UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

SOUTHERN DIVISION

MARSHA FOSTER, ALVIN A. JENSEN, Plaintiffs, vs. ETHICON, INC., JOHNSON & JOHNSON, Defendants.	4:20-CV-04076-RAL OPINION AND ORDER ON DAUBERT MOTIONS

This case began in the Southern District of West Virginia as part of the Ethicon multidistrict litigation (MDL). It is one of thousands of cases involving injuries patients allegedly suffered after being implanted with pelvic mesh products designed, manufactured, and sold by Ethicon, Inc., a wholly owned subsidiary of Johnson & Johnson. Plaintiffs Marsha Foster and Alvin Jensen[1] sued Ethicon, Inc., and Johnson & Johnson (collectively "Ethicon"), claiming that Ethicon's TVT device, which was used for Foster's mid-urethral sling procedure in March 2003, was defectively designed and had inadequate warnings.

The Ethicon MDL was assigned to the Honorable Joseph R. Goodwin in the Southern District of West Virginia. In re: Am. Med. Sys., Inc. Pelvic Repair Sys. Prods. Liab. Litig., 844 F. Supp. 2d 1359, 1362 (J.P.M.L. 2012). When Judge Goodwin transferred Foster's case to this Court, there was a pending motion for partial summary judgment by Ethicon and multiple pending

[1]Alvin Jensen is a plaintiff for purposes of a loss of consortium claim only, so this opinion and order generally refers to the Plaintiffs as "Foster."

Daubert[2] motions filed by both parties. According to the parties, Judge Goodwin ruled on the same or similar Daubert motions in prior waves of the MDL but did not enter any orders on Daubert motions in the wave including Foster's case. This Court allowed the parties to file separate motions on each expert setting out the remaining issues for disposition, but cautioned that it was not interested in the parties relitigating issues that had already been decided and that it would "hew closely to" Judge Goodwin's evidentiary rulings. Doc. 74 at 2. This Court also ruled on Ethicon's motion for summary judgment. Doc. 109. As relevant here, this Court granted summary judgment on the failure-to-warn claim, finding that Foster failed to show a material question of fact on whether her doctor read the TVT's instructions for use (IFU) before her surgery. Doc. 109 at 14–16. Foster's claims remaining for trial are negligence, strict liability – design defect, negligent infliction of emotional distress, and loss of consortium, as well as damages claims and statute of limitations issues.

I. Daubert Standard

The Supreme Court in Daubert held that district courts serve as gatekeepers under Rule 702 of the Federal Rules of Evidence, admitting expert testimony only if it is both reliable and relevant. 509 U.S. at 589, 597; see also Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999) (extending the district court's gatekeeping function to all expert testimony). The current version of Rule 702 largely codifies Daubert and the cases applying it. Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001). The rule allows a qualified expert to testify if four criteria are met:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and

[2]Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993).

(d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The Eighth Circuit has distilled Rule 702's "screening requirement" to three factors: (1) the testimony must be relevant, that is, helpful to the jury in deciding the ultimate issue of fact; (2) the expert must be qualified; and (3) the expert's opinions "must be reliable or trustworthy in an evidentiary sense." Amador v. 3M Co. (In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.), 9 F.4th 768, 777 (8th Cir. 2021) (cleaned up and citation omitted).

"The standard for judging the evidentiary reliability of expert evidence is lower than the merits standard of correctness." Id. at 777 (cleaned up and citation omitted). The reliability of the expert's principles and methods can be judged by several factors, including (1) whether the scientific theory or technique can (and has been) tested; (2) whether the theory or technique has been published and undergone peer review; (3) whether the technique has a known or potential rate of error; (4) whether the theory or technique is generally accepted within the relevant scientific community; (5) whether the expertise was developed for litigation or flowed from the expert's research; (6) whether the expert ruled out alternative explanations; and (7) whether the expert sufficiently connected his testimony to the facts of the case. Daubert, 509 U.S. at 593–94; Lauzon, 270 F.3d at 687. This is a non-exhaustive list, and courts may use or reject these factors as the case requires. Russell v. Whirlpool Corp., 702 F.3d 450, 456 (8th Cir. 2012).

A district court's inquiry under Rule 702 is "a flexible one," focusing on the "principles and methodology" the expert used rather than the correctness of the expert's conclusions. Daubert, 509 U.S. at 594–95. The rule favors admissibility, Johnson v. Mead Johnson & Co., LLC, 754 F.3d 557, 562 (8th Cir. 2014); Lauzon, 270 F.3d at 686, and courts should exclude an expert's opinion "only if it is so fundamentally unsupported that it can offer no assistance to the jury." Sappington v. Skyjack, Inc., 512 F.3d 440, 448 (8th Cir. 2008) (citation omitted). Still, courts will

not admit opinion testimony "that is connected to existing data only by the *ipse dixit* of the expert." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997); see also Marmo v. Tyson Fresh Meats, Inc., 457 F.3d 748, 758 (8th Cir. 2006) ("When the analytical gap between the data and the proffered opinion is too great, the opinion must be excluded."). The party offering the expert testimony must show its admissibility by a preponderance of the evidence. Lauzon, 270 F.3d at 686. With these standards in mind, this Court turns to the parties' Daubert motions.

II. Analysis

A. Foster's Motion to Exclude Dr. Fiegen's Opinion on the Adequacy of the Warnings and IFU for the TVT

Dr. Fiegen opined in his expert report that the IFU for the TVT was appropriate and allowed for the safe use of the device. Doc. 79-1 at 25. Foster argues that this testimony should be excluded because Dr. Fiegen has no expertise in the development of warning labels. Doc. 80 at 4–6. In earlier waves of the MDL, Judge Goodwin ruled that Dr. Fiegen, as a urogynecologist, was qualified to testify that the TVT's IFU "did not include risks observed by" Dr. Fiegen in his clinical practice. In re Ethicon Inc. Pelvic Repair Sys. Prod. Lib. Litig., MDL No. 2327, 2018 WL 3545341, at *3 (S.D.W. Va. July 23, 2018). However, Judge Goodwin ruled that Dr. Fiegen was not qualified to testify about whether "any risks should have been included in an IFU." Id. Ethicon does not challenge Judge Goodwin's ruling that Dr. Fiegen lacks the expertise to testify about what risks should have appeared in the IFU. See Doc. 104. Rather, Ethicon argues that Foster's motion should be denied "to the extent it seeks to exclude Dr. Fiegen's opinions concerning his knowledge of TVT risks/benefits, the knowledge of the medical community at large, and whether those risks appeared on the relevant IFU." Doc. 104 at 4.

This Court grants Foster's motion to exclude Dr. Fiegen's opinions on the TVT's IFU. This Court granted summary judgment on Foster's failure-to-warn claim, so Dr. Fiegen's opinion

about the adequacy of the TVT's IFU is no longer relevant. This Court adopts Judge Goodwin's ruling on Dr. Fiegen's opinions to the extent it is consistent with this opinion and order.

B. Foster's Motion to Exclude Some of Dr. Robert Rodgers's Opinions About the TVT

Dr. Rodgers has been a board-certified obstetrician/gynecologist since 1986, and he became board certified in female pelvic medicine and reconstructive surgery in 2013. Doc. 81-1 at 4. He has spent "many hours" performing cadaveric dissections in a medical school anatomy lab and taught anatomic and surgical instruction to residents for thirteen years. Doc. 81-1 at 4. He has also taught multiple courses on gynecologic surgical anatomy and dissection techniques in unembalmed cadavers. Doc. 81-1 at 6. Since 2008, Dr. Rodgers has performed over 700 surgeries for reconstruction of various vaginal support defects, including over 200 midurethral slings, some of which involved the TVT. Doc. 81-1 at 7. From the late 1990s to 2007, Dr. Rodgers served as an expert consultant for Ethicon on the design and performance of the Prolift, the TVT-O, and TVT Secur products. Doc. 81-1 at 8.

In the MDL, the plaintiffs moved to exclude Dr. Rogers's opinion about cadaver studies Ethicon conducted involving the TVT; any opinions he has about the efficacy of the TVT grounded in his cadaver studies of devices other than the TVT; any opinions he has about the efficacy of the TVT that are grounded in Ethicon's cadaver studies of the TVT; any opinion on whether the cadaver studies Ethicon conducted were appropriate; any opinion on the clinical efficacy of the TVT based on his experience implanting the TVT-O and TVT-Secur; any opinions on the reliability of these non-TVT devices; and his opinion that Ethicon behaved admirably or as a "good" company. Doc. 44-2.

Judge Goodwin granted the plaintiffs' motion to exclude Dr. Rogers's "opinions regarding cadaver studies relating to the TVT device," reasoning that "Dr. Rogers has no knowledge of such

studies as they related specifically to the TVT device." In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2017 WL 1265174, at *4 (S.D.W. Va. Mar. 29, 2017). Judge Goodwin otherwise denied the plaintiffs' motion, finding that the remaining issues the plaintiffs raised were "better suited for cross-examination." Id. This Court adopts Judge Goodwin's ruling on Dr. Rogers's testimony, with one clarification.

As noted above, plaintiffs argued that Dr. Rogers should not be allowed to testify that Ethicon behaved admirably or is a good company. Dr. Rogers's expert report included the following paragraph about his time working with Ethicon:

> I found that at Ethicon all my contacts, discussions and work with the research scientists, biomedical engineers, and clinicians were consistently respectful, appreciated, and honest. The work environment attitude was always one of 'How can we best help the patient with this problem and eliminate any and all possible risks and potential complications.' I never felt pressure to push a product out. All the product development in which I was involved was thoroughly evaluated and reevaluated step by step, in accordance to the Ethicon standards, the industry standards, and of course, the FDA and federal government standards. There was no room for 'fudging' or manipulating data.

Doc. 81-1 at 9. Dr. Rogers's expert report also stated that Ethicon's development of the Prolift and TVT products was "in earnest with the patients' best interests always at the top of each agenda," and that Ethicon's efforts to teach surgeons about the safe and effective use of its products was "sincere and thorough." Doc. 81-1 at 10.

Foster argues that all these statements in Dr. Rogers's expert report are inadmissible character evidence. As relevant here, Judge Goodwin found that any testimony about Ethicon's compliance with design control and risk management standards was of "dubious relevance," but declined to issue a blanket exclusion on such testimony given the variance in state product liability law. In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., 2017 WL 1265174, at *3. Dr.

Rodgers will not be allowed to testify about Ethicon's working environment being "consistently respectful, appreciated, and honest," or that Ethicon behaved admirably or as a "good" company.

C. Foster's Motion to Exclude FDA Expert Timothy Ulatowski's Testimony

Timothy Ulatowski has a bachelor's degree in microbiology and a master's degree in physiology. Doc. 83-3 at 5. He used to work for the Food and Drug Administration (FDA), and now runs a consulting business specializing in medical device regulations, policies, and procedures administered by the FDA. Doc. 83-3 at 5. Foster moves to exclude Ulatowski's testimony about the § 510(k) process as well as fourteen other opinions Ulatowski offers in his expert report.

1. Ulatowski's Testimony about the § 510(k) process

Much of Mr. Ulatowski's single-spaced 94-page expert report concerns the FDA's § 510(k) process. Doc. 83-3. The § 510(k) process lets manufacturers attempting to market a new medical device avoid the FDA's stringent premarket approval review if the device is "'substantially equivalent' to either a pre-1976 device that the FDA hasn't yet classified or a Class I or II device already on the market." Kaiser v. Johnson & Johnson, 947 F.3d 996, 1004 (7th Cir. 2020) (quoting 21 U.S.C. § 360c(f)(1)); see also Huskey v. Ethicon, Inc., 848 F.3d 151, 160–61 (4th Cir. 2017) (discussing the § 510(k) process). "To be substantially equivalent, the device must have 'the same intended use as the predicate device' and either (1) have 'the same technological characteristics' as the predicate device *or* (2) be 'as safe and effective' as the predicate and 'not raise different questions of safety and effectiveness.'" Kaiser, 947 F.3d at 1004 (quoting 21 U.S.C. § 360c(i)(1)(A)). In Mr. Ulatowski's opinion, "the 510(k) review process is robust and truly is a basis for the determination of the safety and effectiveness of medical devices." Doc. 83-3 at 22.

Judge Goodwin disagreed. In a prior wave of the Ethicon MDL, he found that the § 510(k) process "does not speak directly to safety and efficacy," and that the "negligible probative value"

of this evidence was substantially outweighed by the risk of misleading the jury and wasting time. In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4493646, at *3 (S.D.W. Va. Aug. 25, 2016) ("Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors to erroneously conclude that regulatory compliance proved safety." (cleaned up and citation omitted)). He therefore excluded Mr. Ulatowski's "expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussions of the information Ethicon did nor did not submit in its section 510(k) application." Id. Judge Goodwin also excluded Ulatowski's opinions about "Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations." Id.

Judge Goodwin's ruling on § 510(k) evidence is nothing new. He has excluded such evidence in other transvaginal mesh cases, and the Fourth and Eleventh Circuits have affirmed those rulings. Eghnayem v. Bos. Sci. Corp., 873 F.3d 1304, 1317–19 (11th Cir. 2017) (concluding that Judge Goodwin did not abuse his discretion by excluding Boston Scientific's § 510(k) evidence concerning its transvaginal mesh device); Huskey, 848 F.3d at 160–61 (finding no abuse of discretion where Judge Goodwin excluded evidence that Ethicon complied with the § 510(k) process for the TVT-O); Cisson v. C.R. Bard, Inc., 810 F.3d 913, 920–22 (4th Cir. 2016) (holding that Judge Goodwin did not abuse his discretion by excluding evidence that Bard had complied with the § 510(k) process for its transvaginal mesh device); see also Kaiser, 947 F.3d at 1018 (finding that the district court did not abuse its discretion by excluding as more prejudicial than probative Ethicon's evidence that its Prolift device cleared the § 510(k) process). These courts, along with the Seventh Circuit, agreed that the § 510(k) evidence was of minimal relevance to the safety and efficacy of the transvaginal mesh products. See Kaiser, 947 F.3d at 1018; Eghnayem,

873 F.3d at 1318–19; Huskey, 848 F.3d at 160 "[T]he 510(k) process focuses mostly on the *equivalence* between the product in question and an older one, and only *tangentially* examines the safety of the product going through the process." (cleaned up and citation omitted)).

Ethicon now asks this Court to reconsider Judge Goodwin's ruling on the § 510(k) process, arguing that Judge Goodwin mistakenly applied the Supreme Court's decision in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), where the FDA cleared a device for being substantially equivalent to a Class III pre-1976 device, to the TVT, which the FDA cleared after finding that it was substantially equivalent to a post-1976 Class II device. Ethicon raised and lost this same argument in other courts. Willams v. Ethicon, Inc., No. 5:20-CV-234 (MTT), 2021 WL 1087808, at *4 (M.D. Ga. Mar. 22, 2021); In re Ethicon Physiomesh Flexible Composite Hernia Mesh Prods. Liab. Litig., No. 1:17-MD-2782-RWS, 2020 WL 9887565, at *5 (N.D. Ga. Nov. 25, 2020); Salinero v. Johnson & Johnson, No. 1:18-cv-23643-UU, 2019 WL 7753438, at *4–6 (S.D. Fla. Sept. 25, 2019). This Court agrees with those other courts that "even accepting Ethicon's proposition that the 510(k) process had a 'safety component,'[3] the 510(k) safety and effectiveness equivalence pathway to approval still 'does little to inform as to its safety.'" Williams, 2021 WL 1087808, at *4 (quoting In re Ethicon Physiomesh, 2020 WL 9887565, at *6); see also Campbell v. Bos. Sci. Corp., 882 F.3d 70, 77 (4th Cir. 2018) (finding no abuse of discretion where the district court ruled that the danger of confusing the issues and misleading the jury substantially outweighed the probative value of the FDA's clearance of a transvaginal mesh device on the ground that it was substantially similar to a "predicate device that itself received a thorough safety evaluation");

[3]Curiously, Ethicon makes no attempt to detail any sort of safety analysis the FDA may have undertaken when clearing the TVT under the § 510(k) process. For example, Ethicon does not say that the FDA found that the TVT was substantially similar to a predicate device that itself underwent a thorough safety evaluation.

Salinero, 2019 WL 7753438, at *4–5; Lewis v. Johnson & Johnson, 991 F. Supp. 2d 748, 755 (S.D.W. Va. 2014) (rejecting Ethicon's argument that the TVT's clearance under § 510(k) was relevant to safety "because the TVT was cleared 'with reference' to a product that had gone through the premarket approval process").

Ethicon also argues that evidence "like" the § 510(k) process is relevant to its defense under South Dakota law. Doc. 105 at 7. Ethicon cites two cases—Hofer v. Mack Trucks, Inc., 981 F.2d 377 (8th Cir. 1992), and Zacher v. Budd Co., 396 N.W.2d 122 (S.D. 1986)—to support this argument. But these cases neither involved the § 510(k) process nor held that regulations unconcerned with safety are relevant in a design defect case in South Dakota. In any event, neither of these cases suggest that Judge Goodwin was wrong in concluding that the risk of unfair prejudice, waste of time, and misleading the jury substantially outweighs the probative value of Ethicon's § 510(k) evidence. See, e.g., In re Ethicon Physiomesh, 2020 WL 9887565, at *7–8 (rejecting argument that § 510(k) evidence was relevant under Georgia law); In re C.R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig., MDL No. 2187, 2013 WL 11089794, at *2 (S.D.W. Va. July 1, 2013) (holding that § 510(k) evidence was not admissible under state law because the § 510(k) process "does not go to whether the . . . products are safe and effective and . . . does not impose any requirements on its own"). This Court grants Foster's motion to the extent it seeks to exclude Mr. Ulatowski's testimony about the § 510(k) process, including subsequent enforcement actions and discussions of the information that Ethicon did or did not submit in the process.

2. Ulatowski's Other Opinions

Judge Goodwin's Daubert order filed by the parties did not specifically address the fourteen opinions Ulatowski offered near the end of his report. This Court rules on those opinions as follows:

1. Foster's request to exclude Ulatowski's first opinion about a recall of the Protegen Sling is denied as moot because Ethicon does not intend to offer it. Doc. 105 at 8.

2. This Court grants Foster's request to exclude Ulatowski's opinion number 2 that Prolene—which Ulatowski says is the "primary material" used in the TVT—is safe and effective from a regulatory perspective. Ulatowski's opinion is based on the Prolene suture having underwent the FDA's stringent premarket approval process. As Judge Goodwin explained in another case, however, "[t]he product that went through the premarket approval process is not the TVT. It is a different medical device that was approved for a different purpose." Lewis, 991 F. Supp. 2d at 755; see also id. at 757–58 (describing the many differences between the TVT and the Prolene suture). This Court concludes that "[a]llowing Ulatowski to opine that the FDA approved the Prolene suture raises the same Rule 403 problems as the section 510(k) process." Heinrich v. Ethicon, Inc., No. 2:20-cv-00166-APG-VCF, 2021 WL 2801965, at *3 (D. Nev. June 15, 2021).

3. This Court grants Foster's request to exclude Ulatowski's opinion number 3 that "a change in material or PROLENE weave specifications for the TVT Classic would require the submission of a new 510(k) to FDA and clearance by FDA before the modified device could be marketed." Doc. 83-3 at 54. Ethicon argues that this opinion is relevant in any case where the plaintiff claims that there is a safer alternative design to the TVT because "any such design is not, as a matter of law, 'available' if it would have to be cleared by the FDA but has not been cleared." Doc. 105 at 9. However, the only case Ethicon cites to support this argument is Militrano ex. rel. Militrano v. Lederle Labs., 769 N.Y.S.2d 839 (N.Y. Sup. Ct. 2003), a case involving New York law and the pertussis vaccine. The Militrano case discussed the lengthy and thorough process a new drug must undergo before it is approved by the FDA. Id. at 851–52. Miltrano did not mention the 510(k) process at all, and Ethicon has not cited to any South Dakota case suggesting that the need for a new § 510(k) clearance precludes an alternative design. See Baccaro v. Coloplast Corp., 1:19-CV-1088, 2021 WL 3089202, at *17 (N.D.N.Y July 22, 2021) (rejecting argument "that a lack of FDA approval precludes finding that an alternative design is feasible"); Bell v. Ethicon, Inc., No. 4:20-CV-3678, 2021 WL 1111071, at *7 (S.D. Tex. Mar. 23, 2021) (rejecting Ethicon's argument that a "lack of FDA approval precludes an alternative design" where Ethicon did not cite any Texas authority showing that its argument was correct). Ulatowski's opinion number 3 would raise multiple Rule 403 concerns and is properly excluded. Heinrich, 2021 WL 2801965, at *4 (excluding Ulatowski's opinion that a change by Ethicon in the material for the TVT-S would have required clearance by the FDA despite Ethicon's argument that an alternative design is not available if it would have required clearance by the FDA).

4. Foster's request to exclude Ulatowski's opinion number 4 that there was no reason for the FDA to recommend labeling changes to the TVT is granted. Judge Goodwin's Daubert order excluded opinions about Ethicon's compliance with or violation of the FDA's labeling regulations, Ethicon has not shown that Ulatowski's opinion on labeling is more probative than prejudicial, and this Court granted summary judgment on Foster's failure-to-warn claim.

5. Foster's request to exclude Ulatowski's opinions 5 and 6 on Ethicon's patient brochures is granted. This Court granted summary judgment on Foster's failure-to-warn claim, and this Court does not foresee the patient brochures being relevant at trial.

6. Foster's request to exclude Ulatowski's opinion number 7 that "the FDA recall and Warning Letter databases do not document common or unusual TVT device manufacturing problems" is granted. This Court granted summary judgment on Foster's claim for manufacturing defect, so opinion number 7 is irrelevant.

7. Foster's request to exclude Ulatowski's opinion number 8 on complaint and medical device reporting procedures is denied as moot. Ethicon represented that it will only offer this opinion if Foster offers medical device reports evidence, Doc. 105 at 11–12, and Foster indicated she does not intend to do so, Doc. 114 at 22–23.

8. Foster's request to exclude Ulatowski's opinion number 10 that Ethicon "substantially complied with all FDA premarket and related quality system requirements prior to and during marketing for the TVT Classic, including, for example, 510(k) and design control requirements" is granted as this Court has excluded § 510(k) evidence.

9. Foster's request to exclude Ulatowski's opinion number 11 on the issue reports and MedWatch reports for the TVT is denied as moot. Ethicon advised it would only offer this opinion defensively, Doc. 105 at 12, and Foster does not intend to offer evidence about the FDA regulations or issue or MedWatch reports, Doc. 114 at 22–23.

10. Foster's request to exclude Ulatowski's opinion number 12 comparing the amount of clinical evidence supporting the safety and effectiveness of the TVT to the clinical evidence for other § 510(k) devices is granted because this Court has excluded § 510(k) evidence. This Court excludes Ulatowski's opinion number 13, which asserts that the § 510(k) process for the TVT included an analysis of the safety and effectiveness of the device, for the same reason.

11. Foster has no failure-to-warn claim, so this Court grants Foster's request to exclude Ulatowski's opinion number 14 on the labeling of the TVT.

12. This Court denies as moot Foster's request to exclude Ulatowski's opinion number 16 that adverse press and a litigious environment resulted in an atypical surge of medical device reports. Neither party intends to offer evidence of medical device reports. Doc. 114 at 22–23; Doc. 105 at 13–14.

13. This Court denies as moot Foster's request to exclude Ulatowski's testimony about certain risk management policies. See Doc. 83-3 at 13–14. Neither party intends to offer evidence about these polices or regulations. Doc. 114 at 22–23; Doc. 105 at 14.

D. Foster's Motion to Exclude the Opinions of Dr. Michael Woods

Dr. Woods is a board-certified obstetrician and gynecologist focused on treating incontinence, prolapse, and other pelvic floor disorders. Doc. 85-2 at 5. He has performed thousands of procedures using TVT mesh. Doc. 85-2 at 9. In his expert report, Dr. Woods opined that his patients have a mesh exposure rate of "approximately 1%" and a reoperation rate of "approximately 3%." Doc. 85-2 at 8. He also stated that mesh exposures and erosions can occur "on average in about 1–3% of women." Doc. 85-2 at 33. During his deposition, Dr. Woods testified that his "success rate" from a "patient satisfaction standpoint" is "probably about 95, 96 percent." Doc. 85-3 at 6.

In an earlier wave, the plaintiffs' moved to exclude Dr. Woods's "design" opinions, his testimony about the complication rates for his patients, and his opinions about product warnings. Doc. 46-2. Judge Goodwin excluded Dr. Woods's opinion about the complication rates for his own patients and his opinion about what an IFU should or should not include. In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4582231, at *3 (S.D.W. Va. Sept. 1, 2016). However, Judge Goodwin denied as moot the plaintiffs' motion on design opinions, finding that Dr. Woods had "not expressed any opinions about the process of designing a product." Id.

This Court adopts Judge Goodwin's order on Dr. Woods's testimony. In ruling on the complication rates, Judge Goodwin noted that Dr. Woods's "complication rates derive entirely from mental estimates and not from accumulated data or patient records," and that Dr. Woods "described his estimates as a 'ballpark figure that is probably pretty close.'" Id. Judge Goodwin found that Dr. Woods's complication rate opinions were "unreliable" and "lack[ed] any vestige of a scientifically-applied methodology." Id. Although Ethicon argues that Dr. Woods's complication rate opinions are reliable, the cases Ethicon cites did not involve the sort of opinion Dr. Woods gives here.[4]

E. Ethicon's Motion to Exclude Opinions of Dr. Peggy Pence

Peggy Pence has a Ph.D. in toxicology and over 40 years of experience in the research and development of medical devices. Doc. 87-1 at 8, 12. In the MDL, Ethicon moved to exclude Dr. Pence's opinions that the TVT was misbranded under the Federal Food, Drug, and Cosmetic Act (FDCA) because of Ethicon's failure to meet the postmarket vigilance standard of care; that the TVT was misbranded because Ethicon failed to include adequate warnings and used false or misleading warnings; and that Ethicon failed to conduct appropriate testing for the TVT. Doc. 40-2 at 1–2. Judge Goodwin did not specifically address Dr. Pence's opinion about the TVT being misbranded under the FDCA, but rather repeated his ruling excluding § 510(k) evidence and "opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations." In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2017 WL 11502313, at *4 (S.D.W. Va. July 20, 2017). Judge Goodwin denied Ethicon's motion to exclude Dr. Pence's opinion about Ethicon's warnings, finding that Dr. Pence was qualified to

[4]Judge Goodwin did not address Dr. Woods's testimony about the safety and efficacy of the TVT, and this Court is not doing so here.

testify about IFUs and that her opinions were supported by sufficient facts. Id. at *3. As for Dr. Pence's opinion about testing for the TVT, Judge Goodwin found that Dr. Pence was qualified to testify about premarket testing of medical devices, but reserved ruling on whether her testimony was reliable. Id. at *4. He explained that the plaintiffs argued that Dr. Pence's testimony was reliable because of her experience, that the reliability inquiry therefore had to consider the relationship between her experience and her testimony, and that he lacked sufficient information to rule on reliability at that time. Id. He therefore reserved "ruling until further testimony may be offered and evaluated firsthand at trial." Id.

This Court grants Ethicon's motion to exclude Dr. Pence's opinions that the TVT was misbranded because of Ethicon's failure to warn, failure to meet the postmarket vigilance standard of care, and use of false and misleading labeling. Dr. Pence's opinion about the warnings in the TVT's IFU are not relevant to Foster's case. Foster's failure-to-warn claim did not survive summary judgment because she failed to offer sufficient evidence that her doctor read the IFU before her surgery. See Baccaro v. Coloplast Corp., 2021 WL 3089202, at *10 (concluding that Dr. Pence's opinions about the adequacy of a device's instructions were no longer relevant after the court granted summary judgment on the plaintiff's failure-to-warn claim). Nor would Dr. Pence's other opinions on misbranding assist the jury in deciding a fact in issue. See Amador, 9 F.4th at 777 (explaining that expert testimony "must be useful to the finder of fact in deciding the ultimate issue of fact, meaning it must be relevant"). Dr. Pence opines that Ethicon violated § 301(a) of the FDCA by utilizing "labeling that was false and misleading" and that "failed to reveal material facts." Doc. 87-1 at 96. The three examples she gives of this misbranding are promotional pieces Ethicon provided to physicians. Doc. 87-1 at 92–96. Dr. Pence also opines that "Ethicon deviated from the standard of care by its failure to report to FDA a number of adverse events and

malfunctions that met the criteria for Medical Device Reporting, rendering the TVT devices misbranded as a result of failure to furnish information requested under Section 519 of the FDCA." Doc. 87-1 at 116. These opinions are not relevant because Foster has no remaining failure-to-warn claim and has not brought a claim that Ethicon violated the FDCA. See In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig., No. 2:12-MD-02327, 2014 WL 186872, at *19 (S.D.W. Va. Jan. 15, 2014) (excluding Dr. Pence's opinions about misbranding where court had granted summary judgment on the failure-to-warn claim and the plaintiff did not bring a claim based on Ethicon's violation of the FDCA). Beyond that, Dr. Pence's opinions on the FDCA could waste time and confuse the jury, while her opinions on medical device reporting would violate this Court's decision to exclude opinions on Ethicon's compliance with adverse reporting requirements.

That leaves Dr. Pence's opinion that Ethicon failed to conduct adequate testing for the TVT. This Court agrees with Judge Goodwin and other district courts that Dr. Pence's extensive experience in the research and development of medical devices qualifies her to testify about Ethicon's testing of the TVT. Baccaro, 2021 WL 3089202, *10 (finding Dr. Pence qualified to testify about the defendant's testing); Arevalo v. Coloplast Corp., No. 3:19cv3577-TKM-MJF, 2020 WL 3958505, at *8 (N.D. Fla. July 7, 2020) (same). Dr. Pence has "designed clinical trials for diseases of the female genital system and ha[s] been involved in both preclinical and/or clinical testing of novel medical devices and biologics for wound healing applications, including both deep wounds and surgical incisions." Doc. 87-1 at 8. She has also been an "integral or leading member of multiple product development teams to determine the testing requirements for medical devices and drugs/biologics and to make decisions concerning whether additional testing and, if so, what types of additional testing were needed based on initial results of product testing." Doc. 87-1 at 9.

The closer question is whether Dr. Pence's opinion is reliable. Dr. Pence's expert report details several potential concerns about TVT mesh implantation and suggests that Ethicon failed to investigate these concerns through testing. See, e.g., Doc. 87-1 at 60 ("I reviewed no evidence that Ethicon performed additional testing to elucidate the reasons for the cytotoxicity of the sterile TVT mesh as compared to the non-cytotoxicity of normal production sterile PROLENE mesh and nonsterile raw material polyprolylene mesh."); id. ("I have not seen any evidence of any studies conducted to determine long-term whether the fraying and the particles lost inside the body might cause deleterious effects."); id. at 53 ("Yet Ethicon never studied the difference between a lightweight, large-pore mesh in the tissue in and around the urethra for slings versus its old-construction, very first Prolene surgical mesh."). She states that:

> [I]n my professional opinion, Ethicon failed to perform testing that was critical to learning the long-term safety of the TVT permanent implant. Ethicon fell below the standard of care required of a reasonably prudent medical device manufacturer. Moreover, Ethicon failed to comply with its own credo, specifically, that the company's first responsibility is to the doctors and patients who use Ethicon's products.

Doc. 87-1 at 60.

Judge Goodwin excluded this opinion of Dr. Pence in a 2014 bellwether case, finding that she failed to provide a reliable foundation for it. Lewis, 2014 WL 186872, at *18–19 (noting that Dr. Pence did not point to any regulations, authorities, or other manufacturers' testing practices that would suggest that Ethicon's testing was inadequate).

Dr. Pence has since issued a supplemental expert report identifying the Global Harmonization Task Force (GHTF) guidelines as the applicable industry standards and stating that these guidelines "establish additional foundation for" her opinions. Doc. 87-2 at 4. She also discussed sources stressing the need for more clinical studies of vaginal mesh implants. Doc. 87-

2 at 5–9. One such source was a 2006 study by the French National Authority for Health (HAS) evaluating the safety and effectiveness of vaginally implanted mesh for treating genital prolapse. Doc. 87-2 at 5. HAS concluded that "the use of mesh implants for transvaginal correction of genital prolapse remained a matter of clinical research." Doc. 87-2 at 6. It recommended prospective studies on the anatomical and functional outcomes of mesh implantation, the medium and long-term effects, adverse events like erosion, and the management of erosions and retractions. Doc. 87-2 at 6. Dr. Pence also discussed a 2012 article by the 2nd International Urogynecological Association Grafts Roundtable on "optimizing safety and appropriateness of graft use in transvaginal pelvic reconstructive surgery." Doc. 87-2 at 9 (cleaned up and citation omitted). This article noted that new implants and ancillary devices had been introduced to the market in the previous 10 years "with little or no clinical data or research." Doc. 87-2 at 9 (cleaned up and citation omitted). The authors concluded that "minimum standards should be demanded for new products prior to marketing, including . . . upfront clinical studies." Doc. 87-2 at 9 (cleaned up and citation omitted).

This Court denies Ethicon's motion to exclude Dr. Pence's opinion that Ethicon failed to perform adequate testing for the TVT and that its conduct fell below the standard of care.[5] Judge Goodwin admitted a similar opinion from Dr. Pence after she supplemented her expert report with additional sources, including the HAS study just discussed. Sanchez v. Bos. Sci. Corp., No. 2:12-cv-05762, 2014 WL 4851989, at *33–34 (S.D.W. Va. Sept. 29, 2014). He found that unlike the previous situation where he excluded Dr. Pence's opinion, Dr. Pence's supplemented opinion in the case before him was "backed by authoritative studies that recommend the performance of

[5]Dr. Pence should not testify about Ethicon allegedly violating its credo, however, as such testimony is not relevant to whether the TVT was defectively designed.

clinical trials and long-term follow-ups before using polypropylene mesh." Id. at *34. Other courts have also allowed Dr. Pence to opine that a manufacturer should have conducted more testing on its vaginal mesh device. Baccaro, 2021 WL 3089202, *10. Ethicon's other arguments about Dr. Pence's opinions can be addressed on cross examination.

F. Ethicon's Motion to Exclude the Opinions of Dr. Jimmy Mays

Jimmy Mays has a Ph.D. in polymer science and is an expert witness for Foster. Ethicon acknowledges that Judge Goodwin resolved all its challenges to Dr. Mays's testimony in Wave 4 but filed its motion in this case to preserve its objections to Judge Goodwin's adverse rulings. Docs 89, 90. This Court adopts Judge Goodwin's order on Dr. Mays, found at Doc. 99-1, in this case. Ethicon has preserved its objections to Dr. Mays's testimony, but its motion is denied to the extent it asks this Court to reconsider Judge Goodwin's ruling.

G. Ethicon's Motion to Exclude the Opinions of Dr. Bruce Rosenzweig

Bruce Rosenzweig, M.D., is a pelvic surgeon and urogynecologist. Doc. 92-1 at 1–2. He is currently an assistant professor of obstetrics and gynecology at Rush University Medical Center in Chicago, Illinois. Doc. 92-1 at 1. He has performed over a thousand pelvic floor surgical procedures, including over 300 surgeries dealing with complications related to synthetic mesh. Doc. 92-1 at 2. Some of these surgeries involved the removal of TVT devices. Doc. 92-1 at 2. As relevant here, Dr. Rosenzweig opined that the Burch procedure and pubovaginal slings are safer alternatives to the TVT, Doc. 92-1 at 93; described problems with both mechanical-cut mesh and laser-cut mesh, Doc. 92-1 at 42–56; and concluded that the warnings in the TVT's IFU were inadequate, see, e.g., Doc. 92-1 at 21–24, 56–61, 65–80. In a prior wave, Judge Goodwin ruled that Dr. Rosenzweig could testify about the warnings in the IFU, but reserved ruling on the other two opinions. Doc. 92-2 at 9–11. He explained that he needed more information to determine

whether Dr. Rosenzweig's experience provided a reliable foundation for his opinions about mechanical-cut mesh and laser-cut mesh, and that the relevance of Dr. Rosenzweig's testimony on alternative procedures was better determined on a case-by-case basis.[6] Doc. 92-2 at 9–10. Ethicon now asks this Court to exclude Dr. Rosenzweig's opinions on safer alternative procedures, the cut of TVT mesh, and the TVT's warnings.

1. Alternate Procedures

Ethicon argues that Dr. Rosenzweig's opinion that the Burch procedure and pubovaginal slings are safer alternatives to the TVT is not relevant. It cites to several cases concluding that alternative procedures do not constitute a safer alternative design for a design-defect claim. See, e.g., Mullins v. Johnson & Johnson, 236 F. Supp. 3d 940, 943 (S.D.W. Va. 2017) (applying West Virginia law and stating that "[e]vidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT"); Schmidt v. C.R. Bard, Inc., No. 2:11-CV-00978-PMP-PAL, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) (concluding that "non-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim); see also In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017) (finding that testimony about alternative procedures was not relevant because "alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists"). In response, Foster cites to a district court case applying Illinois law and concluding that Dr. Rosenzweig could testify about the use of the Burch procedure as an alternative to TVT devices. Herrera-Nevarez v. Ethicon, Inc., No. 17 C 3930, 2017 WL 3381718, at *7–8 (N.D. Ill. Aug. 6, 2017). That court found Dr.

[6]Judge Goodwin's order also ruled on other challenges Ethicon made to Dr. Rosenzweig's opinions. This Court adopts those rulings to the extent they are consistent with this opinion and order.

Rosenzweig's testimony relevant under Illinois's risk-utility test and admissible to counter Ethicon's contention that "the TVT-O and similar products are the 'gold standard' for treating SUI." Id. at *7. As the opinions in Mullins and Herrera-Nevarez suggest, the relevance of Dr. Rosenzweig's testimony about alternative procedures turns in large part on state law. See also Tucker v. Ethicon, No. 4:20-CV-1543 RLW, 2021 WL 3910768, at *10 (E.D. Mo. Sept. 1, 2021) (applying Missouri law and denying Ethicon's motion to exclude Dr. Rosenzweig's opinion about alternative procedures); Bell, 2021 WL 1111071, at *6–7 (applying Texas law and denying Ethicon's motion to exclude Dr. Rosenzweig's opinion about alternative procedures). Here, the parties' briefing does not discuss South Dakota products liability law at all. Thus, this Court will reserve ruling on this issue until the parties adequately brief it, which can be done via motions in limine.

2. Opinions on Mechanical-Cut Mesh and Laser-Cut Mesh

Dr. Rosenzweig's expert report discusses problems with both mechanical-cut mesh and laser-cut mesh. Doc. 92-1 at 42–56. He opines that the mechanical-cut mesh is defective because it frays, ropes, curls, deforms, and loses particles, Doc. 92-1 at 42–54; and that the laser-cut mesh is defective because it too stiff and rigid, Doc. 92-1 at 54–56. Ethicon claims that Dr. Rosenzweig's testimony about mechanical-cut mesh is unreliable because it is not based on any studies. It also argues that Dr. Rosenzweig lacks the clinical experience necessary to provide reliable testimony about laser-cut mesh because he testified during a deposition that the laser-cut mesh likely came out after he stopped using mesh in his patients and that he could not recall whether he ever used the laser-cut mesh in the TVT devices. Doc. 92-7 at 2.

This Court agrees with other courts that "Dr. Rosenzweig's clinical experience with both laser-cut and mechanical-cut mesh is sufficient to satisfy the threshold reliability requirements of

Rule 702." Tucker, 2021 WL 3910768, at *11; see also Laderbush v. Ethicon, Inc., No. 20-CV-62-JD, 2020 WL 3001958, at *2 (D.N.H. June 4, 2020) (concluding that Dr. Rosenzweig could testify about laser-cut mesh based on his experience and rejecting Ethicon's argument that this testimony was inadmissible because he did not cite any supporting studies). Dr. Rosenzweig has performed over 300 mesh-removal surgeries, "a significant percentage" of which involved laser-cut mesh. Doc. 101-7 at 2; see McBroom v. Ethicon, Inc., No. CV-20-02127-PHX-DGC, 2021 WL 2709292, at *20 (D. Ariz. July 1, 2021) (finding that Dr. Rosenzweig's experience was "sufficient to satisfy the threshold reliability requirements of Rule 702" and rejecting Ethicon's argument that Dr. Rosenzweig's opinion was unreliable because he could not recall ever implanting laser-cut mesh).

Ethicon also argues that Dr. Rosenzweig's opinions on mechanical-cut mesh and laser-cut mesh are "unreliably inconsistent" because he criticizes both types of mesh. Doc. 93 at 4–5. This argument may be addressed on cross-examination, but it is not a basis for excluding Dr. Rosenzweig's opinions. Tucker, 2021 WL 3910768, at *11 ("That Dr. Rosenzweig finds issue with both methods of cutting mesh does not make his opinions fatally inconsistent or unreliable."); McBroom, 2021 WL 2709292, at *19 (rejecting Ethicon's argument that Dr. Rosenzweig's opinions on laser-cut mesh and mechanical-cut mesh are unreliably inconsistent); Heinrich v. Ethicon, Inc., No. 2:20-cv-00166-APG-VCF, 2021 WL 2290996, at *3 (D. Nev. June 4, 2021) ("Any inconsistencies in Dr. Rosenzweig's opinions about whether laser versus mechanically cut mesh are safer alternative designs to each other are matters for cross examination, not exclusion.").

3. Opinions on Warnings in the TVT's IFU

This Court grants Ethicon's motion to exclude Dr. Rosenzweig's opinions on warnings in the TVT's IFU. With no failure-to-warn claim, these opinions are not relevant. See Williams v.

Ethicon, Inc., No. 1:20-cv-04341-SDG, 2021 WL 857747, at *6 (N.D. Ga. Mar. 8, 2021) (holding that Dr. Rosenzweig's opinions on the adequacy of the warnings in the TVT's IFU were not relevant after the court granted summary judgment on the plaintiff's failure-to-warn claim).

H. Ethicon's Motion to Exclude the Testimony of Dr. Jerry Blaivas

Jerry Blaivas, M.D., is a board-certified urologist with extensive experience treating patients with complications from synthetic mesh sling surgery. Doc. 98-1 at 2–3. According to his report, he is "one of the pioneers of sling surgery for women with sphincteric incontinence." Doc. 98-1 at 2. Dr. Blaivas offered several opinions but only two need to be addressed here. Specifically, Dr. Blaivas opined that non-synthetic mesh procedures like the autologous facial sling are safer than mesh slings, Doc. 98-1 at 11–13, and described problems with both mechanical-cut mesh and laser-cut mesh, Doc. 98-1 at 18–20. Judge Goodwin reserved ruling on both issues, concluding that the relevance of Dr. Blaivas's opinion on alternative procedures should be decided case by case and that he needed more information to determine whether Dr. Blaivas's experience provided a reliable foundation for his opinions on alternative procedures and mechanical-cut mesh and laser-cut mesh.[7] Doc. 94-2 at 10–12. Ethicon now asks this Court to exclude Dr. Blaivas's opinions on alternative procedures and mechanical-cut mesh and laser-cut mesh.

1. Alternate Procedures

Ethicon argues that Dr. Blaivas's opinions that non-synthetic mesh surgical procedures are safer than the TVT is not relevant because an alternative method of treatment is not an alternative design that can support a design defect claim. Ethicon also claims that Dr. Blaivas's opinion is unreliable because it is "grounded on his unreliable perception of TVT complication rates" and his

[7]Judge Goodwin's order also ruled on other challenges Ethicon made to Dr. Blaivas's opinions. This Court adopts those rulings to the extent they are consistent with this opinion and order.

statements about the benefits of the autologous slings are based "solely on his own unreliable personal experiences." Doc. 95 at 4. Ethicon cites to several statements Dr Blaivas made during a September 2015 deposition to support its argument that his opinion about the benefits of the autologous slings is unreliable. Doc. 95 at 4–8. Foster responds by arguing that Ethicon ignores that Dr. Blaivas supplemented his expert report and gave additional deposition testimony in late August 2016. She asserts that Dr. Blaivas's August 2016 deposition testimony establishes that his opinion on alternative procedures is reliable. Doc. 98 at 5–6. Ethicon counters by moving to strike Dr. Blaivas's August 2016 deposition, arguing that it was an ex parte deposition taken without proper notice and improper under the MDL court's protocol. Docs. 110, 111.

This Court denies Ethicon's motion to strike Dr. Blaivas's August 2016 deposition. Judge Goodwin in the MDL denied an identical motion raising the same arguments Ethicon makes now. Docs. 119-1, 119-3. Allowing the parties to relitigate issues already decided by Judge Goodwin would be inefficient and would undermine a main purpose of the MDL process. See 28 U.S.C. § 1407 ("[T]ransfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions."); 15 Richard D. Freer, Federal Practice and Procedure § 3867 (4th ed.) (explaining that a refusal to follow the MDL court's previous ruling "would result in the sort of piecemeal decision making that MDL centralization is intended to avoid"). This Court will reserve ruling on the relevance and reliability of Dr. Blaivas's opinion that non-synthetic mesh procedures are safter than mesh slings.[8] As with the briefing on Dr. Rosenzweig, the parties do not discuss South Dakota products liability law at all when arguing

[8]Unlike with Dr. Blaivas, Ethicon did not challenge the reliability of Dr. Rosenzweig's testimony about alternative procedures being safer than its mesh products. Doc. 92-2 at 9.

about the relevance of Dr. Rosenzweig's opinion. The parties may address this issue via motions in limine.

2. Opinions on Mechanical-Cut Mesh and Laser-Cut Mesh

Similar to Dr. Rosenzweig, Dr. Blaivas opines that mechanical-cut mesh and laser-cut mesh each present unique problems. He opines that mechanical-cut mesh can fray, deform, and lose particles, while laser-cut mesh is stiff and rigid. Doc. 98-1 at 18–20. Ethicon argues that these opinions should be excluded as unreliable and inconsistent. Ethicon can address its argument on inconsistency through cross-examination. See Tucker, 2021 WL 3910768, at *11; McBroom, 2021 WL 2709292, at *19; Heinrich, 2021 WL 2290996, at *3. However, this Court reserves ruling on whether Dr. Blaivas's experience with laser-cut mesh and mechanical-cut mesh satisfies the threshold reliability requirements of Rule 702. True, this Court found that Dr. Rosenzweig's experience satisfied Rule 702's reliability requirement. And Dr. Blaivas has operated on "about 75–100 patients with severe synthetic mesh complications." Doc. 98-1 at 3. Unlike with Dr. Rosenzweig, however, Foster has not pointed to any statements by Dr. Blaivas that he operated on patients implanted with the TVT or that he saw some of the problems discussed when he used or removed laser-cut mesh and machine-cut mesh. See Doc. 92-1 at 44; Doc. 101-7 at 2–3. Dr. Blaivas may very well have the necessary experience to testify about laser-cut mesh and machine cut-mesh, but this Court lacks the information to decide that issue now.

III. Conclusion

For the reasons stated above, it is hereby

ORDERED that Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Michael Fiegen, Doc. 79, is granted to the extent set forth above. If is further

ORDERED that Plaintiffs' Motion to Exclude the General Opinion Testimony of Robert M. Rogers, Doc. 81, is granted in part as set forth above. It is further

ORDERED that Plaintiffs' Motion to Exclude the Opinions of FDA Expert Timothy Ulatowski, Doc. 83, is granted to the extent set forth above. It is further

ORDERED that Plaintiffs' Motion to Exclude the General Causation Opinions of Defense Expert Michael P. Woods, Doc. 85, is granted to the extent set forth above. It is further

ORDERED that Ethicon's Motion to Exclude Peggy Pence, Doc. 87, is granted in part and denied in part as set forth above. It is further

ORDERED that Ethicon's Motion to Preserve Objections to the Opinions and Testimony of Dr. Jimmy W. Mays, Doc. 89, is denied to the extent that it seeks a different ruling than rendered in the MDL. It is further

ORDERED that Ethicon's Motion to Exclude Certain General Opinions of Bruce Rosenzweig, Doc. 92, is granted in part and denied in part as set forth above. It is further

ORDERED that Ethicon's Motion to Exclude Certain General Opinions of Jerry Blaivas, Doc. 94, is denied to the extent set forth above. It is finally

ORDERED that Ethicon's Motion to Strike August 29, 2016 Deposition of Jerry Blaivas, Doc. 110, is denied.

DATED this 30th day of September, 2021.

BY THE COURT:

/s/ Roberto A. Lange

ROBERTO A. LANGE
CHIEF JUDGE