports his conclusion. The Court reserves ruling on the admissibility of this testimony until further testimony may be offered and evaluated firsthand at trial. *See In re: Ethicon, Inc.*, MDL No. 2327, 2016 WL 4500766, at *4 (S.D.W. Va. Aug. 26, 2016).

It is **ORDERED** that the defendant's motion to exclude or limit the opinion testimony of Bruce Rosenzweig, M.D., Doc. 40, is **DENIED**. The Court reserves ruling on the admissibility of Dr. Rosenzweig's opinions on safer alternatives until trial.

This the 21st day of January, 2020.

UNITED STATES DISTRICT JUDGE