IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ETHICON PHYSIOMESH FLEXIBLE COMPOSITE HERNIA MESH PRODUCTS LIABILITY LITIGATION, Plaintiffs, v. ETHICON, INC. and JOHNSON & JOHNSON, Defendants.	Civil Action No. 1:17-MD-2782-RWS [Lead Case MDL 2782]

ORDER

This MDL matter comes before the Court on several (though not all) of the parties' Motions to Exclude the Testimony of Expert Witnesses [Plaintiffs: Doc. 624, Doc. 625, Doc. 626; Defendants: Doc. 631, Doc. 632]. Having carefully reviewed the record, the Court enters the following Order.

BACKGROUND

This multidistrict litigation proceeding includes various product liability actions against Defendant Ethicon and its parent company, Defendant Johnson & Johnson (collectively, "Ethicon"), arising from the implantation of Ethicon's PHYSIOMESH Flexible Composite Mesh ("Physiomesh"), a synthetic

polypropylene-based mesh indicated for the repair of the Plaintiffs' hernia defects. The Plaintiffs allege that the Physiomesh caused them injuries. Accordingly, they have sued the Defendants for design defect, manufacturing defect, failure to warn, negligence, and gross negligence, among other related claims.

In support of these claims, the Plaintiffs rely upon the opinion testimony of several expert witnesses, who state that Physiomesh had a design defect that proximately caused their injuries. These experts also state that Ethicon did not adequately warn Plaintiffs' physicians about the risks associated with Physiomesh. In their defense, the Defendants also rely upon the opinion testimony of several expert witnesses who, unsurprisingly, take contrary positions.

In these Motions, and others filed in the bellwether trial case,[1] both parties seek to exclude the testimony of the other's experts.

DISCUSSION

In these Motions, each party challenges the admissibility of the other's experts' opinions under Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). The Court begins by setting out the legal standard before turning to each party's challenges.

[1] This Order addresses challenges to the general expert opinions and applies to all cases in the MDL. It is filed contemporaneously with an Order in the bellwether trial case, Crumbley v. Ethicon, 1:18-CV-748, which addresses challenges specific to that case.

I. Expert Witness Legal Standard

According to Federal Rule of Evidence 702, a qualified expert may offer testimony "in the form of an opinion or otherwise" if the testimony will "help the trier of fact to understand the evidence or to determine a fact in issue," is "based upon sufficient facts or data" and is "the product of reliable principles and methods" which have been reliably applied "to the facts of the case." Under the Supreme Court's decision in Daubert, assuming the expert is qualified,[2] the Rule's requirements can be boiled down to a two-part test that governs the admissibility of expert testimony: the evidence should be admitted if it "rests on a reliable foundation" and is "relevant to the task at hand." 509 U.S. at 597. The burden to establish reliability and relevance rests on the proponent of the expert. Williams v. Mosaic Fertilizer, LLC, 889 F.3d 1239, 1245 (11th Cir. 2018) (citation omitted).[3]

The Daubert decision "requires the trial court to act as a gatekeeper to [e]nsure that speculative and unreliable opinions do not reach the jury." Id. at 1244 (citation omitted). Thus, the trial court must conduct its own assessment of

[2] As is to be expected in a case of this magnitude, the experts proffered by each party generally boast remarkable credentials. Except where otherwise noted, the parties do not challenge the qualifications of the other side's experts.

[3] The Court refers here to 11th Circuit authority, but there is no suggestion for choice of law purposes that the framework differs elsewhere.

"whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. at 1245. Still, the trial court has "considerable leeway in deciding how to go about determining whether the particular expert testimony is reliable," and the decision is ultimately discretionary. Id. (citing Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999)).

II. Plaintiffs' Challenges to Ethicon's Experts

In their Motions, the Plaintiffs seek to exclude the testimony of Ethicon's regulatory and surgeon experts. These are addressed in turn below.

A. Plaintiffs' Challenges to Ethicon's Regulatory Experts: Timothy Ulatwoski [Doc. 624] & Reynaldo Librojo [Doc. 625]

Both of Ethicon's regulatory experts, Timothy Ulatowski and Reynaldo Librojo, are expected to testify concerning Ethicon's compliance with FDA regulations. However, in an Order filed contemporaneously with this one, the Court has granted the Plaintiffs' Motion to Exclude any FDA evidence (as defined in that Order) at trial. As the Plaintiffs correctly note, it follows that, to the extent Ethicon's regulatory experts intend to opine about the excluded FDA evidence, their opinions would also be inadmissible. Thus, the only question here is whether these experts can reliably testify about any *other* matters relevant to the remaining issues in the case.

As for Mr. Ulatowski, the Plaintiffs challenge two aspects of his opinion that purport to go beyond the FDA evidence. One is his excerpting from published studies; the other is his opinion #7 concerning warning labels. Ethicon makes clear that it does not intend to proffer Mr. Ulatowski to discuss the studies (a topic better addressed by its surgeon experts), but it does contend that he should be allowed to compare the labels on Physiomesh with those of other products.

Ethicon's argument is unavailing, for two reasons. First, as Mr. Ulatowski makes clear in his report and deposition, his opinion about the labels concerns regulatory compliance rather than the efficacy of the warning itself, which is not relevant to the issues in the case. Second, his "method" is essentially to compare the words in the Physiomesh warning with that of other products. While Ethicon argues that doing so provides important context, that is only true if the FDA evidence itself is admissible. Without it, Mr. Ulatowski's comparisons—essentially reading the labels side by side—are no different than what any lay juror could do with guidance from the attorneys.

In sum, the Court finds that, given the prior exclusion of the FDA evidence, Mr. Ulatowski's opinion #7 concerning the warning labels does not meet the standard under Rule 702 and Daubert. Cf. In re Zimmer Nexgen Knee Implant Prod. Liab. Litig., 2015 WL 5145546, at *16 (N.D. Ill. Aug. 31, 2015)

(Ulatowski's testimony concerning labels excluded). Accordingly, the Plaintiffs' Motion to exclude his testimony [Doc. 624] is **GRANTED**. Ethicon is hereby **PRECLUDED** from calling Mr. Ulatowski as an expert witness in this case.

As for Mr. Librojo, neither party suggests that his testimony goes beyond the FDA evidence.[4] Accordingly, the Plaintiffs' Motion to exclude his testimony [Doc. 625] is **GRANTED**. Ethicon is also **PRECLUDED** from calling Mr. Librojo as an expert in this case.

B. Plaintiffs' Challenge to Ethicon's Surgeon Experts: Dr. William Cobb, Dr. Jarrod Kaufman, Dr. Karl LeBlanc, Dr. Bruce Ramshaw, & Dr. Guy Voeller [Doc. 626]

Plaintiffs next move to exclude opinions of some of Defendants' surgeon experts, Dr. William Cobb, Dr. Jarrod Kaufman, Dr. Karl LeBlanc, Dr. Bruce Ramshaw, Dr. Guy Voeller.[5] Here, however, their challenge does not so much

[4] The parties' only dispute centered on Mr. Librojo's status as a non-retained expert, a disagreement which is irrelevant given the Court's ruling.

[5] Though Plaintiffs' Motion was filed in the MDL, it centers on the surgeons Ethicon initially designated as witnesses in the Crumbley trial. Because Ethicon will no longer call Doctors Kaufman and Ramshaw to testify in the Crumbley trial, it argued this Motion was moot as to them and did not offer specific evidence as to their involvement with their expert reports. Similarly, Plaintiffs did not move to exclude opinions of Doctors Diego Camacho, Dr. Eugene Dickens, and Dr. David Zabel because they were not designated as Crumbley experts, though Plaintiffs suggest their reports contain the same parallel language. So long as these surgeons were similarly qualified and invested in their reports, this Order will apply to similar challenges against to them should Defendants seek to use their testimony in another case.

concern the content or basis of the expert testimony; instead Plaintiffs argue that portions of the surgeon's reports are impermissibly ghostwritten and so violate the procedural requirements set out in Federal Rule of Civil Procedure 26. Any opinions stemming from those sections, Plaintiffs contend, should therefore be excluded. Defendants concede that all five of these reports contain nearly identical language in the "Physiomesh" and "Plaintiff Expert Witness Opinions" sections, but maintain the reports comply with Rule 26. The Court agrees.

Rule 26(a)(2)(B) requires that a party seeking to offer expert witness testimony at trial provide a "written report—prepared and signed by the witness." This rule, however, does not "preclude counsel from providing assistance to experts in preparing the reports." FED. R. CIV. P. 26(a)(2)(B) advisory committee's note to 1993 amendment. "Determining whether counsel crosses the line separating permissible assistance from improper participation in the expert's report writing calls for a fact-specific inquiry." Numatics, Inc. v. Balluff, Inc., 66 F. Supp. 3d 934, 942 (E.D. Mich. 2014) (internal citations omitted). The key question is "whether counsel's participation so exceeds the bounds of legitimate assistance as to negate the possibility that the expert actually prepared his own report." Id.

Here, while there is no dispute that counsel drafted portions of the reports, "there is also no indication that the experts were not sufficiently involved in their

preparation such that the reports may not be fairly considered as setting forth their own opinions." First Midwest Bank v. Rush Univ. Med. Ctr., 2020 WL 4284554, at *2 (N.D. Ill. July 27, 2020). Ethicon's uncontested evidence showed that the surgeons each spent at least 90 hours working on their reports; reviewed their reports before signing them; clearly adopted all relevant opinions, which were supported by evidence; and were qualified to provide each of those opinions.

Further, these reports provide Plaintiffs with sufficiently detailed notice of the surgeons' opinions and direct testimony so that they can be cross-examined, confronted with contrary expert opinions, and effectively deposed, as these surgeons were. FED. R. CIV. P. 26(a), 1993 advisory committee's note (stating the report is "intended to set forth the substance of the direct examination"); see also Fist Midwest Bank, 2020 WL 4284554, at *2; Meyers v. Nat'l R.R. Passenger Corp. (Amtrak), 619 F.3d 729, 734 (7th Cir. 2010) ("The purpose of the report is to provide adequate notice of the substance of the expert's forthcoming testimony and to give the opposing party time to prepare for a response.").

While the reports comply with the letter of Rule 26, perhaps they do not comply with the spirit. Both Parties have submitted expert reports containing such parallel language. In the future, reports more truly tailored to the particular expert would better support the idea that each expert prepared his or her own report.

Nevertheless, because the reports comply with Rule 26, Plaintiffs' Motion [Doc. 626] is **DENIED**.

III. Ethicon's Challenges to Plaintiffs' Surgeon Experts: Dr. Sean Orenstein, [Doc. 631] & Dr. Eric Pauli [Doc. 632]

In these Motions, Defendant Ethicon seeks to exclude the testimony of two surgeon experts proffered by the Plaintiffs: Dr. Sean Orenstein and Dr. Eric Pauli. The nature of Ethicon's challenges are essentially identical for both doctors, and so they are treated together here.

Both doctors identified three defects in Physiomesh: (1) large pores, which allegedly make the mesh incompatible with some commonly used fixation devices; (2) the anti-adhesion barrier on both sides of the mesh, which allegedly delayed tissue ingrowth of the mesh into the abdominal wall; and (3) the mesh's weight, which allegedly made it prone to tears and central mesh failure. They are also expected to testify that Ethicon eschewed safer alternative designs and that the company failed to warn users of Physiomesh of its dangers.

Ethicon challenges the reliability of their testimony concerning each of the defects and the safer alternative design. It also contends that the doctors are not qualified to testify concerning warnings. For all three types of defects, the basis for Ethicon's challenges is similar: namely, that the doctors rely overmuch on cherry-

picked anecdotal evidence from Ethicon's internal documents and ignore other, better sources like experimental testing or peer-reviewed studies.

The Plaintiffs contend that neither testing nor reliance on published or peer-reviewed data is required for an expert to offer an opinion, and that reliance on internal company documents is a critical part of an expert's duty to reliably apply the scientific finds "to the facts of the case," as the Rule requires. Moreover, they argue that both doctors in fact did rely on published studies for many of their conclusions, and Ethicon's disagreement about which studies they chose to review goes to the weight of the testimony, rather than its admissibility. Finally, they argue that the doctors are qualified to testify about warnings because they are practicing surgeons who customarily rely on such warnings.

Concerning the defects, though the Court is somewhat troubled by a lack of clear scientific support for some of the conclusions in each expert's report, the Court ultimately agrees with the Plaintiffs that the doctors are entitled to rely on the sources outlined in their report. Ethicon concedes—as it must—that reliance on company data is allowed. See, e.g., In re: Ethicon Inc., 2016 WL 4582232, at *3 (S.D.W. Va. Sept. 1, 2016) ("[A]n expert may testify as to a review of internal corporate documents for the purpose of explaining the basis of his expert opinions."). And its remaining contentions—that the doctors failed to address

studies with contrary results, or that they drew incorrect conclusions from the studies they did review—can be adequately addressed on cross-examination. They do not render the expert opinions inadmissible. Moreover, because these doctors can testify concerning those defects, they can also testify concerning recurrence rates and safer alternative designs.

Concerning the warnings, the Court finds that the doctors are qualified. It is true, as Ethicon notes, that some courts have excluded experts who lacked experience drafting warnings. See, e.g., Cason v. C.R. Bard, Inc., 2015 WL 9913809, at *10 (N.D. Ga. Feb. 9, 2015). But in Cason, for example, in addition to a lack of experience drafting warnings, the doctor at issue also did not "have a medical degree, medical training, or surgeon experience," and thus was "not in a position to offer an opinion as to how a warning label might have affected a surgeon's decision to use the device." Id.

Here, by contrast, both doctors are surgeons accustomed to relying on such warnings in performing mesh implantations with their patients. In accordance with the status of each as a "learned intermediary" and thus, the intended target of the warnings, the doctors are knowledgeable and experienced concerning those warnings. So, the Court joins other courts who have held that practicing surgeons are qualified to testify about the adequacy of warnings upon which they

customarily rely. See, e.g., Huskey v. Ethicon, Inc., 29 F. Supp. 3d 691, 719 (S.D.W. Va. 2014) ("Dr. Blaivas need not be an expert on product warnings per se. Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT–O and whether those risks were adequately expressed on the TVT–O's IFU.").

Because Dr. Orenstein and Dr. Pauli are both qualified and capable of offering reliable opinions to the jury concerning relevant issues in their case, the Plaintiffs are entitled to proffer them as experts. Ethicon's Motions to exclude their testimony [Doc. 631, Doc. 632] are **DENIED**.

CONCLUSION

For the foregoing reasons, the Court rules as follows:

The Plaintiffs' Motion to Exclude Timothy Ulatwoski [Doc. 624] and Motion to Exclude Reynaldo Librojo [Doc. 625] are **GRANTED**; Ethicon is hereby **PRECLUDED** from calling them as expert witnesses.

The Plaintiff's Motion to Exclude Ethicon's Surgeon Experts (Dr. William Cobb, Dr. Jarrod Kaufman, Dr. Karl LeBlanc, Dr. Bruce Ramshaw, Dr. Guy Voeller) [Doc. 626] is **DENIED**.

Defendant Ethicon's Motion to Exclude Dr. Sean Orenstein [Doc. 631] and Motion to Exclude Dr. Eric Pauli [Doc. 632] are **DENIED**.

SO ORDERED this 25th day of November, 2020.

RICHARD W. STORY
United States District Judge