IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
FAYETTEVILLE DIVISION

KIMBERLY WILICHOWSKI and
KENT WILICHOWSKI **PLAINTIFFS**

V. **CASE NO. 5:21-CV-5024**

BOSTON SCIENTIFIC CORPORATION **DEFENDANT**

MEMORANDUM OPINION AND ORDER

This case was transferred to this Court from the District Court for the Southern District of West Virginia, where the Honorable Joseph R. Goodwin was presiding over seven separate multi-district litigations ("MDL") concerning products sold by Defendant Boston Scientific Corporation ("BSC"). The instant matter was related to one of the seven MDLs. *See* Transfer Order, Doc. 53. Though Judge Goodwin ruled on most of the pre-trial issues concerning expert testimony, the parties represent[1] that he did not fully rule on seven such motions: BSC's Motion to Exclude Testimony of Jimmy W. Mays, M.D. (Doc. 54-56); BSC's Motion to Exclude Testimony of Dr. Bruce Rosenzweig, M.D. (Doc. 54-67); BSC's Motion to Exclude Testimony of Abbas Shobeiri, M.D. (Doc. 54-78); Plaintiffs Kimberly and Kent Wilichowski's First Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D. (Doc. 54-39); Plaintiffs' Second Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D. (Doc. 54-40); Plaintiffs' Third Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D. (Doc. 54-87); and Plaintiffs' Motion to Exclude Case-Specific Testimony of Peter Rosenblatt, M.D. (Doc. 54-41).[2] The parties have directed

[1] *See* Doc. 75.
[2] The Court notes that these Motions were filed at various times during the course of the MDL, and it appears that most of the briefing is quite stale. For example, BSC's three Motions were filed on November 4, 2019 (Docs. 54-56 & 54-78) and May 13, 2019 (Doc.

the Clerk of Court to attach all the relevant briefing for the Motions, as well as any prior orders entered by Judge Goodwin with respect to the expert testimony of the witnesses identified in the Motions.

The MDL record is composed of multiple cases, and within those cases over the course of several years, Judge Goodwin has issued many orders concerning expert testimony. The Court has therefore primarily relied on the parties to identify the pertinent briefing and MDL orders related to the seven Motions identified above. In the discussion that follows, the Court will review the relevant law governing the exclusion of proposed expert testimony and then address each Motion in turn.

I. LEGAL STANDARD

Whether to exclude expert testimony from trial is a decision committed to a district court's discretion, subject to the Federal Rules of Evidence, including Rule 702. *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 561 (8th Cir. 2014). Rule 702 states that:

> 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.

The Eighth Circuit has "boiled down" these requirements into a three-part test:

> First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence

54-67), and Plaintiffs' four Motions were filed October 18, 2018 (Doc. 54-39), January 11, 2018 (Doc. 54-40), August 1, 2014 (Doc. 54-87), and November 4, 2019 (Doc. 54-41). Still, the parties represent that all Motions require a ruling, so the Court has endeavored to treat each one as live—even though it is obvious that the MDL court issued opinions on many issues referenced in the Motions. *See, e.g.*, Docs. 54-45, 54-77, 54-91.

> must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires.

Johnson, 754 F.3d at 561 (quoting *Polski v. Quigley Corp.*, 538 F.3d 836, 839 (8th Cir. 2008)).

It follows that the proponent of expert testimony bears the burden of showing by a preponderance of the evidence that the above requirements are satisfied; however, "[c]ourts should resolve doubts regarding the usefulness of an expert's testimony in favor of admissibility." *See Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757–58 (8th Cir. 2006). When assessing the validity of scientific information in particular, the trial court may consider one or more of the following non-exclusive factors: "(1) whether the theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error; and (4) whether the theory has been generally accepted [in the relevant scientific community]." *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 687 (8th Cir. 2001) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593–94 (1993)). A district court possesses broad discretion in making its reliability determination. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 142 (1999).

II. MOTIONS

A. BSC's Motion to Exclude Testimony of Jimmy W. Mays, M.D.

BSC's first Motion asks the Court to exclude certain expected testimony of Dr. Jimmy W. Mays, a chemist. First, BSC observes that Dr. Mays "bases some of his opinions [in his expert report] on testing that he and Dr. [Samuel P.] Gido conducted" on the oxidative degradation of polypropylene pelvic mesh. (Doc. 54-56, p. 5). Dr. Mays's report references a study that was published in the scientific journal *Biomaterials* in

December of 2015. The article was titled "In Vivo Oxidative Degradation of Polypropylene Pelvic Mesh," and it was authored by Dr. Mays, Dr. Gido, and three other scientists. BSC's rationale for excluding any reference to this article—or to the experiments and data discussed in the article—stems from previous *Daubert* rulings issued by the MDL court in related cases. BSC contends that the studies conducted by Dr. Mays and Dr. Gido are too scientifically unreliable to be the subject of expert testimony.

From the Court's review of the docket, it appears that more than a year *before* the *Biomaterials* article was published, the experiment that was the subject of the article was discussed in a 2013 expert report written by Drs. Mays and Gido for the MDL case of *Tyree v. Boston Scientific Corporation*, Civil Case No. 2:12-CV-08633 (S.D. W.Va.). In the *Tyree* case, BSC raised a *Daubert* challenge to the Mays/Gido experiments, and Judge Goodwin issued an order on October 17, 2014, finding that the testing described in that report was too unreliable to be presented to the jury at trial. At the time, Judge Goodwin was persuaded that Drs. Mays and Gido had failed to control for error or bias and did not establish or adhere to testing protocols. *See Tyree v. Bos. Sci. Corp.,* 54 F. Supp. 3d 501, 535–37 (S.D. W.Va. 2014). Despite this adverse ruling, however, Judge Goodwin found Dr. Mays competent to testify "generally that polypropylene is susceptible to oxidation and degrades, without specifically referencing the unreliable testing he conducted with Dr. Gido." *Id.* at 539. Importantly, more than a year *after* Judge Goodwin's ruling, Drs. Mays and Gido partnered with other scientists to write an article about the tests they conducted. That article was then published in 2015 in *Biomaterials*, a peer-reviewed scientific journal.

In comparing the *Daubert* inquiry that was before the MDL court in 2014 to the inquiry that is before this Court today, there are several material differences. First, the instant *Daubert* challenge references an expert report written by Dr. Mays in 2018, not 2013. Second, the experiments Dr. Mays conducted with Dr. Gido have now been subject to peer review and published in a scientific journal—which was not the case when the MDL court was considering the reliability of the underlying experiments. Third, Dr. Mays's report from 2018 does not simply discuss his now-published experiments with Dr. Gido; in addition, the report broadly reviews the literature concerning oxidation and degradation of polypropylene under certain conditions and offers Dr. Mays's opinions as an expert in this field.

In deciding whether expert testimony should be excluded before trial, the Court may reasonably consider whether the scientific theory at issue has been subjected to peer review and publication. See *Lauzon*, 270 F.3d at 687. It strikes the Court that the main difference between the *Daubert* inquiry now and the one that was before Judge Goodwin in *Tyree* is that the experiments that were previously considered too unreliable have now been subjected to peer review and publication in a scientific journal. In addition, other scientists besides Drs. Mays and Gido co-authored the article, thus endorsing the scientific reliability of the underlying experiments. Under the circumstances, the Court finds the article sufficiently trustworthy in the evidentiary sense to warrant presentation to the jury. Accordingly, Dr. Mays will be permitted to refer to the *Biomaterials* article and discuss its contents, including his own participation in the testing referenced in the article and his opinions concerning the results of that testing. The first request for exclusion is therefore **DENIED**.

The next issue raised by BSC has to do with a component product of the mesh devices, which is known as Marlex polypropylene. The companies that manufacture Marlex propylene—Phillips Sumika and Chevron Phillips—issued a Material Data Safety Sheet ("MSDS") in 2004 that cautioned against the product's use in human subjects. BSC now argues that if Dr. Mays is permitted at trial "to opine about the potential reasons behind Phillips Sumika and Chevron Phillips' addition of the MSDS [Material Safety Data Sheet] Medical Application Caution in 2004," that testimony will not assist the jury, as it goes to the manufacturers' state of mind, which Dr. Mays could not possibly know. (Doc. 54-56, p. 7). In response, Plaintiffs observe that no such state-of-mind opinions appear in Dr. Mays's 2018 expert report. Instead, on a single page of the report, Dr. Mays quotes from the MSDS for Marlex polypropylene and then claims the MSDS "cautions against using the material in the human body . . . ." *Id.* at p. 96. Dr. Mays offers his own opinion that the "[a]ddition of anti-oxidants to a polymer cannot permanently prevent its oxidation" and that degradation or deterioration of the polymer is inevitable "as long as the implant remains in the body." *Id.* The Court agrees with Plaintiffs that Dr. Mays's report does not contain impermissible state-of-mind opinions about the makers of Marlex polypropylene. He has merely paraphrased the MSDS warning and explained how his own scientific opinion about the product reinforces the validity of the warning. For these reasons, the second request for exclusion is **DENIED**.

Finally, BSC contends that "Dr. Mays attempts to opine on matters that go to the state or mind or corporate intent of BSC," when he states in his report that "BSC did not take into account polypropylene's propensity for oxidation during design of its seven pelvic repair meshes." *Id.* at pp. 7–8. BSC is correct that this testimony attempts to guess

at BSC's corporate state of mind—and Plaintiffs concede the point. *See* Doc. 54-57, pp. 9–10. The MDL court previously excluded this testimony in a related MDL case. *See Sanchez v. Bos. Sci. Corp.*, 2014 WL 4851989, at *30 (S.D. W. Va. June 13, 2016). Accordingly, Dr. Mays's opinion regarding what BSC did or did not take into account when designing the device in question will be excluded under Federal Rule of Evidence 702, and the third request in the Motion is **GRANTED**.

In sum, the Motion to Exclude Testimony of Jimmy W. Mays, M.D. (Doc. 54-56) is **GRANTED IN PART AND DENIED IN PART**. The Motion is **GRANTED** as to Dr. Mays's state-of-mind opinion on what BSC "took into account" when designing the device but **DENIED** in all other respects.

B. Motion to Exclude Testimony of Dr. Bruce Rosenzweig, M.D.

In BSC's next Motion, it asks this Court to adopt the prior rulings made by the MDL court on May 29, 2018, (Doc. 54-77), with respect to Dr. Rosenzweig's causation testimony. BSC contends that Dr. Rosenzweig, a licensed urogynecologist, offers the following improper opinions in his expert report: (1) corporate state-of-mind opinions using BSC's internal documents; (2) opinions on the testing of mesh products; (3) opinions asserting an association between mesh products and cancer; and (4) opinions about whether mesh products should be used in the human body based on Dr. Rosenzweig's review of the MSDS warning for Marlex polypropylene. *See* Doc. 54-67, p. 2. Plaintiffs take issue with BSC's first, second, and fourth arguments but claim the third one—concerning opinions about a link between mesh and cancer—is moot because Dr. Rosenzweig has agreed not to testify about alleged cancer risks associated with mesh

products. The Court will therefore confine its discussion to BSC's first, second, and fourth arguments.

BSC first argues that Dr. Rosenzweig "spends a significant portion of his general report regurgitating Boston Scientific's internal documents, which were provided to him by Plaintiffs' counsel," *id.* at p. 6, and does so only to insinuate BSC's culpable corporate state of mind. In the MDL, Judge Goodwin issued an order finding that Dr. Rosenzweig was prohibited from offering state-of-mind testimony about BSC. *See* Doc. 54-77. Judge Goodwin explained that "experts may not testify about what other parties did or did not know," as such testimony would not be based on the expert's personal knowledge or expertise, but would instead be rank speculation, which is unreliable in the evidentiary sense. *Id.* at p. 4. In Dr. Rosenzweig's expert report, *see* Doc. 54-73, pp. 34–36, he does, in fact, explain the contents of several of BSC's internal documents. While he claims to do so only "for the purpose of explaining the basis for [his] opinions," *id.* at p. 34, the Court is skeptical for the reasons explained below.

Dr. Rosenzweig's report at Section IV.A.7. is titled, "BSC Internal Documents Concerning Mesh's Defective Properties Are Consistent With and Support My Opinions Expressed Herein." *See id.* at pp. 34–36. As previously stated, this portion of the report contains a summary of internal BSC documents, including Power Point presentations presented to BSC by consultants and notes on medical presentations made to BSC by outside clinicians. Despite how he characterizes these documents in this section of his report, Dr. Rosenzweig does not actually rely on them to arrive at his own opinions on the safety or efficacy of BSC's product. Instead, he cites to the documents in an attempt to illustrate BSC's knowledge of its own wrongdoing. Clearly, Dr. Rosenzweig believes

BSC's product is dangerous and poorly designed, so in a sense, BSC's internal documents can be read to support his opinion in this regard. However, as Judge Goodwin explained in the *Sanchez* case, "[a]lthough an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." 2014 WL 4851989, at *4. This Court agrees. Accordingly, if Dr. Rosenzweig references BSC's internal documents at trial, as he did in Section IV.A.7. of this report, he may not use the documents to illustrate what he believes to be BSC's state of mind. He may, of course, refer to any documents that he relied on in arriving at his own opinions.

Next, Section IV.C. of Dr. Rosenzweig's report is titled, "BSC Disregarded Prior Experience With The Protegen Device When Manufacturing the Advantage, Advantage Fit, Lynx, Obtryx, Solyx, Prefyx, Pinnacle, and Uphold Products." (Doc. 54-73 at pp. 46–48). BSC contends that this section of the report also contains Dr. Rosenzweig's opinions on BSC's corporate state of mind and should be excluded. Section IV.C. is, for the most part, Dr. Rosenzweig's review and critique of certain public-facing documents authored by BSC. He concludes that the company made representations to the public regarding the safety and effectiveness of its mesh products without having factual, clinical, medical, and scientific support for those representations. To the extent Section IV.C. is a straightforward critique of the product information that BSC presented to the public, there is no argument by BSC that Dr. Rosenzweig lacks the experience and qualifications to offer such a critique in light of his personal experience with patients who have been

implanted with the products. However, to the extent this section of the report speculates as to why BSC discontinued the sale of any mesh products or failed to perform clinical trials, *see id.* at p. 47, such speculation will be excluded as improper state-of-mind opinion testimony. Accordingly, BSC's first argument in favor of exclusion of certain testimony is **GRANTED** as set forth above.

BSC's second argument is that the Court should exclude Dr. Rosenzweig's opinions on the testing of mesh products, as his professional experience in product development only involved the creation of a catheter in the late 1980s, and he did not conduct any of his own testing on the product at issue here. Judge Goodwin opined in the related MDL case of G*riffin v. Boston Scientific*, 2016 WL 3031700, at *11 (S.D. W.Va. 2016), that Dr. Rosenzweig was "unqualified to testify on the adequacy or inadequacy of BSC's product testing," since he lacked experience, education, or knowledge about such matters. BSC refers to certain pages of Dr. Rosenzweig's report to highlight examples of his improper opinions about BSC's testing methods.

In reviewing Dr. Rosenzweig's qualifications as an expert, the Court notes that he is Assistant Professor of Obstetrics and Gynecology at Rush University Medical Center in Chicago, Illinois. (Doc. 54-69, p. 2). He has written articles and delivered lectures on such topics as pelvic organ prolapse, urinary incontinence, and repair of pelvic organ relapse. *Id.* at p. 3. He has also performed "over a thousand pelvic floor surgical procedures" and has used "numerous synthetic pelvic mesh products" in these surgeries. *Id.* The Court finds that Dr. Rosenzweig is qualified to opine on the nature and characteristics of mesh products, including the Obtryx Transobturator Mid-Urethral Sling System ("Obtryx") that Mrs. Wilichowski had implanted in her body. He is also qualified

to opine about how such products are implanted in the body and the positive and negative outcomes patients experience, given his surgical practice and research in those areas. Finally, he may discuss the medical literature he has reviewed concerning the structure and performance of mesh products in the human body. What he may not testify about is whether BSC should have undertaken further and more extensive testing of the Obtryx before offering it for sale. In this regard, the Court adopts Judge Goodwin's opinion in *Griffin* that there is insufficient evidence that Dr. Rosenzweig is qualified to opine on BSC's product testing. Accordingly, BSC's second argument in favor of exclusion is **GRANTED**.

Lastly, the Court examines BSC's fourth argument in favor of exclusion, which claims Dr. Rosenzweig should be precluded from opining that BSC's mesh devices should not be used in the body because a component product, Marlex polypropylene, carries with it a warning about the risks of permanent human implantation. BSC references Judge Goodwin's earlier opinion in *Griffin* that Dr. Rosenzweig "lacks the experience and knowledge necessary to opine on what testing a manufacturer should perform on his products" and should not be permitted to testify "that BSC did not perform the necessary testing that it should have to investigate the MSDS warning" concerning Marlex polypropylene. 2016 WL 3031700, at *12. The Court adopts Judge Goodwin's reasoning in *Griffin* and finds that Dr. Rosenzweig is not qualified to provide expert testimony on the quality and quantity of testing that BSC "should have done" in view of the product warning associated with Marlex polypropylene. The testimony to be excluded appears in the expert report at Document 54-73, pages 26 to 28. Accordingly, the fourth argument in favor of exclusion is **GRANTED**.

To sum up, the Court resolves the Motion to Exclude Testimony of Dr. Bruce Rosenzweig, M.D. (Doc. 54-67) as follows: The Motion is **GRANTED IN PART** as to testimony regarding BSC's state of mind, whether BSC should have conducted further testing of its mesh products before offering them for sale, and whether BSC should have conducted testing in view of the product warning associated with Marlex polypropylene. The Motion is **MOOT IN PART** as to testimony concerning an alleged link between mesh products and cancer.

C. Motion to Exclude Testimony of Abbas Shobeiri, M.D.

BSC seeks to exclude certain testimony offered by Dr. Shobeiri, a urogynecologist and Professor of Obstetrics and Gynecology at Virginia Commonwealth University. BSC claims Dr. Shobeiri is not qualified to opine about the Obtryx's Directions for Use ("DFU"). Dr. Shobeiri claims in his expert report that the DFU for the Obtryx does not fully and accurately describe and warn of the complications that patients, including Mrs. Wilichowski, have experienced. He bases his opinion "on the information known or knowable to Boston Scientific from the peer-reviewed scientific literature and [his] own experience." (Doc. 54-78, p. 5). BSC argues that Dr. Shobeiri should be barred from testifying about the adequacy and/or completeness of the DFU because he has no prior experience writing DFUs and has not received training on the regulatory requirements associated with DFUs. Further, BSC contends that Dr. Shobeiri improperly offered opinions concerning BSC's corporate knowledge, state of mind, or intent when he claimed that it was "known or knowable" to the company, based on the scientific literature available at the time, that the DFU was misleading or inaccurate. *Id.*

Dr. Shobeiri is a practicing gynecologist with decades of experience in the specialty field of urogynecology. In his medical practice, he has had the opportunity to review many product-related DFUs. His clinical practice centers on treating pelvic organ prolapse and stress urinary incontinence ("SUI"), and he is familiar with surgical complications that tend to be associated with pelvic mesh. He has been published in the area of pelvic floor ultrasonography, and he has personally observed mesh devices *in vivo* and correlated his own observations of mesh products with patient symptoms. *See* Doc. 54-79, p. 50. Dr. Shobeiri's CV also claims he receives referrals "from around the country for mesh-related complications" and is considered by the medical community to be an expert in treating patients who have experienced negative outcomes related to mesh devices. *Id.* at p. 52.

In light of his background, education, training, and experience, the Court finds Dr. Shobeiri qualified to opine generally about how physicians use and evaluate DFUs in their practice. He is also qualified to opine about whether incomplete or inaccurate DFUs can affect patient treatment decisions. More specifically, he is qualified to offer expert testimony about whether the usage directions for the Obtryx were complete and accurate, based on his own research, teaching, and practical experience with patients who have been implanted with this device. With that said, however, Dr. Shobeiri will not be permitted to offer his opinion as to whether the DFU for the Obtryx failed to meet regulatory compliance standards, including with the FDA. He also will be barred from offering speculative testimony about BSC's reasons or motives for developing the DFU and for selecting the language used in the DFU.

Accordingly, the Motion to Exclude Testimony of Abbas Shobeiri, M.D. (Doc. 54-78) is **DENIED** except as noted above.

D. First Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D.

Plaintiffs' First Motion regarding Dr. Spiegelberg concerns testimony he offered in a supplemental expert report dated April 11, 2018. (Doc. 54-39, pp. 15–18).[3] Initially, Plaintiffs assert that Dr. Spiegelberg does not have the qualifications to claim that "Boston Scientific followed regulatory and industry standards in the design and manufacture of its polypropylene mesh devices, including its failure analysis and testing of its devices." *Id.* at p. 18. According to Plaintiffs, Dr. Spiegelberg is not qualified to opine on the design or manufacture of any of the mesh products that were at issue in the MDL because his "expertise lies within the field of chemical engineering, like Dr. Mays—not medical device regulatory compliance . . . ." *Id.* at p. 7. Plaintiffs further characterize his testimony on regulatory and industry standards as *ipse dixit*. In response, BSC admits Dr. Spiegelberg is not qualified to opine about the Food and Drug Administration's ("FDA") certification process—and will not do so at trial—but is well qualified to testify about International Organization for Standardization ("ISO") standards and American Society for Testing and Materials ("ASTM") standards for medical devices. The Court agrees with BSC on this point.

Dr. Spiegelberg holds a Ph.D. in chemical engineering and specializes in the area of polymer characterization, including assisting clients in product analysis and modification. *Id.* at pp. 54-45. At the time he authored the expert report in question, he

[3] The Court understands that nearly every expert, including Dr. Spiegelberg, produced multiple expert reports during the course of the years-long MDL. The discussion in this section of the Opinion is limited to statements Dr. Spiegelberg made in a report authored in April of 2018, as that is the only report referenced in this particular Motion.

was the task force chairman for ASTM standards "involving the cleanliness of biomedical devices and characterization methods for polymers" and "co-chair on standards for characterization techniques for polyolefins." *Id.* at p. 46. In addition, he is "president and co-founder of Cambridge Polymer Group, Inc." and in that capacity "direct[s] a team of scientists who perform contract research, analytical testing, and device development for the biomedical and polymer communities, as well as other fields." *Id.* at p. 44. The Court finds Dr. Spiegelberg experienced, educated, and qualified to provide reliable expert testimony in accordance with Rule 702 on the regulatory and industry standards for the design or manufacture of mesh products, including the Obtryx that was implanted in Ms. Wilichowski. With that said, Dr. Spiegelberg may not specifically opine on the FDA's particular testing and certification processes and standards, as he admittedly has no FDA-related training or experience.

Lastly, Plaintiffs maintain that Dr. Spiegelberg failed to consider contrary literature when he criticized certain aspects of the Mays/Gido study published in *Biomaterials*. According to Plaintiffs, "[i]n reaching [his] opinion, Dr. Spiegelberg failed to consider the *Thompson* (2017) study that criticized the cleaning methodology in the *Thames* study." *Id.* at p. 10. Plaintiffs conclude that Dr. Spiegelberg's entire critique must be deemed "unreliable" because the scientific literature refutes his ultimate conclusions. *Id.* BSC responds that the *Thompson* study is more of an "editorial" than a scientific paper and was written "by a mesh plaintiffs' attorney and plaintiffs' experts," so Dr. Spiegelberg's failure to cite to it is of little consequence. (Doc. 54-41, pp. 4–5).

The Court finds that Plaintiffs' criticism of Dr. Spiegelberg's opinions on the Mays/Gido study go to the weight and credibility of his findings rather than to their

admissibility. Plaintiffs' counsel is free to cross-examine Dr. Spiegelberg regarding the bases for his scientific opinions and may suggest that the scientific literature is in conflict with his views and/or that he failed to consider all relevant studies. Regardless, given Dr. Spiegelberg's training and qualifications, it cannot be said that his opinions will not possibly offer any assistance to the jury. "As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination." *Loudermill v. Dow Chem. Co.,* 863 F.2d 566, 570 (8th Cir. 1988). Moreover, Dr. Spiegelberg's critique of Plaintiffs' experts, *see* Doc. 54-39, pp. 17–18, is simply that—a critique—and not, as Plaintiffs suggest, an attempt to suggest a legal opinion.

Accordingly, Plaintiffs' First Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D. (Doc. 54-39) is **DENIED**.

E. Second Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D.

In this Motion, Plaintiffs take issue with the cleansing/preparation protocol Dr. Spiegelberg employed during his physical examination of explanted mesh and with the techniques he used to analyze the mesh. They contend his methods are unreliable and should not be presented to the jury. First, Plaintiffs point out that Dr. Spiegelberg's earlier expert reports referenced and relied on so-called "position statements" published by medical organizations. They admit Dr. Spiegelberg "did not include opinions relating to any positions statements . . . in his current report" but nonetheless ask the Court to "find any opinions or testimony regarding position statements improper." (Doc. 54-40, p. 4). Plaintiffs do not cite the Court to any of Dr. Spiegelberg's prior opinions that contain the problematic position statements. Further, they agree that his report from 2018 does not

contain those references. It is not the Court's job to read through the entire record searching for expert reports in order to find testimony that one side or the other might find problematic. That is counsel's job. Therefore, Plaintiffs' first request to exclude Dr. Spiegelberg's testimony is **DENIED AS MOOT**.

Second, Plaintiffs urge the Court to exclude Dr. Spiegelberg's opinions regarding Chevron Phillips's "state of mind" when it issued a product warning in its MSDS for Marlex polypropylene. Plaintiffs argue that Dr. Spiegelberg "should not be permitted to speculate regarding the scientific validity of this [MSDS product] warning" because the reasons why Chevron Phillips placed the warning on its product are not known to Dr. Spiegelberg, and any speculation he might offer in that regard will not assist the jury. (Doc. 54-40, p. 5). BSC responds that Dr. Spiegelberg "is not offering opinions regarding Chevron Phillips' state of mind or intent regarding the Medical Application Caution." (Doc. 54-42, p. 4). Instead, Dr. Spiegelberg intends to testify about "whether there is scientific evidence that polypropylene should or should not be permanently implanted in the human body," based on his review of the literature and personal observations about the product. *Id.* at p. 5. The Court finds that Plaintiffs' second objection seeking to exclude testimony is **DENIED**. Dr. Spiegelberg, a chemical engineer with experience evaluating the chemical composition of biomedical devices, is qualified to offer an expert opinion on whether Marlex polypropylene is dangerous when implanted in the human body, and relatedly, whether the MSDS warning the manufacturer placed on the product is justified or appropriate in view of the medical data he reviewed and studies he conducted. This sort of expert testimony is not improper and would assist the factfinder in understanding the product at issue in the lawsuit. In addition, BSC avers that Dr. Spiegelberg is aware that

he is not permitted to offer state-of-mind opinions concerning the corporate motivations behind Chevron Phillips's decision to include certain information in the MSDS.

Third, Plaintiffs seek to exclude Dr. Spiegelberg's opinions on matters related to FDA product-approval requirements and compliance with FDA regulatory standards. As previously discussed, *see supra*, Section II.C., the Court found Dr. Spiegelberg qualified to testify about ISO and ASTM product standards but not qualified to testify about the FDA's certification, testing, and review process. Plaintiffs' request therefore appears to be **MOOT** in view of the fact that BSC has assured the Court that Dr. Spiegelberg will not testify about the FDA's compliance and approval processes or reference the FDA when testifying on product standards.

Fourth, Plaintiffs contend the Court should exclude Dr. Spiegelberg's opinion about the cause of "black specks" observed on the explanted mesh product. These black specks were noted by another scientist, Dr. Russell F. Dunn, in the explanted samples he tested. *See* Doc. 54-40, p. 130. Dr. Spiegelberg believes the specks Dr. Dunn observed are simply reflections of light and not defects or inclusions in the mesh. The Court notes that this sort of scientific disagreement is commonplace and is an appropriate subject for cross-examination, particularly when the dueling scientists are both qualified to assert their expert opinions and have personally examined the product at issue. The Court therefore declines to exclude Dr. Spiegelberg's opinions on black specks, as it is undisputed that he examined the explanted mesh using scientific procedures that can be reproduced, and he formed his opinions according to his scientific training and specialized knowledge of mesh and similar products. The fourth request to exclude testimony is **DENIED**.

Fifth, Plaintiffs criticize the methodology Dr. Spiegelberg used to examine and test samples of explanted mesh. They claim he prepared and cleaned the mesh using a unique protocol he developed, and they believe the chemicals he used may have damaged the samples and "create[d] reactive species that could destroy plaintiffs' evidence of oxidation." *Id.* at p. 8. Plaintiffs also believe "proper care was not taken to understand or prevent the destruction of evidence in Plaintiffs' explanted samples," and therefore, "Dr. Spiegelberg could not possibly tell a jury that his protocol did not destroy evidence of oxidation—the very thing that he claims he was looking for." *Id.* at p. 9.

BSC responds by explaining that Dr. Spiegelberg's testing protocol involved the following steps: (1) removing biologic tissue and materials from samples, (2) conducting Fourier Transform Infrared Spectroscopy ("FTIR") and Scanning Electron Microscopy ("SEM") on all samples, and (3) conducting Electron Dispersive Spectroscopy ("EDS") on any samples containing "cracking," as observed in the SEM. (Doc. 54-42, p. 8). According to Dr. Spiegelberg, his method for cleaning explanted medical devices is in line with standard laboratory practices as well as the ASTM's recommended protocols. He confirmed this in his deposition. *See id.* at pp. 121–23. As for Plaintiffs' claim that his cleaning protocols destroyed evidence that they had hoped to present about the properties of explanted mesh, BSC responds that Plaintiffs' "own experts had access to the same specimen samples and could have completed testing to affirm their theory of oxidation." *Id.* at p. 10.

The Court concludes that Plaintiffs' objections to Dr. Spiegelberg's testing methods do not warrant excluding his testimony as unreliable or deficient. The Court, as gatekeeper for expert testimony, need only be persuaded that the proposed evidence is

reliable or trustworthy in an evidentiary sense and potentially helpful to the factfinder to allow the testimony to be admitted under Rule 702. BSC has carried its burden to show that Plaintiffs' dispute with Dr. Spiegelberg's cleaning protocols is nothing more than a fair topic for vigorous cross-examination. Accordingly, the fifth request to exclude testimony is **DENIED**.

The sixth and final argument in Plaintiffs' Second Motion is that Dr. Spiegelberg "should be prevented from making sweeping statements regarding any lack of evidence—either in peer-reviewed literature or from his own examinations—to indicate that polypropylene mesh oxidizes *in vivo*, when those opinions are based on FTIR or EDS results, alone." (Doc. 54-40, pp. 11–12). BSC responds that Dr. Spiegelberg's opinions are not based on FTIR or EDS alone; instead, they are based "on his experience and knowledge working with polymers and biomaterials, his review of the scientific and medical literature, and his own testing and analysis of polypropylene inside and outside of litigation." (Doc. 54-42, p. 12). The Court agrees with BSC. To the extent Dr. Spiegelberg previously made certain admissions concerning the limitations of the FTIR or EDS testing procedures, Plaintiffs' counsel may bring up those admissions on cross-examination. The sixth request to exclude testimony is therefore **DENIED**.

In sum, Plaintiffs' Second Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D. (Doc. 54-40) is **DENIED IN PART AND MOOT IN PART**, as specifically set forth above.

F. Third Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D.

Plaintiffs' Third Motion begins by raising a topic that has already been discussed previously in this opinion: the admissibility of opinions referencing medical industry

"position statements." The Third Motion, which was written in 2014, refers to an expert report by Dr. Spiegelberg dated June 2, 2014. *See* Doc. 54-90, pp. 2–7. In that report, Dr. Spiegelberg referenced a January 2014 position statement issued by the American Urogynecologic Society and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction that states, "Polypropylene material is safe and effective as a surgical implant" and "has been used in most surgical specialties . . . for over five decades, in millions of patients in the US and the world . . . ." *Id.* at pp. 4–5. Plaintiffs point out that Dr. Spiegelberg is a chemical engineer, not a medical doctor, and he therefore lacks the background and qualifications to evaluate these position statements critically; instead, he is merely quoting them because they tend to support his own opinion that the mesh product is safe. Though BSC responds that Dr. Spiegelberg "never offers opinions about the correctness, or validity of these statements," (Doc. 54-88, p. 4), this is not entirely true. It is clear from context that Dr. Spiegelberg cites to the position statements in his June 2014 expert report in order to lend greater credence to his own opinion that the mesh is safe—even though he has no background or experience similar to the doctors who crafted and issued those statements. The Court therefore **GRANTS** Plaintiffs' request to exclude this testimony under Rule 702.

Next, Plaintiffs object to Dr. Spiegelberg's references in his June 2014 report to Chevron Phillips's MSDS warning about Marlex polypropylene. Plaintiffs contend that Dr. Spiegelberg improperly opines that Chevron Phillips included the product warning only to protect itself against future liability and did not have a true, scientific basis for suggesting that Marlex polypropylene might be unsafe for human implantation. In Plaintiffs' view, Dr. Spiegelberg's testimony attempts to explain Chevron Phillips's state of mind when it

issued the warning, and Dr. Spiegelberg lacks the ability to offer such state-of-mind testimony. Judge Goodwin already considered this exact issue in an order issued on October 29, 2014. *See* Doc. 54-91, pp. 101–03. He reasoned that Dr. Spiegelberg's attempt to infer the knowledge, motivations, intent, or state of mind of Chevron Phillips is not the subject of proper expert testimony. The Court agrees with his reasoning and adopts his conclusions. Accordingly, Plaintiffs' second request for exclusion regarding Dr. Spiegelberg's 2014 report is **GRANTED**.

In sum, Plaintiffs' Third Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D. (Doc. 54-87) is **GRANTED**.

G. Motion to Exclude Case-Specific Testimony of Peter Rosenblatt, M.D.

The final *Daubert* motion before the Court concerns certain testimony offered by Dr. Peter Rosenblatt, a board-certified obstetrician/gynecologist with a subspecialty certification in female pelvic medicine reconstructive surgery. He is the Director of Urogynecology and Reconstructive Pelvic Surgery at Mount Auburn Hospital in Cambridge, Massachusetts. In his expert report, he explains that he has been using synthetic mesh products to treat SUI in patients since the early 1990s and has published case studies on the effectiveness of these products. *See* Doc. 41-1, p. 8. His opinion is that "the minimally-invasive synthetic sling has been shown to be safe, effective and reproducible and is considered the gold-standard surgical treatment for [SUI]." *Id.* at p. 19. He also maintains that he "ha[s] not seen any degradation of polypropylene fibers or mesh" in patients. *Id.*

Plaintiffs ask that that the Court prohibit Dr. Rosenblatt from testifying that there is not likely to be any correlation between Mrs. Wilichowski's subjective complaints of pain

and the Obtryx. Dr. Rosenblatt opines in his report that "just because you can elicit pain on palpation does not always correlate with the subjective complaint of pain that the patient has." *Id.* at p. 35. Certainly, Plaintiffs disagree with this opinion, but that does not mean Dr. Rosenblatt is not qualified to offer it at trial. The subject matter of his opinion is well within his knowledge, experience, and training as a clinician who has practiced in this specialty area of gynecological medicine for decades. Plaintiffs' counsel is free to test his opinion through cross-examination. Further, Dr. Rosenblatt's disagreement with the opinions of Plaintiffs' experts, Drs. Veronikas and Shobeiri, on the cause or causes of Mrs. Wilichowski's complaints of pain is another appropriate topic for expert testimony in view of Dr. Rosenblatt's experience and qualifications. Accordingly, Plaintiffs' first request to exclude testimony is **DENIED**.

Next, Plaintiffs argue that Dr. Rosenblatt's opinion about the properties of polypropylene mesh lack a reliable scientific foundation, as he is neither a pathologist nor a biomaterials expert. The Court agrees that he is not qualified to testify about the *chemical* properties of mesh; however, his surgical experience does qualify him to testify about the *physical* properties of mesh. Dr. Rosenblatt has performed surgeries in which he has both implanted and explanted mesh devices, including the Obtryx. He is therefore qualified to testify on topics that draw on his personal experience and observation with mesh devices. In particular, he may offer opinions on whether mesh devices tend to migrate from their original site of implantation, whether mesh devices tend to shrink or constrict after implantation, and whether and how mesh devices affect nearby organs and structures in the body or otherwise "integrate" into the surrounding tissue. Plaintiffs' second request for exclusion of testimony is **DENIED**.

Dr. Rosenblatt also opines that that he has "seen no evidence that there is any scientific basis supporting the medical application caution language in the [MSDS]" for Marlex polyproplene. *Id.* at p. 23. This statement or opinion will be excluded from trial as lacking an adequate scientific basis. The fact that Dr. Rosenblatt has "seen no evidence" supporting the MSDS cautionary statement for Marlex polypropylene proves nothing and would not assist the jury in deciding any question of fact. Further, he admits that he "do[es] not review MSDS information sheets for medical devices [he] use[s] because it is not a source of scientific information" applicable to his clinical practice. Plaintiffs' request to exclude opinions related to the MSDS warning is **GRANTED**.

Plaintiffs next ask that "all references by Dr. Rosenblatt to the FDA be stricken from his report and [that] he be precluded from offering testimony at the trial of this matter regarding the same . . . ." (Doc. 42, p. 11). Plaintiffs refer the Court to several pages in Dr. Rosenblatt's report that mention the FDA's clearance of mesh devices. *See* Doc. 41-1, pp. 7–10. In these pages, Dr. Rosenblatt merely recites the history of mesh-device usage, including when such devices were first approved for sale by the FDA. He does not opine about the FDA's approval process or claim that the Obtryx must be safe if it was cleared by the FDA. Yet Plaintiffs argue that Dr. Rosenblatt references FDA approval for some ulterior purpose. They assert that what he is really claiming in this section of the report is that the Obtryx device is safe and effective because it was cleared by the FDA. (Doc. 42, p. 10). The Court disagrees. Dr. Rosenblatt is permitted to mention in his report the fact that the FDA cleared the Obtryx. He is not permitted, however, to draw conclusions about the safety and efficacy of the product by virtue of its FDA approval. As

the Court does not believe that the report contains impermissible expert opinions about the FDA and its review process, the request for exclusion of these references is **DENIED**.

Lastly, Plaintiffs ask the Court to exclude references in Dr. Rosenblatt's opinion to "position statements" issued by certain medical organizations. *See* Doc. 41-1, pp. 24–26. Plaintiffs are correct that position statements do not qualify as expert opinions. Dr. Rosenblatt will be permitted to explain to the jury the materials he reviewed and relied on in forming his own expert opinions; however, he will not be permitted to simply regurgitate the content of position statements issued by medical organization as though they were his own opinions. Similarly, Dr. Rosenblatt may not testify in a manner that equates these position statements to his own medical opinions. For these reasons, Plaintiffs' request to exclude these references is **GRANTED** except as noted above.

To sum up, Plaintiffs' Motion to Exclude Case-Specific Testimony of Peter Rosenblatt, M.D. (Doc. 41) is **GRANTED IN PART AND DENIED IN PART**. Plaintiffs' request to exclude Dr. Rosenblatt's opinions related to the MSDS warning for Marlex polypropylene and references to position statements issued by medical organizations is **GRANTED**, but all other requests for exclusion are **DENIED**.

III. CONCLUSION

IT IS THEREFORE ORDERED that BSC's Motion to Exclude Testimony of Jimmy W. Mays, M.D. (Doc. 54-56) is **GRANTED IN PART AND DENIED IN PART**. The Motion is **GRANTED** as to Dr. Mays's state-of-mind opinion on what BSC "took into account" when designing the device but **DENIED** in all other respects.

IT IS FURTHER ORDERED that BSC's Motion to Exclude Testimony of Dr. Bruce Rosenzweig, M.D. (Doc. 54-67) is **GRANTED IN PART AND MOOT IN PART**.

IT IS FURTHER ORDERED that BSC's Motion to Exclude Testimony of Abbas Shobeiri, M.D. (Doc. 54-78) is **DENIED** except as noted above.

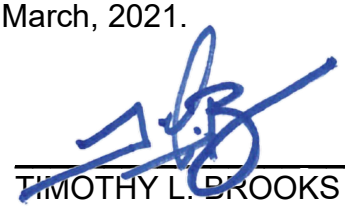
IT IS FURTHER ORDERED that Plaintiffs' First Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D. (Doc. 54-39) is **DENIED**.

IT IS FURTHER ORDERED that Plaintiffs' Second Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D. (Doc. 54-40) is **DENIED IN PART AND MOOT IN PART**.

IT IS FURTHER ORDERED that Plaintiffs' Third Motion to Exclude Testimony of Stephen H. Spiegelberg, Ph.D. (Doc. 54-87) is **GRANTED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Case-Specific Testimony of Peter Rosenblatt, M.D. (Doc. 54-41) is **GRANTED IN PART AND DENIED IN PART**. The Motion is **GRANTED** as to opinions about the scientific basis for MSDS warnings and references to position statements issued by medical organizations but **DENIED** in all other respects.

IT IS SO ORDERED on this 29th day of March, 2021.



TIMOTHY L. BROOKS
UNITED STATES DISTRICT JUDGE