IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

DENISE PITLYK, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 20-cv-00886-SRB
	)	
ETHICON, INC., et al.,	)	
	)	
Defendants.	)	

ORDER

Before the Court is Plaintiff Denise Pitlyk ("Ms. Pitlyk") and William Pitlyk's (collectively, the "Plaintiffs") Amended Motion to Exclude Certain Opinions and Testimony of John R. Wagner, M.D. (Doc. #44). For the reasons set forth below, the motion is DENIED.

I. BACKGROUND

Plaintiffs are residents of Missouri. On December 19, 2006, Ms. Pitlyk underwent implantation of a TVT-Secur ("TVT-S") pelvic mesh device to treat stress urinary incontinence. The TVT-S was sold, manufactured, and/or designed by Defendants Ethicon, Inc. and Johnson & Johnson (collectively, the "Defendants"). Dr. John McCarthy performed the surgery in Chesterfield, Missouri. The mesh device allegedly caused various injuries to Ms. Pitlyk, including "severe pelvic floor pain, systemic pain, blood in urine . . . and chronic and severe fatigue." (Doc. #38-1, p. 6.) Ms. Pitlyk subsequently had two surgeries to remove or revise mesh.

On December 30, 2014, Plaintiffs directly filed suit in a multidistrict litigation ("MDL") case related to allegedly defective TVT-S products. Plaintiffs' Short Form Complaint asserts the following claims against Defendants: negligence (Count I); strict liability – manufacturing

defect (Count II); strict liability – failure to warn (Count III); strict liability – defective product (Count IV); strict liability – design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); unjust enrichment (Count XV); loss of consortium (Count XVI); punitive damages (Count XVII); and discovery rule and tolling (Count XVIII). (Doc. #1, pp. 4-5.) On or about June 17, 2020, this case was remanded from the MDL court to this Court for further proceedings. (Doc. #49.)

Plaintiffs now move to preclude certain opinions offered by Defendants' general and case-specific expert, Dr. John R. Wagner. Plaintiffs argue that Dr. Wagner's opinions are not admissible under Federal Rules of Evidence 702 and 703, and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Defendants oppose the motion, and the parties' arguments are addressed below.

II. LEGAL STANDARD

Federal Rule of Evidence 702 governs the admission of expert testimony. *See* Fed. R. Evid. 702; *Wagner v. Hesston Corp.*, 450 F.3d 756, 758 (8th Cir. 2006). Rule 702 provides that a "witness who is qualified as an expert . . . may testify in the form of an opinion or otherwise if:

> (a) the expert's . . . 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(a)-(d). Federal Rule of Evidence 703 provides in part that "[a]n expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703.

To fulfill its "gatekeeping" role, a court faced with a proffer of expert testimony must determine at the outset whether the evidence "both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. *Daubert* emphasized that the inquiry required by Rule 702 is intended to be flexible. *Id.* at 594. "The proponent of the expert testimony must prove its admissibility by a preponderance of the evidence." *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001).

Due to the liberalization of expert testimony admission standards signaled by *Daubert* and its progeny, and the codification of this trend in Rule 702, the Eighth Circuit has held that expert testimony should be liberally admitted. *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 562 (8th Cir. 2014) ("*Daubert* and Rule 702 thus greatly liberalized what had been the strict . . . standards for admission of expert scientific testimony."); *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) ("A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.") (citations and quotations omitted). As long as the expert testimony "rests upon good grounds, based on what is known, it should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded by the court at the outset." *Johnson*, 754 F.3d at 562 (citations and quotations omitted). The exclusion of expert testimony is proper "only if it is so fundamentally unsupported that it can offer no assistance to the jury[.]" *Wood v. Minn. Mining & Mfg. Co.*, 112 F.3d 306, 309 (8th Cir. 1997) (citations and quotations omitted).

III. DISCUSSION

Plaintiffs move to exclude Dr. Wagner from offering several opinions at trial. Each opinion is addressed below.

A. Opinions regarding whether the relevant instructions for use ("IFU") are adequate, including the warnings the IFUs should or should not include.

Plaintiffs move to exclude Dr. Wagner's opinion that the IFU applicable to Ms. Pitlyk's mesh device was adequate and did not need additional warnings. Plaintiffs argue that Dr. Wagner is not qualified to offer such opinions. Plaintiffs emphasize that Dr. Wagner has never been involved in writing or preparing an IFU for any product or the product in this case, has never been asked to serve as a consultant on product development or IFUs, and has never been asked to provide any input regarding warning statements.

Upon review of the record, Plaintiffs' arguments are rejected. Dr. Wagner graduated medical school from Mount Sinai School of Medicine in 1987. He then completed an internship and residency at University Hospital in Stony Brook, New York. Dr. Wagner is a board certified urogynecologist. He currently specializes in female incontinence and pelvic reconstructive surgery.

Based on his background and experience, Defendants contend that Dr. Wagner is qualified to offer opinions that relate to the accuracy—and not the adequacy—of the IFUs. Defendants highlight three such opinions: "(1) Dr. Wagner's statement that '[t]he possible risk of extrusion or erosion is addressed in the IFU for TVT Secur;' (2) his statement that '[t]he Warnings section of the TVT Secur IFU in use at the time of the Plaintiff's implant specifically discusses detrusor instability;' and (3) his statement that he 'disagree[s] with Dr. Raybon's opinions regarding the TVT Secur IFU.'" (Doc. #45, p. 3.) Defendants represent that "Dr. Wagner's report does not include any opinions on the adequacy of the IFU." (Doc. #45, p. 3.)

Based on the current record, the Court finds that Dr. Wagner's opinions relate to the accuracy and not the adequacy of the IFUs. Consequently, Dr. Wagner may offer opinions regarding the accuracy of the relevant IFUs at trial. *See In re Ethicon Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, 2016 WL 4958312, at * 3 (S.D. W. Va. Aug. 25, 2016) (recognizing that "an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU"). Plaintiffs may reassert their objections at trial if Dr. Wagner is asked about or offers testimony regarding the adequacy of any alleged warnings.

B. Opinions or testimony that complications from Dr. Wagner's patients in clinical practice are uncommon or rare.

Next, Plaintiffs move to exclude "any and all opinions and testimony regarding Dr. Wagner's perceived safety and efficacy rates with the TVT-Secur product from his own practice." (Doc. #43, p. 5.) Plaintiffs state they "anticipate that Dr. Wagner may attempt to bolster his opinions by testifying regarding his own practice and experience involving mesh implants and suggest that complications from mesh implants are uncommon or rare or words to that effect." (Doc. #43, pp. 4-5.) Plaintiffs argue that such testimony should be excluded because "Dr. Wagner did not include in his report any opinions and/or statements regarding what his personal safety or efficacy rates are." (Doc. #43, p. 5) (citing Fed. R. Civ. P. 26(a)(2)(B)(i)).

Defendants acknowledge that although Dr. Wagner's case-specific report does not include the complication rate of his TVT-Secur patients, his case-specific report states that it is based in part on his general report. (Doc. #44-1, p. 2.) Dr. Wagner's general report states in part that "After TVT Secur was introduced, it quickly became my primary mid-urethral sling of choice." (Doc. #45-1, p. 45.) Dr. Wagner further states that "the initial benefits of the TVT Secur sling, particularly in terms of patient discomfort, were immediately apparent," and that he

"found very few clinical failures in [his] practice, despite using the TVT Secur as [his] primary urethral sling." (Doc. #45-1, p. 45.)

Under these circumstances, the Court finds that Dr. Wagner's testimony regarding his TVT-Secur patients was properly disclosed under Rule 26. The Court further finds that Dr. Wagner's education and experience renders him qualified to offer those opinions at trial. Plaintiffs' request to exclude such testimony is therefore denied.

C. Opinions regarding the cause of Ms. Pitlyk's injuries.

Finally, Plaintiffs argue that Dr. Wagner's causation opinions should be excluded because he did not perform a reliable differential diagnosis. "A differential diagnosis determines all of the possible causes for the patient's symptoms and then eliminates each of these potential causes until reaching one that cannot be ruled out, or deduces which of those that cannot be excluded is the most likely." *Johnson*, 754 F.3d at 560 n.2. "Differential diagnoses are generally admissible," but "should be excluded if they are scientifically invalid." *Junk v. Terminix Int'l Co.*, 628 F.3d 439, 449 (8th Cir. 2010).

Plaintiffs contend that "[i]t appears that Dr. Wagner came into his opinions with the idea that all of plaintiff's problems were caused by other factors and he was not willing to seriously consider the possibility that the TVT-Secur mesh device was the cause of her injuries." (Doc. #43, p. 6.) Plaintiffs emphasize that Dr. Wagner admitted during his deposition that he was unable to rule out the mesh or TVT-Secur device as the cause of Ms. Pitlyk's injuries.

The Court finds that Dr. Wagner's opinions should not be excluded. His report expressly states that:

> I have formed a differential diagnosis where I have considered all the possible etiologies of Ms. Pitlyk's symptoms, including the TVT Secur, and then ruled out or deemed less likely the potential causes that I do not feel are supported by the evidence in the factual record or in the peer-reviewed medical literature.

(Doc. #44-1, p. 25.) Dr. Wagner then discusses Ms. Pitlyk's symptoms and explains why he believes they are "not due to the TVT Secur sling[.]" (Doc. #44-1, pp. 25-36.)

The Court finds that Plaintiffs' arguments regarding Dr. Wagner, including his deposition testimony, go to the weight and not the admissibility of his opinions. *Johnson*, 754 F.3d at 564 (recognizing that "a differential expert opinion can be reliable even 'with less than full information'" and that "such considerations go to the weight to be given the testimony by the factfinder, not its admissibility"). Consequently, and at this time, the Court declines to exclude Dr. Wagner's opinions on the basis that he did not perform an adequate differential diagnosis.

IV. CONCLUSION

Accordingly, Plaintiffs' Amended Motion to Exclude Certain Opinions and Testimony of John R. Wagner, M.D. (Doc. #44) is DENIED.

IT IS SO ORDERED.

/s/ Stephen R. Bough
STEPHEN R. BOUGH
UNITED STATES DISTRICT JUDGE

Dated: August 12, 2020