

**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 the parties' Motions to Exclude the Testimony of Expert Witnesses, namely, Plaintiffs' Motion to Exclude the Testimony of Marta L. Villarraga, Ph.D. ("Dr. Villarraga") [Doc. 627], and Defendants' Motion to Exclude the Testimony of Bernd Klosterhalfen, M.D. ("Dr. Klosterhalfen") [Doc. 630]. This Order supplements the Court's November 25, 2020 Order, which provides additional background information. [Doc. 696/697]. Also, before the Court is Defendants' Motion to Strike the Errata Sheet of Dr. Klosterhalfen [Doc. 623]. Having 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 (“Physiomesb”), a synthetic polypropylene-based mesh indicated for the repair of hernia defects.¹

Plaintiffs allege that implantation of Physiomesb was a proximate cause of their individual injuries. Plaintiffs bring claims against Ethicon alleging strict product liability for defective design, failure to warn, and manufacturing defects, as well as liability for negligence, violation of state consumer protection laws, gross negligence, and loss of consortium. [Doc. 239 - Master Long Form Complaint (“Master Complaint”), *passim*]. The parties offer the opinions of competing expert witnesses to either support or defend against Plaintiffs’ claims.

¹ Of particular relevance to several of the Daubert challenges, a unique characteristic of the Physiomesb design was its structure with polypropylene mesh between two layers of a Monocryl® anti-adhesive barrier.

DISCUSSION

As discussed below, Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993) provide the governing standard.

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, 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).

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 “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’ Motion to Exclude Testimony from Dr. Villarraga [Doc. 627]

Dr. Villarraga, a biomedical engineer, is one of Ethicon’s witnesses offered as an expert in biomechanics and failure analysis, focusing on the evaluation of the performance of medical devices and biomaterial-tissue interactions. [Doc. 627-4, Plaintiffs’ (“Pls.”) Exhibit 4 – Expert Report of Dr. Villarraga]. Dr. Villarraga is a principal and shareholder of Exponent, Inc. (“Exponent”), a multi-disciplinary engineering and scientific consulting firm that has a longstanding business relationship with Ethicon. [Doc. 627-1, Pls. Exhibit 1].

To rebut Plaintiffs’ defective design claim, Ethicon proffers Dr. Villarraga’s opinions as follows:

The Physiomesh Flexible Composite Mesh was not defective in design, and considered the needs of both surgeons and patients[;]

The approach for mesh fixation is a physician decision with various options available depending on surgeon preferences and patient factors[;]

Ethicon acted as a reasonably prudent medical device company in the design, development, manufacturing, and testing of Physiomesh[;]

Ethicon had a robust product postmarketing surveillance program and used reasonable and industry standard practices in monitoring the performance of Physiomesh while analyzing clinical data and was reasonable when deciding to withdraw Physiomesh from the market[;] and

The performance of a medical device, such as the Physiomesh Flexible Composite Mesh, is multifactorial, and is influenced by device, patient, and surgical factors.

[Pls. Exhibit 4 at 10 (alterations omitted)].

As an initial matter, Plaintiffs oppose Dr. Villarraga testifying regarding FDA regulations and post-marketing surveillance efforts by Ethicon for the same reasons they oppose this testimony by other witnesses. The Court's November 25, 2020 Order [Doc. 690/691] excluding FDA evidence applies to Dr. Villarraga's testimony.

Plaintiffs also seek to preclude Dr. Villarraga from offering general factual narratives and summaries of documents as well as testimony concerning historical Ethicon documents. Plaintiffs argue that Dr. Villarraga had no part in assembling the information or developing the materials cited within her report, that she should not be allowed to testify concerning materials that she does not even have second-hand knowledge of, and that much of the subject matter is outside her field of

expertise as she is not a surgeon. Admittedly, most of the work done by the company for which she works, Exponent, was done by other persons. Implying bias, Plaintiffs point out the substantial amount of business that Exponent does with Ethicon and others in the industry and suggest that this testimony should be scrutinized more closely. [Doc. 627 at 2-3, 6 (referring to Dr. Villarraga as an “industry expert for hire” and “hired gun”)]. Plaintiffs assert that Exponent’s work is done “for purposes of litigation.” [Doc. 627 at 7]. These matters are for cross-examination.

Approximately 65 pages of Dr. Villarraga’s expert report consists of factual narrative. Plaintiffs raise specific objections to Sections 3 and 4 of Dr. Villarraga’s report. Section 3 is entitled “Mesh Repair Background” and gives a retrospective on the historical use and development of various tissue repair materials in the body. It is a summary of general background materials, including dozens of scientific and medical journal articles. There are only three (3) paragraphs in Section 3 that relate to Physiomesh. Plaintiffs contend that recitation of these facts does not require expert analysis and is not helpful to the jury. Section 4 addresses “Physiomesh Product Development” and summarizes hundreds of internal company documents provided to Exponent by Defendants’ lawyers. This section consists of materials reviewed by other Exponent employees. Plaintiffs complain

that they have no ability to cross-examine the other Exponent employees that contributed to the report and that, if admitted, this testimony is more appropriately offered by a corporate witness. Plaintiffs also contend that this section is largely what amounts to argument Ethicon's attorneys can make as opposed to expert opinion.

In response, Ethicon argues that Plaintiffs do not object to the opinions offered by Dr. Villarraga, but rather object to the foundation for those opinions. See FED. R. CIV. P. 703. In addition, Ethicon dismisses Plaintiffs' challenge that Dr. Villarraga is not a surgeon and counters that Dr. Villarraga does not offer any medical opinions. Ethicon states that these kinds of materials are routinely relied upon by biomedical engineers in evaluating a product. See, e.g., In re C.R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig., 948 F. Supp. 2d 589, 608, 645-46 (S.D.W.Va. 2013); see also In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig., 2018 WL 514798, at **2-3 (S.D.W.Va. January 23, 2018).² Defendants

² Both parties cite to rulings in the pelvic mesh MDL in support of their legal positions. [Doc. 627 at 10, 15; Doc. 649 at 4; Doc. 658 at 6 n.3]. In the 2013 Bard decision, *supra*, considering Plaintiffs' similar Daubert challenge to Dr. Villarraga's proposed testimony in another MDL, the court declined to exclude the portions of Dr. Villarraga's factual narrative testimony presented as the bases for her expert opinions. In re C.R. Bard, Inc., 948 F. Supp. at 645-46. The court granted only partial relief, explaining, "To the extent that the Exponent Experts purport to simply make arguments that [Defendant's] lawyers may make, such testimony is not expert opinion and should be excluded. Simply pointing out inconsistencies does not require any 'scientific, technical, or other

correctly assert that the proper challenge to this testimony is through a motion *in limine*.

Next, Plaintiffs identify two (2) specific opinions of Dr. Villarraga that they seek to exclude, namely, Dr. Villarraga's opinions that "[t]he approach for mesh fixation is a physician decision with various options available depending on surgeon preferences and patient factors[;]" and that "[t]he performance of a medical device, such as the Physiomesh, is multifactorial and is influenced by device, patient, and surgical factors." [Doc. 627 at 16-17; Doc. 658 at 10-11]. According to Ethicon, both "observations are unnecessary for [Dr. Villarraga's] ultimate opinions and are withdrawn." [Doc. 698]. Plaintiffs' challenge to these portions of Dr. Villarraga's testimony is moot.

In sum, the Court will not exclude Dr. Villarraga's testimony on either ground advanced by Plaintiffs. Dr. Villarraga will be permitted to use information within Sections 3 and 4 of her report that serves as foundation for her opinions. The Court will limit Dr. Villarraga's testimony at trial, consistent with this ruling.

specialized knowledge." *Id.* (quoting FED. R. EVID. 702). In the 2018 Bard decision, the court rejected some of the same challenges to Dr. Villarraga's testimony raised in this case and only limited the factual narrative portions of her proposed testimony. In re C.R. Bard, Inc., 2018 WL 514798, at **2-3. The undersigned intends to limit Dr. Villarraga's testimony as well.

As suggested by Ethicon, the parameters of Dr. Villarraga's testimony will necessarily be defined within the context of the trial.

Plaintiffs' Motion to Exclude Dr. Villarraga's testimony is granted in part and denied in part. Plaintiffs' Motion is granted with respect to FDA evidence consistent with the Court's previous ruling and denied as to the remaining challenges.

III. Ethicon's Motion to Exclude Testimony of Dr. Klosterhalfen [Doc. 630]

Dr. Klosterhalfen, a pathologist, is identified by Plaintiffs as a general expert in surgical pathology and biomaterials.³ Dr. Klosterhalfen offers opinion testimony that Physiomesh was defectively designed. His theory is that the double-sided Monocryl on the Physiomesh impedes tissue integration. Ethicon contends that Dr. Klosterhalfen's opinions are irrelevant and unreliable and should be excluded in their entirety. Alternatively, if Dr. Klosterhalfen is permitted to testify, Ethicon asks that the Court preclude Dr. Klosterhalfen from offering testimony about his personal "data pool."

In the early 1990's through early 2010, as a hobby or special interest, Dr. Klosterhalfen maintained personal data on explanted hernia meshes he obtained from various doctors around Europe, constituting approximately 6,000 specimens.

³ Dr. Klosterhalfen does not purport to be an expert concerning surgical technique.

Dr. Klosterhalfen's "data pool" refers to both actual tissue specimens that no longer exist and Dr. Klosterhalfen's statistical analyses of the data. The data pool did not include explanted Physiomesh since he ceased collecting samples prior to Physiomesh becoming available on the market in April 2010.

Notably, Dr. Klosterhalfen is a former consultant for Ethicon. Dr. Klosterhalfen worked with Defendants for years to design surgical meshes and evaluate their performance in both animals and humans. In 2011, Ethicon hired Dr. Klosterhalfen to review and examine five (5) Physiomesh explants. Dr. Klosterhalfen broke ties with Ethicon in December 2011 after he advised Ethicon of his concerns related to Physiomesh. [Doc. 650-17, Pls. Exhibit 17].

In this Physiomesh MDL, Dr. Klosterhalfen offers two primary opinions:

OPINION 1: For a mesh-based hernia repair to be successful, it is critical that there be proper tissue ingrowth into the mesh product.

OPINION 2: The double-sided Monocryl coating that encapsulates Physiomesh inhibits proper ingrowth of Physiomesh into a patient's abdominal wall and thereby increases the risk of a mesh failure and related complications.

[Doc. 630-3, Defendants' ("Defs.") Exhibit 2 – Dr. Klosterhalfen Expert Report].

Ethicon focuses its challenge on the latter, Opinion 2.

Ethicon first argues that Dr. Klosterhalfen's opinions are irrelevant because they lack a connection or "fit" to the facts of the case. According to Ethicon, Eric

Pauli, M.D. (“Dr. Pauli”), Plaintiffs’ causation expert offering general and case-specific opinions, does not contend that Physiomesh’s double-sided Monocryl coating is a factor in the first bellwether trial and, therefore, does not fit Plaintiffs’ theory of the case.⁴ [Doc. 630-1 at 6-8, 16]. As an initial matter, Dr. Klosterhalfen is offered as a general causation expert; not a case-specific or specific causation expert. Moreover, in connection with Ethicon’s Motion for Summary Judgment in Crumbley, the Court has already explained that, with respect to claims alleging design defect, Ethicon’s “one theory” argument is without merit. [Civil Action No. 1:18-cv-748-RWS, Doc. 120 at 7 n.3]. And Dr. Klosterhalfen’s double-sided Monocryl coating testimony is similar to the opinions of Plaintiffs’ other general causation experts, including Dr. Pauli and Sean Orenstein, M.D. (“Dr. Orenstein”), whose opinions the Court has deemed admissible and, of course, subject to cross-examination. [Doc. 693/696/697, Section III at 9-12]. In short, the opinions offered by Dr. Klosterhalfen are probative of Plaintiffs’ claims alleging defective design and failure to warn. The Court, therefore, finds that Dr. Klosterhalfen’s opinions are, in fact, relevant.

⁴ The First Trial Case selected is Jim B. Crumbley and Diane Crumbley v. Ethicon, Inc., et al. (“Crumbley”), Civil Action No. 1:18-cv-748-RWS.

Ethicon also contends that Dr. Klosterhalfen's opinions are unreliable. Ethicon's challenges go more to the weight to assign opinion testimony and credibility than admissibility.⁵ Plaintiffs emphasize that Dr. Klosterhalfen's methodology is the same methodology employed by Dr. Klosterhalfen when Ethicon hired him to examine Physiomesh explants as well as the same facts, data, and methodology utilized by Ethicon's own experts. Further, Ethicon relied upon Dr. Klosterhalfen's analysis in subsequently modifying their ventral hernia device design (i.e., the Physiomesh Open). [Doc. 650 at 5-6].

Ethicon asserts that Dr. Klosterhalfen's opinions concerning Physiomesh's double-sided Monocryl coating are based largely on the five (5) Physiomesh explants (and arguably 3 more) he evaluated at Ethicon's request. Ethicon argues that five explants is an insufficient sample size to support statistically significant findings. In response, Plaintiffs point out that Dr. Klosterhalfen's opinion is not based *solely* on the five (5) explants, but also based on his experience and

⁵ For example, Ethicon argues that Dr. Klosterhalfen's opinions are untested, that it is improper to rely on animal studies (i.e., that Dr. Klosterhalfen fails to offer evidence that the human response would be the same as animal response), and that he does not rely on any published or peer reviewed medical literature to support his opinions. Ethicon also posits that, with respect to Opinion 1, Dr. Klosterhalfen fails to address alternative causes for the lack of tissue ingrowth. As previously stated, Plaintiffs do not proffer Dr. Klosterhalfen as a case-specific expert and there is no reason for him to opine on or rule out potential alternative causes.

knowledge, Defendants' own documents, and peer-reviewed animal and clinical studies. The Court agrees with Plaintiffs that this not a valid basis for exclusion of Dr. Klosterhalfen's testimony.

Finally, the Court declines to prohibit Dr. Klosterhalfen's testimony about his personal data pool generally as an underlying factual basis for his proffered opinions. As persuasively argued by Plaintiffs, the data pool is Dr. Klosterhalfen's life's work and his observations of the data pool specimens comprise part of his background knowledge and accumulated experience with mesh. Plaintiffs further contend that the principles Dr. Klosterhalfen derives from the data pool are generally accepted, uncontroversial facts that have been adopted by the scientific community. Certainly, Dr. Klosterhalfen should be permitted to discuss how and why he arrives at the conclusions he reaches about mesh and how mesh design might affect the way mesh behaves in the body. According to Plaintiffs, even Defendants have previously recognized Dr. Klosterhalfen as "THE expert on mesh pathology." [Doc. 650 at 2, Pls. Exhibits 2-4].

Ethicon's specific "data pool" arguments are equally unconvincing. Ethicon asserts that the "data pool" does not support any of Dr. Klosterhalfen's opinions about Physiomesh and that no expert report was produced regarding Dr. Klosterhalfen's data. Ethicon challenges testimony based upon the "data pool"

since it does not contain Physiomesh explant samples and does not include any meshes with double-sided Monocryl. Lastly, Ethicon argues that Dr.

Klosterhalfen's data pool has no "key" and cannot be meaningfully analyzed. See, e.g., Wise v. C.R. Bard, Inc., 2015 WL 521202, at *8 (S.D.W. Va. February 7, 2015) (excluding specific reliance on personal data pool in context of Ethicon motion to compel production of raw data, which request was denied; stating that "without a fully synthesized representation of Dr. Klosterhalfen's database, specific reliance on that database is unreliable").⁶ However, as Ethicon itself acknowledges, Dr. Klosterhalfen does not premise any specific Physiomesh opinion on his work surrounding the data pool. Indeed, Plaintiffs expressly state that "Dr. Klosterhalfen is not basing any opinions about the design of Physiomesh

⁶ Plaintiffs distinguish the Wise decision in two ways: 1) that Ethicon has never requested or sought to compel Plaintiffs to produce a "key" to assist with evaluating Dr. Klosterhalfen's data pool as was done in Wise; and 2) that Dr. Klosterhalfen's opinions in this case rely on general principles gleaned from the data pool that are not in dispute, specifically, the behavior of non-porous or microporous meshes. [Doc. 650 at 16]. While Ethicon did not move to compel a "key," Ethicon did request and was provided a summary chart containing raw data related to 1,000 of the approximately 6,000 explants, which they contend is not helpful. [Doc. 630-8, Defs. Exhibit 7]. Dr. Klosterhalfen's expert testimony has been accepted by other courts and similar Daubert challenges overruled in pelvic mesh litigation. See In re C.R. Bard, 948 F. Supp. 2d at 618-22 (allowing personal data pool to be relied upon as part of knowledge and experience and in forming opinion); and see Huskey v. Ethicon, 29 F. Supp. 3d 691, 708-709 (S.D.W.Va. 2014); see also Edwards v. Ethicon, 2014 WL 3361923, at **20-21 (S.D.W.Va. July 8, 2014).

on specific findings from any statistical analysis from the data pool.” [Doc. 650 at 13]. For this reason, the Court will allow testimony about the data pool as a part of Dr. Klosterhalfen’s experience and general knowledge base. Ethicon will have the ability to cross-examine Dr. Klosterhalfen about alleged flaws or weaknesses concerning the factual underpinnings for his opinions.

Defendants’ Motion to Exclude Dr. Klosterhalfen’s testimony is denied.

IV. Defendants’ Motion to Strike Dr. Klosterhalfen’s Errata Sheet [Doc. 623]

Defendants move to strike Dr. Klosterhalfen’s errata sheet.⁷ Ethicon asserts that Dr. Klosterhalfen made improper material and substantive changes to his deposition testimony through his errata sheet. Ethicon also asserts that Dr. Klosterhalfen failed to comply with the requirements of FED. R. CIV. P. 30(e) in that he failed to state the reasons for making substantive changes to his testimony. Contemporaneously with filing their response to Ethicon’s Motion, Plaintiffs filed an amended errata sheet and statement of reasons for Dr. Klosterhalfen’s proposed revisions. [Doc. 640, Pls. Exhibit F]. Ethicon did not file a reply brief.

Rule 30(e) provides a mechanism for a deponent to review and make changes to deposition testimony as outlined below:

⁷ Ethicon did not meet and confer with Plaintiffs before filing the instant Motion, which is a prerequisite under the Court’s Standing Order Regarding Civil Litigation.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

FED. R. CIV. P. 30(e) (as amended 2015).

The Eleventh Circuit has never squarely addressed whether or to what extent substantive and contradictory corrections to deposition testimony via Rule 30(e) errata sheets are permitted. See WTI, Inc. v. Jarchem Indus., Inc., 2012 WL 3101656, at *3 (N.D. Ga. July 30, 2012); see also DS Waters of America, Inc. v. Fontis Water, Inc., 2011 WL 13122270, at *2 (N.D. Ga. December 14, 2011) (citation omitted) (considering motion to strike errata sheet raising question “whether a deponent may make material, some contradictory, changes to his deposition transcript[,]” recognizing Eleventh Circuit has not opined, and answering in the affirmative; changes in the “form or substance” of testimony are allowable); Dering v. Serv. Experts All. LLC, 2007 WL 4299968, at *5 (N.D. Ga. December 6, 2007) (“this issue is not settled in the Eleventh Circuit”); and see

Purdee v. Pilot Travel Centers, LLC, 2007 WL 3143716, at *2 (S.D. Ga. October 23, 2007) (discussing construction of Rule 30(e); denying motion to strike contradictory errata sheet).

At the outset, the Court notes that Dr. Klosterhalfen is a German native who speaks English as a second language. In addition, Dr. Klosterhalfen's deposition was conducted via ZOOM over the course of two (2) days and the subject matter of his testimony was scientific. Here, excerpts of the deposition transcript tend to show that language was at least a factor given Dr. Klosterhalfen's German accent. [Doc. 640 at 16 n.10 (discussing Dr. Klosterhalfen's use of "filler words"), 17-18, 24; Doc. 640-3, Pls. Exhibit C]. Plaintiffs also point out that the 444-page transcript contains numerous instances where the audio was muffled or inaudible, which Plaintiffs explain contributed to the need to supplement Dr. Klosterhalfen's deposition testimony to avoid confusion and provide necessary context.

Plaintiffs first contend that Dr. Klosterhalfen's amended errata cures any deficiencies in his original errata and explains the need for clarification of deposition testimony. See, e.g., Estate of Duckett by & through Calvert v. Cable News Network, LLLP, 2010 WL 11508194, *3 (M.D. Fla. May 14, 2010) (denying motion to strike errata sheet where witness "cured" "shortcoming" by providing an amended errata that included reasons for changes). More importantly, Plaintiffs

correctly argue that courts within the Eleventh Circuit allow a witness to make changes of the kind made by this witness. Generally, witnesses may add to or revise testimony “in order to clarify, expound upon, and correct deposition answers.” [Doc. 640 at 9 n.5 (listing cases)]. And clarifications or corrections that are in line with the witness’s other testimony or documents in the case are typically allowed. See, e.g., In re Abilify (Aripiprazole) Prod. Liab. Litig., No. 3:16-MD-2734, 2018 WL 1627812, at *4 (N.D. Fla. Apr. 4, 2018) (denying motion to strike errata where clarifications were consistent with and supported by witness’s later deposition testimony); see also Dering, 2007 WL 4299968, at *5 (declining to strike errata where witness’s proposed revisions were not contradictory and were consistent with other deposition testimony).

Ethicon identifies and objects to eighteen (18) proposed revisions contained within Dr. Klosterhalfen’s errata. The Court has reviewed each of the proposed corrections and finds that they are permissible and consistent with Rule 30(e).

Accordingly, Defendants’ Motion to Strike Dr. Klosterhalfen’s Errata is denied.

CONCLUSION

For the foregoing reasons:

It is **ORDERED** that Plaintiffs' Motion to Exclude Testimony of Dr. Villarraga [Doc. 627] is **GRANTED in part** and **DENIED in part**. Plaintiffs' Motion is granted with respect to the exclusion of FDA evidence consistent with the Court's November 25, 2020 Order [Doc. 690/691] and denied as to the remaining challenges.

It is further **ORDERED** that Defendant Ethicon's Motion to Exclude Testimony of Dr. Klosterhalfen [Doc. 630] and Motion to Strike Errata [Doc. 623] are likewise **DENIED**.

SO ORDERED this 4th day of December, 2020.



RICHARD W. STORY
United States District Judge