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. Currently before the Court is Defendants' Motion to Exclude Expert Opinions of Ralph Zipper, M.D. (ECF No. 134), filed pursuant to Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993).

Tedder designated Dr. Zipper, who is board certified in Female Pelvic Medicine and Reproductive Surgery (FPMRS) and Obstetrics/Gynecology, as a general and specific causation expert. The parties agree that the MDL court's Wave 1 order, which addresses many of Defendants' challenges to Dr. Zipper's testimony, applies here. Defendants thus challenge only general causation issues the MDL court did not address or on which the MDL court reserved ruling and seven of Dr. Zipper's specific causation opinions.

I. Background

Tedder is a sixty-three-year-old nurse with a pre-implant history of stress urinary incontinence (SUI), pelvic organ prolapse (POP), and dyspareunia. On April 12, 2007, Ms. Tedder visited Dr. Fossum, complaining of "'los[ing] urine when

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

lifting, especially when her bladder [was] full and at other times with laughing, coughing, sneezing.'" ECF No. 134 at 3. Dr. Fossum diagnosed SUI and recommended "'a transvaginal tape procedure done at the time of her hysterectomy and anterior and posterior repair.'" *Id.*

On May 15, 2007, Dr. Fossum implanted Ms. Tedder with the TVT-S device. On May 4, 2010, Ms. Tedder returned to see Dr. Fossum, complaining of "'some incontinence especially at night.'" *Id.* Dr. Fossum recommended "'a repeat transvaginal tape procedure with a longer tape.'" *Id.* On May 25, 2010, Dr. Fossum implanted Ms. Tedder with the TVT-O device. Dr. Fossum did not remove any portion of the previously implanted TVT-S device, which he indicated was not curled, roped, twisted, bunched, or frayed. And he did not observe any infection associated with the TVT-S device.

In the MDL, Dr. Zipper served two sets of general causation expert reports. In Wave 1 of the MDL, Dr. Zipper served expert reports about Ethicon's Prolift, Prolift +M, and Prosima products, which are used to treat POP. Ethicon moved to exclude the POP-related opinions, and the MDL court entered an order on Ethicon's motion in Wave 1 on September 1, 2016. *See In re: Ethicon Inc. Pelvic Repair Sys.*

Prod. Liab. Litig., MDL No. 2327, 2016 WL 4944991 (S.D. W. Va. Sep. 1, 2016). In Waves 2 through 5, the MDL court continued to adopt its prior Wave 1 order for Dr. Zipper. In Wave 6, Dr. Zipper served a new general causation report regarding TVT-S.[3] Ethicon moved to exclude Dr. Zipper's TVT-S-related opinions, but the MDL court did not rule on the motion before remanding the case.

On remand, the parties agreed to brief only those issues reserved or not addressed by the MDL court. Although the MDL court never ruled on Ethicon's challenges to Dr. Zipper's TVT- S opinions, many of Dr. Zipper's TVT-S opinions are the same as his Prolift/Prosima opinions. Accordingly, the MDL court adjudicated the majority of Ethicon's challenges as part of its Wave 1 order and adopted that order in adjudicating other Wave challenges.[4]

[3] Dr. Zipper has never produced a general causation report about TVT-O.

[4] Specifically, the MDL court precluded Dr. Zipper from: (1) testifying about the adequacy of the POP devices' Instructions for Use (IFU) (*see In re: Ethicon*, 2016 WL 4944991, at *3); (2) offering opinions on the FDA's 510(k) process and Ethicon's compliance with or violation of FDA labeling or adverse-event reporting regulations (*see id.* at *4); (3) testifying about Ethicon's state of mind or offering legal-conclusion testimony (*see id.* at *5); and (4) parroting corporate documents as a conduit for corporate information (*see id.*).

II. 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.

III. Discussion

A. General causation opinions

1. TVT-S and TVT-O IFU

Defendants argue that Dr. Zipper does not have the requisite qualifications to opine on product warnings. In its Wave 1 ruling on Dr. Zipper's POP device opinions, the MDL court precluded Dr. Zipper from opining on the adequacy of the products' IFUs, finding that "'Dr. Zipper is not an expert in the development of

warning labels'" and "'does not possess the additional expertise to offer expert testimony about what an IFU should or should not include.'" ECF No. 134 at 6 (citing *In re: Ethicon*, 2016 WL 4944991, at *3).[5] Defendants urge this Court to apply the MDL court's rulings pertaining to Dr. Zipper's opinions regarding POP product warnings to Dr. Zipper's opinions regarding warnings on the TVT-S and TVT-O devices.

In his TVT-S report served in Wave 3, and in his case-specific report for this case, Dr. Zipper contends that the IFUs that accompanied the TVT-S and TVT-O devices were defective and failed to provide adequate warnings and information to treating surgeons. Defendants argue that to the extent Tedder presents renewed arguments for allowing Dr. Zipper to offer opinions on TVT-S labeling, the Court

[5] The MDL court ruled, however, that a urogynecologist may testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *See, e.g., 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). Dr. Zipper's opinions are not so limited. Indeed, Dr. Zipper criticizes Ethicon for not including in the IFU certain methods for insertion of the device; opinions of Ethicon key opinion leaders; situations in which implant removal may be required; "instruction for managing . . . adverse reactions . . . warning of the risk of inability to remove the device in its entirety . . . a discussion of uncertainties and differing opinions . . . the entirety of human safety and efficacy data at the time of product launch . . . [or] qualif[ication] or quantif[ication] [of the] risks." ECF No. 134 at 6 n.2.

should grant Defendants' motion because Dr. Zipper still has insufficient expertise in developing warning-related documents.

According to Defendants, Dr. Zipper first admitted in deposition testimony that he did not "'hold [himself] out as a regulatory expert.'" ECF No. 134 at 7. He later testified that he had become an expert in recent years—essentially during the pelvic mesh litigation.[6] Defendants state that in his deposition for TVT-S, Dr. Zipper tried to strengthen his experience by testifying that in his role as CEO of two medical device companies, he is "'intimately involved in the creation of labels.'" ECF No. 134 at 8. Defendants argue that Dr. Zipper's testimony reveals that he remains unqualified to testify about the TVT-S IFU.

In support of their position, Defendants point to the following testimony of Dr. Zipper: "'we are submitting a sub Q application for both an IDE and randomized

[6] Defendants argue Tedder's position in this regard "holds no water," citing cases expressing concern about opinions developed by experts through litigation consulting, including *Salinero v. Johnson & Johnson*, No. 1:18-CV-23643-UU, 2019 WL 7753441, at *4 (S.D. Fla. Oct. 28, 2019) ("One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.") (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995)), and *In re Air Crash Disaster*, 795 F.2d 1230, 1234 (5th Cir. 1986) (expressing skepticism of experience gained by expert through litigation consulting). ECF No. 134 at 7.

control trials for new indications of use and those applications are associated with new labels and *I'm in the process of writing those labels*.'" *Id.* Defendants maintain that this testimony shows that neither of the products on which Dr. Zipper was working had a finished warning label at the time of Dr. Zipper's deposition and that while Dr. Zipper may have attempted the initial stages of drafting labels, he has not seen the IFU process through to completion and cannot show that either of his drafts has been or will be approved. According to Defendants, "[i]t is a stretch to see how present involvement in his first ever experience with the IFU process," regarding devices or procedures different from those at issue in this case, "is enough to make him an 'expert' in the development of warning labels." *Id.*

Defendants also point to Dr. Zipper's opinion that Ethicon's labeling failed to warn of "'acute and chronic groin pain, leg pain, dyspareunia, recurrent urinary tract infections, chronic erosion, vaginal dysbiosis, the signs and symptoms of such adverse events, and instructions for managing such adverse reactions.'" ECF No. 134 at 9. In his deposition, Dr. Zipper admitted that the risk of mesh erosion from a synthetic sling was commonly known within the relevant medical community and that erosion is a potential complication of any polypropylene mesh sling. He also

acknowledged that the risk of dyspareunia as a potential complication was commonly known by pelvic floor surgeons and that dyspareunia was a potential risk of a sling he developed. Dr. Zipper further acknowledged that incontinence surgery alone is associated with the risk of dyspareunia and that there is no such thing as a risk-free surgery. Defendants argue that Dr. Zipper's personal opinions conflict with controlling federal regulations, citing 21 C.F.R. § 801.109(c), which provides that prescription device manufacturers may omit from the label information on directions, hazards, warnings, and other information commonly known to practitioners licensed by law to use the device.

Tedder insists that Dr. Zipper has recently acquired expertise, through drafting IFUs for medical devices, on what information manufacturers should or should not include in an IFU. Tedder points out that Dr. Zipper is not only a clinical urogynecologist but also an industry executive of two medical device companies who works on drafting IFUs for laser technology for FPMRS and a proprietary RF generator for sealing vessels in FMPRS and general surgery, which are being submitted for regulatory approval.

The Court finds that Dr. Zipper's recent experience with IFUs does not undermine the MDL court's ruling on Dr. Zipper's qualification to testify to IFUs beyond that which the MDL court allowed. The motion is **GRANTED**. *See, e.g., Mason v. Ethicon, Inc.*, No. 6:20-cv-1078-RBD-DCI, 2021 WL 2580165, at *8 n.8 (M.D. Fla. June 10, 2021).

2. Safer alternative procedures and products

In its Wave 1 ruling on Dr. Zipper's POP opinions, the MDL court determined it was "without sufficient information to draw the fine line between reliable and unreliable expert testimony on th[e] issue" of safer alternative designs; the court thus reserved ruling on the issue. *In re: Ethicon*, 2016 WL 4944991, at *3. Ethicon provided additional argument and analysis in its Wave 3 *Daubert* motion, which the MDL court never addressed.

Dr. Zipper opines that there were a number of alternative procedures and products that would have been equally effective to treat SUI as the TVT-S and TVT-O devices. In particular, Dr. Zipper opines that "'natural tissue, native tissue surgery is more likely than not safer and better in the long run, if not in the short run,'" and that a "'safer alternative' to Prolene," the polypropylene used in Ethicon's devices,

"is a lightweight, large pore mesh called Ultrapro." ECF No. 134 at 11. Dr. Zipper also opines that a "sutured device," such as the Burch procedure, conventional slings, and mid-urethral slings, are safer alternative designs. *Id.* Defendants argue that Dr. Zipper should be precluded from testifying to safer alternatives because the alternatives he suggests are (a) alternative treatments for SUI, not alternative designs for TVT-S, or (b) were never available on the market to treat SUI and for which there is no safety data to support the opinion.

Tedder responds that opinions regarding alternative procedures and products are relevant to the risk-utility aspect of Florida design defect law—specifically, utility to the user and the public as a whole and whether Ethicon was negligent in designing the products at issue and placing them on the market. The Court agrees. "In Florida, a plaintiff need not demonstrate the existence of a reasonable alternative design for a strict liability design defect claim."[7] *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

[7] 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).

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. Zipper's opinions regarding alternative procedures and products 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 medical 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 *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). The fact that a product may not have been commercially

available at the time of Tedder's surgeries "does not bear on the 'feasibility of a safer and equally efficacious design[.]'" *Jackson*, 2022 WL 110422, at *6 (internal marks omitted). The motion thus is **DENIED**.

B. Specific Causation Opinions

1. Product warnings and IFU

For the reasons set forth in Section III. A. 1., *supra*, the motion is **GRANTED**.

2. "Ethicon's teachings" and "double dose of mesh"

Defendants seek to exclude Dr. Zipper's testimony that Tedder's symptoms stemmed from the placement of mesh on top of mesh, which Dr. Zipper characterizes as a "double dose of mesh" and a dangerous process encouraged by Ethicon. Defendants argue that Dr. Zipper provides no evidentiary basis for the assertion that Ethicon advocated placing mesh on top of mesh and that even if he did, Dr. Zipper's opinions in that regard are irrelevant and unreliable because there is no evidence that Dr. Fossum chose to implant a second mid-urethral sling in Tedder because of anything Ethicon did or said. To the contrary, Defendants assert, Dr. Fossum testified that as of the time he recommended the TVT-O implant, he had not read the literature regarding efficacy rates for repeat sling procedures and "'just had been

doing that on [his] own.'" ECF No. 134 at 20. Defendants also assert that Dr. Zipper's opinions conflict with the findings of the scientific community, which Defendants say show favorable cure and improvement rates with implantation of a second mesh device, and amount to mere speculation or *ipse dixit* assertions.

Tedder counters that the testimony Defendants seek to exclude consists of factual statements, not opinions. Tedder states that Defendants misunderstand Dr. Zipper's opinion about the reason for the double dose of mesh implanted in Tedder. According to Tedder, Dr. Zipper's opinion is that the defective teachings of the TVT-S and TVT-O methods, and the defective labels on the devices, which Dr. Zipper opines failed to warn of adverse events and complications associated with the defective material, resulted in the need for two separate sling implants. In other words, Dr. Zipper is not opining that Ethicon was teaching a method of placing mesh on mesh; rather, Dr. Zipper is opining that due to Defendants' failure to warn, Tedder had two separate implants, which ultimately caused an inflammatory response. Tedder asserts that Dr. Zipper's opinion is supported by Tedder's treating physician, Dr. Bela Kudish, who noted tenderness only in the area directly above the double

layer of mesh, and Dr. Zipper's examination, which revealed duplication of dyspareunia and pelvic pain with palpation of the tender mesh contracted band.

The Court finds Dr. Zipper's opinions regarding the effects of mesh on top of mesh to be both relevant and reliable. *See, e.g., Geery*, 2021 WL 2580144, at *3. The motion thus is **DENIED**.

3. Mesh migration and contraction

Defendants move to exclude Dr. Zipper's testimony that the mesh implanted in Tedder migrated and contracted. In support of their motion, Defendants point to the fact that Dr. Zipper does not identify which of the two slings allegedly migrated and contracted. They also point out that no mesh pathology specimen is available and that Dr. Zipper, therefore, was not able to examine the mesh implanted in Tedder or perform tests or experiments to verify whether either or both devices in fact migrated or contracted. Defendants assert that the only reliable evidence regarding possible migration and contraction comes from Dr. Fossum, who implanted both devices and was operating in the same space as the TVT-S when implanting the TVT-O and did not observe the TVT-S device to be curled, roped, twisted, bunched, or frayed or any infection.

Defendants argue that in reaching his opinion that the mesh migrated and contracted, Dr. Zipper relies on his physical examination of Tedder, which "'was remarkable for a palpable band consistent with a twisted and contracted sling,'" and an earlier physical examination by Dr. Kudish, who noted "'palpable movable suburethral sling arms.'" ECF No. 134 at 22. Dr. Zipper does not claim that any mesh was eroded or exposed. Considering that Dr. Zipper was unable to visualize or palpate the mesh itself, Defendants contend that Dr. Zipper has provided insufficient support for his conclusion that a sling was twisted and contracted or that mesh migrated *in vivo*.

In response, Tedder notes that the MDL court found Dr. Zipper qualified to opine on the properties of mesh and mesh's effect on and reaction to the human body, as follows:

> "Dr. Zipper is a board-certified pelvic surgeon and urogynecologist who has performed thousands of transvaginal mesh procedures and explanted over 500 mesh devices. Additionally, he has experience developing devices for the treatment of pelvic pain and overactive bladder. This extensive clinical and product development experience, combined with Dr. Zipper's review of the medical literature, qualifies him to opine on the biomaterial properties of mesh to the extent the testimony centers on mesh's effect on and reaction to the human body. Ethicon's Motion is DENIED on this matter."

ECF No. 156 at 21. Tedder says that in formulating his opinions in this case, Dr. Zipper relied on his extensive experience as a pelvic floor surgeon and teacher, extensive review of the scientific literature regarding mesh products, extensive review of Tedder's medical records, review of Ethicon corporate documents, physical examination of Tedder, and a detailed differential diagnosis. Tedder argues that Defendants mischaracterize the foundation for Dr. Zipper's opinion, pointing out that in addition to the findings of physical examinations, Dr. Zipper addresses the risk of vaginal banding, with citations to peer reviewed articles on the topic. And Dr. Zipper confirms that his examination demonstrated the mesh banding described in peer reviewed articles, which is the end result of mesh migration and contraction.

For the reasons Tedder states—namely, Dr. Zipper's extensive experience as a pelvic floor surgeon, extensive review of the scientific literature regarding mesh products, extensive review of Tedder's medical records, physical examination of Tedder, and differential diagnosis—the Court finds Dr. Zipper's opinions regarding mesh migration and contraction to be both reliable and relevant. *See, e.g., Mason*, 2021 WL 2580165, at *2, *4; *Geery*, 2021 WL 2580144, at *3, *6. The motion, therefore, is **DENIED**.

4. Inflammation

Defendants seek to exclude Tedder from introducing evidence that she was harmed by "'the inflammatory process associated with mesh,'" arguing that Dr. Zipper's opinions in that regard are speculative, unreliable, and lack foundation. ECF No. 134 at 23. Again, Defendants emphasize that despite operating in the same space, Dr. Fossum saw no evidence of infection at the TVT-S site when he implanted the TVT-O device and did not document any signs of inflammation. Moreover, within three months of the TVT-O implant, Tedder was "'doing well'" and was "'active,'" with no indication of fever or other signs of inflammation. *Id.* Defendants argue that although Dr. Zipper concluded that his physical examination of Tedder was "'consistent with'" inflammation, he provides no reliable scientific foundation linking his palpation of Tedder to inflammation. ECF No. 134 at 24.

In response, Tedder states that Dr. Zipper's report includes a seven-page description of the body's adverse effect on polypropylene mesh, with specific references to peer reviewed literature. In addition, Dr. Zipper describes the process of mesh degradation and chronic and acute inflammation resulting from foreign body reaction. Dr. Zipper also references Ethicon's ninety-one-day rat study, which

revealed inflammation in all Prolene mesh, demonstrating that the Prolene mesh used in the devices at issue in fact is reactive and creates chronic inflammation. Finally, Dr. Zipper identifies the TVT materials implanted in Tedder as those associated with inflammation and states that inflammation of the periurethral tissue is a known cause of irritative voiding symptoms, like those Tedder experienced. Hence, Tedder asserts that Dr. Zipper, who has extensive experience in the field, based his opinion on Tedder's symptoms, such as obstructed voiding, pulling and pinching sensations while biking and sitting, and pelvic pain, which indicate contracted, migrated mesh causing inflammation and pain.

The motion is **DENIED** for the reasons stated in Section III. B. 3, *supra*.

5. Material defects

Defendants move to exclude Dr. Zipper's testimony regarding material defects in TVT-S and TVT-O that did not cause Tedder injury. Defendants again point out that Dr. Zipper did not examine the mesh implanted in Tedder and argue that Dr. Zipper's opinions regarding defects and their alleged impact on Tedder are contradicted by Dr. Fossum's findings, or lack thereof. Defendants argue that Dr. Zipper is unable to point to any scientifically reliable case-specific evidence

documenting that the alleged material defects he identifies were present in a device implanted in Tedder. According to Defendants, such vague generalities do not withstand *Daubert* scrutiny.

Tedder responds that Defendants are overlooking the scientifically reliable evidence on which Dr. Zipper relies, including studies performed by Ethicon and Johnson & Johnson, the results of which contain evidence of material defects in the Prolene mesh used in the devices at issue. Tedder maintains that if Defendants dispute that Dr. Zipper presented reliable evidence of material defects in the devices implanted in Tedder, they may address the issue on cross-examination.

The Court agrees with Tedder that Defendants' criticisms of Dr. Zipper's opinions regarding material defects go more to the weight of the evidence than to its admissibility. Dr. Zipper is qualified to testify to the properties of the mesh used in the devices at issue and the manner in which he believes the mesh performed in this case. The motion thus is **DENIED**.

6. Prognosis and future care

Defendants seek to exclude Dr. Zipper's opinions regarding Tedder's prognosis and future care, arguing the opinions are speculative, unreliable, and based

largely on hypothetical and conditional phrasing. According to Defendants, Dr. Zipper's opinions regarding prognosis and future care essentially boil down to the speculative assertion that mesh devices remain implanted in Tedder and because it may be impossible to remove them, Tedder is likely to experience future harm. Defendants point out that Dr. Zipper is not Tedder's treating physician and examined her only once when performing an independent medical examination. Dr. Zipper has not examined the mesh implanted in Tedder, and Tedder has not undergone any revision procedure through which a provider attempted to remove any of the mesh.

Tedder does not address this issue.

The Court finds Dr. Zipper qualified to testify to possible future complications and that Dr. Zipper's opinions in that regard are sufficiently reliable. The motion, therefore, is **DENIED**. *See, e.g., Warren v. C.R. Bard, Inc.*, No. 8:19-cv-2657-T-60JSS, 2020 WL 1899838, at 3 (M.D. Fla. Apr. 14, 2020) (finding Dr. Zipper's opinions on future possible complications supported by the record, sufficiently grounded, and admissible).

7. Alternative designs

Finally, Defendants argue that Dr. Zipper's alternative design opinions set forth in his case-specific report are speculative and irrelevant. In addition to the arguments set forth above with regard to Dr. Zipper's general causation opinions, Defendants argue that Dr. Zipper does not identify any specific safter alternative design for TVT-S or TV-O. Defendants say Dr. Zipper references an "unspecified 'full length retropubic midurethral sling' only 'by way of example,' but never explains why, and to what extent, a retropubic sling would have been a more appropriate option for Tedder in 2007 or 2010." ECF No. 134 at 26–27. Defendants argue that Dr. Zipper's opinion that certain non-mesh procedures, such as autologous slings and traditional retropubic urethropexies, would have been better is speculative and irrelevant. Defendants also argue that Dr. Zipper's speculation as to the availability of alternative non-mesh procedures is irrelevant because it does not address whether there was a feasible alternative design for TVT-S or TVT-O.

The motion is **DENIED** for the reasons set forth in Section III. A. 2., *supra*.

SO ORDERED this 31st day of March 2022.

M. Casey Rodgers

M. CASEY RODGERS
UNITED STATES DISTRICT JUDGE