UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

JUDY L. TEDDER,

Plaintiff,

v. **CASE NO. 3:20cv5611-MCR-MJF**

ETHICON, INC. and
JOHNSON & JOHNSON,

Defendants.
_____/

ORDER[1]

This case is before the Court on remand from the Southern District of West Virginia, *In re: Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2012-MD-2327-JRG. On May 15, 2007, and May 25, 2010, respectively, Plaintiff Judy L. Tedder had two pelvic mesh devices surgically implanted by Dr. Basil D. Fossum—TVT-Secur (TVT-S) and TVT-Oturator (TVT-O), both of which were manufactured and sold by Defendant Ethicon, Inc.[2] Tedder alleges she was injured as a result of defects in the devices. Currently before the Court is Defendants' Motion to Exclude Certain Opinions of Daniel Elliott, M.D. (ECF No. 136).

[1] The Court assumes the parties' familiarity with the nature of this litigation, the claims and defenses, and the current evidentiary record. Thus, this Order sets out only what is necessary to explain the Court's rulings.

[2] Ethicon is a part of the Johnson & Johnson Medical Device Companies. *See https://www.jnjmedicaldevices.com/en-US/companies/ethicon*.

Tedder designated Dr. Elliott, a pelvic floor surgeon and urologist, to provide general opinions about TVT-S and TVT-O. The MDL court ruled on a number of Defendants' challenges to Dr. Elliott's testimony but did not rule on the admissibility of the following testimony Tedder seeks to elicit from Dr. Elliott at trial: (1) that TVT-S and TVT-O are unsafe for the surgical treatment of stress urinary incontinence (SUI), (2) testimony regarding certain duties of a medical device manufacturer, which Tedder contends Defendants breached, (3) that non-synthetic mesh surgeries are a safer alternative to TVT-S and TVT-O, and (4) that a device with a lighter-weight, larger-pore mesh would serve as a safer alternative to TVT-S and TVT-O.

I. Legal Standard

Rule 702, as explained by *Daubert* and its progeny, governs the admissibility of expert testimony. *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005). Under Rule 702 and *Daubert*, district courts must act as "'gatekeepers'" to ensure the reliability and relevancy of expert testimony. *Id.* (citing *Daubert*, 509 U.S. at 589, 113 S. Ct. 2795). Expert testimony is reliable and relevant—and, therefore, admissible—when the following criteria are met: (1) the expert is sufficiently qualified to testify about the matters he intends to address; (2) the methodology used

is "sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue." *Id.* The Eleventh Circuit refers to these criteria separately as "qualification, reliability, and helpfulness," *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004), and has emphasized that they are "distinct concepts that courts and litigants must take care not to conflate," *Quiet Tech. DC-8, Inc. v. Hurel–Dubois UK Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003). The party offering the expert has the burden of showing, by a preponderance of the evidence, that each of these requirements is met. *Rink*, 400 F.3d at 1292.

To meet the qualification requirement, a party must show that its expert has sufficient "knowledge, skill, experience, training, or education" to form a reliable opinion about an issue that is before the court. *Hendrix ex. Rel. G.P. v. Evenflo Co., Inc.*, 609 F.3d 1183, 1193 (11th Cir. 2010) (citing Fed. R. Evid. 702) ("*Hendrix II*"), *aff'g* 255 F.R.D. 568 (N.D. Fla. 2009) ("*Hendrix I*"). If a "'witness is relying solely or primarily on experience, then 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.'" *Frazier*, 387 F.3d

at 1261 (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendments). The qualifications standard for expert testimony is "not stringent," and "[s]o long as the witness is minimally qualified, objections to the level of [his] expertise [go] to credibility and weight, not admissibility." *Hendrix I*, 255 F.R.D. at 585 (internal marks omitted).

To meet the reliability requirement, an expert's opinion must be based on scientifically valid principles, reasoning, and methodology that are properly applied to the facts at issue. *Frazier*, 387 F.3d at 1261–62. The reliability analysis is guided by several factors, including: (1) whether the scientific technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review or publication; (3) whether the technique has a known or knowable rate of error; and (4) whether the technique is generally accepted in the relevant community. *Daubert*, 509 U.S. at 593–94, 113 S. Ct. 2786. "[T]hese factors do not exhaust the universe of considerations that may bear on the reliability of a given expert opinion, and a federal court should consider any additional factors that may advance its Rule 702 analysis." *Quiet Tech.*, 326 F.3d at 1341. The court's focus must be on the expert's principles and methodology, not the conclusions they generate. *Daubert*, 509 U.S. at 595, 113 S. Ct. 2786. The test for reliability is "flexible," and courts have "broad

latitude" in determining both how and whether this requirement is met. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141–42 (1999).

Finally, to satisfy the helpfulness requirement, expert testimony must be relevant to an issue in the case and offer insights "beyond the understanding and experience of the average citizen." *United States v. Rouco*, 765 F.2d 983, 995 (11th Cir. 1985). Relevant expert testimony "'logically advances a material aspect'" of the proposing party's case and "'fit[s]'" the disputed facts. *McDowell v. Brown*, 392 F.3d 1283, 1298–99 (11th Cir. 2004) (quoting *Daubert*, 509 U.S. at 591, 113 S. Ct. 2786). Expert testimony does not "fit" when there is "too great an analytical gap" between the facts and the proffered opinion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

"Because of the powerful and potentially misleading effect of expert evidence, sometimes expert opinions that otherwise meet the admissibility requirements may still be excluded [under Federal Rule of Evidence] 403." *Frazier*, 387 F.3d at 1263 (internal citation omitted). "Exclusion under Rule 403 is appropriate if the probative value of otherwise admissible evidence is substantially outweighed by its potential to confuse or mislead the jury, or if the expert testimony is cumulative or needlessly time consuming," or if it is otherwise unfairly prejudicial. *Id*. (internal citation

omitted). "Indeed, the judge in weighing possible prejudice against probative force under Rule 403 . . . exercises more control over experts than over lay witnesses." *Id*. (internal marks omitted). "Simply put, expert testimony may be assigned talismanic significance in the eyes of lay jurors, and, therefore, . . . district courts must take care to weigh the value of such evidence against its potential to mislead or confuse." *Id*.

When scrutinizing the reliability, relevance, and potential prejudice of expert testimony, a court must remain mindful of the delicate balance between its role as a gatekeeper and the jury's role as the ultimate factfinder. *Id.* at 1272. The court's gatekeeping role "is not intended to supplant the adversary system or the role of the jury." *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1311 (11th Cir. 1999). Only the jury may determine "where the truth in any case lies," and the court "may not usurp this function." *Frazier*, 387 F.3d at 1272. Thus, a court may not "evaluate the credibility of opposing experts" or the persuasiveness of their conclusions, *Quiet Tech.*, 326 F.3d at 1341; instead, the court's duty is limited to "ensur[ing] that the fact-finder weighs only sound and reliable evidence," *Frazier*, 387 F.3d at 1272.

II. Discussion

A. TVT-S and TVT-O unsafe for the surgical treatment of SUI

Dr. Elliott opines that the mesh used in TVT-S and TVT-O "'should not be used in the pelvic floor'" or "'implanted in the human body for use in the treatment of SUI.'" ECF No. 136 at 3. Defendants urge the Court to exclude Dr. Elliott's testimony in that regard, arguing the opinions directly contradict opinions Dr. Elliott gave in published literature.

The motion is **DENIED**. According to Tedder, Dr. Elliott was only a corresponding author of the 2019 article Defendants cite. In any event, any alleged inconsistencies between Dr. Elliott's current opinions and those set forth in the article go more to the weight of the opinions than to their admissibility and can be addressed on cross-examination. *See, e.g., Ellerbee v. Ethicon, Inc.*, No. 8:20-cv-1514-TPB-AEP, 2021 WL 2010641, at *2 (May 20, 2021); *Geery v. Ethicon, Inc.*, No. 6:20-cv-1975-RBD-LRH, 2021 WL 2580144, at *6 (M.D. Fla. Apr. 9, 2021).

B. Duties of a medical device manufacturer

Defendants argue the Court should preclude Dr. Elliott from suggesting that Ethicon failed to act as a reasonable medical device manufacturer with regard to

research/testing and physician outreach because the opinions are beyond his expertise, unreliable, and do not fit the facts of this case.

1. Research/Testing

Dr. Elliott criticizes Ethicon for failing to perform certain studies and testing before placing the products on the market. Defendants argue that a lack of research and testing, or a flaw in the design process, does not alone constitute a design defect and that, in asserting such a claim, Tedder is attempting to shift the burden to Defendants to prove the absence of a design defect. Defendants also argue the opinions, which they contend are of questionable relevance, should be excluded because Dr. Elliott is not competent to testify about the level of testing a manufacturer should have performed, particularly considering that his opinions in that regard are contradicted by the 2019 article.

With regard to reliability, Defendants point out that Dr. Elliott has never manufactured or designed a medical device, much less had any involvement with FDA clearance, and has not identified a single rule or regulation that would require Ethicon to conduct additional research or testing. Dr. Elliott also has not identified any basis for his opinions regarding research and testing, which Defendants assert are based solely on "unscientific personal belief." ECF No. 136 at 8. According to

Defendants, when asked about how certain studies or testing should be conducted, Dr. Elliott responded that he did not know. Moreover, according to Defendants, Dr. Elliott can only speculate as to what the results of further studies or testing would have shown. Finally, Defendants argue Dr. Elliott's testimony regarding research and testing should be excluded because Dr. Elliott's criticisms of studies relative to the devices at issue in this case are unreliable given that they are directly refuted by the 2019 article, which states that "'[s]ynthetic midurethral sling placement is the most extensively researched surgical treatment of SUI, with more than 2000 published studies establishing the effectiveness and describing their safety profile.'" ECF No. 136 at 10–11. Dr. Elliott also references "'high-quality evidence'" supporting the efficacy of synthetic mid-urethral slings, "including 'multiple randomized trial[s] describing [the] safety and efficacy, with results out to 5 years.'" ECF No. 136 at 11.

According to Tedder, Defendants misunderstand the opinions Dr. Elliott seeks to offer regarding duties of a medical device manufacturer. Dr. Elliott does not intend to offer opinions regarding the legal adequacy of Ethicon's testing; instead, he intends to testify about whether the factual circumstances dictated that additional testing was needed to ensure the safety and efficacy of the devices at issue in this

case before placing them on the market. Specifically, Dr. Elliott intends to testify, based on his review of the literature and internal Ethicon documents, that when safety issues arose—including through reports about mesh degradation—Ethicon did not conduct additional testing and should have. Tedder argues that Dr. Elliott's opinion in that regard relates to the safety of the devices, not the legal or regulatory requirements surrounding a medical device manufacturer's duty to conduct testing. Tedder also urges that Dr. Elliott should be allowed to state the facts on which he relied in determining the scope and prevalence of certain complications associated with polypropylene mesh products. Tedder asserts Dr. Elliott is more than qualified to opine on testing that was or was not conducted by a medical device manufacturer considering that, over the course of his career, he has reviewed hundreds of journal articles, published more than sixty articles in peer reviewed publications, and been an investigator in seven industry studies.

The motion is **GRANTED in part and DENIED in part**. Dr. Elliott may not testify about regulatory research or testing requirements or what research or testing he contends Ethicon should have conducted. Whether Ethicon should have researched or performed tests after becoming aware of complications, however, is a factual matter that does not implicate Rule 702. *See, e.g., Geery*, 2021 WL 2580144,

at *6 & n.4; *Williams v. Ethicon, Inc.*, No. 5:20cv234(MTT), 2021 WL 1087808, at *6 (M.D. Ga. Mar. 22, 2021).

2. Physician training

Defendants also seek to exclude Dr. Elliott from suggesting that Ethicon failed to properly train physicians to use TVT-S and TVT-O, arguing that Dr. Elliott's opinions in that regard do not fit the facts of this case because no expert has opined that Tedder's implanting surgeon, Dr. Fossum, was not properly trained and, in fact, Tedder's case-specific expert, Dr. Zipper, opines that Dr. Fossum's "'care of Ms. Tedder was within the standard of care.'" ECF No. 136 at 11. Defendants also argue Dr. Elliott is not qualified to opine about the level of training a manufacturer is required to provide and that testimony regarding physician training is irrelevant under Florida law, which does not recognize a duty to train physicians.

Tedder responds that Dr. Elliott intends to offer opinions regarding training from a surgical perspective, which the jury otherwise will not have. Specifically, Tedder points to the following opinion set forth in Dr. Elliott's report:

> "Ethicon refused to formally address the problem [of sheath removal/tensioning issues] through changes to the [Instructions for Use (IFU)] or Procedural steps (for example by adding the Babcock technique used by the inventor of TVT-O) leaving many physicians in the dark about why the sheath removal problems were occurring and what they could do about it."

ECF No. 146 at 11. Tedder says Dr. Elliott seeks to testify to the adequacy of the IFU and Ethicon's method of explaining the procedure to surgeons, rather than opinions on industry or company training requirements.

The MDL court found that "[w]hile an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536885, at *2 (S.D.W. Va. Aug. 30, 2016). There is no indication Dr. Elliott has the expertise to offer expert testimony regarding information that should or should not be included on an IFU in general. However, to the extent Dr. Elliott's opinions pertain to complications he has encountered in his practice that were not included among the risks identified on the IFU, Dr. Elliott would be competent to testify. Nevertheless, the Court is not persuaded that evidence of Ethicon's failure to adequately train physicians is relevant in this case given that Tedder does not appear to allege that her implanting surgeon was not properly trained. *See Geery,* 2021 WL 2580144, at *4. The motion is **GRANTED**.

C. Non-synthetic mesh surgeries as a safer alternative to TVT-S and TVT-O

Defendants also seek to exclude testimony from Dr. Elliott that traditional surgical procedures not involving a medical device, such as autologous slings and Burch colposuspension, are safer alternatives than TVT-S and TVT-O for the surgical treatment of SUI. Defendants argue the opinions are irrelevant to a design defect claim. Defendants also argue the opinions are unreliable because Dr. Elliott does not address complication rates and testified that the true complication rate is unknown.

Defendants further argue that Dr. Elliott's opinions regarding alternative treatments should be excluded because Dr. Elliott "improperly relies on a personally perceived *lack of data* as a basis for his opinions," rather than medical studies and other sound scientific methodology. ECF No. 136 at 14 (emphasis in original). Defendants point to Dr. Elliott's testimony that "'[t]he data overall with all sling products is very poor,' including studies relating to autologous slings, '[a]nd that's why we're in the situation we're in now.'" *Id.* Defendants say Dr. Elliott stated that he disagrees with the conclusion of the American Urological Association (AUA) that synthetic polypropylene mesh has minimal morbidity compared to alternatives, but the basis for Dr. Elliott's disagreement is simply his belief that "'there have been

very few randomized control trials, none which are long-term, comparing head-to-head autologous pubovaginal slings versus TVT.'" *Id.* Defendants argue that aside from the fact that Dr. Elliott has a misperception about the literature, he improperly infers that this perceived lack of studies demonstrates that the AUA is wrong and that TVT-S and TVT-O are less safe than alternative surgical approaches. Defendants argue "[t]his approach is far from trustworthy scientific methodology." ECF No. 136 at 15.

As an example, Defendants cite the fact that when asked about mesh-related pain, Dr. Elliott responded "'[t]he true incidence, unfortunately, is not known.'" *Id.* Defendants say Dr. Elliott could not reconcile his testimony with the AUA guideline and Society of Gynecological Surgeons' meta-analysis and systematic review, both of which reported higher rates of dyspareunia, pain, and sexual dysfunction with the autologous sling and Burch procedure than with a mid-urethral mesh device. According to Defendants, even Dr. Elliott's employer, the Mayo Clinic, recognizes that "'[u]sing surgical mesh is a safe and effective way to treat stress urinary incontinence,'" and Dr. Elliott's 2019 article states that devices such as TVT-S and TVT-O are the "'standard of care,'" "a 'great advance,'" and "'provide excellent' outcomes." *Id.* Defendants further aver that Dr. Elliott has arbitrarily discounted

literature he cites in his report, including a Cochrane review, in which the authors concluded

> "[m]id-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have a good safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long term. This review illustrates their positive impact on improving the quality of life of women with SUI."

ECF No. 136 at 16–17.

Finally, Defendants urge the Court to find that Dr. Elliott's experiences, which Defendant argue are unsupported by any reliable studies or trustworthy scientific methodology, fall far short of setting forth a reliable foundation for his opinions. Defendants note that Dr. Elliott testified about a basic unfamiliarity with autologous sling literature and the experiences of other physicians, saying "'I can't speak to those. I can speak to my own experience.'" ECF No. 136 at 17 n.5.

Tedder urges the Court to reject Defendants' arguments regarding Dr. Elliott's testimony about treatment options, arguing availability of alternative procedures is highly relevant to the issue of whether Ethicon acted with reasonable care. The Court agrees. "In Florida, a plaintiff need not demonstrate the existence of a

reasonable alternative design for a strict liability design defect claim."[3] *Geery*, 2021 WL 2580144, at *5 (citing *Aubin v. Union Carbid Corp.*, 177 So. 3d 489, 511 (Fla. 2015)). "In proving strict liability, Florida courts use both the consumer expectations test and the risk utility test." *Id.* (citing *Aubin*, 177 So. 3d at 511; *Messina v. Ethicon, Inc.*, No. 6:20-cv-1170-Orl-40LRH, 2020 WL 7419586, at *4 (M.D. Fla. Dec. 17, 2020)). "Under the consumer expectation test, a product is defectively designed if it fails to perform as safely as the ordinary consumer would expect." *Id.* "And under the risk utility test, a 'product is considered unreasonably dangerous" when "the risk of danger in the design outweighs the benefits.'" *Id.* (quoting *Pierre v. Intuitive Surgical, Inc.*, 476 F. Supp. 3d 1260, 1271 (S.D. Fla. 2020)).

The Court finds that Dr. Elliott's opinions regarding alternative treatments are relevant to the risk utility test because they will assist the jury in determining whether the risks of TVT-S and TVT-O outweighed the benefits given the safety of alternative procedures and products. *See, e.g., Geery*, 2021 WL 2580144, at *5; *see also Jackson v. Johnson & Johnson*, No. 1:11-CV-3903-TWT, 2022 WL 110422, at

[3] The Court is exercising diversity jurisdiction over this matter, so it applies state substantive law. *See Bravo v. United States*, 577 F.3d 1324, 1325 (11th Cir. 2009).

*6 (N.D. Ga. Jan. 12, 2022); *Mason v. Ethicon, Inc.*, No. 6:20-cv-1078-RBD-DCI, 2021 WL 2580165, at *4–5 (M.D. Fla. June 10, 2021); *Dotson v. Am. Med. Sys., Inc.*, No. 1:20-CV-00788-LMM, 2020 WL 2844738, at *3 (N.D. Ga. Mar. 11, 2020). Moreover, based on his clinical experience and review of the medical literature, the Court finds Dr. Elliott competent to offer testimony in that regard. *See, e.g., Mason*, 2021 WL 2580165, at *5; *Ellerbee*, 2021 WL 2010641, at *2; *Geery*, 2021 WL 2580144, at *7; *Williams*, 2021 WL 1087808, at *6. The motion is **DENIED**.

D. Device with a lighter-weight, larger-pore mesh as a safer alternative to TVT-S and TVT-O

Finally, Defendants seek to exclude Dr. Elliott from testifying that a device with a lighter-weight, larger-pore mesh would have been a safer alternative to TVT-S and TVT-O. First, Defendants argue that Dr. Elliott's opinions regarding mesh materials are not supported by testing or medical literature. According to Defendants, none of the eleven sources Dr. Elliott cites in support of his opinions regarding alternative materials support the statement that a lighter weight and/or larger pore mesh is safer for the treatment of SUI than the Prolene mesh used in TVT-S and TVT-O. Second, Defendants argue that Dr. Elliott's opinions are not supported by his personal experience because Dr. Elliott has never treated a patient for SUI with a lighter weight, larger pore mesh than Prolene. Defendants state that

a device with mesh lighter than Prolene has never been cleared by the FDA or made available by any manufacturer to treat SUI. In fact, Ethicon attempted to launch a SUI product using lighter-weight Ultrapro mesh, but its lab tests failed, and the FDA rejected its 510k application.

Last, Defendants argue that even if Dr. Elliott could reliably testify that a TVT-S or TVT-O device with a different mesh would be safer than a device with Prolene mesh, his opinions are improper because there is no evidence that any such alternative device would be as efficacious for the treatment of SUI. According to Defendants, because neither Dr. Elliott nor any other expert can identify any reliable studies demonstrating that some other mesh device is as efficacious as TVT-S or TVT-O for the surgical treatment of SUI, Dr. Elliott's opinions in that regard lack a reliable methodology and should be excluded.

Tedder counters that Dr. Elliott is competent to determine the adverse effects of a medical drug or device based on his observations in practice and his review of studies and medical literature. Tedder says Dr. Elliott has cited extensive data from multiple studies showing that lighter weight, larger pore mesh leads to fewer complications, including less chronic pain, less contraction, less shrinkage, less foreign body reaction, and less folding of the mesh. According to Tedder, Dr. Elliott

explains in detail in his report why heavier weight, smaller pore mesh causes the "cascade of complications resulting in life-altering harm to a woman." ECF No. 146 at 17. In fact, Tedder says, even Ethicon's own personnel agree that lighter weight, larger pore mesh reduces complications. Finally, Tedder argues that the type of mesh Dr. Elliott proposes has been studied in the treatment of hernias and pelvic organ prolapse and has proven effective. Even if there is some decrease in efficacy, which Tedder says has not been established, Dr. Elliott believes that alleviation of the risks involved with small pore, heavy weight mesh would far outweigh the loss of efficacy.

The MDL court found Dr. Elliott competent to "'testify about the alleged benefits of mesh that is lighter-weight and has larger pores, and in general found him qualified to testify about whether one mesh is safer than another.'" *Ellerbee*, 2021 WL 2010641, at *3 (quoting *Wiltgen v. Ethicon, Inc.*, No. 12-cv-2400, 2017 WL 4467455, at *5 (N.D. Ill. Oct. 6, 2017)). And this Court agrees with the *Ellerbee* court that "Defendants' attacks on Dr. Elliott's opinions here go toward the weight of the evidence rather than admissibility." *Id.* (citing *Herrera-Nevarez by Springer v. Ethicon, Inc.*, No. 17 C 3930, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017);

see also Mason, 2021 WL 2580165, at *5; *Geery*, 2021 WL 2580144, at *7–8; *Williams*, 2021 WL 1087808, at *7. The motion is **DENIED**.

SO ORDERED this 31st day of March 2022.

M. Casey Rodgers

M. CASEY RODGERS
UNITED STATES DISTRICT JUDGE