IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge William J. Martínez

Civil Action No. 20-cv-1933-WJM-STV

LEAH R. SHOSTROM,

Plaintiff,

v.

ETHICON, INC., and
JOHNSON & JOHNSON,

Defendants.

ORDER GRANTING IN PART AND DENYING IN PART ETHICON'S MOTION TO LIMIT THE CASE-SPECIFIC TESTIMONY OF BRUCE ROSENZWEIG, M.D.

This product liability action was transferred to this Court from a multi-district litigation ("MDL") proceeding in the United States District Court for the Southern District of West Virginia. *In re Ethicon, Inc. Pelvic Repair Systems Products Liability Litigation*, No. 2:12-md-2327 (S.D. W. Va.). The MDL involves claims of harm resulting from implantation of various polypropylene-based mesh products.

Before the Court is Defendants Ethicon, Inc. and Johnson & Johnson's (jointly, "Ethicon") Motion to Limit the Case-Specific Testimony of Bruce Rosenzweig, M.D. ("Motion to Limit"). (ECF No. 102.) Plaintiff Leah R. Shostrom responded in opposition (ECF No. 104), and Ethicon replied (ECF No. 106).

Neither party requested an evidentiary hearing on the Motion to Limit, and the Court finds it does not need one to resolve the Motion to Limit. (ECF No. 102 at 10; ECF No. 104 at 2 n.4.) For the following reasons, the Motion to Limit is granted in part

and denied in part.

I. LEGAL STANDARDS

A district court must act as a "gatekeeper" in admitting or excluding expert testimony. *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1232 (10th Cir. 2005). Expert opinion testimony is admissible if it is relevant and reliable. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589, 594–95 (1993). The opinions are relevant if they would "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. They are reliable if (1) the expert is qualified "by knowledge, skill, experience, training, or education," (2) his opinions are "based upon sufficient facts or data," and (3) they are "the product of reliable principles and methods." *Id.* The proponent of expert testimony has the burden to show that the testimony is admissible. *United States v. Nacchio*, 555 F.3d 1234, 1241 (10th Cir. 2009).

Federal Rule of Evidence 401 provides that evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action.

Federal Rule of Evidence 402 provides that relevant evidence is admissible unless any of the following provides otherwise, including the United States Constitution; a federal statute; these rules; or other rules prescribed by the Supreme Court. Further, Rule 402 provides that irrelevant evidence is not admissible.

Federal Rule of Evidence 403 provides that "[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."

II. ANALYSIS

The Court presumes the parties' familiarity with the background and procedural history of this case, and incorporates by reference the Background section from its Order Granting In Part, Denying In Part, and Deferring In Part Ethicon's Motion for Summary Judgment. (ECF No. 100 at 4–6.)

Dr. Rosenzweig is a surgeon in the field of urogynecology and pelvic surgery and will serve as an expert witness for Shostrom. (ECF No. 102-1.) Dr. Rosenzweig has been qualified and allowed to testify as an expert witness in pelvic mesh cases across the country, including cases involving the two products at issue here: TVT-Secur ("TVT-S") and Prolift. (ECF No. 104-1.)

In the Motion, Ethicon requests that the Court:

- On relevancy grounds, preclude Dr. Rosenzweig from testifying about surgical treatments for stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP") that do not involve synthetic mesh as alternative designs or guarantees against injury;
- On relevancy grounds, preclude Dr. Rosenzweig from testifying about the alleged susceptibility of TVT-S to degradation and deformation, and opinions that Shostrom's mesh was deformed; and
- On relevancy and reliability grounds, preclude Dr. Rosenzweig from testifying about the subjective knowledge of Shostrom's implanting surgeons.

(ECF No. 102 at 2.)

A. Opinions that surgical procedures without mesh are alternative designs and would have prevented Shostrom's injuries[1]

Ethicon seeks to exclude testimony from Dr. Rosenzweig that suggests that surgical procedures without mesh are safer alternative designs to the TVT-S and Prolift, and that Shostrom's claimed injuries would have been avoided if her implanting surgeon had selected those treatments. (ECF No. 102 at 3.) Ethicon explains that in his expert report, Dr. Rosenzweig opines that Shostrom would not have suffered the injuries described in his report

> had the following alternatives to TVT-Secur been used: "(1) the use of sutures, including delayed absorbable sutures like PDS, in a colposuspension procedure like the Burch; (2) autologous fascia sling; (3) an allograft sling such as Repliform." . . . Similarly, Dr. Rosenzweig claims Ms. Shostrom would not have suffered injuries if the following alternatives to Prolift had been used: "(1) the use of sutures, including delayed absorbable sutures like PDS, in a uterosacral ligament suspension and a sacrospinous fixation; an anterior colporrhaphy; a sacrocolpopexy; (2) autologous fascia lata POP repair; and (3) Repliform cadaveric fascia POP repair.

(*Id.* (citing ECF No. 102-1 at 25–26).) According to Ethicon, none of these options are alternative designs of the TVT-S or Prolift because they do not contain synthetic mesh. (*Id.* at 4.) Instead, Ethicon characterizes these purported alternatives as "tantamount to

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[1] In its reply, Ethicon states that "[w]hile Ethicon did not initially object to Dr. Rosenzweig's opinion that Ultrapro may serve as an alternative design to the TVT-Secur device, based on the [*Wood v. Am. Med. Sys. Inc.*, 2021 WL 1178547 (D. Colo. Mar. 26, 2021)] opinion, which serves as supplemental authority and directly addresses the use of Ultrapro as an 'alternative design' to a polypropylene mesh sling to treat SUI, Ethicon respectfully requests the Court exclude this opinion." (ECF No. 106 at 3 n.2.)

Because Ethicon raises this argument regarding Ultrapro for the first time in its reply, and Shostrom did not have an opportunity to respond to Ethicon's reply, *see* D.C.COLO.LCivR 7.1(d), the Court finds that Ethicon has waived these arguments. *See United States v. Harrell*, 642 F.3d 907, 918 (10th Cir. 2011) (arguments raised for the first time in a reply brief generally are deemed waived). Key here is the fact that nothing prevented Ethicon from moving for relief in connection with the Ultrapro prior to the unpublished *Wood* decision.

not using these products at all." (*Id.*)

Notably, as Shostrom points out, Ethicon does not claim that Dr. Rosenzweig is not qualified to provide his opinions or that his methodology is flawed. (ECF No. 104 at 2.) Moreover, Ethicon underscores that it is not seeking to preclude Dr. Rosenzweig from testifying about surgical procedures not involving synthetic mesh in any context. (ECF No. 102 at 3.)

In her response, Shostrom argues that Dr. Rosenzweig should be permitted to testify regarding all safer alternative treatments for SUI and POP, including those with and without mesh. (ECF No. 104 at 2.) She argues, among other things,[2] that his opinions are relevant to a number of the *Armentrout v. FMC Corp.*, 842 P.2d 175, 184 (Colo. 1992), factors[3] regarding her design defect claim, and not only the third factor,

[2] Upon review of Shostrom's response, the Court concludes that she has improperly attempted to expand the scope of the issues under review. The Court will not issue what would amount to an advisory opinion by addressing issues beyond the scope of the Motion to Limit in this Order. The Court cautions the parties against repeating this approach in future briefing.

[3] The seven non-exclusive *Armentrout* factors, which are used to determine whether a design is unreasonably dangerous, are:

> (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
>
> (2) The safety aspects of the product—the likelihood that it will cause injury and the probable seriousness of the injury.
>
> (3) The availability of the substitute product which would meet the same need and not be as unsafe.
>
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
>
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
>
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability because of general public

which examines the availability of a substitute product. (*Id.* at 7.) Rather than describe them as alternative "designs," Shostrom describes Dr. Rosenzweig's alternatives as safer alternative "treatments." (*Id.*) As such, she contends that a medical device's usefulness and desirability (factor 1) and its safety aspects (factor 2) should reasonably be assessed in comparison to other available treatments, including traditional surgical procedures and non-mesh repairs. (*Id.*) Shostrom argues that the "jury should decide whether [Ethicon's] products were unreasonably dangerous, including because safer alternative treatments existed, regardless of whether or not they are 'designs.'" (*Id.*)

The core question before the Court is whether Dr. Rosenzweig's opinions about safer alternatives to the TVT-S and Prolift, which can be categorized broadly into three groups—the use of sutures in a procedure like the Burch; the autologous fascia sling or autologous fascia lata POP repair; and the allograft sling such as Repliform or Repliform cadaveric fascia POP repair—can be considered alternative designs of those devices such that they are relevant to the existence of substitute products under the third *Armentrout* factor.

Regarding the use of sutures in a procedure like the Burch, numerous courts have considered this exact issue and have determined that "alternative, feasible design must be examined in the context of products—not surgeries or procedures." *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942 (S.D.W. Va. 2017); *see also*

> knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
>
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Armentrout, 842 P.2d at 184.

Heatherman v. Ethicon, Inc., 2020 WL 5798533, at *8 (D. Colo. Sept. 29, 2020) (same). Examining the use of polypropylene sutures as a proposed alternative, feasible design for the TVT, United States District Judge Joseph R. Goodwin reasoned in *Mullins*:

> Evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT. Whether an alternative procedure could have been performed without the use of the TVT does nothing to inform the jury on the issue of an alternative, feasible design for the TVT. Instead, 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. In other words, alternative surgeries or procedures concern the medical judgment of the doctors who use TVT devices to treat stress urinary incontinence ("SUI"); other surgeries or procedures do not inform the jury on how the TVT's design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries.

Mullins, 236 F. Supp. 3d at 943. Numerous courts have followed the *Mullins* court's reasoning. *See, e.g.*, *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017) ("I agree with Ethicon that alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists."); *Willet v. Johnson & Johnson*, 2020 WL 2988299, at *8–9 (S.D. Iowa June 3, 2020) (excluding expert opinion on "native tissue repair and surgical procedures using human and animal donor tissue" because neither is classified as a medical device and thus the opinion was not relevant to the existence of an alternative pelvic mesh medical device); *Moultrie v. Coloplast Corp.*, 2020 WL 1249354, at *11 n.20 (W.D. Pa. Mar. 16, 2020) (noting that the autologous fascia sling and the Burch colposuspension "appear to be medical procedures rather than medical devices" and that the expert "did not address the issue of how [defendant] could have 'modified' its Aris device by

abandoning it altogether in favor of a surgical procedure"); *Salinero v. Johnson & Johnson*, 2019 WL 7753453, at *17 (S.D. Fla. Sept. 5, 2019), *reh'g denied*, 2019 WL 7753439 (S.D. Fla. Oct. 25, 2019) (agreeing with Judge Goodwin that surgical procedures such as biological grafts are not alternative designs to synthetic pelvic mesh products, and thus excluding testimony that autologous fascia lata and allografts are "safer alternative designs").

Like the *Heatherman* court and so many others, this Court, too, agrees with Judge Goodwin's analysis. The existence of alternative *procedures* to the one that Shostrom underwent is not relevant to any purported defects in Ethicon's medical *devices*. The Burch procedure is a "surgical procedure used to treat SUI in which the neck of the bladder is suspended from nearby ligaments with sutures." (ECF No. 102 at 4.) Similarly, Ethicon explains—and Shostrom does not dispute—that uterosacral ligament suspension and sacrospinous fixation are procedures used to treat POP by suspending the vaginal vault with sutures to adjacent ligaments. (ECF No. 102-3.) Ethicon provides evidence that Dr. Rosenzweig has admitted these are surgical procedures and not products. (See ECF No. 102-4 at 5 ("Q. We can agree that the Burch is not a design, it is a surgery, correct? . . . A. It is a surgical procedure to treat stress urinary incontinence. Q. The Burch is not a medical device, right? A. It is not a medical device.").)

Therefore, the Court concludes as a matter of law that use of sutures, including delayed absorbable sutures like PDS, in a colposuspension procedure like the Burch, and the use of sutures, including delayed absorbable sutures like PDS, in a uterosacral ligament suspension and a sacrospinous fixation, or an anterior colporrhaphy or a

sacrocolpopexy, are not alternative products to the TVT-S or Prolift. The Court grants this portion of the Motion to Limit and excludes Dr. Rosenzweig's opinions about these procedures as a safer alternative to the TVT-S or Prolift, to the extent Shostrom would offer them as evidence of the availability of substitute products or devices which would meet the same need and not be as unsafe as Defendants' devices at issue here.

Next, the Court considers Dr. Rosenzweig's opinions regarding autologous slings and allograft slings. Ethicon explains that autologous repairs use the patient's own native tissues to fashion a biological (non-synthetic) sling. (ECF No. 102 at 4.) Repliform repairs use cadaverous tissue (allografts), rather than synthetic mesh, in SUI or POP repairs; the allograft undergoes a proprietary process and is often sold in sheets. (*Id.* at 5.) It is regulated by the FDA as human tissue for transplantation. (*Id.*)

In *Heatherman*, United States District Judge R. Brooke Jackson pointed out that the relevance of opinions on the autologous sling are "more complex" than those concerning the Burch procedure. *See Heatherman*, 2020 WL 5798533, at *9. Citing various cases in which courts ruled that allografts (another word for autologous slings, according to *Heatherman*) are not products, Judge Jackson observed that "those decisions do not directly address the fact that, unlike the Burch procedure, an autologous sling is a tangible thing and not just a process." *Id.* (citing cases). Observing that the only apparent difference between an autologous sling and a TVT sling is the substance from which the slings are made—native tissue versus synthetic material—Judge Jackson stated that he believed "an autologous sling could properly be considered a 'substitute product' for the TVT." *Id.* Determining that a jury is best suited to answer the question of whether an autologous sling is a product for purposes of

alternative design, Judge Jackson denied Ethicon's motion to exclude the expert opinion on the autologous sling as a safer alternative to the extent that plaintiff would offer it as evidence of the existence of a substitute product under *Armentrout* factor three. *Id.* at *10.

The issue of what constitutes a product is normally a question of law, *Sanders v. Acclaim Entm't, Inc.*, 188 F. Supp. 2d 1264, 1277 (D. Colo. 2002), and "[t]he question of whether a product is defective and unreasonably dangerous is generally an issue for the jury," *Bartholic v. Scripto-Tokai Corp.*, 140 F. Supp. 2d 1098, 1107 (D. Colo. 2000). Although other aforementioned courts have concluded differently,[4] the undersigned concludes that although the autologous sling and allografts use non-synthetic materials, they are sufficiently similar to the synthetic mesh products at issue to render Dr. Rosenzweig's opinions on them relevant, such that the jury may consider Dr. Rosenzweig's opinions on the alternatives as substitute products. Thus, the Court will deny Ethicon's Motion to Limit on this point, and determines that Dr. Rosenzweig may opine that autologous slings and allografts are substitute products under *Armentrout* factor three. Of course, the jury must still determine whether, considering the evidence, the TVT-S and Prolift devices are unreasonably dangerous.

B. Opinions concerning degradation, deformation, and other alleged characteristics of TVT-S mesh

Ethicon seeks to exclude Dr. Rosenzweig's opinions that Shostrom was injured because her TVT-S device sustained deformations in the mesh, including rigidity, fraying, roping, cording, curling, sharp edges, loss of pore size, fibrotic bridging, and

[4] In reaching its opinion, the Court notes that neither party has provided any binding authority on this point which the Court must follow.

shrinkage/contraction. (ECF No. 102 at 9.) Specifically, Ethicon argues that Dr. Rosenzweig's testimony lacks foundation and is irrelevant because Shostrom's TVT-S was never explanted or revised; thus, no pathological sample is available for examination to determine whether any of these issues occurred. (*Id.*) Ethicon also posits that these opinions could confuse the issues and mislead the jury because they are confusing topics which require substantial time and testimony to explain their causes and effects.

In response, Shostrom argues that in taking this position, Ethicon ignores the medical evidence and direct deposition testimony. (ECF No. 104 at 9.) Shostrom cites numerous portions of Dr. Rosenzweig's deposition testimony in which he confirms that her TVT-S had undergone contraction, which is a form of deformation. (*See id.* at 9–10 (citing ECF No. 104-5).)

Based on the cited testimony from Dr. Rosenzweig's deposition, the Court agrees with Shostrom that Dr. Rosenzweig has relied on medical evidence in forming his opinions about the deformations of Shostrom's TVT-S device. *See Wood*, 2021 WL 1178547, at *9 (while it's true that Dr. Rosenzweig did not personally examine Ms. Wood's mesh, his opinions specific to Ms. Wood are reliable because they are based on a review of her medical records and how they compare to broader research on the topic). Therefore, the Court will deny this portion of the Motion to Limit.

C. Opinions about Shostrom's implanting surgeons' subjective knowledge

Ethicon seeks to preclude Dr. Rosenzweig from speculating that Shostrom's implanting surgeons were not fully informed of the risks associated with the TVT-S and Prolift devices. (ECF No. 102 at 10.) For support, Ethicon cites numerous cases decided by the MDL court which preclude experts from testifying as to the state of mind

of the plaintiffs' implanting physicians. (*Id.* (citing *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4493457, at *3 (S.D.W. Va. Aug. 25, 2016); (precluding expert from testifying about "what physicians know or should know about specified topics"); *Nall v. C.R. Bard, Inc.*, 2018 WL 524632, at *2 (S.D.W. Va. Jan. 23, 2018) (excluding evidence regarding implanting physician's state of mind); *Martin v. Ethicon, Inc.*, 2017 WL 6348627, at *2 (S.D.W. Va. Dec. 12, 2017) (same); *Guinn v. Ethicon, Inc.*, No. 2:12-cv-1121, Doc. 119 at 5 (S.D.W. Va. Feb. 3, 2017) (same); *Free v. Ethicon, Inc.*, 2017 WL 660017, at *3 (S.D.W. Va. Feb. 14, 2017) ("To the extent that testimony seeks to attribute a state of mind to the implanting surgeon, I agree with Ethicon. Experts may not testify as to what other individuals did or did not know.")).)

In response, Shostrom argues that Ethicon mischaracterizes Dr. Rosenzweig's opinions as involving an attempt to read the minds of her implanting physicians. (ECF No. 104 at 10.) Rather, according to Shostrom, Dr. Rosenzweig will testify about how Ethicon failed to share an actively concealed risk information from the medical community and patients. (*Id.*) Shostrom cites no cases in support of her argument in which a court has permitted Dr. Rosenzweig to testify as she describes. (*See id.*)

Upon review, the Court finds that it is possible to read Dr. Rosenzweig's expert report as speculating about what Shostrom's physicians knew. (*See, e.g.*, ECF No. 102-1 at 27–28 ("Shostrom did not receive information about the above risks because Ethicon did not disclose them fully in its IFUs, and surgeons, including the implanting surgeons in Ms. Shostrom's case, were not made aware of them."; "Ms. Shostrom's implanting surgeons were not able to provide the necessary and required information to Ms. Shostrom for an informed consent because Ethicon failed to fully reveal such

information and failed to fully evaluate said information prior to launch.").) It is for Shostrom's physicians—not Dr. Rosenzweig—to explain to the jury what they knew and understood from Ethicon's disclosures.

Accordingly, the Court determines that it will follow the MDL courts' decisions on this issue. To the extent that his proffered testimony seeks to attribute a state of mind to Shostrom or her implanting physicians, the Court will preclude Dr. Rosenzweig from testifying as to what other individuals did or did not know. However, to the extent Ethicon seeks to exclude Dr. Rosenzweig's testimony about the adequacy of warnings and the knowledge of the medical community in general, the Court denies such a request. As an expert witness, Dr. Rosenzweig may properly offer opinions on these topics. Therefore, the Court will grant this portion of the Motion to Limit to the extent Ethicon seeks to exclude evidence regarding Shostrom's implanting physicians' state of mind.

III. CONCLUSION

Defendants Ethicon, Inc. and Johnson & Johnson's Motion to Limit the Case-Specific Testimony of Bruce Rosenzweig, M.D. (ECF No. 102) is GRANTED IN PART AND DENIED IN PART as set forth above.

Dated this 10th day of February, 2022.

BY THE COURT:

William J. Martinez
United States District Judge