Amsden v. Johnson & Johnson et al Doc. 109

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Included in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Michael Thomas Margolis, M.D.)

Pending before the court is the Motion to Exclude Certain Opinions of Michael Thomas Margolis, M.D. [ECF No. 2029] filed by the defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon"). The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara

Dockets.Justia.com

J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order ("PTO") No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.[1]

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony

[1] Ethicon identified the Wave 1 cases affected by its Motion in its Exhibit A [ECF No. 2029-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only 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. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my

interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal

Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Margolis is a pelvic surgeon and urogynecologist. Ethicon seeks exclusion

of his testimony on a number of fronts.

a. Warnings

Ethicon claims Dr. Margolis is not qualified to offer expert testimony about product warnings, which includes expert testimony about the adequacy of the relevant Instructions for Use ("IFU"). According to Ethicon, Dr. Margolis is not an expert in the development of warning labels and thus is not qualified to offer expert testimony about warnings. Dr. Margolis is not an expert in the development of warning labels. While an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Margolis does not possess the additional expertise to offer expert testimony about what an IFU should or should not include. Accordingly, Dr. Margolis's expert testimony about these matters is **EXCLUDED**.

b. Complications

Ethicon seeks to exclude Dr. Margolis's complications opinions on the grounds that they are unreliable. Ethicon argues that Dr. Margolis's opinion that laser-cut mesh causes fewer complications than mechanical-cut mesh because the mesh experiences less particle loss is unreliably attributed to the TVT. Ethicon states that Dr. Margolis admitted in a deposition—for a different case—that he had no scientific literature to support his opinions. In this case, however, Dr. Margolis does support

his opinions with citation to scientific studies and articles, making Ethicon's citation to the record of another case to support its arguments dubious. Ethicon does not address in its Motion any of Dr. Margolis's cited literature in his report, thus giving me no reason to exclude Dr. Margolis on reliability grounds. Ethicon's Motion is **DENIED** on this point.

Ethicon also challenges Dr. Margolis's opinions regarding sarcomas or cancer allegedly caused by the TVT, but the plaintiffs state that Dr. Margolis will not offer these opinions. Accordingly, Ethicon's Motion is **DENIED as moot** on this point.

c. Safety and Efficacy

Ethicon makes a very narrow challenge to the reliability of Dr. Margolis's expert testimony about safety and efficacy, or the propriety of using the relevant mesh products. According to Ethicon, Dr. Margolis's expert testimony is unreliable because Dr. Margolis cannot cite any supportive medical literature. I disagree. Upon review, Dr. Margolis has cited medical literature that supports his safety and efficacy opinions. To the extent Ethicon disagrees with this medical literature or wishes to explore nuances, its efforts are better saved for cross-examination. Accordingly, Ethicon's Motion is **DENIED** on this point.

d. Mesh Properties

The plaintiffs seek exclusion of Dr. Margolis's opinions on the biomaterial properties of mesh because he is unqualified. Specifically, they object on the grounds that he is not a biomaterials expert, does not possess an engineering degree in materials science, and has not performed "bench research" on polypropylene. Mem.

13 [ECF No. 2031]. Such qualifications are not necessary to opine on the clinical properties of mesh, which is what Dr. Margolis purports to do. Dr. Margolis is a board-certified urogynecologist with a subspecialty in female reproductive surgery who has performed over 1,500 pelvic mesh surgeries and over 300 explant surgeries. This extensive clinical experience, combined with his review of and contributions to the medical literature, qualifies Dr. Margolis to opine on mesh reaction to and effect on the human body. The plaintiffs' Motion is **DENIED** on this matter.

e. Marketing

Ethicon next argues that Dr. Margolis should be excluded from offering expert opinions on medical device manufacturers' alleged marketing practices because he is unqualified to offer them. Dr. Margolis opines that a certain subset of women "provides an attractive target for marketing campaigns by device manufacturers seeking to capture a high market share for devices used in the treatment of these conditions." Margolis Report 6 [ECF No. 2029-3]. Nothing in the record demonstrates that Dr. Margolis is qualified to offer expert opinions regarding marketing strategy or techniques. Further, these opinions amount to discussions of corporate conduct and state-of-mind, which have been consistently precluded. Accordingly, Dr. Margolis's marketing opinions are **EXCLUDED**.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to

discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue

in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trail court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend*

Eng'g Co., 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the expert testimony to be excluded, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to

offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion to Exclude Certain Opinions of Michael Thomas Margolis, M.D. [ECF No. 2029].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified the Exhibit attached hereto.

ENTER: August 30, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

EXHIBIT A TO MOTION TO EXCLUDE
CERTAIN OPINIONS OF MICHAEL THOMAS MARGOLIS, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants"), in support of their their motion to exclude certain opinions of Michael Thomas Margolis, M.D., do hereby state that the instant motion applies to the following cases[1]:

Case Name	Case Number	Product
Donna Amsden v. Ethicon, Inc., et al.	2:12-cv-00960	Prolift
Karen Bollinger v. Ethicon, Inc., et al.	2:12-cv-01215	TVT
Myra & Richard Byrd v. Ethicon, Inc., et al.	2:12-cv-00748	TVT-O
Angela & Timothy Coleman v. Ethicon, Inc., et al.	2:12-cv-01267	TVT-O
Mary F. Cone v. Ethicon, Inc., et al.	2:12-cv-00261	TVT-O
Karyn E. & Douglas E. Drake v. Ethicon, Inc., et al.	2:12-cv-00747	TVT
Monica & Kenneth Freitas v. Ethicon, Inc., et al.	2:12-cv-01146	TVT

[1] Defendants reserve the right to supplement this list should any plaintiff designate Dr. Margolis as general causation expert in MDL Wave 1.

Case Name	Case Number	Product
Rose & Jesus Gomez v. Ethicon, Inc., et al.	2:12-cv-00344	Prolift & TVT-O
Dawna Hankins v. Ethicon, Inc., et al.	2:12-cv-00369	TVT
Donna Hankins v. Ethicon, Inc., et al.	2:12-cv-01011	TVT
Margaret Kirkpatrick v. Ethicon, Inc., et al.	2:12-cv-00746	TVT-O
Miranda Patterson v. Ethicon, Inc., et al.	2:12-cv-00481	TVT-O
Rebecca Pratt v. Ethicon, Inc., et al.	2:12-cv-01273	TVT
Stacy Shultis v. Ethicon, Inc., et al.	2:12-cv-00654	TVT-O
Jennifer Sikes v. Ethicon, Inc., et al.	2:12-cv-00501	TVT-O
Carrie Smith v. Ethicon, Inc., et al.	2:12-cv-00258	TVT-O
Krystal Teasley v. Ethicon, Inc., et al.	2:12-cv-00500	TVT-O
Laura & David Waynick v. Ethicon, Inc., et al.	2:12-cv-01151	TVT

Respectfully submitted,

ETHICON, INC. AND
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CERTIFICATE OF SERVICE

I certify that on April ___, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

*/s/ Christy D. Jones*_____
Christy D. Jones

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