IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

KULWINDER KAUR,	)	
	)	
Plaintiff,	)	
	)	C.A. No.: N19C-07-117 PEL
v.	)	
	)	
BOSTON SCIENTIFIC CORPORATION (d/b/a MANSFIELD SCIENTIFIC, INC. & MICROVASIVE, INC.),	)	
	)	
Defendant.	)	

Submitted: January 5, 2022
Decided: May 11, 2022

Robert J. Leoni, Esquire, Shelby & Leoni, 221 Main Street, Wilmington, DE 19804, Attorney for Plaintiffs

Colleen D. Shields, Esquire, Eckert, Seamans, Cherin & Mellott LLC, 222 Delaware Avenue, 7th Floor, Wilmington, DE 19801, Attorney for Defendant

Jones, J.

Introduction

This opinion constitutes the Court's decision on Defendant's, Boston Scientific Corporation, d/b/a Mansfield Scientific, Inc. & Microvasive, Inc. ("BSC"), eight (8) *Daubert* motions. BSC asks this Court to determine whether the opinions and testimony of the Plaintiff's experts should be excluded under Delaware Rule of Evidence 702, *Daubert v. Merrell Dow Pharmaceuticals, Inc.* and *M.G. Bancorporation, Inc. v. Le Beau*.

This is a products liability claim that involves one of Boston Scientific's surgical mesh products – the Obtryx. Plaintiff has alleged that this polypropylene surgical mesh implant – midurethral slings ("MUS") – which was used by her surgeon to treat her for stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP") has caused her to experience injuries.

This Court has reviewed both parties' materials and for the reasons set forth fully below, this Court GRANTS, in part, and DENIES, in part, BSC's motions.

Standard of Review

Delaware Rule of Evidence 702 governs the admissibility of expert testimony. Delaware has adopted the holdings in *Daubert v. Merrell Dow Pharmaceuticals Inc.*[1] and *Kumho Tire Co., Ltd. v. Carmichael* [2] to interpret the Delaware Rule. [3] In

[1] 509 U.S. 579 (1993).
[2] 526 U.S. 137 (1993).
[3] *Bowen*, 906 A.2d at 794 (citing *M.G. Bancorporation, Inc. v. Le Beau*, 737 A.2d 513, 522 (Del. 1999)).

Daubert and *Kumho*, the United States Supreme Court interpreted and explained Federal Rule of Evidence 702, which is "substantially similar" to the Delaware Rule.[4] Delaware Rule 702 states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise, if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based upon sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the witness has applied the principles and methods reliably to the facts of the case.[5]

To be admissible, expert testimony must be "relevant and reliable." [6] To make this determination, the trial judge engages in a five-step analysis.[7] This analysis provides that the trial judge finds that:

> (1) the witness is qualified as an expert by knowledge, skill, experience, training, or education;
> (2) the evidence is relevant;
> (3) the expert's opinion is based on information reasonably relied upon by experts in the particular field;
> (4) the expert testimony will assist the trier of fact to understand the evidence or to determine a fact in issue; and
> (5) the expert testimony will not create unfair prejudice or confuse or mislead the jury.[8]

The burden of establishing that the expert testimony is admissible lies with its proponent by a preponderance of the evidence.[9] "A strong preference exists" for

[4] *Smack-Dixon v. Walmart Inc.*, 2021 WL 3012056 (Del. Super. Ct. Jul. 16, 2021) (citing *Bowen v. E.I. DuPont de Nemours & Co., Inc.*, 906 A.2d 787, 794 (Del. 2006)).
[5] D.R.E. 702. *See also Smack-Dixon*, 2021 WL 3012056 (Del. Super. 2021).
[6] *Daubert*, 508 U.S. at 597.
[7] *Smack-Dixon*, 2021 WL 3012056 at *2 (citing *Bowen*, 906 A.2d at 795).
[8] *Id.*
[9] *Id.*

admitting expert opinions "when they will assist the trier of fact in understanding the relevant facts or the evidence."[10]

Reliable expert testimony is premised on scientific or specialized knowledge which requires the testimony to be grounded in scientific methods and procedures and "supported by appropriate validation – *i.e.*, 'good grounds,' based on what is known."[11]

Many scientific, technical, or specialized fields are not subject to peer review and publication which is why the test of reliability is "flexible." Rigid application of the *Daubert* factors cannot just be engaged to determine testimonial reliability in every field of expertise.[12] Even with all the advances of medical science, the practice of medicine remains an art, and a diagnosis in the practice of clinical medicine "is not an exact science."[13]

Again, a gatekeeping judge has "broad latitude" to determine whether an expert's proffered opinion is based upon the "proper factual foundation and sound

[10] *Smack-Dixon*, 2021 WL 3012056 at * 2 (quoting *Delaware ex. Rel. French v. Card Compliant, LLC*, 2018 WL 4151288 at *2 (Del. Super. Ct. Aug. 29, 2018) (quoting *Normal v. All About Women, P.A.*, 193 A.2d 726, 730 (Del. 2018)).
[11] *Daubert*, 508 U.S. at 590.
[12] *Henlopen Hotel v. United Nat'l Ins. Comp.*, 2020 WL 233333 at *3 (Del. Super. Ct. Jan. 10, 2020).
[13] *State v. McMullen*, 900 A.2d 105, 114 (Del. Super. Ct. 2006). *See also Moore v. Ashland Chem.*, 126 F.3d 679, 688-690 (5th Cir. 1997), *vacated on reh'g en banc*, 151 F.3d 269 (5th Cir. 1998) ("First, the goals of the disciplines of clinical medicine and hard Newtonian science are different….Second, the subject matter and conditions of study are different…Finally, clinical medicine and hard science have marked different methodologies….In sum, hard Newtonian scientific knowledge…is knowledge of a particular and limited kind….Although clinical medicine utilizes parts of some hard sciences, clinical medicine and many of its subsidiary fields are not hard sciences…. Consequently, the *Daubert* factors, which are hard scientific methods selected from the body of hard scientific knowledge and methodology generally are not appropriate for use in assessing the relevance and reliability of clinical medical testimony."). The Fifth Circuit's discussion of the significant differences between disciplines in "hard science" and clinical medicine still holds true even though the decision in that case was ultimately vacated. *Id.*

methodology."[14] This "proper factual foundation" language has been distilled from Delaware Rule 702.[15] To meet the criterion for a "proper factual foundation," an expert's opinion must be based on "facts" and not "suppositions."[16] When applied to a medical expert, a causation opinion is admissible when it's "based on his analysis of the circumstances … not mere speculation over the cause."[17] And a proponent need only show by a preponderance of the evidence that her expert's opinions are reliable, not that they are correct.[18] So, this Court's Rule 702 reliability examination must focus on principles and methodology, not on the resultant conclusions.[19]

Delaware courts generally recognize that challenges to the "factual basis of an expert opinion go[] to the credibility of the testimony, not the admissibility, and it is for the opposing party to challenge … the expert opinion on cross-examination."[20] "The different depth with which [an expert] pursued particular lines of investigation and the different assumptions they made are readily subject to cross-

[14] *Russum v. IPM Development Partnership LLC*, 2015 WL 2438599 at *2 (Del. Super. Ct. May 21, 2015).
[15] *Id.*
[16] *Id.* at *3.
[17] *Smack*-Dixon, 2021 WL 3012056 at *5 (quoting *Norman v. All About Women, P.A.*, 193 A.3d 726, 732 (Del. 2018).
[18] *State v. McMullen*, 900 A.2d 105, 114 (Del. Super. Ct. 2006) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994)).
[19] *Henlopen Hotel*, 2020 WL 233333 at *2 ("At bottom, the Court's examination of an expert's opinion must be solely focused on principles and methodology, not on the conclusions they generate.") (quoting *Tumlinson v. Advanced Micro Devices*, 81 A.3d 1264, 1269 (Del. 2013)).
[20] *Perry v. Berkley*, 996 A.2d 1262, 1271 (Del. 2010). *See also Hodel v. Ikeda*, 2013 WL 226937 at *4 (Del. Super. Ct. Jan. 18, 2013); *Daubert*, 509 U.S. 679, 596 (1993) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." (internal citations omitted); *Russum*, 2015 WL 2438599 at *3.

examination and to evaluation by the fact finder for credibility and weight."[21] An expert's testimony will only be excluded in the narrow circumstance where he is shown to have completely neglected the core facts of the case.[22] And, under Delaware Rule 702, a medical doctor's opinion "based on his own knowledge" and informed by his review of a patient's records may certainly be sufficient to clear the *Daubert/Bowen* reliability threshold.[23]

Analysis

General Objections

BSC raises various general objections as to the challenged experts. BSC asserts that the experts should be precluded from offering narrations of BSC's company documents, opinions on BSC's corporate conduct, and opinions in the form of legal conclusions.

As has been consistently held by the MDL Court,[24] the foregoing topics exceed the scope of expert witness's testimony and will not assist the trier of fact.[25] Thus, in accord with various courts that have ruled on these issues, this Court will

[21] *Henlopen Hotel*, 2020 WL 233333 at *4; *Perry v. Berkley*, 996 A.2d at 1271 (noting cross-examination rather than exclusion can be the proper method of exploring the bases of an expert's opinion and the weight to be ascribed thereto).
[22] *Russum*, 2015 WL 2438599 at *3.
[23] *Smack-Dixon*, 2021 WL 3012056 (citing *Norman*, 193 A.3d at 731-32).
[24] The federal multi-district court handling the federal pelvic mesh cases is venued in West Virginia.
[25] *Sanchez v. Bos. Sci. Corp.*, 2014 WL 4851989, at *4 (S.D.W.Va. Sept. 29, 2015); *Eghnayem v. Bos. Sci. Corp.*, 57 F.Supp.3d 658, 669 (S.D.W.Va. 2014); *Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 702 (S.D.W.Va. 2014); *In re C.R. Bard,* Inc., 948 F.Supp.2d 589, 611, 629 (S.D.W.Va. 2013).

not permit the experts to offer their opinions about BSC's state of mind.[26] Nor will the experts be permitted to offer opinions about the reasonableness of BSC's actions.[27] As to narratives of BSC's corporate documents, assuming these opinions are otherwise admissible, the experts are permitted to offer testimony regarding BSC's corporate documents to the limited extent that they relied upon the documentation to form the basis of their opinions.[28]

The experts will also be precluded from offering any opinions phrased as legal conclusions. "[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."[29] By allowing such testimony would be to allow the trier of fact's fact-finding function to be usurped and this Court will not allow that.

Bruce Rosenzweig, M.D.

Dr. Rosenzweig is a urogynecologist and a professor of obstetrics and gynecology in Chicago, Illinois. Plaintiffs offer Dr. Rosenzweig as a general causation expert on the properties of polypropylene mesh used in the Obtryx, its reaction when implanted in the body, and the possible complications associated with their use to treat SUI.

A. Properties of Polypropylene Opinions

[26] *Sanchez v. Bos. Sci. Corp.*, 2014 WL 4851989 at *4 (S.D.W.Va Sept. 29, 2015) (citing *Huskey v. Ethicon, Inc.*, 2015 WL 3362264 at *3 (S.D.W.Va. July 8, 2014); *Lewis, et al. v. Ethicon, Inc.*, 2014 WL 186872 at *6, *21 (S.D.W.Va. Jan. 15, 2014); *In re C.R. Bard, Inc.*, 948 F.Supp.2d 589, 611, 629 (S.D.W.Va. 2013)).
[27] *Id.*
[28] *Sanchez*, 2014 WL 4851989 at *4.
[29] *United States v. Mclver*, 470 F.3d 550, 562 (4th Cir. 2006).

BSC argues that Dr. Rosenzweig is neither qualified nor are his opinions reliable on this topic, especially as to his opinions relating to degradation of mesh. Plaintiff responds that this Court, in a previous ruling, permitted Dr. Rosenzweig to offer his opinions on this point and that the Court should do the same here.

In *Harris v. Bos. Sci. Corp.*,[30] this Court found Dr. Rosenzweig both qualified to offer his opinions about polypropylene properties and that his opinions were reliable under *Daubert*. As to Dr. Rosenzweig's qualifications, this Court relied on the rationale of the Court in *Wilkerson v. Bos. Sci. Corp.*,[31] where the Court explained:

> Dr. Rosenzweig's established background and skills in pelvic surgery, polypropylene, and the complications associated with degradation qualify him to opine on the degradation process, even though his knowledge about the precise biochemical interactions involved might not be as extensive as that of others… Any gaps in Dr. Rosenzweig's knowledge go to his credibility, not his admissibility as an expert.[32]

Also, BSC argues that Dr. Rosenzweig's opinions on this point are unreliable. This Court did not agree with BSC when it raised this argument in *Harris* and still does not.[33] Dr. Rosenzweig has more than twenty years of experience in examining patients. In addition to his experience, Dr. Rosenzweig has reviewed an abundance of medical literature regarding the degradation of polypropylene. In lieu of his

[30] C.A. No. N15C-06-216 PEL (Apr. 11, 2017).
[31] 2015 WL 2087048 (S.D.W.Va. May 5, 2015).
[32] *Id.* at 5.
[33] *Id.* at 6.

experience and review, Dr. Rosenzweig's opinions about polypropylene properties, including his opinion that mesh degrades, is sufficiently reliable under *Daubert*.

Based on the foregoing, this Court concludes that Dr. Rosenzweig is qualified to offer his opinions about the properties of polypropylene, including degradation, and that these opinions are sufficiently reliable under *Daubert*.

B. BSC's Product Testing Opinions

BSC argues that Dr. Rosenzweig is not qualified to offer opinions about BSC's product testing. Plaintiff concedes that Dr. Rosenzweig will not be offering these opinions. Therefore, BSC's motion on this point is GRANTED.

C. Link Between Cancer and Polypropylene Mesh Opinions

BSC argues that Dr. Rosenzweig's cancer opinions must be excluded. Plaintiff does not respond to this argument, and by doing so, foregoes the opportunity to do so. Moreover, as Plaintiff is not claiming a cancer related injury, the testimony is irrelevant and unduly prejudicial. Therefore, BSC's motion on this point is GRANTED.

D. Material Safety Data Sheet ("MSDS") Opinions

BSC argues that Dr. Rosenzweig's opinions on the MSDS are irrelevant and unhelpful and that he is not qualified to offer such opinions. As noted by BSC, the MDL Court has routinely excluded these opinions because Dr. Rosenzweig does not

possess the proper qualifications to opine on this topic.[34] Plaintiff offers no response relating to Dr. Rosenzweig's qualifications on this point. Rather, Plaintiff argues that the opinions are relevant and should be admitted. While that may be true, it means nothing if Dr. Rosenzweig does not possess the requisite qualifications to offer such opinions.

The basis for the MDL Court finding Dr. Rosenzweig to be unqualified was based on his lack of "experience and knowledge necessary to opine on what testing a manufacturer should perform on his products."[35] In the instant litigation, Plaintiff has conceded that Dr. Rosenzweig will not be offering his product testing opinions. But, because Dr. Rosenzweig's qualifications to opine on product testing relate to his MSDS opinions, this Court must determine whether Dr. Rosenzweig possesses the requisite qualifications to opine on product testing.

This Court chooses to follow the lead of the MDL Court and concludes that Dr. Rosenzweig's opinions on product testing go beyond the bounds of his expertise. In *Sanchez*, the Court explained:

> While Dr. Rosenzweig has years of experience operating with polypropylene mesh products, his expert report does not convey any similar experience, education, or knowledge about the appropriate testing a medical device manufacturer should perform on its products prior to sale. The plaintiff's response does not allude to any relevant experiences either. Therefore, I agree with BSC and find Dr.

[34] *Id.* at 9. *See also Sederholm v. Bos. Sci. Corp.*, 2016 WL 3282587 at *10 (S.D.W. Va. Jun. 14, 2016); *Flandro v. Bos. Sci. Corp.*, 2016 WL 3282734 at *10 (S.D.W. Va. Jun 14, 2016) *Griffin v. Bos. Sci. Corp.*, 2016 WL 3031700 at *11-12 (S.D.W. Va. May, 25, 2016).
[35] *Wilkerson*, 2015 WL 2087048 at *7.

> Rosenzweig unqualified to testify on the adequacy or inadequacy of BSC's product testing.[36]

Similarly here, Dr. Rosenzweig's expert report and Plaintiff's response is lacking with any indicia that he is qualified to offer opinions related to a medical device manufacturer's product testing. Dr. Rosenzweig's lack of qualifications relating to product testing has led the MDL court to also find him unqualified to offer his opinions about the MSDS. This Court has no reason to deviate from the MDL Court's prior rulings, and thus, Dr. Rosenzweig's opinions on this point are excluded.

Vladimir Iakovlev, M.D.

Dr. Iakovlev is an anatomical pathologist and Director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada.

A. General Causation Opinions

Dr. Iakovlev offers two general causation opinions in the instant litigation: (1) the various symptoms which pelvic mesh can purportedly cause, such as inflammation, pain, scarring, or nerve entrapment; and (2) the changes which pelvic mesh purportedly undergoes *in vivo* – specifically mechanical deformation of the

[36] *Id.*

mesh itself and chemical degradation of its polypropylene materials – and how those changes allegedly contribute to the aforementioned symptoms.

The crux of BSC's arguments relating to Dr. Iakovlev's general causation opinions is his reliance on his own study which BSC advances is "not good science." Plaintiff responds that Dr. Iakovlev's mesh samples are relevant and reliable because he kept reliable records identifying which samples were Advantage products, as opposed to transvaginal implants made by another manufacturer.

BSC correctly notes that the MDL Court has routinely excluded Dr. Iakovlev's opinions because they are unreliable.[37] The rationale for excluding Dr. Iakovlev is focused on the uncertainty surrounding his study, specifically the polypropylene mesh samples chosen and provided to him. Dr. Iakovlev is unable to provide any information about the methodology employed by Plaintiffs' counsel, who supplied him with seventy percent of the samples, in choosing the mesh explant samples he relied upon in his study – the study which now forms the basis of his opinions in the pelvic mesh litigation. The fact that Dr. Iakovlev study was subjected to publication and peer-review does not cure this Court's reliability concerns relating to his study. "'[P]ublication (which is but one element of peer review) is not a *sine qua non* of

[37] *See In re Bos. Sci. Corp.*, 2018 WL 2419058 at *2 (S.D.W. Va. May 29, 2018); *Trevino v. Bos. Sci. Corp.*, 2016 WL 2939521 at *30 (S.D.W. Va. May 19, 2106); *Young v. Mentor Worldwide, LLC*, 312 F.Supp. 765, 772 (E.D. Ark. 2018).

admissibility; it does not necessarily correlate with reliability,' and is not dispositive."[38]

Further, the samples relied upon by Dr. Iakovlev in his study are of all varying degrees of mesh. In *Young*, the Court explained that Dr. Iakovlev's opinions lack reliability because there was a specific mesh product at issue but his study involved examination of various polypropylene products. [39] Dr. Iakovlev, by his own admission, stated that different mesh products cause different types of pathological changes.[40] Similarly, in the instant litigation, there is a specific mesh product at issue – Obtryx, which contains a monofilament polypropylene mesh.

This Court's concerns revolving around the uncertainty of Dr. Iakovlev's study have been left uncured by his report. As such, this Court, in accord with the MDL Court and its previous rulings, concludes that Dr. Iakovlev's opinions on this point must be excluded for falling short of the reliability standard of *Daubert*.

Peggy Pence

Dr. Peggy Pence is a clinical and regulatory consultant who provides advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the FDA.

A. Premarket Clinical Testing

[38] *Trevino*, 2016 WL 2939521 at *31.
[39] *Young*, 312 F.Supp.3d at 771.
[40] *Id.*

BSC argues that Dr. Pence's opinions regarding the adequacy of BSC's premarket clinical testing should be excluded because the methodology she used is unreliable and not generally accepted for various reasons. Plaintiff responds that Dr. Pence's opinions are reliable based on her reliance on GHTF standards, the HAS study, and NICE standards.

The MDL Court has consistently permitted Dr. Pence to offer her opinions on this point and this Court chooses to do the same.[41] At the outset, this Court notes that "'general acceptance' is not a necessary precondition to the admissibility of scientific evidence."[42] Rather, Rule 702 "assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. Pertinent evidence based on scientifically valid principles will satisfy those demands."[43]

Most, if not all, courts that have addressed this issue have relied on the rationale from *Sanchez v. Bos. Sci. Corp.*[44] In *Sanchez*, Dr. Pence offered an opinion identical to the one offered in the instant litigation:

> [T]hat BSC should have performed adequate preclinical and clinical testing and evaluation of the Prefyx Sling, the Solyx SIS, and Uphold PFR Kits prior to marketing to ensure the devices were reasonably safe for permanent implantation. By its failure to do so, BSC fell below the

[41] *See Sanchez v. Bos. Sci. Corp.*, 2014 WL 48519 at *33-34 (S.D.W.Va. Sept. 29, 2014); *Mathison v. Bos. Sci. Corp.*, 2015 WL 2124991 at *15-16 (S.D.W.Va. May 6, 2015); *Trevino v. Bos. Sci. Corp.*, 2016 WL 2939521 at *17-18 (S.D.W.Va. May 19, 2016); *Frankum v. Bos. Sci. Corp.*, 2015 WL 1976952 at *19-20 (S.D.W.Va. May 1, 2015); *Carlson v. Bos. Sci. Corp.*, 2015 WL 1931311 at *24-25 (S.D.W.Va. Apr. 28, 2015).
[42] *Daubert v. Merrell Dow Pharm., Inc.*, 508 U.S. 579, 597 (1993).
[43] *Id.*
[44] 2014 WL 4851989 (S.D.W.Va. Sept. 29, 2014).

> standard of care required of a reasonably prudent medical device manufacturer[.][45]

As in *Sanchez*, here, Dr. Pence relies on various materials to support her opinions. This includes the risks associated with polypropylene mesh, statements in Material Safety Data Sheets provided by the polypropylene supplier in 2004 indicating that polypropylene should not be used for permanent implantation in the human body, and development history of BSC products.[46]

BSC takes issue specifically with Dr. Pence's reliance on the French National Authority for Health ("HAS") and the National Institute for Health and Care Excellence ("NICE") to substantiate her opinions. However, in *Sanchez*, the Court's previous reliability concerns about Dr. Pence's premarket testing opinions were dispelled based on her "bolstered expert report" that included cites to the HAS and NICE. As to the HAS and NICE, the Court stated:

> [Dr. Pence] describes a 2006 study conducted by the [HAS], in which it evaluated the safety and efficacy of vaginally implanted mesh for the treatment of genital prolapse. HAS concluded that "the research" and recommended prospective studies on the anatomical and functional outcomes of mesh implantation, the mid- to long-term effects, possible adverse events like erosion, and the management of erosions and retractions. Dr. Pence also discusses the recommendations of the [NICE], which include the warning that transvaginal mesh repair "should be used with special arrangements for clinical governance, consent and audit or research."[47]

[45] *See* Exhibit "B" to Defendant's Motion to Exclude the Opinions and Testimony of Peggy Pence, PH.D., at 52. *See also Sanchez,* 2014 WL 4851989 at *33.
[46] *See* Exhibit "B" to Defendant's Motion to Exclude the Opinions and Testimony of Peggy Pence, PH.D., at 32-42.
[47] *Id.*

In following the pattern of the MDL Court, this Court chooses to adopt the rationale of the *Sanchez* Court as to the instant litigation. Dr. Pence's premarket opinions are "backed by authoritative studies that recommend the performance of clinical trials and long-term follow-ups before using polypropylene mesh."[48] Therefore, these opinions are admissible and BSC's motion on this point is DENIED.

B. BSC's Product Labeling

BSC argues that Dr. Pence improperly relies on FDA and GHTF standards that do not substantiate her opinions about the alleged inadequacy of BSC's pelvic mesh product labeling. The MDL Court has consistently excluded Dr. Pence's opinions on this topic because they are unreliable under *Daubert*.[49] Plaintiff responds that this Court should admit Dr. Pence's opinions because she has bolstered her report from the time the MDL Court had rejected her opinions.

The bolstering Plaintiff is referring to is Dr. Pence's reliance on the GHTF standards. Despite Plaintiff's position, this Court finds that Dr. Pence's reliance on non-FDA standard does nothing to "bolster" her report and her opinions remain unreliable for the purposes of *Daubert*. In so finding, this Court adopts the rationale

[48] *Id.*
[49] *Sanchez v. Bos. Sci. Corp.*, 2014 WL 4851989 (S.D.W.Va. Sept. 29, 2014). *See also Eghnayem v. Bos. Sci. Corp.*, 57 F.Supp.3d 658, 696-97 (S.D.W.Va. 2014); *Tyree v. Bos. Sci. Corp.*, 2015 WL 5486694 at *28 (S.D.W.Va. Oct. 29, 2014).

of the Court in *Carlson v. Bos. Sci. Corp.*[50] The *Carlson* Court explained: "[t]he GHTF document on product labels does not state—expressly or otherwise – that manufacturers should include the severity, frequency, and/or permanency of adverse event in a warning, nor does it state that a label should qualify the difficulty of removing the device."[51] Further, in both *Carlson* and the instant litigation, Dr. Pence testified during her deposition that no non-FDA standard "gets to that level of specificity."[52] This Court concludes that Dr. Pence's opinions on this point remain unreliable for *Daubert* purposes and are excluded.

As to Dr. Pence's reliance on FDA standards, this Court again finds the *Sanchez* Court's rationale to be instructive. In *Sanchez*, Dr. Pence offered identical opinions to the ones offered in the present litigation. The *Sanchez* Court excluded these opinions as unreliable and explained:

> Indeed, Dr. Pence cites to various publications and data throughout her report. However, the information she references – literature and data on the reported complications associated with Pinnacle mesh – does not go to the heart of her opinions – that BSC failed to meet the "standard of care required of a medical device manufacturer" in its deficient labeling of its products….In other words, although this authority demonstrates that complications occurred, it does not provide any guidance as to whether these complications should have been included as warning in the Pinnacle's IFU. Eliminating this peripheral information, Dr. Pence is left with *ipse dixit* sources like "the standard of care"… and "a matter of ethics" …, both of which fall short of *Daubert's* reliability prong.[53]

[50] 2015 WL 1931311 (S.D.W.Va. Apr. 28, 2015).
[51] *Id.* at 26.
[52] *See* Exhibit "C" to Defendant's Motion to Exclude the Opinions and Testimony of Peggy Pence, PH.D., at 261.
[53] 2014 WL 4851989 at *35 (internal citations omitted).

Based on the foregoing and finding no reason to ignore the rationale articulated by the *Sanchez* Court, Dr. Pence's opinions about BSC's product labeling lacks a reliable basis and are excluded.

C. BSC's Postmarket Vigilance

BSC argues that the methodology underlying Dr. Pence's opinions is not reliable – specifically, her reliance on the FDA MAUDE Database and GHTF documents. Plaintiff responds that Dr. Pence's opinions should not be excluded because she relied on industry standards rather than FDA documents.

First, whether BSC violated FDCA reporting requirements is of "minimal relevance" to the present litigation.[54] Plaintiff has not asserted any claim concerning the FDA and FDCA reporting requirements. Second, any opinion by Dr. Pence, or any expert, that BSC did or did not comply with the FDCA constitutes a legal conclusion which exceeds the scope of expert testimony and is generally inadmissible.[55] Lastly, the probative value of testimony concerning the regulations of the FDCA is far outweighed by the substantial risk of confusing and misleading the jury.[56]

Next, this Court addresses Dr. Pence's opinions which she relied in whole, or in part, on the MAUDE Database. The MDL Court in *Carlson* found the MAUDE

[54] *Sanchez*, 2014 WL 4851989 at *36.
[55] *Carlson*, 2015 WL 1931311 at *27.
[56] *Id.*

Database to be an unreliable source. In excluding Dr. Pence's opinions on this topic, the Court stated that "[h]ow and to what end Dr. Pence uses the data [from the MAUDE Database] is inapposite... because further investigation into the MAUDE database reveals that it is unreliable, at least for the purposes of *Daubert*."[57] The Court had this to say of the MAUDE database and its unreliability:

> The MAUDE system is a "passive surveillance system" that does not account for the "potential submission of incomplete, inaccurate, untimely, unverified, or biased data." … As such, the data has not been reviewed for accuracy at all, let alone peer-reviewed, and the court has no way to determine the rate of error associated with Dr. Pence's use of it. In addition, given that FDA warns users that the data alone "cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices," [] I can readily conclude that … application of the data to reach a scientific conclusion about a manufacturer's conduct is not generally accepted in the scientific or medical community.[58]

The Court further stated that despite "BSC's communication, or alleged lack thereof, with the FDA through the MAUDE database[, this] has 'no bearing on whether BSC provided adequate warnings or whether its products were defective.'"[59] This Court has no reason to ignore the rationale of the *Carlson* court as to Dr. Pence's opinions about BSC's postmarket vigilance. As such, this Court chooses to adopt the *Carlson* Court's rationale in the instant litigation and excludes Dr. Pence's opinions because they fall short of the *Daubert* reliability standard.

[57] *Id.*
[58] *Id.*
[59] *Id.*

D. Dr. Pence's Qualifications

BSC next argues that Dr. Pence's opinions far exceed the scope of her "knowledge, skill, experience, training, or education[,]" required by Rule 702. Plaintiff responds that Dr. Pence has been found to be qualified in numerous other cases and that her qualifications have not since changed. Upon this Court's own review of the relevant case law, *no* court has found that Dr. Pence lacks the qualifications necessary to qualify as an expert.[60] Additionally, Dr. Pence has appeared the most out of any expert within the multi-district litigation.[61]

Thus, this Court concludes that Dr. Pence is no less qualified to offer her opinions in the instant litigation than she was in the prior eight instances the MDL Court found her to be qualified. Therefore, BSC's request that Dr. Pence's opinions be excluded based on lack of Dr. Pence's qualifications is DENIED.

E. Cancer Opinions

BSC argues that Dr. Pence's opinions regarding the carcinogenicity of polypropylene mesh must be excluded because she is unqualified to do so and her opinions are otherwise unreliable and irrelevant. Plaintiff does not respond to this

[60] *See Nunez v. Coloplast Corp.*, 2020 WL 2315077 at *6 (S.D. Fla. May 11, 2020) ("The Court sees no reason to second-guess the MDL Court's *eight* instances of finding Dr. Pence qualified as an expert.") (emphasis added)). *See also Armstrong v. Bos. Sci. Corp.*, 2018 WL 3824375 at *5 (S.D.W.Va. Aug. 10, 2018); *Heatherly v. Bos. Sci. Corp.*, 2018 WL 3797507 at *7 (S.D.W.Va. Aug. 9, 2018); *Waltman v. Bos. Sci. Corp.*, 2016 WL 3198322 at *9 (S.D.W.Va. Jun. 8, 2016); *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4493685 at *3 (S.D.W.Va. Aug. 5, 2016); *Carlson v. Bos. Sci. Corp.*, 2015 WL 1931311 at *28 (S.D.W.Va. Apr. 28, 2015); *Eghnayem v. Bos. Sci. Corp.*, 57 F.Supp. 3d 658, 698 (S.D.W.Va. 2014); *Tyree v. Bos. Sci. Corp.*, 54 F.Supp. 3d 501, 541 (S.D.W.Va. 2014).
[61] *Id.*

argument and foregoes the opportunity to do so. Therefore, BSC's motion on this point is GRANTED.

F. Disclosures BSC Allegedly Failed to Make[62]

BSC argues that Dr. Pence's opinion, that BSC did not conduct appropriate testing or disclose information to the FDA as part of the process, should be excluded because it is preempted under *Buckman Co. v. Plaintiffs Legal Committee*[63] and *PLIVA v. Mensing*.[64] Plaintiff argues that she is not pursuing any state-law fraud claims against BSC and thus *Buckman* and *PLIVA* are not applicable. The relevance of Dr. Pence's opinions, Plaintiff argues, relates to BSC's ongoing and continuing course of action as to the manufacture and sale of the Obtryx sling.

At the outset, this Court finds that Dr. Pence's opinions are not preempted under *Buckman* and *PLIVA* because, as correctly noted by Plaintiff, she is not pursuing any state-law fraud claim against BSC. However, this Court still finds that Dr. Pence's opinions must be excluded. In *In re Ethicon, Inc.*,[65] Dr. Pence's opinions about "whether Ethicon violated particular sections of the FDCA or failed to furnish information to the FDA[,]" were excluded.[66] The Court stated that there were no

[62] As this Court has already stated with respect to Dr. Parisian and her opinions involving discussion of the FDA, despite this Court's decision on the *Daubert* issue, Dr. Parisian's opinions may or may not be found to be admissible based on any respective Motion in Limine filed by the parties. The issues raised by the parties in the Motions in Limine will be addressed in a separate opinion.
[63] 531 U.S. 341 (2001).
[64] 564 U.S. 604 (2011).
[65] 2014 WL 186872 (S.D.W.Va. Jan 15, 2014).
[66] *Id.* at 19.

facts in issue under Rule 702 because Plaintiffs had not raised any FDA related claims.[67] Further, as to Plaintiffs' failure to warn and breach of warranties claims, the court stated that that the opinions would not help the jury but rather confuse and mislead them.[68]

This Court finds that by allowing Dr. Pence to offer her opinions regarding BSC's alleged failure to adequately test and disclose certain information to the FDA during the 510(k) process would run afoul of Rule 401 and 702 of the Delaware Rules of Evidence. This testimony not only lacks probative value but is likely to confuse a jury. In *Bowling v. C.R. Bard, Inc.*,[69] the Court explained:

> Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative 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."[70]

Based on the foregoing, Dr. Pence's opinions about disclosures BSC's allegedly failed to make are excluded because they are not relevant and ergo not helpful to the jury.

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[67] *Id.*
[68] *Id.*
[69] 2017 WL 1113314 (S.D.W.Va. Mar. 23, 2017).
[70] *Id.* at 3.

Russell Dunn, Ph.D.

Dr. Dunn is a registered professional engineer and the president and founder of Polymer Chemical Technologies LLC, a company that focuses on process and product design issues, process and product safety, and polymer product analysis.

A. Delaware's "fit" Requirement

BSC argues that Dr. Dunn's opinions do not satisfy Delaware's "fit" requirement. Specifically, that Dr. Dunn's opinions will not be helpful to the jury because they are irrelevant as he is unable to apply any of his opinions to Plaintiff or her claims. Plaintiff responds that Dr. Dunn, with his testimony, will address the fundamental issue in this litigation – the Obtryx and its alleged defective design – and that an understanding of this issue is critical to understanding Plaintiff's injuries and how they occurred.

At the outset, this Court notes that it has already addressed Dr. Dunn's opinions in this context in separate litigation.[71] In *Harris*, the parties relied on the same expert report of Dr. Dunn that the parties in the instant litigation rely upon. Thus, this Court will choose to adopt its holding in *Harris* where it explained:

> All right. I'm going to grant this motion because Dr. Dunn's testimony did not turn out the way that we expected it to in drawing that causal connection with the plaintiff, and not hearing anything different with regard to this plaintiff, I find that he is not—that his testimony is not

[71] Motion Hearing, *Harris v. Bos. Sci. Corp.*, N15C-06-216 PEL. *See also* Exhibit "K" to Defendant's Motion to Exclude the Opinions and Testimony of Peggy Pence, PH.D.

> relevant and also cumulative. So, I am going to grant the Motion to Exclude Dr. Dunn's testimony on this case.[72]

As in *Harris*, absent from Plaintiff's Response is any causal connection between Dr. Dunn's opinions and her claims in the instant litigation, making Dr. Dunn's testimony wholly irrelevant. If this Court were to permit Dr. Dunn to testify then it would be allowing cumulative and irrelevant evidence to be admitted, and that this Court will not do. Therefore, Dr. Dunn's opinions are excluded, in full.

Scott Guelcher

Dr. Guelcher is a chemical engineer offered by Plaintiff to opine on how the human body responds to polypropylene once it is implanted and the reactions that occur on the surface of the implant.

BSC raises various arguments regarding Dr. Guelcher's proffered opinions. BSC advances that: (1) Dr. Guelcher's opinions would not assist the trier of fact; (2) that his opinion regarding oxidative degradation and its *in vivo* effects are unreliable; and (3) that his opinions are beyond his field of expertise.

This Court on two previously occasions has addressed Dr. Guelcher' s opinions. Most recently, this Court permitted Dr. Guelcher to offer his opinions in *Harris v. Bos. Sci. Corp*.[73] In so doing, the Court relied on its prior ruling in *Barba v. Bos. Sci. Corp.*[74] In short, Dr. Guelcher has been permitted to testify *generally*

[72] Motion Hearing, at 56-57, *Harris v. Bos. Sci. Corp.*, N15C-06-216 PEL (Del. Super. Ct. Apr. 11, 2017).
[73] Exhibit "B" to Defendant's Motion to Exclude the Opinions and Testimony of Scott Guelcher, PH.D.
[74] Exhibit "C" to Defendant's Motion to Exclude the Opinions and Testimony of Scott Guelcher, PH.D.

about polypropylene oxidative degradation. However, as to Dr. Guelcher's opinions about complications that stem from degradation, these opinions have been excluded. This Court in *Harris* explained:

> I am going to let Dr. Guelcher testify as I permitted him to testify in the *Barb[a]* case. The Boston Scientific objections go to the weight of the evidence, but as to the *Barb[a]* case, I am not going to permit Dr. Guelcher to testify, for example, that degradation leads to certain complications. In other words, he can't testify degradation leads to pain, for example, because that's outside of his area of expertise. A foundation will have to be laid that his opinions are based on the fact that there are chemical changes in polypropylene products when placed in a dynamic environment and that the human body is a dynamic environment. Also, to make it clear, I'm not going to let him specifically discuss what happens in the pelvis, because he's not done any work in that area.[75]

Similarly, in the instant litigation, most of BSC's objections go to the weight of the evidence. But the credibility of Dr. Guelcher and his opinions are outside the bounds of this Court's gatekeeping function on a *Daubert* motion. As such, this Court chooses to follow its prior rulings in *Barba* and *Harris*. This Court reemphasizes that Dr. Guelcher is qualified to offer his general opinions about polypropylene oxidative degradation. But, to the extent his opinions relate to

[75] Exhibit "B" to Defendant's Motion to Exclude the Opinions and Testimony of Scott Guelcher, PH.D., at 63. *See also* Exhibit "K" to Defendant's Motion to Exclude the Opinions and Testimony of Scott Guelcher, PH.D ("All right. What he started to say is not objectionable. He said it can cause pain and – but if you are anticipating that he's going to say it causes vaginal pain or something specific to gynecology, I think that's a fair objection. But what he said now is appropriate.") *Id.* at 124.

specifics – including complications stemming from degradation – such opinions go beyond Dr. Guelcher's field of expertise, and thus, are excluded.

Based on the foregoing, BSC's motion is GRANTED, in part, and DENIED, in part.[76]

Suzanne Parisian, M.D.

Dr. Parisian is a pathologist who works as a regulatory consultant and intends to testify on behalf of Plaintiff.

A. Legal Conclusions

This Court has already addressed in a previous section of this opinion that experts are generally precluded from offering opinions in the form of legal conclusions. However, this Court finds that, specifically as it relates to Dr. Parisian, a further explanation is required.

BSC takes issue with three opinions offered by Dr. Parisian in her report that:

- BSC failed to meet its "duties to the FDA, physicians or patients;
- BSC's marketing claims constitute "misbranding…not permitted by Defendant's 510(k) and…not permitted by the Federal Food, Drug and Cosmetics Act"; and
- BSC's "insertion accessories were non-exempt class II accessories to a class II device, namely surgical mesh, making them regulated also as a

[76] This Court notes that the MDL Court has routinely excluded Dr. Guelcher as an expert in this litigation. However, this is so because BSC argued, and the MDL Court agreed, that Dr. Guelcher's opinions were unreliable because they were based on the unreliable testing of another Plaintiff expert, Dr. Russell Dunn. However, in the instant litigation, BSC does not assert that Dr. Guelcher's opinions are unreliable because of his reliance on Dr. Dunn's testing. Here, BSC argues that Dr. Guelcher is not qualified. This Court chooses to follow its own previous rulings as it relates to Dr. Guelcher's opinions. This Court also notes that the MDL Court's decisions excluding Dr. Guelcher as a witness were available to this Court at the time it issued its ruling in *Harris*. *See Winebarger v. Bos. Sci. Corp.*, 2015 WL 1887222 at *25 (S.D.W.Va. Apr. 24, 2015); *Sederholm v. Bos. Sci. Corp.*, 2016 WL 3282587 at *6 (S.D.W.Va. Jun. 14, 2016); *Wilkerson v. Bos. Sci. Corp.*, 2015 WL 2087048 at *19 (S.D.W.Va. May 5, 2015); *Trevino v. Bos. Sci. Corp.*, 2016 WL 2939521 at *21 (S.D.W.Va. May 19, 2016).

> class II device requiring 510(k) clearance by the FDA prior to marketing."

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BSC argues that these opinions constitute impermissible legal conclusions and should be excluded. In support, BSC cites to *Pritchett v. I-Flow Corp.*,[77] where the Court precluded Dr. Parisian from offering a host of her opinions because they were "legal conclusions … outside of Dr. Parisian's area of expertise and improperly invades the provinces of both the jury and the court."[78] This Court finds that the opinions BSC takes issue within the present litigation and those excluded in *Pritchett* are distinguishable, with one exception. In *Pritchett*, Plaintiff sought to offer Dr. Parisian's opinion that "I-Flow's promotional activities *misbranded* both its own 501(k) cleared pain pumps as well as other pharmaceutical manufacturer's NDA (ANDA) approved drugs."[79] Here, Plaintiffs seek to offer Dr. Parisian's opinion that:

> Defendant's marketing would imply to physicians that its introduction of 'de-tang' (heat melting on the edges with an iron) provides a possible added benefit that would help reduce the sling's risk of erosion (i.e. improved safety). This was not a claim that had been cleared by the FDA for Defendant's pubourethral surgical mesh and is only one example of *misbranding*. *Misbranding* is not permitted by Defendant's 510(k) and it is not permitted by the Federal Food, Drug and Cosmetic Act.[80]

This Court finds this opinion to be nearly identical to the one offered in *Pritchett*, and thus, will not permit Dr. Parisian to offer it. As to Dr. Parisian's other

[77] 2012 WL 1059948 (D. Colo. Mar. 28, 2012).
[78] *Id.* at 7.
[79] *Id.*
[80] *See* Exhibit "A," to Plaintiff's Response to Defendant's Motion to Exclude the Opinions and Testimony of Suzanne Parisian, M.D., at ¶ 76.

opinions that BSC contests, this Court finds those opinions do not constitute impermissible legal conclusions. As Plaintiffs point out in their Response Brief, the *In re Fosamax*[81] Court permitted Dr. Parisian to testify about the regulatory process, FDA guidelines, and labeling as to the product at issue. In doing so, the Court explained that the applicable law to the case was state law and Dr. Parisian's testimony was about federal regulations.[82] The Court found that this testimony would be helpful to the jury in determining whether the defendant acted as a reasonably prudent manufacturer.[83] Similarly, here, state law applies to Plaintiff's claims and Dr. Parisian's testimony regarding the FDA will be helpful to a jury to determine an ultimate fact at issue – whether BSC acted as a reasonably prudent medical device manufacturer.

Based on the foregoing, this Court concludes that Dr. Parisian is permitted to offer the opinions previously stated except for her conclusion about misbranding, which she is *not* permitted to offer at trial as it constitutes an impermissible legal conclusion.

B. Medical Causation and Scientific Opinions

BSC argues that Dr. Parisian is not qualified to offer medical causation and scientific opinions. Plaintiff concedes that Dr. Parisian will not be offering these

[81] 645 F.Supp.3d 164 (S.D.N.Y. 2009).
[82] *Id.* at n.16.
[83] *Id.*

opinions.[84] Therefore, BSC's motion on this point is GRANTED and the opinions are excluded.

C. Adequacy of BSC's Labeling

BSC argues that Dr. Parisian is not qualified to opine on the adequacy of BSC's warnings to physicians. Plaintiff responds that Dr. Parisian is well-qualified to offer these opinions and courts have routinely allowed her to do so. BSC cites to *Reece v. Astrazeneca Pharmaceuticals, LP* [85] in support but this Court does not find that decision relevant on this set of facts.[86] Instead, this Court finds persuasive the various courts' decisions finding Dr. Parisian to be well-qualified to offer her opinions about the adequacy of BSC's labeling.

[84] Even if Plaintiffs sought to offer Dr. Parisian's medical causation opinions, this Court would preclude them from doing so. As stated by the Court in *Georges v. Novartis Pharmaceuticals Corp.*, "Dr. Parisian's expertise lies in issues relating to the FDA, and not in issues relating to the diagnosis or treatment of disease. As such, she is not qualified to offer any testimony relating to the cause or diagnosis of Plaintiff's or any other patient's ONJ. Further, allowing her to testify as to causal association would confuse the issue of causation and impermissibly allow the jury to rely on Dr. Parisian's opinions regarding the cause of Plaintiff's ONJ. The danger of unfair prejudice outweighs the probative value of this evidence." 2012 WL 9064768 at *10 (C.D. Cal. Nov. 2, 2012).

[85] 500 F.Supp.2d 736 (S.D. Ohio 2007).

[86] In *Reece*, the Court precluded Dr. Parisian from offering the opinion that the defendant did not provide adequate warnings and labels because "the special population of patients with chronic muscle pain … may not be able to report unexplained muscle pain, tenderness or weakness, and defendants should have advised physicians regarding the risks of delay for detection of rhabdomyolysis and renal failure in patients with chronic muscle pain." *Id.* at 745.The Court stated that while Dr. Parisian "is a medical doctor, plaintiff has not demonstrated that there is anything in Dr Parisian's background or training that qualifies her to testify as an expert on chronic pain patients, rhabdomyolysis, or renal failure." *Id.* Plaintiffs have not sought to offer any such opinions in the present litigation and BSC hasn't alleged as much.

In *Bartoli v. Novartis Pharmaceuticals Corp.*,[87] the Court permitted Dr. Parisian to offer her labeling opinions finding that the methodology she relied upon was reliable.[88] Further, the Court in *In re Nuvaring*[89] explained:

> I find that Dr. Parisian's knowledge, skill, experience, training, and education qualify her to offer testimony concerning FDA regulatory and labeling issues. Dr. Parisian's FDA and pharmaceutical consulting experience, as well as the knowledge gained through researching and authoring her book on FDA regulations, provide her with specialized knowledge that will assist the jury in this case. These qualifications are further bolstered by the eighteen years Dr. Parisian has spent conducting reviews and analyses of FDA regulations in the context of providing expert testimony in drug litigation.[90]

In *Rowland v. Novartis Pharmaceuticals Corp.*,[91] the Court also permitted Dr. Parisian's testimony about labeling "with the exception of any testimony as to what prescribing oncology physicians would have done had they received different warnings from Zometa."[92] The Court stated that by allowing such testimony "would require an impermissible degree of speculation from Dr. Parisian, as she is not an oncologist."[93]

Based on the foregoing, this Court is satisfied that Dr. Parisian is well-qualified to offer her opinions about the adequacy of BSC's labeling. However, like

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[87] 2014 WL 1515870 (M.D. Pa. Apr. 17, 2014).
[88] *Id.* at 7 (internal citations omitted). *See also Forman v. Novartis Pharmaceuticals Corp.*, 794 F.Supp.2d 282, 384 (E.D.N.Y. 2011); *Lemons v. Novartis Pharmaceuticals Corp.*, 849 F.Supp.3d 608, 615 (W.D.N.C. 2012); *In re Nuvaring Prods. Liab. Litig.*, 2013 WL 791835 at *3 (E.D.Mo. Mar. 4, 2013); *Barnes v. Orthofix Intern. NV*, 2012 WL 191224 at *5 (W.D. Wash. May 23, 2013).
[89] 2013 WL 791835 (E.D. Mo. Mar. 4, 2013).
[90] *Id.* at 3.
[91] 9 F.Supp. 3d 553 (W.D. Pa. 2014).
[92] *Id.* at 562.
[93] *Id.*

in *Rowland*, this Court will not permit Dr. Parisian to offer any opinions about what physicians would have done had BSC's labeling contained different warnings. Dr. Parisian is a regulatory expert, not a surgeon, and thus such testimony exceeds her expertise.

D. Reliability of Dr. Parisian's Opinions

BSC argues that Dr. Parisian's opinions are not supported by any regulatory authority and are therefore unreliable. Plaintiff responds that Dr. Parisian's review and analysis of BSC documents and FDA materials make her opinions about BSC's conduct and whether it comported with industry standards and regulatory guidelines a proper subject of expert testimony in this litigation.

Dr. Parisian's report and accompanying *curriculum vitae* demonstrate her extensive knowledge, skill, experience, and training which she derived from her tenure with the FDA.[94] In her various roles within the Agency, it is clear that Dr. Parisian is well-versed as it relates to medical devices and the requirements and standards the manufacturers of those products must satisfy.[95]

In Dr. Parisian's report, she states that she has used the same methodology in forming her opinions for the instant litigation that she had "at the FDA to analyze pre-and post-market documentation for [BSC's] design, development and promotion

[94] *See* Exhibit "A" and "B" to Plaintiff's Response to Defendant's Motion to Exclude the Opinions and Testimony of Suzanne Parisian.
[95] *See* Exhibit "A" to Plaintiff's Response to Defendant's Motion to Exclude the Opinions and Testimony of Suzanne Parisian at ¶¶ 3,4,6,8.

for commercial Sling Systems for treatment of symptoms of [SUI] and [POP]."[96] Further, Dr. Parisian states that she reviewed the following documents: BSC's documents and testimonies obtained through this litigation; FDA publicly available documents; and medical literature. [97]

BSC argues that when Dr. Parisian departs from the FDA regulatory scheme her opinions are unfounded personal opinions about industry standards. But this Court does not agree. "An imperfect fit between the expert's knowledge and experience and the issues before the court impacts the weight given to the expert's testimony, not it's admissibility."[98] In fact, in *Baldonado v. Wyeth*,[99] the Court concluded that the challenges raised by the defendant, while significant, went to the weight of Dr. Parisian's opinions rather than admissibility.[100] In reaching its conclusion, the *Baldonado* Court provided a detailed analysis similar to the foregoing analysis by this Court.[101]

Therefore, this Court is satisfied that Dr. Parisian's opinions are sufficiently reliable for the purposes of *Daubert*. BSC may raise any challenges as to the weight of these opinions at trial during Dr. Parisians' cross-examination.

E. Disclosures BSC's Allegedly Failed to Make

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[96] *Id.* at ¶16.
[97] *Id.* at ¶ 17.
[98] *Radiance Foundation, Inc. v. National Ass'n for the Advancement for Colored People*, 27 F.Supp.3d 671, 674 (E.D. Va. 2013).
[99] 2012 WL 323420 (N.D. Ill. Aug. 6, 2012).
[100] *Id.* at 7.
[101] *Id.* at 5-7.

BSC argues that Dr. Parisian's opinions about disclosures it allegedly failed to make to the FDA during the 501(k) process are preempted by *Buckman*. Plaintiff responds that *Buckman* does not apply in the instant litigation and that Dr. Parisian's opinions relate directly to the negligence and products liability claims.

The admissibility of the regulation process was addressed by this Court in *Barba v. Bos. Sci. Corp.*[102] In that case, this Court acknowledged that the MDL rulings, consistently excluding this type of evidence, would make the case "much cleaner."[103] However, this Court noted that it was unable to follow the MDL rulings because "regulatory evidence, regardless of the extent or comprehensive nature of the process, consistently has been allowed in Delaware state court toxic tort cases. I don't know of one incident where it has been excluded." In finding this evidence to ultimately be admissible, this Court explained:

> It is clear that the regulation process and whether or not defendant has complied with that process is one factor that the jury can consider as to whether the defendant breached the standard of care. However, [I do] not want this to become prolonged testimony and evidence. Less is more. I advise counsel that *you need to focus on the process, not the detailed regulations.*
> In fairly short order you were able to describe for me in layman's terms the various levels of this review and what the review in this case constituted and what it didn't constitute. So, keep it simple. It's possible to keep this issue clean as to the various levels of FDA review …. And even defendants acknowledge that this is only one factor that goes to consideration of their compliance with the duty.

[102] Motion in Limine Transcript, *Barba v. Bos. Sci. Corp.*, N15C-08-050 (Del. Super. Ct. Jun. 26, 2014).
[103] *Id.* at 37.

> Now, having said that, this is the way that I am going to go and I feel that this is at the level of a ruling that I make because I feel that this is the only ruling I can make consistent with Delaware law. Defendants know that it opens the door to plaintiff saying you did not give the FDA everything they needed to give you this clearance or notification, so I'm certainly going to allow that.
> And in light of this, I'm going to have to give the plaintiffs leeway on that, that's just all there is to it, because that's the way it works. So, unless defendants are willing to voluntarily waive the discussion of approval process, the door is open.
> Now, that brings me to a couple things. First of all, the defendant's motion for fraud on the FDA, I understand that that is not a stand-alone cause of action by law. I am referring in this motion, I think consistent with what I've just said, if there is evidence that Boston Scientific somehow manipulated the FDA approval procedure, didn't provide information they were supposed to provide, provided false or misleading information, well that information is now going to be relevant, that evidence is going to be admitted. But I'm not saying that there is a separate count for fraud on the FDA, I don't know if that's what the motion encompassed, but I think you understand where I'm going with that.[104]

Based on the foregoing, this Court chooses to follow its rationale articulated in *Barba*. Dr. Parisian's opinions are not preempted by *Buckman* and she may offer her opinions about the disclosures BSC allegedly failed to make during the regulatory process.

Michael Thomas Margolis, M.D.

Dr. Margolis is a pelvic floor surgeon and urogynecologist. He seeks to offer several opinions regarding polypropylene mesh slings, alternative procedures, and complications associated with mesh products.

[104] *Id.* at 37-39 (emphasis added).

I. General Causation Opinions

A. Reliability of Opinions

BSC argues that Dr. Margolis' opinions should be excluded because they are unreliable based on his "biased and incomplete" review of the medical literature regarding polypropylene transvaginal mesh and mid-urethral slings. Plaintiff responds that Dr. Margolis' opinions are reliable because they are based on scientific literature and his experience. This Court will address each argument in turn.[105]

1. Use of Polypropylene Mid-Urethral Slings as Safe and Effective for SUI.

Dr. Margolis opines that polypropylene slings are *not* safe and effective for the treatment of SUI. BSC argues that Dr. Margolis in forming this opinion failed to consider contrary evidence and employed an inconsistent methodology in his literature analysis. As such, it is BSC's position that Dr. Margolis' opinions are unreliable. BSC's arguments go to the weight of Dr. Margolis' opinions, not their admissibility. This Court finds that Dr. Margolis, in forming his general causation opinions, has considered the contrary medical literature. Therefore, BSC's motion is DENIED and Dr. Margolis is permitted to offer his opinion on the safety and effectiveness of the use of polypropylene mid-urethral slings for SUI.

[105] A very similar motion was filed and decided *in Sanchez v. Bos. Sci. Corp*., 2014 WL 4851989 (S.D.W.Va. Sept. 29, 2014) and *Flores-Banda v. Bos. Sci. Corp*., No. 2:13-CV-04434, attached as Exhibit "G" to Defendant's Motion to Exclude the Opinions and Testimony of Thomas Margolis, M.D. This Court draws liberally from these decisions. *See also 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).

2. Complication Rates in Women with Polypropylene

Next, BSC argues that Dr. Margolis' methodology for his opinions that complication rates with polypropylene vaginal mesh products are high is unreliable. Specifically, Dr. Margolis opined during his deposition that more than 50% of women with polypropylene mesh experience pain. [106]

When Dr. Margolis was confronted with other studies showing pain rates lower than the 50% rate that he testified to during his deposition, he characterized his disagreement with the lower rates as "not biologically plausible[,]" and "that's not what I've seen, read[,] studied, [and] observed."[107] However, absent a more adequate explanation as to why he disagrees with these studies, Dr. Margolis' opinions on this point lack the indicia of reliability that is required by *Daubert*.[108] Therefore, BSC's motion on this point is GRANTED and Dr. Margolis' opinions on this point are excluded.

3. Complication Rate of Pain Due to Polypropylene Mesh

Dr. Margolis also offered his opinion that 25% of women experience dyspareunia as a result of vaginally-placed polypropylene mesh used to treat pelvic organ prolapse.[109] Again, when Dr. Margolis was confronted with studies that show

[106] Exhibit "B" to Defendant's Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D., at 230:11-16. *See also* Exhibit "A" to Defendant's Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D., at 9.
[107] Exhibit "B" to Defendant's Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D., at 239-8:13.
[108] *See* Exhibit "G" to Defendant's Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D., at 10. *See also Sanchez v. Bos. Sci. Corp*., 2014 WL 485189 at *12-13 (S.D.W.Va. Sept. 29, 2014).
[109] *Id.* at 255-24:25, 256-1:2

a lower percentage of dyspareunia rates he stated, "I don't think they're representative of the true rate in the population, in the general population."[110] When further pressed why he did not think they were representative of the true rate he stated, "I don't know I just don't think they're representative."[111]

When Dr. Margolis was confronted with the Shah and Badlani study where the dyspareunia rate was noted as low as 6.2%, he stated that the percentage was reasonable "[i]n this study. But I have to take – I'm going to *give the benefit of the doubt* to the patient."[112]

This methodology of Dr. Margolis – giving the patients the "benefit of the doubt" has consistently been rejected by the MDL Court.[113] In *Flores-Banda v. Bos. Sci. Corp.*,[114] the Court explained that "[i]n other words, [Dr. Margolis] assumes the worst-case scenario and errs on the side of opining as to a higher complication rate to better protect a patient. This is not a reliable, scientific basis for determining the complication rates associated with a mesh device."[115] This Court agrees with the MDL Court and finds that Dr. Margolis' methodology of giving the patient the "benefit of the doubt" is not sufficiently reliable for purposes of *Daubert*. Therefore,

[110] *Id.* at 256-12:18
[111] *Id.* at 256-21:22
[112] *Id.* at 259-3:9 (emphasis added).
[113] *See* Exhibit "G" to Defendant's Motion to Exclude the Opinions and Testimony of Thomas Margolis, M.D., at 10. *See also Sanchez*, 2014 WL 4851989 at *13-14.
[114] *See* Exhibit "G" to Defendant's Motion to Exclude the Opinions and Testimony of Thomas Margolis, M.D.
[115] *Id.* at 11.

BSC's motion on this point is GRANTED and Dr. Margolis' opinions on this point are excluded.

4. Safer Alternative Designs

BSC challenges Dr. Margolis' opinion on safer alternative designs. Specifically, BSC challenges Dr. Margolis' opinions that the Burch procedure and the Xenform slings are more effective than polypropylene mid-urethral slings.

The basis for BSC's challenge is that there is no medical support for either of these opinion and that it is based on Dr. Margolis' own personal opinion. This exact argument was addressed by the MDL Court in *Sanchez v. Bos. Sci. Corp*.[116] and rejected.

This Court will follow the MDL decision, and therefore, BSC's motion on this point is DENIED.

5. Uncontested Challenges

BSC also raises challenges to various other opinions offered by Dr. Margolis including: (1) that the infection rate of polypropylene mesh is up to 100%; (2) that the complication rate of urethral obstruction is greater than 10% with polypropylene mid-urethral slings; and (3) that he has removed 10 to 15% of BSC products. Plaintiff provides no response to this argument in their Brief and, as such, waive the opportunity to do so.

[116] 2014 WL 4851989 (S.D. W.Va. Sept. 29, 2014).

Plaintiff does offer a response to BSC's position that Dr. Margolis' opinions are unreliable because he failed to consider three specific long-term studies evaluating cure rates, complications, and adverse events. However, as this Court has already noted, it will not consider credibility arguments on a *Daubert* motion. The Court's role at this stage of the litigation is to determine the admissibility of Dr. Margolis' opinions and any credibility concerns BSC has may more appropriately be raised during cross-examination.

Based on the foregoing, BSC's motion is GRANTED, in part, and DENIED, in part.

B. Qualifications

BSC argues that various opinions that Dr. Margolis offers are outside his field of expertise as a surgeon and urogynecologist. Specifically, BSC takes issue with Dr. Margolis' qualifications to opine on: (1) biomaterials, medical device design and development; and or (3) marketing. Plaintiff has conceded that Dr. Margolis will not be offering opinions on these topics, and therefore, BSC's motion on these points is GRANTED.

II. Specific Causation Opinions

In addition to being identified as a general expert, Dr .Margolis has also been identified as a case specific expert in Ms. Kaur's case. BSC has filed a number of challenges to Dr. Margolis in his capacity as a case specific expert.

First, BSC moves to exclude any opinion testimony from Dr. Margolis regarding Plaintiff's failure to warn claims because, according to BSC, Dr. Margolis failed to provide any case specific opinion on that topic.[117] Plaintiff responds that Dr. Margolis has fully disclosed his opinions on the adequacy of BSC's Directions for Use for the Obtryx device in his general expert report.

Based on this Court's own review of Dr. Margolis' reports containing his general and specific opinions relating to Plaintiff's case, it is apparent that BSC has been put on adequate notice of Dr. Margolis' failure to warn opinions.[118] This is especially the case in the instant litigation where the Plaintiff has abandoned her failure to warn claims and any testimony of Dr. Margolis touching on this issue is limited to Plaintiff's punitive damages claim.

Next, BSC requests that any opinion testimony outside of Dr. Margolis' areas of expertise be excluded. Plaintiff responds by conceding that Dr. Margolis will not be offering opinions in the areas of biomaterials, medical device design and development,[119] and marketing. Thus, BSC's motion on this point is GRANTED and these opinions are excluded. As to Dr. Margolis' opinions regarding "foreign body reaction" and degradation of mesh, this Court is without sufficient information at

[117] The Court make no decision at this point on whether the testimony is relevant to these claims.
[118] *See* Exhibits "C" and "D" to Plaintiff's Response in Opposition to Defendant's Motion to Exclude Specific-Causation Testimony of Michael Thomas, Margolis, M.D.
[119] Medical device design does not include testimony on alternative design.

this time and reserves ruling on this issue until a more complete trial record is developed.

Next, BSC argues that Dr. Margolis's specific causation opinions relating to Plaintiff's alleged injuries fail to "fit" the facts of the case and are nothing more than *ipse dixit*. Specifically, BSC challenges his opinions relating to alleged defects of the Obtryx because he fails to provide a basis and explanation for his decision and whether Plaintiff actually experienced any alleged defects. However, in reading Dr. Margolis' general and specific causation reports together, this Court finds that Dr. Margolis has, in fact, provided a sufficient explanation and basis for his opinions. However, as it relates to alleged defects of the Obtryx, this Court limits Dr. Margolis' opinions to only those defects actually experienced by the Plaintiff. Testimony regarding other alleged defects of the Obtryx not suffered by the Plaintiff is not relevant to the instant litigation, and even if relevant, would be prejudicial and lend to confuse the jury.

IT IS SO ORDERED this 11th day of May, 2022.

/s/ Francis J. Jones, Jr.,
Francis J. Jones, Judge