

brought a number of claims against Defendants Ethicon, Inc. and Johnson & Johnson for their role in designing, manufacturing, marketing and selling the Prolift device. [See R. 1; R. 53-1.] This case was initially filed in the Ethicon MDL in January 2013 and, following extended proceedings at that level, was transferred to this Court in October 2019. [R. 1; R. 52.]

Pursuant to this Court's Order allowing the parties to submit supplemental memoranda on outstanding *Daubert* issues, Defendants have filed four separate motions. [See R. 72 at 3.] Defendants' supplemental motions seek to exclude portions of the following experts' testimony: Peggy Pence, Ph.D [R. 80]; Prof. Dr. Med. Uwe Klinge [R. 81]; Vladimir Iakovlev, M.D. [R. 82]; and Daniel Elliot, M.D. and Bobby Shull, M.D. [R. 83]. Ms. Owens has responded in opposition, requesting the Court deny Defendants' motions in their entirety. [R. 92; R. 93; R. 94; R. 95.] These matters are now fully briefed and ripe for adjudication.

II

A

The Court will address each motion in turn. First, the Court notes that Defendants' challenge to Dr. Iakovlev's testimony, Ms. Owen's pathology expert, is now moot. [R. 82.] In her response, Ms. Owens represents that she "will not be introducing the testimony of Dr. Iakovlev at trial." [R. 92 at 1.] Accordingly, the Court denies Defendants' motion at Docket Entry # 82 as moot.

B

Defendants also seek to exclude the testimony of Peggy Pence, Ph.D, Ms. Owen's regulatory expert. [R. 80.] Specifically, Defendants seek to exclude Dr. Pence's labeling opinions as unreliable, arguing the opinions "all suffer from a fatal flaw in methodology." *Id.* at 1. Ms. Owen argues this motion should be denied because, as part of the MDL Case (MDL

2327, Case No. 2:12-md-2327 (S.D. W. Va.), Judge Joseph R. Goodwin addressed and fully resolved the challenge to this portion of Dr. Pence’s testimony. [R. 93 at 2.] Indeed, Defendants acknowledge this ruling, noting that “[i]n Wave 1, the MDL Court denied Ethicon’s motion to exclude this opinion” [R. 80 at 1.] Importantly, on January 3, 2020, this Court expressly adopted Judge Goodwin’s order that included this denial. [R. 72 at 3 (citing R. 69-5).]

This established, Defendants argue that, in denying their motion, Judge Goodwin mischaracterized their argument and so the Court should revisit this issue. *Id.* at 2. But the Court has expressly cautioned the parties to avoid requesting rulings on matters resolved in the adopted orders, directing the parties to limit their supplemental briefing “to only those *Daubert* challenges which were previously raised . . . and not resolved by any ruling of the MDL Court, Judge Goodwin’s orders included.” [R. 72 at 2; *see also id.* (“[T]o revisit each of these *Daubert* challenges would fly in the face of the one of the main purposes of multi-district litigation”). Clearly, in asking the Court to resolve an issue already decided by Judge Goodwin, Defendants’ motion goes beyond the scope of the allowed supplemental briefing. Consequently, the Court denies Defendants’ motion at Docket Entry # 80. As Judge Goodwin stated, Defendants “may attempt to expose any perceived shortcomings [of Dr. Pence’s testimony] through cross-examination.” [R. 69-5 at 12.]

C

Next, Defendants seek to exclude portions of Prof. Dr. Med. Uwe Klinge’s testimony, Ms. Owen’s materials expert. [R. 81.] Specifically, Defendants seek to exclude two portions of Dr. Klinge’s testimony: (1) “any testimony from Dr. Klinge regarding alternative designs to Prolene Soft,” and (2) “Dr. Klinge’s opinions regarding fraying and particle loss in Prolene Soft.” *Id.* at 3, 5. In response, Ms. Owens argues that the challenge to Dr. Klinge’s alternative

design testimony has already been addressed by Judge Goodwin when he determined in an MDL Order that this testimony was permitted. [R. 94 at 4.] As to the fraying and particle loss testimony, Ms. Owens argues that Dr. Klinge’s testimony is sufficiently reliable, as explained in prior rulings from Judge Goodwin in other MDL cases. *Id.* at 2–4.

1

Defendants’ motion to exclude Dr. Klinge’s alternative design testimony is quickly resolved by closer consideration of Judge Goodwin’s prior orders. Ms. Owens and Defendants each rely on separate orders from Judge Goodwin to support their positions on this issue. Defendants point to an order entered by Judge Goodwin in *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473 (S.D. W. Va. Nov. 20, 2014). [See R. 81 at 4 (citing R. 81-2).] In that 2014 order, Judge Goodwin granted Ethicon’s motion to exclude Dr. Klinge’s alternative design opinions as it related to the Prolene mesh used in the Prolift device. [R. 81-2 at 17–18.] Ms. Owens, on the other hand, relies on an order entered by Judge Goodwin in Wave 1 of the Ethicon MDL in August 24, 2016, in which Judge Goodwin *denied* Ethicon’s motion to exclude as it related Dr. Klinge’s alternative design opinions as it related to the Prolene mesh. [R. 94 at 4 (citing R. 69-3 at 5).] That August 2016 order was subsequently adopted in July 2018 in Ethicon Wave 4 cases and, in January 2020, this Court expressly adopted the order following transfer. [R. 72 at 3.]

Of course, as it relates to this case, only one of these orders has controlling effect: the August 2016 order entered in the MDL master case which has already been adopted by this Court. *See id.* And, on review, the Court sees no reason to alter its earlier ruling adopting this order and the rulings within. Indeed, in the order Judge Goodwin clarified that, as it related to prior rulings on experts, he was only bound “to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess

the parties' *Daubert* arguments anew." [R. 69-3 at 7.] Plainly, as between the two orders the parties rely on, the August 2016 order is more recent and was intended by Judge Goodwin to have a broader effect. *See id.* at 6 (noting that the parties were "to file only one *Daubert* motion per challenged expert . . ."). So, as before, the Court declines to revisit this issue and denies this portion of Defendants' motion at Docket Entry # 81.

2

Defendants' attempt to exclude Dr. Klinge's opinions regarding fraying and particle loss in the Prolene Soft mesh requires closer review. Here, Defendants argue that Dr. Klinge's opinion is unreliable because the sources relied on as the basis for his opinion are not sufficiently germane. [R. 81 at 5–8.] Ms. Owens argues this "issue has already been ruled upon by the MDL Court" which found that this portion of Dr. Klinge's testimony was admissible and, separately, that a substantive review reveals that this portion of his testimony is sufficiently reliable. [R. 94 at 2–4.]

So, again, the parties disagree on whether and to what extent Judge Goodwin has ruled on this issue. Based on the express nature of Judge Goodwin's orders and this Court's previous Order adopting only certain of those orders, the effect of Judge Goodwin's various rulings as it relates to the present case should be straightforward. For future purposes the Court makes clear: the orders entered as part of the MDL master case by Judge Goodwin and subsequently adopted by this Court as part of the January 3 Order are controlling, and the rulings within will not be revisited; the orders entered by Judge Goodwin in individual cases and *not* expressly adopted by this Court are simply persuasive and, when appropriate, the reasoning and rulings within may be revisited.

Here, the orders pointed to by Ms. Owens fall into the latter category: persuasive but not

controlling. [See R. 94 at 2 (citing two such orders).] The orders were either issued in individual cases or did not address the exact question in front of the Court: whether Dr. Klinge’s opinion as to deficiencies in the Prolene Soft mesh should be excluded. In fact, as noted by Defendants, Judge Goodwin explicitly reserved ruling on this issue “until this matter may be probed further at trial.” [R. 69-3 at 11.] Therefore, the Court will review the challenged portion of Dr. Klinge’s testimony in light of Judge Goodwin’s persuasive orders and the parties’ latest arguments.

a

Admissibility of expert testimony is governed by Federal Rule of Evidence 702, which states:

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. The current challenge turns on whether Dr. Klinge’s testimony is sufficiently reliable—the third prong of Rule 702.

Rule 702 provides a number of standards by which a district court in its gatekeeper role is to gauge reliability. A court should look to whether the testimony is based upon “sufficient facts or data;” whether it is the “product of reliable principles and methods;” and whether the expert “has applied these principles or methods reliably to the facts of the case.” *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (quoting Fed. R. Evid. 702). Additionally, a district court is to consider “such factors as testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique’s operation, and general acceptance in the relevant scientific [or technical] community.” *United States v. Langan*, 263

F.3d 613, 621 (6th Cir. 2001) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593–94) (1993)). The reliability inquiry is a flexible one, and the above factors are not a “definitive checklist or test.” *Daubert*, 509 U.S. at 593.

District courts are given broad discretion in determining whether a particular expert’s testimony is reliable. *See, e.g., Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 672 (6th Cir. 2010); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (“[T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.”). Notably, in exercising this discretion, a court must be careful not “to impinge on the role of the jury or opposing counsel.” *Burgett v. Troy-Bilt LLC*, 579 F. App’x 372, 377 (6th Cir. 2014). Instead, “vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 509 U.S. at 596.

b

On review, this portion of Dr. Klinge’s testimony is sufficiently reliable. Defendants’ argue the sources relied on by Dr. Klinge to support his opinion on the Prolene Soft mesh technically concern another product, the Prolene mesh. [*See* R. 81 at 6.] Defendants contend, however, that there are differences between the two meshes: “Prolene and Prolene Soft have different designs, including different pore sizes and different weights (Prolene Soft has larger pores and weighs less).” *Id.* This argument is well taken but does not warrant the exclusion of this portion of Dr. Klinge’s testimony.

First, Dr. Klinge’s opinion on degradation and fraying of the vaginal mesh products was broad and not specific to one particular mesh. For example, in his expert report cited by Defendants he states: “In my opinion, it has been proven to a reasonable degree of scientific

certainty that surgical mesh made of PP [polypropylene] and used in the pelvic tissues is not biologically inert and does in fact undergo degradation at the surface of the mesh fiber” [R. 81-4 at 19.] Importantly, Dr. Klinge relies on scientifically valid methods and relevant sources to form his opinions as to the polypropylene meshes. *See id.* (citation omitted) (“In fact, Piet Hinoul, Ethicon’s WW Medical Director, in a 2009 presentation stated that “[modern day meshes] are not biologically inert.”).

So, based on the reports and literature regarding certain polypropylene meshes, Dr. Klinge drew a conclusion regarding polypropylene meshes more broadly. To be sure, Defendants may challenge his testimony for lack of specificity based on the differences in the meshes. But Defendants have failed to show that Dr. Klinge’s testimony amounts to “subjective belief and unsupported speculation” such that it should be excluded for lack of reliability. *Daubert*, 509 U.S. at 590. “*Daubert* and Rule 702 require only that the expert testimony be derived from inferences based on a scientific method and that those inferences be derived from the facts of the case at hand, . . . not that they *know* answers to all the questions a case presents” *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 390 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 590–92). Finally, the Court notes that other courts in this district have reached the same conclusion as to this portion of Dr. Klinge’s testimony. *See Cutter v. Ethicon, Inc.*, No. CV 5:19-443-DCR, 2020 WL 2060342, at *5 (E.D. Ky. Apr. 29, 2020). The Court denies this portion of Defendants’ motion at Docket Entry # 81.

D

Lastly, Defendants seek to exclude certain portions of the testimony from Plaintiff’s pelvic surgeon experts, Daniel Elliott, M.D. and Bobby Shull, M.D. [R. 83.] Defendants seek to exclude two separate portions of the doctors’ testimony: (1) testimony concerning alternative

procedures which may have been used to treat Ms. Owens' condition, and (2) testimony concerning duties "allegedly owed by Ethicon as a medical device manufacturer that are well outside of their expertise." *Id.* at 3, 8. In Rule 702 terms, Defendants challenge the relevancy of the alternative procedures testimony and the qualifications of the doctors to opine on the duties owed by Ethicon. As to the alternative procedures testimony, Ms. Owens counters that the testimony is admissible because it is relevant as to certain of her claims. [R. 95 at 3–4.] Next, Ms. Owens argues that Defendants overstate the scope of the doctors' testimony on Ethicon's alleged "duties" and, this in mind, the doctors are "more than qualified" to offer this proposed testimony. *Id.* at 5–7. The Court turns first to the portion of Defendants' motion challenging the alternative procedures testimony.

1

a

Under Rule 702's second prong, district courts "must ensure that the proposed expert testimony is relevant to the task at hand and will serve to aid the trier of fact." *United States v. Smithers*, 212 F.3d 306, 313 (6th Cir. 2000). The Supreme Court in *Daubert* referred to this prong as the "fit" requirement. *Daubert*, 509 U.S. at 591–93. Because "scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes," courts must consider whether a particular expert's testimony will truly assist the trier of fact in understanding the evidence in the case. *Id.* at 591. Notably, "under *Daubert* and its progeny, a party proffering expert testimony must show by a 'preponderance of proof' that the expert whose testimony is being offered . . . will testify to scientific knowledge that will assist the trier of fact in understanding and disposing of issues relevant to the case." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000).

b

Presently, Ms. Owens maintains the following claims against Defendants: Count I (Negligence); Count III (Strict Liability-Failure to Warn); Count V (Strict Liability Design Defect); Count XIV (Gross Negligence); and Count XVII (Punitive Damages). [See R. 72 at 4.] In seeking to exclude the alternative procedures testimony of Dr. Elliot and Dr. Shull, Defendants argue solely that the testimony “should be excluded from trial in this case because it is not evidence of a safer alternative design of a medical device”—an argument that concerns only the design defect claim (Count V). [R. 83 at 7–8.] As with Defendants’ prior motion to exclude, the Court finds this argument to be well taken on the design defect claim. [See R. 90 at 6 (“While the alternative procedures and treatment options identified by Dr. Fogelson may have been legitimate ways to address Ms. Owens’ condition, these alternatives have no bearing on the elements of a design defect claim.”).] But unlike her response to that previous motion, Ms. Owens’ latest response provides a sufficient explanation as to the relevancy of the testimony to her other claims and the Court will deny Defendants’ present motion.

In granting Defendants’ motion to exclude the alternative procedures testimony of Dr. Fogelson, the Court found that “Ms. Owens’ failure to explain the relevance of this testimony is significant.” *Id.*; *see also id.* (“It is . . . unclear, more generally, how this portion of Dr. Fogelson’s testimony is relevant to any of Ms. Owens’ claims.”). In other words, Ms. Owens failed to meet her initial burden of showing that Dr. Fogelson’s testimony would assist the trier of fact. *Pride*, 218 F.3d at 578. In contrast, here, Ms. Owens explains in her response that Dr. Shull and Elliot’s testimony is relevant because “[k]nowledge of alternative procedures, whether qualifying as safer alternative design or not, can still be evidence of negligence, gross negligence and punitive damages.” [R. 95 at 5.] While Ms. Owens has not provided any citation to case

law in support of this proposition, the Court finds this explanation it is sufficient to avoid wholesale exclusion of this portion of the doctors' alternative procedures testimony. Thus, the Court denies this portion of Defendants' motion at Docket Entry # 83. Of course, because the alternative procedures identified by Dr. Shull and Dr. Elliot have no bearing on the elements of a design defect claim, Plaintiff's counsel must tailor the testimony at trial accordingly.

2

Defendants also argue Dr. Shull and Dr. Elliot are not qualified to offer opinions on certain "duties allegedly owed by Ethicon as a medical device manufacturer." [R. 83.] Outside of one portion of the challenged testimony, Ms. Owens disagrees entirely. [R. 95 at 5–8.] The Court will address each "duty" in turn.

a

As an initial matter, the Court notes that Ms. Owens represents that "Drs. Shull and Elliott will not offer testimony regarding whether or not Ethicon properly trained physicians." *Id.* at 8. Accordingly, the Court will deny the portion of Defendants' motion attempting to exclude this testimony [*see* R. 83 at 12] as moot.

b

Next, the Court turns to Defendants' argument that Dr. Shull and Dr. Elliot are unqualified to offer testimony regarding the level of testing performed by Ethicon on the Prolift device. [R. 83 at 9.] Under the first prong of Rule 702, courts must ensure as a threshold matter that the proposed expert is qualified to render his or her opinion. Here, courts are to consider not "the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994). This requirement has always been treated liberally but, even so, this "does

not mean that a witness is an expert simply because he claims to be.” *Pride*, 218 F.3d at 577 (internal quotations and citations omitted).

Here, Defendants argue that Dr. Shull and Dr. Elliot “do not have specialized knowledge about the testing that medical device manufacturers like Ethicon supposedly should have performed.” [R. 83 at 9.] Ms. Owens responds that the doctors “are not seeking to opine on the adequacy of the testing done by Ethicon—but merely on the lack of testing from a factual standpoint and how the lack of testing impacted their opinions.” [R. 95 at 5.] And, based on this limitation, Ms. Owens argues each doctor is “more than qualified” to offer testimony. *Id.*

Ms. Owens’s argument regarding the scope of the doctors’ testimony amounts to a distinction without a difference. Logically, opining that there was a complete lack of testing attacks the adequacy of the testing completed. Indeed, Dr. Elliot’s report explicitly states that “[t]he Prolift was never *adequately* studied before or after launch.” [R. 95-2 at 13.] Similarly, Dr. Shull’s report concludes that “Ethicon lacked scientific rigor in the testing and reporting of its pelvic floor products.” [R. 95-1 at 3.] This type of testimony gives the Court pause. As noted by Defendants, “Plaintiff’s experts have not identified a single rule or regulation that would require Defendants to conduct different testing.” [R. 83 at 2.] This established, it is unclear exactly how Ms. Owens intends to use this testimony.

Ms. Owens states that Defendants “misunderstand[] Plaintiff’s experts’ ultimate opinion on this matter: ‘As a physician, I expect companies to provide me with complete and accurate information. This cannot be accomplished without sufficient data.’” [R. 95 at 6 (citing Dr. Shull’s report at R. 95-1).] Ms. Owens argues further that “[t]his relatively unremarkable opinion does not require specialized knowledge of the testing Defendants should have performed, rather it only requires knowledge of whether or not the testing was in fact completed .

. . which informs [Dr. Shull’s] opinion on what type of information he thinks he should be provided.” *Id.* This line of argument does little to clarify the need for Plaintiff’s expert to comment directly on the testing performed, or not performed, by Defendants. If Dr. Shull and Dr. Elliot are simply seeking to opine on “what type of information” should be ordinarily be provided by companies, then they can offer such an opinion without directly discussing what testing was performed here. Indeed, Ms. Owens cites the doctors’ extensive participation in studies which provide their bases for such an opinion. [*See* R. 95-1 at 50–51; R. 95-2 at 83–87.]

Distilled down, Ms. Owens is simply attempting to introduce corporate evidence through her expert witnesses. In an individual case in the Ethicon MDL, Judge Goodwin cautioned against this use of expert testimony: “Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his opinions—assuming the opinions are otherwise admissible—he may not be offered solely as a conduit for corporate information. There is no reason why the plaintiff requires an expert to opine on such facts.” *Carlson v. Bos. Sci. Corp.*, No. 2:13-CV-05475, 2015 WL 1931311, at *3 (S.D.W. Va. Apr. 28, 2015). This admonition holds true here. Accordingly, the Court will grant this portion of Defendants’ motion at Docket Entry # 83, consistent with the below clarifications.

Ms. Owens may introduce evidence regarding Defendants’ apparent lack of testing, to the extent it is relevant, through other appropriate means. Relatedly, to the extent it is relevant, Dr. Shull and Dr. Elliot may explain what type of information is typically provided by companies when bringing a new medical product to market and, with this foundation established, testify about the apparent lack of information provided by Ethicon as it concerns the Prolift product.¹

¹ Importantly, Ms. Owens must lay a proper foundation at trial in eliciting this testimony. In Ms. Owens’ response, in attempting to establish the qualifications of the doctors, she simply cites to their entire reports. [*See* R. 95 at 5 (citing R. 95-1 and R. 95-2).] At trial, this type of broad reference to the doctors’

Outside of this narrow exception, Ms. Owens must avoid offering testimony from the doctors on the alleged inadequacy of the testing.

c

A similar holding is warranted as it relates to Defendants’ motion to exclude the portion of Dr. Shull and Dr. Elliot’s testimony concerning Ethicon’s adverse event reporting. [R. 83 at 11.] Specifically, Defendants request the Court “exclude Drs. Elliott and Shull from criticizing the manner by which Ethicon monitors Prolift and collects adverse event reports.” [R. 83 at 11.] Again, Ms. Owens’ response in opposition is largely unpersuasive. She explains, for example, that “Dr. Shull is not offering an opinion as to the nature or quality of the adverse event reporting that should have occurred, but rather, he is stating that it did not occur. This opinion is not conjecture” [R. 95 at 7.]

The doctors’ opinions on this matter may very well be substantiated by corporate records but, as above, it is unclear why they must opine on the content of those records. Again, it appears Ms. Owens is simply attempting to use the doctors as a conduit for corporate information and so the Court will grant this portion of Defendants’ motion at Docket Entry # 83. Here, because Ms. Owens has failed to establish Dr. Shull or Dr. Elliot are qualified to testify about adverse event reporting more generally, their testimony on adverse event reporting is excluded entirely. Ms. Owens may introduce evidence regarding Defendants’ failure to collect adverse event reports, to the extent it is relevant, through other appropriate means.

3

Finally, Defendants ask the Court to “preclude Drs. Elliot and Shull from testifying about irrelevant alleged complications.” [R. 83 at 13.] Here, the Court agrees with Ms. Owens—this

qualifications will be inadequate.

motion is premature. [See R. 95 at 8.] The Court will reconsider whether such evidence is permitted in the context of trial when the substance, context, and purpose for which the evidence is offered can be considered. The Court denies this portion of Defendants' motion at Docket Entry # 83 as premature.

III

The Court has now resolved all outstanding evidentiary issues. A telephonic scheduling conference for purposes of scheduling a final pretrial conference and trial will be set by separate Order. Accordingly, and the Court being otherwise sufficiently advised, it is hereby **ORDERED** as follows:

1. Defendants' Motion to Exclude as to Peggy Pence, Ph.D [R. 80] is **DENIED**;
2. Defendants' Motion to Exclude as to Prof. Dr. Med. Uwe Klinge [R. 81] is **DENIED**;
3. Defendants' Motion to Exclude as to Vladimir Iakovlev, M.D. [R. 82] is **DENIED AS MOOT**;
4. Defendants' Motion to Exclude as to Daniel Elliot, M.D. and Bobby Shull, M.D. [R. 83] is **GRANTED in part** and **DENIED in part**, consistent with the findings of this Order.

This the 9th day of October, 2020.



Gregory F. Van Meter
United States District Judge