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 General Opinions of Jerry Blaivas, M.D. (ECF No. 131).

[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. Blaivas, a board certified urologist and surgeon, to provide general opinions about TVT-S and TVT-O. The MDL court ruled on a number of Defendants' challenges to Dr. Blaivas's testimony but reserved ruling on two issues Defendants raise in the instant motion—the relevance and reliability of Dr. Blaivas's opinions that non-synthetic mesh procedures present a safer alternative to TVT-S and TVT-O and the reliability of Dr. Blaivas's opinions regarding the distinction between mechanical-cut and laser-cut mesh. Defendants raise two additional issues as well.[3]

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

[3] Defendants also argue that the Court should preclude Dr. Blaivas from offering opinions that the MDL court excluded. The motion is **DENIED as moot** in that respect, as Tedder is not asking that the Court reconsider any of the MDL orders regarding Dr. Blaivas. *See* ECF No. 152 at 1.

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. Non-synthetic mesh procedures as a safter alternative

Dr. Blaivas opined that fewer serious complications occur "'in the alternative surgical treatments for stress urinary incontinence (such as biologic slings, or the polypropylene sutures used in the Burch procedure or autologous fascia pubovaginal slings)'" than in procedures using TVT-S or TVT-O. ECF No. 131 at 3. Defendants argue that any alleged comparative benefit of the procedures is not relevant to Tedder's design defect claims because they are surgical approaches, not medical devices, and do not entail altering the design of the devices at issue. Defendants also argue that Dr. Blaivas's opinions are grounded on his unreliable perception of complication rates associated with TVT-S and TVT-O and that Dr. Blaivas improperly bases his opinions regarding the benefits of autologous slings solely on his personal experience. The MDL court determined that the relevance of Dr. Blaivas's testimony regarding alternative procedures should be decided on a case-by-case basis and thus reserved ruling on the issue.

Tedder does not contend the different surgical mesh treatments Dr. Blaivas proposes constitute alternative designs; rather, Tedder argues Dr. Blaivas's opinions regarding alternative treatments are relevant to whether Ethicon was negligent in

placing its products on the market and whether the risks associated with the products outweigh their utility. "In Florida, a plaintiff need not demonstrate the existence of a reasonable alternative design for a strict liability design defect claim."[4] *Geery v. Ethicon, Inc.*, No. 6:20-CV-1975-RBD-LRH, 2021 WL 2580144, at *5 (M.D. Fla. Apr. 9, 2021) (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 need not decide whether Dr. Blaivas's opinions regarding alternative procedures are relevant to the risk utility test because the Court finds the opinions lack reliability. As Defendants assert, Dr. Blaivas's opinions regarding

[4] 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).

alternative procedures are based, at least in part, on conclusions regarding complication rates associated with TVT-S and TVT-O, which Dr. Blaivas never implanted. Dr. Blaivas bases his opinions regarding complication rates on his experience with the biologic sling and treating women who have suffered complications from synthetic mesh slings, which he effectively acknowledges is not representative of complication rates in general. Dr. Blaivas also relies on an article that reports his own personal experiences and another article that describes complications associated with use of transvaginal mesh to treat pelvic organ prolapse.

The MDL court excluded Dr. Blaivas's opinions in that regard, finding as follows:

> Ethicon challenges the reliability of Dr. Blaivas's expert testimony about safety and efficacy and complication rates by pointing out numerous perceived flaws in the foundation of Dr. Blaivas's expert testimony. Two primary problems render this expert testimony unreliable. First, Dr. Blaivas continues to rely quite heavily on complication rates this court has excluded time and again. *E.g., Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 721 (S.D. W. Va. 2014). In *Huskey*, I excluded this expert testimony because "Dr. Blaivas did not explain his methodology and admitted that it was impossible to calculate an accurate complication rate." *Id.* He has not remedied these shortcomings. Second, Dr. Blaivas does not provide a reasonable explanation for his disagreement with guidelines that he helped author and that conclude mesh products are suitable surgical options. *See, e.g., Bethune v. Bos. Sci. Corp.*, No. 2:13-cv-6199, 2016 WL 2983697, at *4

> (S.D. W. Va. May 20, 2016) (noting an expert's methodology "may be flawed if he does not provide an adequate explanation for why he disagrees with [contrary] studies"). Accordingly, the expert testimony is **EXCLUDED**.

In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 8737388, at *4 (S.D.W. Va. Aug. 26, 2016). As another court noted in a case on remand from the MDL,

> Dr. Blaivas explains that he relied on a case study he conducted himself to support his opinion that the complication rate of women implanted with pelvic mesh devices exceeds 15%. However, Dr. Blaivas later revises this figure to "greater or equal" to 15% and cannot explain how he arrived at this statistic, testifying instead that "these things are not as precise, none of this stuff."

Boneta v. Am. Med. Sys., Inc., No. 20-CIV-60409-RAR, 2021 WL 6134790, at *6 (S.D. Fla. Sept. 27, 2021) (internal citation omitted). "Multiple courts have previously identified similar shortcomings in Dr. Blaivas's complication rate testimony." *Id.* (citing *Wood v. Am. Med. Sys. Inc.*, No. 1:20-cv-00441-DDD-KLM, 2021 WL 1178547, at *8 (D. Colo. March 26, 2021) (agreeing that Dr. Blaivas's opinion regarding complication rates is unreliable and noting that such conclusion "is consonant with the MDL court's exclusion of Dr. Blaivas's complication-rate testimony"); *see also Swintelski v. Am. Med. Sys., Inc.*, No. 20-60410-CIV, 2021 WL 4527451, at *6 (S.D. Fla. Aug. 6, 2021) (finding Dr. Blaivas's testimony

regarding complication rates of women who undergo implantation of pelvic mesh devices unreliable, noting "Dr. Blaivas explains that he relied on the findings of multiple medical researchers and his own calculations to support his opinion that the complication rate of women who are implanted with pelvic mesh devices exceeds 15%" but "does not describe the method used for arriving at this complication rate figure . . . and . . . concedes that '[e]valuating the incidence, severity and consequence' of various pelvic mesh devices is a 'daunting task'"). This Court discerns no basis upon which to reach a different conclusion.

The motion to exclude Dr. Blaivas's opinions regarding alternative procedures is **GRANTED**.

B. Dr. Blaivas's opinions regarding mechanically-cut and laser-cut mesh

According to Defendants, "Dr. Blaivas suggests that either laser-cut mesh or mechanically-cut mesh is preferable, apparently depending on which type of mesh was not implanted in a plaintiff." ECF No. 131 at 13. Defendants argue that any suggestion that either mechanically-cut or laser-cut mesh provides a safer alternative lacks a reliable, scientific foundation. Defendants point out that Dr. Blaivas has never compared mechanically-cut mesh with laser-cut mesh and cites no scientific studies or experiences in support of his opinions regarding the cutting of mesh.

Defendants say Dr. Blaivas "has been playing both sides of the fence on this issue" and request that if the Court allows Dr. Blaivas to critique laser-cut mesh, it preclude him from referencing mechanically-cut mesh as a viable alternative design.

Tedder argues that Dr. Blaivas's report explains the problems caused by mechanically-cut mesh and laser-cut mesh, supported by Ethicon's internal documents and scientific literature. Tedder maintains that each method has it owns issues and that Dr. Blaivas's opinions are not contradictory. Tedder asserts that the MDL court has consistently held that urologists and urogynecologists who have extensive experience with mesh devices are qualified to proffer opinions on the design aspects of mesh devices, including the polypropylene used to construct them. Tedder maintains that Dr. Blaivas is qualified to render such opinions and does not intend to testify that one cut is safer than the other; instead, Dr. Blaivas will describe the particular problems that each type of cut presents—specifically, that mechanically cut mesh can have fraying and particle loss, as well as curling, roping, deformation, loss of pore size, and sharp edges, and laser cut mesh is approximately three times stiffer when stretched and thus difficult to insert and can lead to erosion. Tedder says that Ethicon's original clinical studies were performed with mechanically cut mesh and that Ethicon never studied the impacts of laser-cut mesh.

The MDL court noted that Dr. Blaivas cited in his report internal Ethicon documents, which the court found offer some support for his opinions regarding cut mesh. The court also noted that Dr. Blaivas's opinions seemed to be based on his experience and concluded that it lacked sufficient information to assess whether there was a reliable foundation for Dr. Blaivas's opinions in that regard. The court thus reserved ruling "'until further testimony [could] be offered and evaluated firsthand at trial.'" ECF No. 152 at 15.

Criticizing both methods of cutting mesh does not alone render Dr. Blaivas's opinions on cut mesh unreliable. *See, e.g.*, *Geery*, 2021 WL 2580144, at *4 (noting that in his general report, Dr. Rosenzweig notes complications with both mechanical and laser-cut mesh and concluding that "finding issues with both methods does not make his opinion unreliable") (citing *Laderbush v. Ethicon*, No. 20-cv-62-JD, 2020 WL 3001958, at *2 (D.N.H. June 4, 2020); *Herrera v. Nevarez by Springer v. Ethicon, Inc.*, No. 17 C 3930, 2017 WL 3381718, at *8 (N.D. Ill. Aug. 6, 2017)). The motion, therefore, is **DENIED**.

C. Testimony about chronic mesh pain syndrome

Defendants urge the Court to preclude Dr. Blaivas from testifying about the

alleged existence of "Chronic Mesh Pain Syndrome." Defendants say Dr. Blaivas claims that such a condition is "'described in the medical literature'" but cites only a single article that has used the term. ECF No. 131 at 14. The MDL court found the single citation sufficient to support Dr. Blaivas's use of the term, which Ethicon argues was erroneous.

In support of their position, Defendants state that in his deposition, Dr. Blaivas acknowledged that he is unaware of chronic mesh pain syndrome being recognized as a diagnostic code for billing purposes. Defendants thus argue that the syndrome is not generally accepted in the medical profession and has negative connotations that would prejudice Ethicon.

Tedder urges the Court to abide by the MDL court's ruling on the issue, stating Dr. Blaivas explained the syndrome in detail, including that it is "'characterized by the transformation of vaginal pain into a multi-organ system process.'" ECF No. 152 at 18. According to Tedder, new treatment methods have been developed to address the issue, and Dr. Blaivas "cites to several scientific articles in further describing this process." ECF No. 152 at 19. Tedder says Dr. Blaivas's clinical experience further supports his opinion, as he has treated hundreds of women who had mesh complications.

The Court agrees with the MDL court and finds that Dr. Blaivas is qualified based on his experience to testify to chronic mesh pain syndrome. The motion thus is **DENIED**.

D. Bias in clinical trials and "industry manipulation"

Finally, Defendants seek to exclude what they characterize as broad statements Dr. Blaivas includes in his report that the medical literature concerning TVT-S and TVT-O is "'seriously flawed,' due to alleged bias, 'industry manipulation of data,' and other alleged factors." ECF No. 131 at 14. Defendants say Dr. Blaivas does not provide any support for the allegation of "'industry manipulation'" and that other statements are not supported by Dr. Blaivas's citations, such as his assertion that Ethicon has contracts with unidentified medical literature authors that "'often contain language that prevents company consultants from reporting or discussing device complications without written company approval.'" ECF No. 131 at 15. In any event, Defendants assert, Dr. Blaivas has no expert qualifications to testify about the potential bias that a financial incentive may play in medical research and sets forth no methodology, instead providing only a narrative summary of events. According to Defendants, the MDL court excluded sweeping statements by Dr. Blaivas that "'Ethicon colluded with other

manufacturers to influence reimbursement.'" *Id.* Defendants ask this Court to "clarify that ruling and explicitly exclude any testimony that suggests 'industry manipulation' on the part of Ethicon." *Id*.

According to Tedder, Dr. Blaivas cites scientific articles and internal Ethicon documents in rendering the opinion that the medical literature regarding Ethicon's products is flawed due to bias and industry manipulation of data. As two examples, Tedder cites the fact that the original contract between the TVT inventor and Ethicon made certain payments contingent on particular study outcomes and one of the TVT-O study authors had a royalty interest in the device. Tedder agues the MDL court did not err in allowing Dr. Blaivas's opinions in that regard and urges the Court to "reject Ethicon's effort to reconstruct the MDL Court's Order as to testimony about the mesh manufacturing industry." ECF No. 152 at 19. Tedder explains that in its order, the MDL court excluded Dr. Blaivas's opinion that Ethicon colluded with other mesh manufacturers to influence reimbursement but allowed Dr. Blaivas's opinion that certain studies in the medical literature are biased. Tedder says despite the manner in which Ethicon characterizes the request, it is seeking reconsideration of the latter decision.

The motion is **DENIED**. The parties are cautioned, however, against attempting to offer unsupported and patently inadmissible expert testimony at trial.

SO ORDERED this 31st day of March 2022.

M. Casey Rodgers

M. CASEY RODGERS
UNITED STATES DISTRICT JUDGE