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

[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.

and sold by Defendant Ethicon, Inc.[2] Tedder alleges she was injured as a result of defects in the devices.

Tedder moves to exclude certain opinions and testimony of four of Defendants' five "general experts"—Dr. Salil Khandwala, Dr. Brian Schwartz, Dr. Jamie Sepulveda, and Dr. Shelby Thames—pursuant to Federal Rules of Evidence 104, 403, and 702 and *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579 (1993) (ECF No. 116). Tedder requests that the Court adopt the prior *Daubert* orders entered by the MDL court and rule on issues as to which the MDL court reserved ruling. Having reviewed the orders of the MDL court, the undersigned finds they are well-reasoned and thus adopts them. This Order thus addresses only issues as to which the MDL court reserved ruling.

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

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

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. Opinions of Dr. Khandwala, Dr. Schwartz, Dr. Sepulveda, and Dr. Thames regarding design process and control standards

Defendants do not intend to elicit these opinions at trial. *See* ECF No. 155 at 2. Thus, the motion is **DENIED as moot**.

B. Dr. Khandwala's opinions regarding mesh properties

Dr. Khandwala opined that polypropylene mesh, such as that implanted in Tedder, does not shrink or contract. Tedder seeks to exclude Dr. Khandwala's opinions on the contraction, degradation, porosity, and stiffness of mesh as unreliable, arguing Dr. Khandwala relied on a limited and flawed body of evidence in formulating his opinions.

Dr. Khandwala is a board-certified obstetrician/gynecologist with a subspecialty in female pelvic medicine and reconstructive surgery. Dr. Khandwala

has performed more than 1,000 implantations of mesh to treat stress urinary incontinence (SUI) and more than 800 surgical implantations of mesh to treat pelvic organ prolapse (POP). He also has performed numerous mesh revision surgeries. In addition, Dr. Khandwala designed and participated in clinical trials related to pelvic reconstruction surgery and pelvic mesh. He has spoken on, published, and taught in the areas of urinary incontinence and POP. In preparing his opinions, Dr. Khandwala relied on his clinical experience, as well as a review of medical literature and other information, including dozens of peer-reviewed scientific articles, Federal Drug Administration sources, and medical society statements.

The MDL court denied a motion to exclude Dr. Khandwala's opinions regarding safety and efficacy and mesh properties, including biomaterials, biocompatibility, and foreign body response, finding the plaintiffs failed to demonstrate Dr. Khandwala's opinions regarding safety and efficacy were unreliable and that Dr. Khandwala was qualified, based on clinical experience, to render an opinion on mesh's reaction to and effect on the human body. *See* ECF No. 96-13 at 6. The court denied as moot a motion to exclude Dr. Khandwala's opinion regarding degradation because Ethicon indicated Dr. Khandwala would not offer this opinion

at trial. *See id.* at 6–7. The MDL court found Dr. Khandwala's opinion as to contraction supported by extensive clinical experience and analysis of scientific literature, which the court noted "[i]n the abstract," constitute "reliable bases on which to form an expert opinion" *Id.* at 7. The court was "unable to judge the reliability of Dr. Khandwala's observations," however, "without more information about his methodology." *Id.* Specifically, the court determined it was "without sufficient information . . . to draw the fine line between reliable and unreliable expert testimony based primarily on a doctor's clinical experience *not* observing something." *Id.* (emphasis in original). The court thus reserved ruling on the admissibility of Dr. Khandwala's opinions regarding contraction, porosity, and stiffness "until further testimony may be offered and evaluated firsthand at trial." *Id.*

Tedder's objections to Dr. Khandwala's opinions regarding mesh properties go more to the weight of the evidence than to its admissibility. *See Quiet Tech.*, 326 F.3d at 1345 (noting that "in most cases, objections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its admissibility") (internal marks omitted). Dr. Khandwala's extensive experience with vaginal mesh procedures and reliance on medical literature and

other information provide a sufficiently reliable basis on which to opine on mesh properties. *See Mason v. Ethicon, Inc.*, No. 6:20-CV-1078-RBD-DCI, 2021 WL 2580165, at *2 (M.D. Fla. June 10, 2021) (finding plaintiff's "objections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its admissibility" and that "Dr. Khandwala's extensive experience with vaginal mesh augmentation procedures and reliance on numerous studies, is a sufficiently reliable basis to opine on mesh contraction") (citing *Huksey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 735 (S.D.W. Va. 2014)); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-MD-02327, 2016 WL 4536885, at *3 (S.D.W. Va. Aug. 30, 2016) (finding urogynecologist who had performed over 1,500 pelvic mesh surgeries and over 300 explant surgeries qualified to testify regarding biomaterial properties, including mesh reaction to and effect on the human body, based on his clinical experience and review of and contributions to the medical literature); *Carlson v Boston Sci. Corp.*, No. 2:16-v-05475, 2015 WL 1931311, at *9–19 (S.D.W. Va. Apr. 28, 2015) (finding clinical experience and review of scientific literature qualified urologist to opine on polypropylene, including degradation, leaching, shrinkage, and contraction); *Tyree v. Boston Sci.*

Corp., 54 F. Supp. 3d 501 (S.D.W. Va. 2014) (finding urogynecologist who had performed almost 3,000 sling procedures and focused his practice largely on the treatment of female urinary incontinence over the past twenty years qualified to testify that mesh does not shrink, contract, degrade, or cause systemic infection based on his experience and the fact that he cited numerous studies and academic papers in his report). The motion, therefore, is **DENIED**.

C. Dr. Thames' opinions regarding degradation

Tedder moves to exclude Dr. Thames' opinion that Prolene does not degrade *in vivo*, arguing the opinion is precluded by an admission of Ethicon's corporate representative, Dr. Thomas Barbolt, who Tedder contends acknowledged that Prolene undergoes *in vivo* surface degradation. Tedder argues Ethicon is bound by Dr. Barbolt's admission and should be precluded from introducing contradictory testimony from Dr. Thames.

Defendants dispute that Dr. Barbolt admitted that Prolene degrades *in vivo* and argue that in the testimony Tedder cites in support of her motion, Dr. Barbolt was referring to subjective observations of surface cracking rather than *in vivo* degradation, which Dr. Barbolt explained were not the same as objective

assessments necessary to establish that Prolene meaningfully degrades *in vivo*. Defendants say Dr. Barbolt testified that certain Ethicon tests contain subjective observations of some Prolene fibers exhibiting surface cracking but that those were not quantitative tests needed to demonstrate that Prolene meaningfully degrades. According to Defendants, Dr. Barbolt's testimony is consistent with Ethicon's position and Dr. Thames's opinion that Prolene does not undergo meaningful or harmful *in vivo* degradation, and Dr. Thames definitively shows that the cracked material is protein from the human body, not degraded mesh.

Defendants further argue that before the mesh litigation, Ethicon had no reason to further explore the alleged degradation of Prolene because there was no evidence of any clinical significance in that regard. It was only after the issue became legally significant that Defendants hired Dr. Thames to examine issues regarding degradation, which he has done over an extended period of time. Moreover, Defendants contend, Ethicon is not bound by Dr. Barbolt's testimony in the manner Tedder asserts.

The Court agrees. Under Rule 30(b)(6), a corporation designates individuals to testify on its behalf. Fed. R. Civ. P. 30(b)(6). The Eleventh Circuit has not

addressed whether the testimony of a Rule 30(b)(6) representative constitutes a judicial admission, with conclusive effect, or merely an evidentiary admission, which can be contradicted or explained at trial. *See Ussery v. Allstate Fire & Cas. Ins. Co.*, 150 F. Supp. 3d 1329, 1344–45 (M.D. Ga. 2015) (distinguishing judicial and evidentiary admissions). Every other circuit to consider the issue has treated 30(b)(6) testimony as an evidentiary admission that is binding in the sense that it can be used against the corporation but not "in the sense that it precludes the [corporation] from [later] correcting, explaining, or supplementing" that testimony. *R&B Appliance Parts, Inc. v. Amana Co., L.P.*, 258 F.3d 783, 786–87 (8th Cir. 2001); *see also Vehicle Mkt. Research., Inc. v. Mitchell Int'l, Inc.*, 839 F.3d 1251, 1260–61 (10th Cir. 2016); *Keepers, Inc. v. City of Milford*, 807 F.3d 24, 35–36 (2d Cir. 2015); *A.I. Credit Corp. v. Legion Ins. Co.*, 265 F.3d 630, 637 (7th Cir. 2001). In other words, a corporation "is no more bound than any witness by his or her deposition testimony. A witness is free to testify differently from the way he or she testified in a deposition, albeit at the risk of having his or her credibility impeached by the introduction of the deposition." *R&B Appliance*, 258 F.3d at 786; *see also Cont'l Cas. Co. v. First Fin. Emp. Leasing, Inc.*, 716 F. Supp. 2d 1176, 1190–91

(M.D. Fla. 2010). The motion to exclude Dr. Thames' testimony thus is **DENIED**. *See, e.g., Mason v. Ethicon*, No. 6:20-cv-1078-RBD-DCI, 2021 WL 2580165, at * (M.D. Fla. June 10, 2021).

D. Dr. Sepulveda-Toro's opinions

Dr. Jaime L. Sepulveda-Toro is a board-certified pelvic surgeon and urogynecologist who Ethicon designated to offer opinions on its SUI products, including TVT-S and TVT-O. The MDL court issued a ruling on Dr. Sepulveda-Toro's testimony, denying many of the MDL plaintiffs' challenges, granting others, and reserving ruling on several issues, to be decided by the trial court. Tedder seeks to exclude Dr. Sepulveda-Toro's opinions on the adequacy of Defendants' brochures and on information extrapolated from studies regarding cytotoxicity, degradation, and inflammatory response.

With regard to Defendants' brochures, Tedder's motion is **DENIED as moot**, as Defendants state they do not intend to elicit any such testimony from Dr. Sepulveda-Toro at trial. *See* ECF No. 155 at 11.

With regard to information extrapolated from studies, Tedder argues Dr. Sepulveda-Toro overstates the number of studies supporting his opinions related to

Ethicon's products, which undermines his opinions on cytotoxicity, degradation, and inflammation. The MDL court reserved ruling on the issue, stating it lacked sufficient information to judge the reliability of Dr. Sepulveda-Toro's methodology in considering the relevant literature and would rule once able to evaluate the evidence firsthand at trial.

In support of her motion, Tedder points to two of Dr. Sepulveda-Toro's opinions—that ''[t]he medical literature including over 100 Gynemesh PS [a POP product] studies, meta-analyses and systematic reviews do not support that the mesh is cytotoxic, that it degrades or leads to a harmful inflammatory response in humans'" and that "'[t]he medical literature including over 1,000 studies, meta-analyses and systematic reviews, and the endorsement of the TVT mesh by the pertinent medical societies do not support that the mesh is cytotoxic, that it degrades or leads to a harmful inflammatory response in humans.'" ECF No. 117 at 16. Tedder argues the statements are not supported by citations to the studies and that the accuracy of Dr. Sepulveda-Toro's characterizations, therefore, cannot be verified. Tedder also says Dr. Sepulveda-Torro admitted in his deposition that he overstated the number of studies in his report. Finally, Tedder challenges Dr.

Sepulveda-Torro's statement that "'[t]he monofilament knitted Prolene TVT sling has pores which are microporous (over 75 microns).'" ECF No. 117 at 17. According to Tedder, Defendants' own engineers classify Prolene mesh as "small pore." ECF No. 117 at 18.

In formulating his opinions, Dr. Sepulveda-Toro relied on an in-depth review of the medical literature, including studies comparing mesh to non-mesh procedures, as well as literature and long-term studies regarding the safety, efficacy, and complications associated with Ethicon's products. Considering Dr. Sepulveda-Toro provided an extensive list of the medical literature he reviewed and explained that he has regularly reviewed the literature in connection with his practice, Dr. Sepulveda-Torro may opine on the general number of studies he contends support his opinions. *See Mason*, 2021 WL 2580165, at *3 (allowing Dr. Sepulveda-Toro to testify to the general number of studies he contends support his opinion); *Geery v. Ethicon, Inc.*, No. 6:20-CV-1975-RBD-LRH, 2021 WL 2580144, at *2 (M.D. Fla. Apr. 9, 2021) (same); *see also In re 3M Combat Arms Earplug Prods. Liab. Litig.*, No. 3:19md2885, 2021 WL 765019, at *16 (N.D. Fla. Feb. 28, 2021). The motion, therefore, is **DENIED**.

SO ORDERED this 31st day of March 2022.

M. Casey Rodgers

M. CASEY RODGERS
UNITED STATES DISTRICT JUDGE