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 Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Timothy Ulatowski)

Pending before the court is the Motion to Exclude the Opinions of FDA Expert Timothy Ulatowski [ECF No. 2060] filed by the plaintiffs. 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, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"), among others.

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 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 and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations

[1] The plaintiffs identified the Wave 1 cases affected by this Motion in their attached Exhibit A [ECF No. 2060-1], 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.

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

Mr. Ulatowski holds a master's degree in physiology and a bachelor's degree in microbiology. Mr. Ulatowski owns a consulting company that specializes in medical device regulations, policies, and procedures administered by the Food and Drug

Administration ("FDA"). Mr. Ulatowski was once an employee of the FDA.

Because I have either excluded or reserved ruling on the admissibility of Mr. Ulatowski's testimony on the grounds explained below in the Recurring Issues section, I find it unnecessary to address alternate challenges to his reliability or qualifications.

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 case, 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 trial 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*, 5-9 U.S. at 595. Hearsay objections are more appropriately raised at trial.

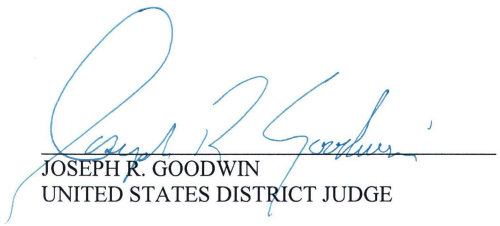
Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

V. Conclusion

The plaintiffs' Motion regarding Mr. Ulatowski falls entirely within the reoccurring issues presented to this court. Accordingly, the court **GRANTS in part**, **DENIES in part**, and **RESERVES in part** the Motion to Exclude the Opinions of FDA Expert Timothy Ulatowski [ECF No. 2060].

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 in the Exhibit attached hereto.

ENTER: August 25, 2016



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

EXHIBIT A – ULATOWSKI DAUBERT MOTION

THIS DOCUMENT RELATES TO PLAINTIFFS:

Daphne Barker
Case No. 2:12-cv-00899

Sharon Carpenter
Case No. 2:12-cv-00554

Mary Cone
Case No. 2:12-cv-00261

Joy Essman
Case No. 2:12-cv-00277

Ida Evans
Case No. 2:12-cv-01225

Shirley Freeman
Case No. 2:12-cv-00490

Rose Gomez
Case No. 2:12-cv-00344

Louise Grabowski
Case No. 2:12-cv-00683

Barbara A. Hill
Case No. 2:12-cv-00806

Jeanie Holmes
Case No. 2:12-cv-01206

Diane Kropf
Case No. 2:12-cv-01202

Danni Laffoon
Case No. 2:12-cv-00485

Alfreda Lee
Case No. 2:12-cv-01013

Dee McBrayer
Case No. 2:12-cv-00779

~~***Charlene Miracle***~~ Romona Greer
Case No. 2:12-cv-00510

Mary Jane Olson
Case No. 2:12-cv-00470

Jennifer Reyes
Case No. 2:12-cv-00939

Brenda Riddell
Case No. 2:12-cv-00547

Carrie Smith
Case No. 2:12-cv-00258

Virginia White
Case No. 2:12-cv-00958

Judy Williams
Case No. 2:12-cv-00657

Christine Wiltgen
Case No. 2:12-cv-01216

Kathleen Wolfe
Case No. 2:12-cv-00337

Donna Zoltowski
Case No. 2:12-cv-00811

Sherry Fox
Case No. 2:12-cv-00878

Lois Durham
Case No. 2:12-cv-00760

Monica Freitas
Case No. 2:12-cv-01146

Beth Harter
Case No. 2:12-cv-00737

Mary Holzerland
Case No. 2:12-cv-00875

Lois Hay
Case No. 2:12-cv-00876

Denise Sacchetti
Case No. 2:12-cv-01148

Sheri Scholl
Case No. 2:12-cv-00738

Margaret Stubblefield
Case No. 2:12-cv-00842

Laura Waynick
Case No. 2:12-cv-01151

Teri Key Shively
Case No. 2:12-cv-00379

~~***Tina Morrow***~~
~~***Case No. 2:12-cv-00378***~~ WAVE 2

Dina Sanders Bennett
Case No. 2:12-cv-00497

Joan Adams
Case No. 2:12-cv-01203

Denise Burkhart
Case No. 2:12-cv-01023

Jo'Ann Lehman
Case No. 2:12-cv-00517

Elizabeth Blynn ~~***Wilson***~~ WOLFE
Case No. 2:12-cv-01286

Patricia Conti
Case No. 2:12-cv-00516

Patricia Ruiz
Case No. 2:12-cv-01021

Barbara Vignos-Ware
Case No. 2:12-cv-00761

Cynthia Nix
Case No. 2:12-cv-01278

Fran Collins
Case No. 2:12-cv-00931

Shirley Walker
Case No. 2:12-cv-00873

Carol Jean Dimock
Case No. 2:12-cv-00401

Karen Forester
Case No. 2:12-cv-00486

Cherise Springer
Case No. 2:12-cv-00997

Joyce Justus
Case No. 2:12-cv-00956

Melissa Clayton
Case No. 2:12-cv-00489

Bonnie Blake
Case No. 2:12-cv-00995

Melissa Ridgley
Case No. 2:12-cv-01311

Pamela Gray Wheeler
Case No. 2:12-cv-00455

Dorothy Baugher
Case No. 2:12-cv-01053

Wendy Hagans
Case No. 2:12-cv-00783

Donna Massey
Case No. 2:12-cv-00880

Angela Morrison
Case No. 2:12-cv-00800

Maria Eugenia Quijano
Case No. 2:12-cv-00799

Lisa Thompson
Case No. 2:12-cv-01199

Rebecca Wheeler
Case No. 2:12-cv-01088

Thema Wright
Case No. 2:12-cv-01090

Rocio Herrera-Nevarez
Case No. 2:12-cv-01294

Debra A. and Donald Schnering
Case No. 2:12-cv-01071

Donna Shepherd
Case No. 2:12-cv-00967

Rebekah Bartlett (Pratt)
Case No. 2:12-cv-01273

Robin Bridges
Case No. 2:12-cv-00651

Myra Byrd
Case No. 2:12-cv-00748

Angela Coleman
Case No. 2:12-cv-01267

Amanda Deleon
Case No. 2:12-cv-00358

Karyn Drake
Case No. 2:12-cv-00747

Paula Fisk
Case No. 2:12-cv-00848

Teresa Georgilakis
Case No. 2:12-cv-00829

Dawna Hankins
Case No. 2:12-cv-00369

Wilma Johnson
Case No. ~~2:12-cv-00809~~ 2:11-cv-0809

Margaret Kirkpatrick
Case No. 2:12-cv-00746

Noemi Padilla
Case No. 2:12-cv-00567

Stacy Shultis
Case No. 2:12-cv-00654

Isabel Swint
Case No. 2:12-cv-00786

Susan Thaman (Reeves)
Case No. 2:12-cv-00279

Kimberly Thomas (Wyatt)
Case No. 2:12-cv-00499

Patricia Tyler
Case No. 2:12-cv-00469

Cathy Warlick
Case No. 2:12-cv-00276

Myndal Johnson
Case No. 2:12-cv-00498

Beverly Kivel
Case No. 2:12-cv-00591

Harriet Beach
Case No. 2:12-cv-00476

Holly Jones
Case No. 2:12-cv-00443

Donna Amsden
Case No. 2:12-cv-00960

Karen Bollinger
Case No. 2:12-cv-01215

Virginia Dixon
Case No. 2:12-cv-01081

Susan Guinn
Case No. 2:12-cv-01121

Heather Long
Case No. 2:12-cv-01275

Penny Rhynehart
Case No. 2:12-cv-01119

Mary and Kenneth Thurston
Case No. 2:12-cv-00505

Nancy Jo Williams
Case No. 2:12-cv-00511

Cheryl Lankston
Case No. 2:12-cv-00755

Maria Stone
Case No. 2:12-cv-00652

Donna Loustaunau
Case No. 2:12-cv-00666

Barbara Kaiser
Case No. 2:12-cv-00887

Pameal Free
Case No. 2:12-cv-00423

Julie Wroble
Case No. 2:12-cv-00883

Ana Ruebel
Case No. 2:12-cv-00663

Jackie Frye
Case No. 2:12-cv-01004

Sandra Wolfe
Case No. 2:12-cv-00335