IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

DANA MEADE, *et al.* **PLAINTIFF**

v. **Case No. 4:20-cv-00694-KGB**

ETHICON, INC., *et al.* **DEFENDANTS**

ORDER

Before the Court is a motion to limit the case-specific opinions and testimony of Konstantin Walmsley, M.D., and a motion to limit the opinions of pathologist Elizabeth A. Laposata, M.D., filed by defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (collectively, "Ethicon") (Dkt. Nos. 39; 41). Plaintiffs Dana Meade and Glen Meade (collectively, "the Meades") have responded in opposition to Ethicon's two motions (Dkt. Nos. 43; 44).

For the following reasons, the Court grants in part and denies in part defendants' motion to limit the case-specific opinions and testimony of Dr. Walmsley (Dkt. No. 39), and the Court denies defendants' motion to limit the opinions of pathologist Dr. Laposata (Dkt. No. 41). As to those matters about which the Court grants an *in limine* motion, all parties, their counsel, and witnesses are directed to refrain from making any mention through interrogation, *voir dire* examination, opening statement, arguments or otherwise, either directly or indirectly, concerning the matters about which the Court grants an *in limine* motion, without first approaching the bench and obtaining a ruling from the Court outside the presence of all prospective jurors and the jurors ultimately selected to try this case. Further, all counsel are required to communicate this Court's rulings to their clients and witnesses who may be called to testify in this matter.

I. Background

The Meades filed suit in this case against defendants on September 27, 2013 (Dkt. No. 1). This case was originally filed in the United States District Court for the Southern District of West Virginia and was related to Multi-District Litigation 2327 ("Ethicon MDL"), 2:12-md-2327, one of seven MDLs assigned to United States District Judge Joseph R. Goodwin by the Judicial Panel on Multidistrict Litigation and totaling over 100,000 cases since inception (Dkt. Nos. 1; 48, at 1; 49-1). The Ethicon MDL includes as plaintiffs women who had one or more of defendants' pelvic mesh products inserted into their bodies to treat medical conditions, primarily pelvic organ prolapse and stress urinary incontinence (Dkt. No. 49-1, ¶ 1). Plaintiffs to the Ethicon MDL also include the spouses and intimate partners of the aforesaid women, as well as others with standing to file claims arising from defendants' products (*Id.*, ¶ 2). Plaintiffs filed suit directly in the Ethicon MDL on September 27, 2013, but served Ethicon on June 7, 2013, pursuant to a delayed filing agreement (Dkt. Nos. 1; 2). On May 14, 2020, Judge Goodwin entered a transfer order transferring 35 cases from the Ethicon MDL to various appropriate jurisdictions (Dkt. No. 48). Judge Goodwin concluded that transferring these 35 cases to the venues from which they arose would better convenience the parties and promote the final resolution of these cases (*Id.*, at 1). As a result, Judge Goodwin transferred the Meades' case to this Court (*Id.*, at 4).

Ms. Meade had a pelvic mesh product called a TVT-Obturator ("TVT-O") implanted on August 14, 2012, to treat stress urinary incontinence, cystocele, and rectocele by Charles McKnight, M.D., in Little Rock, Arkansas (Dkt. Nos. 1, ¶¶ 8-12; 35-1, at 4). Ms. Meade had the TVT-O partially removed on November 27, 2012, by Robert Summit, M.D., at Baptist Memorial Hospital for Women in Memphis, Tennessee, and Ms. Meade had an additional portion of the TVT-O removed on November 7, 2014, by Dionysios Veronikis, M.D., at Mercy Hospital St.

Louis (Dkt. No. 35-1, at 5). Plaintiffs allege that Ms. Meade suffered a variety of bodily injuries resulting from the implantation of the TVT-O, including: exposed sling mesh; pelvic pain; vaginal mesh erosion; dyspareunia; bladder lesion; bladder mesh erosion; infection; urinary urgency/frequency; recurrent incontinence; bowel problems; organ perforation; fistulae; bleeding; neuromuscular problems; vaginal scarring; hematuria; bladder spasms; dysuria; urinary tract infection; and cystitis (*Id.*). Plaintiffs claim that Ms. Meade started experiencing symptoms attributable to the TVT-O in August 2012, but Ms. Meade did not associate those symptoms with the TVT-O until November 2012 (*Id.*, at 6).

Plaintiffs were residents of Arkansas at the time of Ms. Meade's implantation surgery and remained residents through July 2013 (Dkt. No. 36, at 3). Plaintiffs subsequently moved to Punta Gorda, Florida, from July 2013 through August 2014 (*Id.*). In August 2014, plaintiffs moved to Heber Springs, Arkansas (*Id.*). Ms. Meade separated from Mr. Meade in March 2015, and the two subsequently divorced (*Id.*). Ms. Meade moved to Florence, Alabama, in March 2015, and Ms. Meade moved again to Highlands, California, in March 2016 (*Id.*).

In their complaint, plaintiffs assert against defendants, among other claims: Count I – Negligence (apart from negligent manufacturing defect); Count III – Strict Liability – Failure to Warn; and Count V – Strict Liability – Design Defect (Dkt. Nos. 1, ¶ 13; 95).

II. Legal Standard

Federal Rule of Evidence 702 provides that:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (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

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

Fed. R. Evid. 702. "Rule 702 reflects an attempt to liberalize the rules governing the admission of expert testimony. The rule clearly is one of admissibility rather than exclusion." *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001) (internal quotations and citations omitted).

In determining whether expert testimony should be admitted, the district court must decide if the expert's testimony and methodology are reliable, relevant, and can be applied reasonably to the facts of the case. *David E. Watson, P.C. v. United States*, 668 F.3d 1008, 1015 (8th Cir. 2012); *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010). Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the district court must conduct this initial inquiry as part of its gatekeeping function. *Watson*, 668 F.3d at 1015. The Court must be mindful that "*Daubert* does not require proof with certainty." *Sorensen By & Through Dunbar v. Shaklee Corp.*, 31 F.3d 638, 650 (8th Cir. 1994). Rather, it requires that expert testimony be reliable and relevant. *Id.* "The inquiry as to the reliability and relevance of the testimony is a flexible one designed to 'make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'" *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

The proponent of the expert testimony has the burden of establishing by a preponderance of the evidence the admissibility of the expert's testimony. *Id.* at 757-58. To satisfy the reliability requirement for admission of expert testimony, "the party offering the expert testimony must show by a preponderance of the evidence that the expert is qualified to render

the opinion and that the methodology underlying his conclusions is scientifically valid." *Barrett*, 606 F.3d at 980 (internal quotation marks and citation omitted). To satisfy the relevance requirement for the admission of expert testimony, "the proponent must show that the expert's reasoning or methodology was applied properly to the facts at issue." *Id.* (citing *Marmo*, 457 F.3d at 757).

The Court examines the following four non-exclusive factors when determining the reliability of an expert's opinion: (1) "whether it can be (and has been) tested"; (2) "whether the theory or technique has been subjected to peer review and publication"; (3) "the known or potential rate of error"; and (4) "[the method's] 'general acceptance.'" *Presley v. Lakewood Eng'g & Mfg. Co.*, 553 F.3d 638, 643 (8th Cir. 2009) (quoting *Daubert*, 509 U.S. at 593-94). These factors are not exhaustive or limiting, and the Court must use the factors as it deems fit to tailor an examination of the reliability of expert testimony to the facts of each case. *Id.* In addition, the Court can weigh whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case. *Id.* While weighing these factors, the Court must continue to function as a gatekeeper who separates expert opinion evidence based on good grounds from subjective speculation that masquerades as scientific knowledge. *Id.*

The Court recognizes that experts may, at times speculate, "but too much [speculation] is fatal to admission." *Grp. Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8th Cir. 2003) (citations omitted). Thus, speculative expert testimony with no basis in the evidence is inadmissible. *Weisgram v. Marley Co.*, 169 F.3d 514, 518-19 (8th Cir. 1999), *aff'd*, 528 U.S. 440 (2000) (reversing a district court for allowing a witness who was qualified as a fire investigator

"to speculate before the jury as to the cause of the fire by relying on inferences that have absolutely no record support").

Likewise, expert opinion is inadmissible if its sole basis is studies that do not provide a sufficient foundation for the opinion. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 145 (1997). When studies form a basis for an expert's opinion, then, the Court must determine if there is an adequate basis for the experts' opinion and whether there is "too great an analytical gap between the data and the opinion proffered." *See id.* at 146.

"As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929 (8th Cir. 2001) (internal citation omitted). "Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Id.* at 929-30 (quoting *Hose v. Chi. Nw. Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1996)).

In this Order, the Court focuses on arguments made, and rules on objections raised, pursuant to Rule 702. The Court reserves ruling on any other objections to the anticipated testimony until the time of trial. The parties may make contemporaneous objections at trial.

III. Ethicon's Motions To Exclude Expert Testimony

Ethicon moves the Court to exclude expert testimony of Dr. Walmsley and Dr. Laposata pursuant to Federal Rule of Evidence 702 and the standards set forth in *Daubert* and its progeny (Dkt. Nos. 39; 41).[1] Though Ethicon's two motions are similar, the Court will discuss and consider them separately.

[1] When Ethicon filed these motions, this case was still before Judge Goodwin as a part of the Ethicon MDL. As a result, Ethicon's arguments in favor of these motions and the Meades' arguments in response rely heavily on case law and precedent from the United States Court of

A. Defendants' Motion To Limit The Case-Specific Opinions And Testimony Of Dr. Walmsley

Defendants move to exclude certain case-specific testimony and opinions offered by Dr. Walmsley (Dkt. No. 39, at 1). Specifically, defendants move for the Court to preclude Dr. Walmsley from offering the following expert testimony and opinions at trial in this case: (1) general causation opinions, including opinions regarding complications not experienced by Ms. Meade; (2) opinions regarding Ethicon's state of mind, corporate conduct, and marketing; (3) opinions containing legal conclusions, standards, and terms of art; (4) opinions regarding Ethicon's warnings for the TVT-O device, as well as opinions regarding informed consent; and (5) opinions regarding allegedly safer alternatives for the treatment of stress urinary incontinence (Dkt. No. 40, at 1-2).

1. Dr. Walsmley's Opinions And Testimony

Dr. Walmsley is a board-certified urologist and a licensed physician in the State of New Jersey, and the Court has reviewed Dr. Walsmley's expert report (Dkt. No. 39-1, at 1-21). In his report, Dr. Walmsley "offers his opinions on causative factors of Ms. Meade's vaginal pain, dyspareunia, pelvic pain, infection, voiding dysfunction, urinary urgency, urgency urinary incontinence, leg pain, urethral scarring, recurrent urinary tract infections, nerve entrapment syndrome, and chronic mesh pain syndrome" (Dkt. No. 44, at 1-2). Dr. Walmsley's opinions are based on his review of medical records, his extensive clinical experience treating women like Ms. Meade, his education and training, and his knowledge of the relevant medical literature (*Id.*, at 2).

Appeals for the Fourth Circuit and district courts therein (Dkt. Nos. 39; 40; 41; 43; 44). On July 28, 2020, the parties submitted a joint status report stating, in part, that these two *Daubert* motions are ready to be ruled upon by this Court (Dkt. No. 85, at 8-9). Accordingly, the Court has considered the factual arguments raised in these motions and will assess those arguments in the light of case law and precedent from the United States Court of Appeals for the Eighth Circuit and district courts therein.

Dr. Walmsley opines that Ms. Meade should not have been implanted with Ethicon's TVT-O "because the poor design of the device increased the risk of serious complications and caused her specific complications" (Dkt. No. 39-1, at 11). Dr. Walmsley opines that Ethicon's construction mesh used in the TVT-O is not suitable for its intended application as permanent prosthetic implants for stress urinary incontinence because the pore size changes post-implantation, its heavy weight, its degradation over time, and its ability to cause chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, biofilm formation, and infections (*Id.*, at 11-12). Dr. Walmsley opines that Ethicon knew that its TVT-O was not appropriate for use but failed to modify or change the mesh to make it more suitable "because of its economic interest in maintaining its competitive advantage in the market," according to Ethicon's internal documents (*Id.*, at 12). Dr. Walmsley opines that the TVT-O "has design flaws because they cannot adequately describe, inform, or explain to physicians how to properly 'tension' the device" and because "the devices shrink, contract, rope, and curl making it difficult or impossible to tension in a safe manner for patients" (*Id.*). Dr. Walmsley opines that "Ethicon's meshes are not suitable for permanent implant because the Material Safety Data Sheet ('MSDS') for the polypropylene resin used to manufacture Ethicon's polypropylene states that its polypropylene is incompatible with strong oxidizers such as peroxides which are readily found in the vagina" (*Id.*). Dr. Walmsley opines that Ethicon's mesh devices are "not suitable for permanent implant because the toxicity testing of the polypropylene mesh revealed that it was cytotoxic which can cause cell death and complications" (*Id.*). Dr. Walmsley opines that "Ethicon's warnings and disclosures of adverse events in their Instructions for Use ('IFU') for these devises have been inadequate based on the adverse reactions and risks associated with them that have been known to Ethicon from the time these devices were first sold and marketed" and that "Ethicon did not

disclose information to physicians in their IFU regarding characteristics of their devices that makes them unsuitable for their intended application as a permanent prosthetic implant for pelvic floor repair" (*Id.*, at 13). Dr. Walmsley opines that "[t]he design of these devices are flawed because they are not designed for special patient populations, nor does the IFU nor marketing documents inform physicians that certain patients will have poorer outcomes and higher risks" (*Id.*). Dr. Walmsley opines that "Ethicon failed to reveal material facts about complication and conflicts of interest regarding key studies in key marketing documents" (*Id.*). Dr. Walmsley opines that "[t]he benefits of these mesh products are outweighed by the severe, debilitating, and life[-]changing complications associated with them and there were safer alternative options available" (*Id.*). Summarizing these opinions, Dr. Walmsley opines that "[a]s a result of the defects in these meshes, [Ms.] Meade suffered and continues to suffer life-long injuries" (*Id.*). Of additional relevance, Dr. Walmsley also opines that Dr. McKnight's treatment of Ms. Meade met the standard of care and that the pre-operative evaluations of Ms. Meade met the standard of care (*Id.*, at 13-14).

Based on Dr. Walmsley's review of the entire body of literature, his experience, his review of Ms. Meade's medical records, and the deposition testimony provided to him by counsel, "it is [his] opinion, to a reasonable degree of medical certainty, [Ms.] Meade would not have developed the aforementioned symptoms, or the need to undergo additional treatments to the extent that she has, had the Ethicon [TVT-O] never been implanted" (*Id.*, at 17). Dr. Walmsley opines that "there were reasonably feasible alternatives available to Ethicon's mesh devices" for the treatment of Ms. Meade that "would have been a safer alternative to the Ethicon mesh implanted in Ms. Meade" (*Id.*). Dr. Walmsley opines that "[i]f any of these safer alternative designs [had] been used for Ms. Meade, she would not have suffered the injuries [Dr. Walmsley] set forth in [his] report, as her injuries were caused by the specific design flaws of the Ethicon [TVT-O] device" (*Id.*, at 18).

2. Application Of Rule 702 To Dr. Walmsley's Opinions And Testimony

Defendants argue that the Court should exclude Dr. Walmsley's general causation opinions offered in his case-specific report (Dkt. No. 40, at 3-6). Defendants argue that Dr. Walmsley has not been designated as a general causation expert, that Dr. Walmsley offers no foundation for the general causation opinions offered in his case-specific report, and that general causation opinions regarding complications not experienced by Ms. Meade are irrelevant (*Id.*). Defendants maintain that the Court should exclude Dr. Walmsley's case-specific opinions regarding corporate knowledge, state of mind, conduct, and marketing (*Id.*, at 6-7). Defendants argue that the Court should exclude Dr. Walmsley's opinions containing legal conclusions and legal terms of art (*Id.*, at 7). Defendants argue that the Court should exclude Dr. Walmsley's opinions regarding Ethicon's warnings and informed consent because Dr. Walmsley is not qualified to offer opinions regarding the adequacy of the TVT-O IFU and because Dr. Walmsley's opinions regarding the informed consent process are irrelevant and contain improper state of mind opinions (*Id.*, at 8-10). Finally, defendants argue that the Court should limit Dr. Walmsley's opinions regarding safer alternative treatments and procedures (*Id.*, at 10-14). Defendants assert that Dr. Walmsley's opinions regarding safer alternatives are irrelevant and unreliable, that Dr. Walmsley's opinion that erosion/extrusion does not occur in the absence of mesh is unreliable, and that Dr. Walmsley's opinion that a sling constructed out of Ultrapro mesh constitutes a safer alternative is unreliable (*Id.*, at 11-14).

In response, the Meades argue that Dr. Walmsley can opine on "most common" complications related to the TVT-O (Dkt. No. 44, at 3). The Meades assert that Dr. Walmsley will not testify regarding Ethicon's corporate knowledge, state of mind, or corporate conduct (*Id.*, at 3-4). The Meades assert that Dr. Walmsley's opinions do not contain legal conclusion or terms of

art and are relevant and admissible (*Id.*, at 4). The Meades assert that Dr. Walmsley's opinions will inform the jury on the risks contained in the IFU when Ms. Meade was implanted with the TVT-O (*Id.*, at 5-6). Finally, the Meades argue that Dr. Walmsley's opinion that safer alternative designs existed at the time of Ms. Meade's implant is relevant and admissible (*Id.*, at 6-8).

The Court understands that Dr. Walmsley is not being offered as a general causation expert; to the extent defendants attempt to characterize him as such and challenge his opinions as "general causation opinions," the Court rejects that characterization. The Court understands that plaintiffs intend to offer Dr. Walmsley as a case-specific expert, and the Court understands Dr. Walmsley's opinions to be case-specific. Dr. Walmsley directly relates his opinions to Ms. Meade's care and treatment, and Ms. Meade has experienced most of the complications that Dr. Walmsley mentions. Additionally, the Court understands Dr. Walmsley's case-specific opinions to be properly supported. Dr. Walmsley provides his background, education, training, and experience; notes his review of the scientific literature, corporate documents from Ethicon, and other case-specific materials; details Ms. Meade's medical records and medical history; and describes his use of differential diagnosis and differential etiology methodology to "rule in" potential causes of Ms. Meade's injuries and, by process of elimination, "rule out" the least likely causes to arrive at the most likely cause. Thus, to the extent defendants attempt to claim Dr. Walmsley is an improperly presented general causation expert and that the entirety of his testimony should be excluded on this basis, the Court rejects defendants' attempt.

Defendants are correct that expert testimony regarding Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics would not be appropriate subjects of expert testimony because opinions on these matters will not assist the jury. However, the Meades insist that "Dr. Walmsley only intends to testify as to Ethicon corporate documents at trial for the purpose

of explaining how the results of Ethicon's internal studies are consistent with his opinions in this case" (Dkt. No. 44, at 3-4). The Court grants defendants' motion to the extent that this Court will not permit Dr. Walmsley to testify to Ethicon's knowledge, state of mind, or other matters of this sort, but the Court does not understand Dr. Walmsley's report to suggest that he intends to offer such testimony at trial. The Court will not prohibit under Rule 702 Dr. Walmsley from testifying at trial as to Ethicon's corporate documents for the purpose of explaining his case-specific expert opinions, specifically as the Meades suggest "how the results of Ethicon's internal studies are consistent with this opinions in this case." (Dkt. No. 44, at 4). To the extent defendants challenge this anticipated testimony on grounds other than Rule 702, defendants may raise contemporaneous objections to such testimony at trial, and the Court will rule at that time.

As to defendants' contention that Dr. Walmsley's opinions contain legal conclusions and legal terms of art, expert testimony regarding legal matters is inadmissible. *See S. Pine Helicopters, Inc. v. Phoenix Aviation Mangers, Inc.*, 320 F.3d 838, 841 (8th Cir. 2003); *Williams v. Wal-Mart Stores, Inc.*, 922 F.2d 1357, 1360 (8th Cir. 1990). Insofar as Dr. Walmsley imposes legal duties on defendants or applies a standard of reasonable care to defendants in order to testify that they breached that standard, such testimony represents legal conclusions and analysis improper for expert testimony. To the extent Dr. Walmsley intends to offer such testimony, the Court grants defendants' motion and excludes such testimony pursuant to Rule 702.

The Meades maintain that Dr. Walmsley's opinions related to Ethicon's alleged failure to act are admissible as they go to the reasonableness of Ethicon's actions in the light of the legal obligation to warn adequately and label products pursuant to federal regulations. To the extent Dr. Walmsley intends to testify regarding Ethicon's warnings as communicated in the TVT-O's IFU, the Court does not consider Dr. Walmsley qualified to offer such opinions. As an initial matter,

the Court notes that Dr. Walmsley has previously been excluded from offering opinions regarding whether a particular "IFU should have included warnings about particular complications," because "Dr. Walmsley 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." *In re: Ethicon, Inc.*, MDL No. 2327, 2016 WL 4961675, at *3 (S.D. W. Va. Aug. 25, 2016). Nothing in the record indicates that Dr. Walmsley has any experience in drafting IFUs for medical devices, improving existing warnings, preparing alternatives for medical devices, or reviewing the warning labels of similar products. Instead, the Meades have presented no relevant experience Dr. Walmsley possesses with respect to warnings of any kind. While Dr. Walmsley has demonstrated his competency to testify about the risks associated with TVT-Os and related devices, that expertise does not equate to expertise regarding the product IFUs and the adequacy of the warning information contained therein. To the extent Dr. Walmsley intends to offer such testimony, the Court grants defendants' motion and excludes such testimony pursuant to Rule 702.

Additionally, while Dr. Walmsley's opinions regarding the informed consent process would typically be relevant and admissible given that Dr. Walmsley is a practicing urologist with ample experience implanting mid-urethral mesh and non-mesh slings, the Court agrees with defendants that such testimony here would operate to provide a restated opinion that Ethicon's warnings for the TVT-O were inadequate. Dr. Walmsley's proposed testimony opines that Dr. McKnight could not obtain informed consent because of Ethicon's allegedly inadequate warnings. The Meades have failed to meet their burden to demonstrate by a preponderance of the evidence that Dr. Walmsley is qualified to offer expert testimony on the adequacy of defendants' warnings or informed consent in the specific context of Dr. Walmsley's expert opinions before the Court. Accordingly, defendants' motion to exclude Dr. Walmsley's opinions and testimony on the

adequacy of defendants' warnings and the informed consent process will be granted pursuant to Rule 702.

Finally, to the extent defendants challenge Dr. Walmsley's opinions regarding safer alternative treatments and procedures, the Court denies defendants' motion. As a practicing urologist who has implanted both mesh and non-mesh slings, Dr. Walmsley is qualified to educate the jury on alternative procedures that were available to Ms. Meade and that were possibly safer options. The Court will not exclude this anticipated testimony pursuant to Rule 702. To the extent defendants challenge this anticipated testimony on grounds other than Rule 702, defendants may raise contemporaneous objections to such testimony at trial, and the Court will rule at that time.

For the foregoing reasons, consistent with the terms of this Order, the Court grants in part and denies in part defendants' motion to limit the case-specific opinions and testimony of Dr. Walmsley (Dkt. No. 39).

B. Defendants' Motion To Limit The Opinions Of Pathologist Dr. Laposata

Defendants move to limit the opinions of Dr. Laposata (Dkt. No. 41). Specifically, defendants ask the Court to preclude Dr. Laposata from providing general causation opinions and preclude as beyond her qualifications opinions regarding biomechanical "changes" of mesh in the body, such as degradation, and pain (*Id.*, at 1). At the time this motion was filed, defendants had not yet deposed Dr. Laposata and reserved the right to supplement this motion following her deposition (*Id.*). Shortly thereafter, defendants deposed Dr. Laposata on October 17, 2019 (Dkt. Nos. 47; 85, at 6). Defendants have not supplemented this motion, and the parties maintain that this motion is ripe for consideration (*Id.*, at 9).

1. Dr. Laposata's Opinions And Testimony

Dr. Laposata is a forensic pathologist with prior experience as a medical examiner, and the Court has reviewed Dr. Laposata's expert report (Dkt. No. 41-2). Dr. Laposata "was asked to examine the surgical pathology slides prepared from tissues and materials removed from [Ms. Meade] to determine whether the specimens reveal abnormal tissue reactions and, if so, to determine the cause(s)" (*Id.*, at 3). Dr. Laposata was also "asked to identify the anatomic, physiologic, and pathologic events that resulted in the production of clinical signs and symptoms observed by the treating physician(s) and experienced by" Ms. Meade (*Id.*). Dr. Laposata's review of the above-referenced slides and the relevant literature led her to conclude that the "histologic picture" in this case "is consistent with the adverse tissue effects of mesh" (*Id.*, at 16). Dr. Laposata opines that "[n]erve distortion and compression by mesh-associated fibrosis produced Ms. Meade's pelvic and urethra pain" (*Id.*). Dr. Laposata opines that "[t]he bridging fibrosis causes mesh contraction and the potential for mesh migration through tissue and filament erosion through mucosal surfaces as [Ms. Meade] experienced in her bladder" (*Id.*). Dr. Laposata opines that "[t]he presence of skeletal muscle fibers, some with evidence of degeneration, causes pelvic muscular dysfunction and confirms mesh migration" (*Id.*). Dr. Laposata further opines that "[c]hronic inflammation with foreign body giant cell formation indicated continued, ongoing tissue irritation by the implanted mesh" (*Id.*).

Based on these conclusions, Dr. Laposata opines that "to a reasonable degree of medical certainty that the complications and injuries suffered by Ms. Meade, including erosion, dyspareunia, pain at the urethra, pelvic pain, groin pain and urinary retention are consistent with my pathological findings and were a result of the mesh and associated tissue changes caused by the mesh" (*Id.*, at 17). Dr. Laposata opines that "[a]ll abnormalities in the tissue were related to the mesh and there was no other evidence of alterations or abnormalities in the tissues" (*Id.*). In

coming to these opinions, Dr. Laposata "considered and ruled out Ms. Meade's prior medical and surgical conditions such as degenerative disc disease, fibromyalgia, mitral valve prolapse, right ovarian cystectomy, appendectomy, and bilateral tubal ligation as potential causes of her complications and symptoms" (*Id.*).

2. Application Of Rule 702 To Dr. Laposata's Opinions And Testimony

Ethicon asserts that this Court should limit the opinions of Dr. Laposata for three primary reasons: (1) she is not qualified to opine as to supposed changes in the mesh after implantation; (2) she is not qualified to offer opinions regarding Ms. Meade's pain; and (3) she improperly offers general causation opinions (Dkt. No. 41, at 2-4).

On the first point, Ethicon states that Dr. Laposata opines throughout her report that polypropylene mesh degrades and that degraded mesh can cause problems in patients; however, Ethicon asserts that Dr. Laposata has previously admitted that she is not an expert in mesh degradation (Dkt. Nos. 41, at 2; 41-2, at 4-17, 12, 16-17; 41-3, at 3-4). Thus, Ethicon asserts that Dr. Laposata's opinions regarding mesh degradation are outside her area of expertise and that she lacks any specialized knowledge about mesh degradation (Dkt. No. 41, at 2-3). Dr. Laposata is a board-certified pathologist with over 30 years of experience examining tissue from various parts of the human body to identify and determine the cause of injuries, diseases, and death and with extensive recognition and achievements in the field (Dkt. No. 43, at 4-5). Based upon the materials presented in support of plaintiffs' response to this motion, Dr. Laposata's work, training, and the literature for her field qualify her to opine on the possibly degraded mesh in bodily tissue and the properties of that mesh. Dr. Laposata studies and works with the interaction between implanted materials and human tissue, and the Court considers Dr. Laposata's opinions on this issue admissible pursuant to Rule 702.

On the second point, Ethicon asserts that Dr. Laposata, as a forensic pathologist with experience as a medical examiner, is not qualified to offer opinions regarding pain and suffering (*Id.*, at 3). Dr. Laposata is not a clinical physician, and she does not treat or otherwise manage pain of living patients (*Id.*). Thus, Ethicon asserts that there is no evidence that Dr. Laposata is qualified to opine regarding pain (*Id.*). However, the Court considers it within the expertise of a pathologist to opine as to pain. Dr. Laposata studies human tissue and determines cause of injuries and diseases, and Dr. Laposata both works as a pathologist and teaches medical students in a diagnostic lab. The Court considers Dr. Laposata's opinions on the issue of pain to be admissible pursuant to Rule 702.

On the third point, Ethicon asserts that Dr. Laposata's general opinions go beyond her designation as a case-specific expert and should be excluded on that basis alone (*Id.*). Further, Ethicon argues that Dr. Laposata's general opinions as to some "changes" in the mesh that she believes can occur—including degradation, movement stress shielding, infection, and mesh folding—and the symptoms that can be caused by these changes are not relevant to her analysis of Ms. Meade's case as these changes and symptoms were not experienced by Ms. Meade (*Id.*, at 4). Based upon the Court's review, Dr. Laposata does not hold herself out as a general causation expert. Instead, the Court acknowledges that Dr. Laposata's report does offer some general background on the basic science and pathology of tissue reaction to foreign biomaterials and descriptions of changes in tissue after mesh implantation. However, Dr. Laposata provides this general information to then show how this information correlates with physical symptoms of the sort Ms. Meade experienced and to provide a basis upon which her case-specific opinions are founded. The Court considers Dr. Laposata's opinions to accord with her role as a case-specific expert in this matter, and those case-specific opinions are admissible pursuant to Rule 702.

For the foregoing reasons, the Court denies defendants' motion to limit the opinions of pathologist Elizabeth A. Laposata, M.D. (Dkt. No. 41).

IV. Conclusion

Accordingly, consistent with the terms of this Order, the Court grants in part and denies in part defendants' motion to limit the case-specific opinions and testimony of Dr. Walmsley (Dkt. No. 39). The Court denies defendants' motion to limit the opinions of pathologist Dr. Laposata (Dkt. No. 41). As to those matters about which the Court grants an *in limine* motion, all parties, their counsel, and witnesses are directed to refrain from making any mention through interrogation, *voir dire* examination, opening statement, arguments or otherwise, either directly or indirectly, concerning the matters about which the Court grants an *in limine* motion, without first approaching the bench and obtaining a ruling from the Court outside the presence of all prospective jurors and the jurors ultimately selected to try this case. Further, all counsel are required to communicate this Court's rulings to their clients and witnesses who may be called to testify in this matter.

It is so ordered this 2nd day of November, 2020.

Kristine G. Baker
United States District Judge