UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Johns v. CR Bard et al,
Case No. 2:18-cv-01509

EVIDENTIARY MOTIONS ORDER NO. 5

Bard's Motions to Exclude Dr. Grischkan and Dr. Babensee

This matter is before the Court on Defendants Davol Inc. and C.R. Bard, Inc.'s (collectively "Bard") Motion to Exclude the Testimony of Plaintiff's Expert Dr. David Grischkan (ECF No. 31) and Motion to Exclude the Testimony of Plaintiff's Expert Julia Babensee, Ph.D. (ECF No. 112). For the reasons set forth below, the Court **GRANTS IN PART AND DENIES IN PART** Bard's Motions.

I.

Plaintiff Steven Johns' case is the first bellwether trial of the thousands of cases brought against Bard in this multidistrict litigation ("MDL"). The Judicial Panel on Multidistrict Litigation described the cases in this MDL as follows:

> All of the actions share common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections.

(Transfer Order, MDL 2846 ECF No. 1.)

A. Ventralight ST Product

Ventralight ST is a prescription medical device used for hernia repair and is one of Bard's products at issue in this MDL. The FDA cleared it for use through the 510k process on July 15, 2010, and later cleared it for use with the Echo positioning system on April 1, 2011. (*See* FDA website, 510k Premarket Notification Database, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN3/pmn.cfm (last visited August 25, 2020); *see also* Instructions for Use ("IFU") ECF No. 29-4.) It is a multicomponent device made of a mesh of polypropylene, polyglycolic acid (PGA) fibers, and a bioresorbable coating called Sepra Technology ("ST"). (*Id.*)[1] The bioresorbable coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed to maximize tissue attachment to support the hernia repair. (*Id.*)

Plaintiff contends that Bard knew the component parts of the mesh were dangerous and unsafe for use in medical devices. (Pl's Opp. to Bard's Mot. for Summary Judgment, ECF No. 165 at 1.) According to Plaintiff, Bard knew that polypropylene is not suitable for permanent implantation in the human body and that the PGA fibers created an increased inflammatory response. (*Id.*) Most relevant to this action, Plaintiff contends the ST coating on Bard's Ventralight ST devices resorbs too quickly, resulting in bare polypropylene being exposed to internal organs and tissues and increasing the risk of potential complications. (*Id.* at 4-5.)

B. Plaintiff Steven Johns

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Bard's allegedly defective Ventralight ST and asserts claims under Utah law for, *inter alia*, failure to warn, manufacturing defect, and design defect. (*See* Amend. Compl., ECF No. 17.) In

[1] The ST coating is chemically known as HA/CMC/PEG. (*See* Babensee Rep. at 21, ECF No. 112-1.)

2014, Plaintiff began experiencing an abdominal bulge that eventually became painful whenever he stood up, and he was diagnosed with a symptomatic ventral hernia within a diastasis recti (a separation of the two rectus abdominal muscles) in July 2015. (Jensen Dep. at 38:15-41:2, 47:11-48:9, ECF No. 29-2; Johns Dep. 41:23-43:5, ECF No. 29-1.) Plaintiff underwent laparoscopic surgery to repair the hernia and diastasis in August 2015, and Plaintiff's treating physician, Joseph Weldon Jensen, D.O., implanted Plaintiff with Ventralight ST Mesh. (Jensen Dep. at 41:3-7, 47:11-48:18, 49:20-50:3.)

Plaintiff's symptoms returned several months later—specifically, the abdominal bulge and pain. (Johns Dep. 59:1-12.) Plaintiff was diagnosed with a recurrent ventral hernia in September 2016, and underwent a second laparoscopic surgery in October 2016. (Grischkan Supp. Rep. at 9, ECF No. 48-1; Jensen Dep. 61:22-63:2, 65:2-68:10, 71:6-10; Johns Dep. 39:10-16.) During the October 2016 surgery, Dr. Jensen "found significant omental adhesions to the entire Ventralight ST mesh" and performed "lengthy arthroscopic [sic] lysis of the dense omental adhesions from the prior mesh implant, then the old surgical mesh was excised with blunt, sharp, and electrocautery dissections." (Grischkan Supp. Rep. at 9; Jensen Dep. at 65:2-25, 69:2-9; Grischkan Dep. 455:19-456:6; 457:15-25, ECF No. 29-3.) Dr. Jensen removed the Ventralight ST device, and, according to Dr. Grischkan, Dr. Jensen "performed a primary repair of the previous hernia defect." (Grischkan Supp. Rep. at 9.) Bard maintains that while Dr. Jensen had diagnosed a recurrent hernia before surgery based on Plaintiff's complaints, he only found a recurrent diastasis, rather than a recurrent hernia, when he operated. (*See* Bard's Mot. for Summary Judgement at n.1 (citing Jensen Dep. 69:23-70:2), ECF No. 29.) The parties agree, however, that after removing the Ventralight ST device, Dr. Jensen then implanted another Ventralight ST device. (*See* Grischkan Supp. Rep. at 9.)

Plaintiff's symptoms again returned in December 2016, and in April 2019 he was diagnosed with another hernia within the diastasis recti. (Grischkan Supp. Rep. at 9; Johns Depo. at 68:16-70:23, 76:12-15, Jensen Dep. 73:25-74:12.) In April 2019, Dr. Jensen and another surgeon performed an open recurrent ventral repair and implanted a different type of mesh device. (Grischkan Supp. Rep. at 9; Johns Dep. 77:7-10; Jensen Dep. 73:25-76:1, 78:20-81:18.) Dr. Jensen did not enter the intra-abdominal space, and testified that he did not see the prior Ventralight ST mesh, did not remove that device, and did not know what the condition of that mesh was. (Grischkan Supp. Rep. at 9; Jensen Dep. 78:5-11.) The Ventralight ST used during Plaintiff's October 2016 remains implanted today.

In May 2019, Plaintiff testified that he was still recovering from his April 15, 2019 surgery and experiencing pain, and that it was a much more painful recovery because it was an open—rather than laparoscopic—surgery. (Johns Dep. 81:9-82:11; 107:23-108:12.) In November 2019, Plaintiff reported that he was experiencing some left-side abdominal pain near the location of the second Ventralight ST mesh implant. (Grischkan Supp. Report at 10.)

Plaintiff contends the omental adhesions discovered in his October 2016 surgery were a result of the failure of the ST coating on the Ventralight ST, that the second hernia originated from complications to Plaintiff's abdominal wall caused by those adhesions, and that the continued presence of the second Ventralight ST currently inside his body continues to threaten his health and well-being and cause pain. (Pl.'s Opp. at 10-11.) He alleges it is probable he will need additional surgery for either chronic pain or to address these possible complications. (*Id.*)

II.

Plaintiff and Bard have moved to exclude, in full or in part, each of the other's experts' opinions and testimony under *Daubert* and the Federal Rules of Evidence. The instant opinion

addresses Bard's motions to exclude: 1) Plaintiff's specific causation expert David M. Grischkan, M.D., F.A.C.S. (ECF No. 31); and 2) Plaintiff's biomaterials expert Julia Babensee, Ph.D. (ECF No. 112.)

A. Expert Testimony

The Federal Rules of Evidence, in particular Rules 702 and 104(a), govern the admission of expert witness testimony. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993). Rule 702 was amended in 2000 to reflect the United States Supreme Court decisions in *Daubert* and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999):

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

Fed. R. Evid. 702. The Supreme Court mandates that a district court exercises its responsibility in acting as the "gatekeeper" for expert testimony. *Daubert*, 509 U.S. at 588; *Kumho Tire*, 526 U.S. at 141; *see also* Fed. R. Evid. 702 Advisory Committee's Notes, 2000 amend. ("In *Daubert* the Court charged trial judges with the responsibility of acting as gatekeepers to exclude unreliable expert testimony, and the Court in *Kumho* clarified that this gatekeeper function applies to all expert testimony, not just testimony based in science."). This role, however, is not intended to supplant the adversary system or the role of the jury. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 531-32 (6th Cir. 2008). Arguments regarding the weight to be given to any testimony or opinions of an expert witness are properly left to the jury. *Id.* "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*,

509 U.S. at 596.

The burden is on the party proffering the expert testimony to demonstrate by a preponderance of proof that the opinions of their experts are admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility. Fed. R. Evid. 702 Advisory Committee's Notes, 2000 amend. ("A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule."); *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) ("The Court [in *Daubert*] explained that Rule 702 displays a liberal thrust with the general approach of relaxing the traditional barriers to opinion testimony.") (internal quotations omitted).

B. Requirements for Admissibility of Expert Opinions

The Sixth Circuit has set forth three requirements for the admissibility of expert opinions under Rule 702:

> First, the witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Second, the testimony must be relevant, meaning that it "will assist the trier of fact to understand the evidence or to determine a fact in issue." *Id.* Third, the testimony must be reliable. *Id.*

In re Scrap Metal Antitrust Litig., 527 F.3d at 529. These three requirements are discussed in full below.

1. <u>Qualifications</u>

First, an expert witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "The issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994); *In re Welding Fume Prods. Liab. Litig.*, No. 1:03-CV-17000, 2005 WL 1868046, at

*33 (N.D. Ohio Aug. 8, 2005) ("An expert may be highly qualified to respond to certain questions and to offer certain opinions, but insufficiently qualified to respond to other, related questions, or to opine about other areas of knowledge."). The Court must determine "whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert's testimony must be for the trier of fact." *Mannino v. International Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). A party's expert need only meet the "'minimal qualifications' requirement—not one who could teach a graduate seminar on the subject." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (citing *Mannino*, 650 F.2d at 846); *see also Dilts v. United Grp. Servs., LLC*, 500 F. App'x 440, 446 (6th Cir. 2012) ("An expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.").

2. Relevance

Expert testimony must also be relevant, "meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.'" *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 529 (quoting Fed. R. Evid. 702). "Expert testimony which does not relate to any issue in the case is not relevant, and, ergo, non-helpful." *Daubert*, 509 U.S. at 591. "This requirement has been interpreted to mean that scientific testimony must 'fit' the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). "Whether an opinion 'relates to an issue in the case' or helps a jury answer a 'specific question' depends on the claims before the court." *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020). "Thus, when analyzing the relevancy of expert testimony, a court should consider the elements that a plaintiff must prove." *Id.*

3. Reliability

Finally, expert testimony must be reliable. Rule 702 provides the following general standards to assess reliability: whether the testimony is based upon "sufficient facts or data," whether the testimony is the "product of reliable principles and methods," and whether the expert "has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702. Additionally, *Daubert* provides a "non-exclusive checklist for trial courts to consult in evaluating the reliability of expert testimony," including "'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community.'" *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 529 (citing *United States v. Langan*, 263 F.3d 613, 621 (6th Cir. 2001); *Daubert*, 509 U.S. at 593-94). "*Daubert* establishes a 'flexible' test that considers many indicia of reliability, some of which may have more relevance than others depending on the particular science and the particular scientist before the court." *Madej v. Maiden*, 951 F.3d 364, 374 (6th Cir. 2020) (citing *Kumho Tire*, 526 U.S. at 150, 119 S.Ct. 1167; *Daubert*, 509 U.S. at 594, 113 S.Ct. 2786). "[T]he *Daubert* factors do not constitute a 'definitive checklist or test,' but may be tailored to the facts of a particular case." *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 529 (citing *Kumho*, 526 U.S. at 150, 119 S.Ct. 1167; *Daubert*, 509 U.S. at 593, 113 S.Ct. 2786).

"These factors 'are not dispositive in every case' and should be applied only 'where they are reasonable measures of the reliability of expert testimony.'" *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 529 (quoting *Gross v. Comm'r*, 272 F.3d 333, 339 (6th Cir. 2001)). The objective of the reliability requirement is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same

level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

III.

A. David M. Grischkan, M.D., F.A.C.S.

Dr. Grischkan is Plaintiff's expert on specific causation. (Pl.'s Opp. to Bard's Mot. to Exclude 4, ECF No. 64.) Dr. Grischkan is a Board-certified and re-certified general surgeon who specializes in the repair of abdominal wall and inguinal hernias. In 1983, Dr. Grischkan founded the Hernia Center of Ohio where he devotes the bulk of his time to the treatment of hernias. Dr. Grischkan has performed surgery on patients around the world, lectured on hernias at universities in Europe and the United States, and has authored and co-authored over a dozen hernia related articles and abstracts. Dr. Grischkan is a member of several medical and surgical associations, including the International College of Surgeons, Cleveland Surgical Society, and American Hernia Society.

In this case, Dr. Grischkan opines:

> Based upon, my review of the medical records, deposition testimony, Bard's internal documents, the relevant medical literature, and my extensive experience and training, it is my expert opinion, to a reasonable degree of medical certainty, that the protective ST Coating on the visceral side of the Ventralight ST mesh was rapidly absorbed in far less time than what is marketed by Bard. As a result, Mr. Johns' omentum and internal organs were exposed to the bare polypropylene – a disastrous situation that led to intense omental adhesions to the entire mesh and a complex subsequent surgery requiring removal of the mesh. However, this failure could just as easily have caused intestinal obstruction, erosion, chronic severe inflammation, fibrosis, and fistulization – and may still lead to these injuries since the condition of the second Ventralight ST mesh currently implanted is unknown.
>
> It is the failure of the Ventralight ST device to perform in the manner expected as advertised by Bard that has caused Mr. Johns' injuries and has the potential to cause additional disastrous complications in patients such as Steven Johns.

(Grischkan Supp. Rep. at 12.)

Bard contends Dr. Grischkan's opinions and testimony should be excluded because they are "not based on reliable methods, facts, and data, were undisclosed in his report, and/or his proposed testimony is beyond the scope of his expertise." (Bard's Mot. to Exclude, ECF No. 31.) Specifically, Bard contends Dr. Grischkan is not qualified to offer opinions regarding design defects and causation, that he lacks a reliable basis for those opinions, and that those opinions are not helpful to the jury. Bard further contends Dr. Grischkan's opinions regarding warnings are unreliable and not helpful to the jury. Bard also argues Dr. Grischkan's undisclosed opinions about Plaintiff's current pain should be excluded, that Dr. Grischkan should be precluded from offering opinions he disclaimed at his deposition, that other experts should not be permitted to offer opinions unrelated to Dr. Grischkan's opinions.

1. Design Defect and Causation Opinions

Bard first contends Dr. Grischkan lacks qualifications and a reliable basis for his design defect and causation opinions. (Mot. at 5.)

Dr. Grischkan performed a differential diagnosis to determine the cause of Plaintiff's adhesions, opining:

> In Mr. Johns' case, I opine to a reasonable degree of medical certainty that the failure of the ST Coating resulted in the gradual exposure of the omentum to the polypropylene layer of the mesh following the insertion of the Ventralight ST mesh on August 7, 2015. This failure of the ST Coating is the proximate cause of the dense omental adhesions he suffered that necessitated removal of the first Ventralight ST mesh, and created a more complex, prolonged procedure. Furthermore, the failure of the ST Coating due to the resorption occurring far earlier than when Bard represents, also needlessly exposes patients to increased risks of bowel obstruction and fistulization.

(Grischkan Supp. Report at 11.) Dr. Grischkan then concludes that "the protective ST Coating on the visceral side of the Ventralight ST mesh was rapidly absorbed in far less time than what is marketed by Bard" and that "[a]s a result, Mr. Johns' omentum and internal organs were exposed

to the bare polypropylene—a disastrous situation that led to intense omental adhesions to the entire mesh and a complex subsequent surgery requiring removal of the mesh." (Grischkan Supp. Report at 12.)

i. Qualifications

Bard first contends that while Dr. Grischkan may be qualified to discuss adhesions generally, "he is unqualified to discuss the technical aspects of how the ST coating, or lack thereof, caused the asymptomatic omental adhesions in this case." (Mot. at 7.) Bard argues Dr. Grischkan's opinions on the ST coating are not based on any experience with the Ventralight ST or any other absorbable barrier hernia devices, with medical device design, or with medical device testing, but are instead based on animal studies conducted on the Ventralight ST's predicate device, Sepramesh IP. (*Id*.) But according to Bard, Dr. Grischkan is not an expert in preclinical animal studies and has never participated in animal studies for hernia repair models, and is thus unqualified to offer any opinions related to these studies. (*Id*. at 6-8.)

Plaintiff counters that Dr. Griscken is qualified to offer his opinions based on his experience and expertise in hernia surgery and surgical explanation of mesh in general. (Pl.'s Opp. at 9.) Plaintiff points to Dr. Grischkan's thirty years of experience specializing in abdominal wall and inguinal hernia repair using different types of mesh, and his experience designing a non-polypropylene micromesh prosthesis where he was involved with some animal studies. (*Id*. at 10.)

A witness can be qualified as an expert "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Plaintiff is correct that courts have recognized that a surgeon's "extensive experience with performing mesh implant and explant surgeries can qualify him or her to opine on how the product reacts inside the body." *See Wilkerson v. Bos. Sci. Corp.*, No.

2:13-CV-04505, 2015 WL 2087048, at *20 (S.D.W. Va. May 5, 2015) (citing *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014), as amended (Oct. 29, 2014)); *In re C.R. Bard, Inc.*, 948 F.Supp.2d 589, 612 (S.D.W.Va.2013) (finding urogynecologist qualified to opine on product design and biomaterials because he had "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders"); *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2018 WL 3575936, at *3 (S.D.W. Va. July 24, 2018) (finding board certified obstetrician and gynecologist's extensive clinical experience, combined with review of scientific literature, qualified her to opine on degradation, inertness, weight, porosity, and other characteristics of mesh despite lack of experience in materials and engineering and mesh design).

Surgeons without pathology expertise or experience in polymer science or biomaterials have been found qualified to testify as to "mesh degradation on a large scale, focusing on the ways a polypropylene mesh product can change after implantation in the human body." *See Wilkerson*, 2015 WL 2087048, at *20 (holding urogynecologist's lack of experience in polymer science is irrelevant because he was not offering opinions about "'what's happening at the molecular level'" and that his "fifteen-year career as a pelvic surgeon qualifies him to render these opinions to the extent that they are applicable to his differential diagnosis in this specific case.") (internal citations omitted).

Relying on these cases, Plaintiff contends Dr. Grischkan's lack of experience with the Ventralight ST device or with the "technical aspects" of the ST coating is immaterial because "Dr. Grischkan 'is not offering opinions about what is happening at the molecular level,' rather, he is opining on 'mesh degradation on a large scale[.]'" (Opp. at 9.) But in the same breath, Plaintiff claims Dr. Grischkan's is offering opinions on "*how* Defendants' 'protective ST

Coating on the visceral side of the Ventralight ST mesh was rapidly absorbed in far less time than what is marketed by Bard[.]" (Opp. at 9) (emphasis added); (*see also* Supp. Rep. at 11 ("[It is my expert opinion, to a reasonable degree of medical certainty, that the protective ST Coating on the visceral side of the Ventralight ST mesh was rapidly absorbed in far less time than what is marketed by Bard."); *see also* Grischkan Supp. Rep. at 10 (explaining resorption rate); *see also* Grischkan Dep. at 893:12-895:20.)

Yet as Dr. Grischkan admits, he has never used the Ventralight ST product before, or any product with a resorbable barrier similar to the ST coating. (Grischkan Dep. at 47:16-50:1, 66:7-17, 71:8-12, 73:24-74:8, 198:24-199:2.) He is not an expert in the design of bioresorbable coatings for medical devices. (*Id*. at 311:20-25.) He is not an expert in bioengineering, biomaterials, or chemistry, and has no knowledge of how, at a chemical level, any of the aspects of the ST coating are broken down by the human body. (*Id*. at 208:1-8.) Dr. Grischkan has no criticisms of the actual chemicals used in the ST coating because "that was not the focus of [his] review." (*Id*. at 68:12-69:25, 75:13-17.) For example, Dr. Grischkan testified:

> Q. What about the degradation of the ST coating within the human body, do you know anything about that pattern?
>
> A. A pattern in terms of what?
>
> Q. Is it inside out, outside in, simultaneously thinning? How does it work?
>
> A. I don't know. I've not seen any particular studies that have actually documented that in humans.

(*Id*. at 211:8-17) (objections omitted).

Dr. Grischkan's only basis for his opinion regarding the resorption of the ST coating are Bard's internal documents and animal studies conducted by Bard and Genzyme. (*See* Grischkan Supp. Rep. at 5-6.) While these studies could be a reliable basis for an opinion regarding the

resorption of the ST coating, "whether an expert's opinions are supported by scientific literature is an issue of reliability, not his qualifications." *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 722 (S.D.W. Va. 2014) (finding urologist/surgeon unqualified to opine about mesh shrinkage and degradation because he was not "a 'bio/polymer' chemist and has no background in polymer science'" and lacked personal experience with mesh degradation or shrinkage, despite reliance on scientific literature in forming his opinions). Moreover, Dr. Grischkan could not recall the specifics of these studies or the devices involved, and often answered that he did not review or look for additional studies or literature regarding the devices. (Grischkan Dep. 201:12-23, 558:7-11, 214:17-24.). For example, Dr. Grischkan testified:

> Q. Have you ever seen any animal study with the ST coating, the one that's on the Ventralight ST, not some other earlier version without PEG or different thickness or whatever, where polypropylene is in direct contact with bowel after the resorption of the ST coating, subject to the ingrowth of the mesothelial cells?
>
> A. I've not looked for that specific issue.
>
> Q. What was the name of the study where it says the barrier was gone at one day?
>
> A. I'd have to look in the -- in my list of records.
>
> Q. That was one of the ones the Plaintiffs gave you?
>
> A. I'm sure that was.
>
> Q. Are you sure that was on the same coating as the Ventralight ST?
>
> A. I can't be 100 percent certain, but it certainly was a coating.

(*Id*. at 900:16-901:12.) [2] Dr. Grischkan also testified he has never interpreted the results of histology slides on animal studies looking at resorption times or adhesion formation, (*id*. at

[2] *See also id*. at 902:19-903:3 ("Q. And you're not aware of a single study you can cite us where there is some description of essentially adhesion-like complications from the ST coating going away too quickly in people who have been studied with the implant of these products, correct? A. Again, I didn't do a target study for that kind of information.").

430:1-432:1), and has never participated in an animal study in a hernia repair and that and the last time he participated in any animal study was as a resident. (*Id*. at 301:11-22.)

Because Dr. Grischkan does not have the requisite "knowledge, skill, experience, training, or education," Fed. R. Evid. 702, he is not qualified to offer opinions regarding how the ST coating can rapidly resorb. *See also Huskey*, 29 F. Supp. 3d at 722; *see also Tyree v. Bos. Sci. Corp*., No. 2:12-CV-08633, 2014 WL 5486694, at *48 (S.D.W. Va. Oct. 29, 2014) (excluding expert as unqualified based on lack of expertise in biomaterials, reliance on other experts' depositions to educate himself on degradation, failure to perform any tests on shrinkage, and failure to look for or recall studies on mesh shrinkage); *see also id*. at *47 (excluding product design opinions of urologist/surgeon who had lacked design experience and had not implanted the product at issue or any of defendants' mesh products despite experience removing other devices and observing complications during removal process).

Although Dr. Grischkan is not qualified to offer opinions as to how the ST coating can resorb too quickly, that does not render his opinions as to cause of Plaintiff's injuries inadmissible. Dr. Grischkan is qualified to offer medical causation opinions based on his thirty years of surgical experience specializing in the repair of abdominal wall and inguinal hernias. He is the founder of the Hernia Center of Ohio and has "extensive experience working with prosthetic material, having implanted and explanted many varieties of mesh, including synthetics, biologics, and composites" including "uncoated and coated polypropylene meshes, ePTFE, compressed PTFE, polyester and synthetic absorbable meshes as well as meshes derived from human and porcine dermis (biologic)." (Grischkan Supp. Rep. at 1.) He has personally observed the "damaging effects of polypropylene" and worked with W.L. Gore to develop a non-polypropylene prosthesis to the market that was "more compatible for tissue implantation." (*Id*.)

He has lectured and authored on hernia related articles and abstracts, and performed thousands hernia surgeries throughout his career. (*Id.*)

Moreover, "to the extent they are applicable to his differential diagnosis," Dr. Grischkan is qualified to testify as to "mesh degradation on a large scale, focusing on the ways a polypropylene mesh product can change after implantation in the human body" based on his thirty years of experience as a hernia surgeon implanting and explanting mesh. *See Wilkerson*, 2015 WL 2087048, at *20. Judge Joseph R. Goodwin has repeatedly found certain medical doctors qualified to opine as to polypropylene in another large MDL, even though they were not experts in biomaterials, based on their clinical experience and review of scientific literature. *See Winebarger v. Bos. Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *5 (S.D.W. Va. Apr. 24, 2015); *Heatherly v. Bos. Sci. Corp.*, No. 2:13-CV-00702, 2018 WL 3797507, at *3 (S.D.W. Va. Aug. 9, 2018) (finding urologist's clinical experience treating pelvic floor disorders and complications resulting form implantation of transvaginal mesh, in addition to review of scientific literature, "adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction."). Bard's motion on this point is **GRANTED** in part and **DENIED** in part.

ii. Reliability

a. Adhesions

Dr. Grischkan's opinion in this case regarding the cause of Plaintiff's adhesions is based on a differential diagnosis. The Sixth Circuit has recognized that a differential diagnosis is an "appropriate method for making a determination of causation for an individual instance of disease." *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 260 (6th Cir.2001); *see also Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 178 (6th Cir. 2009) (stating that a causation opinion

based upon a reliable differential diagnosis may satisfy the requirements of Rule 702). The Sixth Circuit has explained:

> Differential diagnosis is "a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Hardyman*, 243 F.3d at 260 (internal quotation marks omitted). As we explained in *Best*, a physician who applies differential diagnosis to determine causation "considers all relevant potential causes of the symptoms and then eliminates alternative causes based on a physical examination, clinical tests, and a thorough case history." 563 F.3d at 178 (internal quotation marks omitted).

Pluck v. BP Oil Pipeline Co., 640 F.3d 671, 678 (6th Cir. 2011); *see also In re: E. I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig.*, 337 F. Supp. 3d 728, 739 (S.D. Ohio 2015).

But "merely claiming that an expert used differential diagnosis" is insufficient to satisfy *Daubert's* reliability requirement. *Pluck*, 640 F.3d at 678 (citing *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir.2010)). As the Sixth Circuit explained in *Tamraz*:

> Calling something a "differential diagnosis" or "differential etiology" does not by itself answer the reliability question but prompts three more: (1) Did the expert make an accurate diagnosis of the nature of the disease? (2) Did the expert reliably rule in the possible causes of it? (3) Did the expert reliably rule out the rejected causes? If the court answers "no" to any of these questions, the court must exclude the ultimate conclusion reached.

620 F.3d at 674 (citing *Best*, 563 F.3d at 179). "Not every opinion that is reached via a differential-diagnosis method will meet the standard of reliability required by *Daubert*." *Best*, 563 F.3d at 179. "'The core of differential diagnosis is a requirement that experts at least consider alternative causes.'" *In re: E. I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig.*, 337 F. Supp. 3d at 739 (quoting *Best*, 563 F.3d at 179). "But doctors need not rule out every conceivable cause in order for their differential-diagnosis-based opinions to be admissible." *Best*, 563 F.3d at 182. "The fact that several possible causes might remain uneliminated . . . only goes to the accuracy of the conclusion, not to the soundness of the methodology.'" *Jahn*, 233 F.3d at 390 (quoting *Ambrosini v. Labarraque*, 101 F.3d 129, 140 (D.C. Cir. 1996)).

In performing his differential diagnosis of Plaintiff's omental adhesions, Dr. Grischkan ruled in several possible causes in addition to the failure of the ST coating, including prior abdominal surgeries, adhesive disorders, history of smoking, diabetes, and medications. (Grischkan Supp. Rep. at 11-12.) Bard does not contend Dr. Grischkan failed to rule in any other possible cause of adhesions. Instead, Bard objects to Dr. Grischkan's basis for ruling in the failure of the ST coating as a possible cause, contending "Dr. Grischkan's opinion that the ST coating in Plaintiff's Ventralight ST absorb too quickly leaving bare polypropylene mesh to cause adhesions to the omentum is based on nothing more than conjecture and should be excluded." (Mot. at 11 (citing *Tamraz*, 620 F.3d at 671).) Specifically, Bard contends the only basis for Dr. Grischkan's opinions is a selection of Bard's corporate documents and that he improperly opines as to Bard's corporate intent and state of mind. (Mot. at 9-11.)

Bard's arguments are not-well taken. Dr. Grischkan ruled in the failure of the ST coating as a cause of Plaintiff's injury based on his review of Plaintiff John's medical records and scientific literature, his knowledge, training, and experience, in addition to Bard's internal documents and evidence in this case. As discussed above, Dr. Grischkan may not opine as to the technical properties of the ST coating or how it resorbed too quickly. But Dr. Grischkan's opinion is not that the ST coating itself caused Plaintiff's adhesions. Instead, Dr. Grischkan's opinion is that exposure to bare polypropylene caused Plaintiff's adhesions, explaining that "[t]he early absorption of the protective layer on the visceral surface of the mesh (i.e. the ST coating) would expose the underlying internal organs to bare polypropylene, a condition well known to cause dense adhesions, chronic inflammation, and bowel obstruction." (Grischkan Supp. Rep. at 10.)

Dr. Grischkan has extensive experience implanting and explanting mesh, including

polypropylene mesh, and has personally observed the "damaging effects of polypropylene." (*Id.* at 1.) Throughout his report, Dr. Grischkan also relies on scientific and medical literature for his opinions regarding the effects of bare polypropylene on the body and the clinical complications associated with polypropylene mesh, including the opinion that when "polypropylene comes in contact with hollow visceral organs such as the bladder or intestines, the intense inflammatory reaction can lead to dense adhesions, resulting in, among other things, bowel obstructions with catastrophic consequences." (*Id.* at 6-7; *see also id.* at 3-4.)

Dr. Grischkan reviewed Plaintiff's medical records and noted Dr. Jensen's description of "dense omental attachments through the entire mesh requiring lengthy lysis of adhesions in order to undertake the removal of the previously implanted Ventralight ST mesh and properly repair the recurrent hernia." (*Id.* at 10.) He further opines "[t]here is no question that Dr. Jensen was describing intense/severe adhesions to the visceral coated surface of the Ventralight ST device as there is absolutely no evidence that the mesh folded over or flipped, exposing the fascial/anterior surface of the mesh to the intraabdominal cavity." (*Id.* at 10-11.) He states "Dr. Jensen's operative report is not discussing the thin filmy adhesions one would have expected to find if the ST Coating on the visceral surface of the Ventralight ST functioned in the manner marketed by Bard. Instead, Dr. Jensen's need to perform lengthy lysis of adhesions to all the attachments to the old surgical mesh, is a reflection of the failure of the ST Coating to protect the visceral organs from adhesions to, and obstruction by, the mesh." (*Id.* at 11.)

The Court concludes Dr. Grischkan has a reliable basis, beyond Bard's internal documents, for ruling in the failure of the ST coating as a cause of Plaintiff's omental adhesions. *See In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 738 (N.D. Ohio 2011) ("Courts have admitted expert testimony as reliable where experts extrapolate their opinions from their

knowledge and experience combined with a review of the relevant scientific literature.").

Moreover, Dr. Grischkan's differential diagnosis is not unreliable simply because he relied on those documents, among other sources, for his opinion. *See Huskey*, 29 F. Supp. 3d at 722 (holding urologist's opinions were not "unreliable simply because he relied on internal Ethicon documents" instead of medical literature for statement that approach to implanting device increased risk of complications). "Experts are permitted wide latitude in formulating their opinions." *In re E. I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d 897, 911 (S.D. Ohio 2015) (citing *Daubert*, 509 U.S. at 592, 113 S.Ct. 2786; *Jahn*, 233 F.3d at 388). "An expert may base his or her opinion on information not personally possessed." *Id.* (citing *Walker v. Soo Line R. Co.*, 208 F.3d 581, 588 (7th Cir. 2000) ("[C]ourts frequently have pointed to an expert's reliance on the reports of others as an indication that their testimony is reliable.") (gathering cases); *Buck v. Ford Motor Co.*, 810 F.Supp.2d 815, 844 (N.D. Ohio 2011) (citing *Ohio Envt'l Dev. Ltd. P'ship v. Envirotest Sys. Corp.*, 478 F.Supp.2d 963, 976 (N.D. Ohio 2007) ("[A]n expert's testimony may be formulated by the use of the facts, data and conclusions of other experts.")); *see also Ferrara & DiMercurio v. St. Paul Mercury Ins. Co.*, 240 F.3d 1, 9 (1st Cir.2001) ("[W]hen an expert relies on the opinion of another, such reliance goes to the weight, not to the admissibility of the expert's opinion."); *Monsanto Co. v. David*, 516 F.3d 1009, 1015 (Fed.Cir.2008) ("[N]umerous courts have held that reliance on scientific test results prepared by others may constitute the type of evidence that is reasonably relied upon by experts for purposes of Rule of Evidence 703.").

Specifically, courts have held that "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." *Sanchez*, 2014 WL 4851989, at *4;

see also In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig., No. MDL 2187, 2018 WL 4220602, at *4 (S.D.W. Va. Sept. 5, 2018) ("[T]hough an expert may not simply narrate corporate documents in front of the jury, he may rely on such information in forming and supporting his opinions."); *see also In re Mentor Corp. ObTape Transobturator Sling Prod. Liab. Litig.*, 711 F. Supp. 2d 1348, 1368 (M.D. Ga. 2010) ("As to Mentor's internal documents and the journal articles, the Court finds that those items may be relied upon by Plaintiffs' experts in reaching their opinions."); *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 4220602, at *4 (S.D.W. Va. Sept. 5, 2018) (holding expert "properly used Bard's internal documents to develop and reinforce his opinions rather than to narrate Bard's corporate conduct" and finding "many of the internal documents relied upon by [the expert] could stand alone as medical research and literature.").

Ultimately, Bard's arguments as to Dr. Grischkan's causation opinions regarding Plaintiff's adhesions go to the weight or credibility of his testimony, not its admissibility. *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 531-32 ("The question of whether [an expert's] opinion is accurate in light of his use of [certain] data goes to the weight of the evidence, not to its admissibility[.]"). As the Supreme Court said in *Daubert*, "[v]igorous-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." 508 U.S. at 596. This Court's reliability inquiry focuses "solely on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 595. Bard's motion on this point is **DENIED**.

b. Recurrent Hernia

Dr. Grischkan opinions regarding the cause of Plaintiff's alleged recurrent hernia in 2016, however, are inadmissible. On the second day of his deposition, Dr. Grischkan opined that the

adhesions discovered in Plaintiffs' October 2016 surgery caused a recurrent hernia:

> Q. And do you have an opinion as to whether or not the adhesions found in the surgery on October 4, 2016 caused complications to Mr. Johns' abdominal wall?
>
> A. I do.
>
> Q. What is that?
>
> A. The intensity of those adhesions and the force that's applied to the mesh is enough to distort it and actually result in a recurrent hernia. And that's where I believe, in my Expert opinion, the hernia originated.
>
> Q. And that was the October 4, 2016 hernia?
>
> A. Yes.

(Grischkan Dep. at 886:4-887:8.) Dr. Grischkan admits that this opinion was "not specifically addressed" in either of his expert reports. (*Id*. at 910:20-911:15.) Even if this opinion had been disclosed in Dr. Grischkan's reports, it is not sufficiently reliable for purposes of Rule 702 and *Daubert*. Dr. Grischkan could not identify any published medical literature suggesting adhesions can produce a recurrent hernia. (*Id*. at 64:15-21, 65:21-66:4, 911:16-912:19.) Instead, Dr. Grischkan claims that this opinion is based on his "experience, knowledge and specialization for 30-odd years." (*Id*. at 912:15-21.) While the Court does not dispute Dr. Grischkan is an experienced and knowledgeable hernia surgeon, Plaintiff offers no evidence that Dr. Grischkan performed a reliable differential diagnosis to determine the cause of Plaintiff's recurrent hernia. Dr. Grischkan "need not rule out every conceivable cause" of Plaintiff's alleged recurrent hernia, but "the core of a differential diagnosis is a requirement that experts at least consider alternative causes." *See Best*, 563 F.3d at 179-181. Plaintiff offers no evidence that Dr. Grischkan even considered other causes of Plaintiff's alleged recurrent hernia, let alone reliably ruled out those other causes. Without a reliable differential diagnosis, Dr. Grischkan's opinion that Plaintiff's alleged recurrent hernia was caused by adhesions is based on nothing more than his "*ipse dixit*"

and is inadmissible. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.") Bard's motion on this point is **GRANTED**.

c. Current Pain and Future Surgeries

Bard also moves to exclude Dr. Grischkan's opinions relating to Plaintiff's current abdominal pain and its relation to Plaintiff's currently implanted Ventralight ST. In his original report, Dr. Grischkan had opined that while there was "no evidence of the condition of the second Ventralight ST mesh," it was still "definitely possible, if not probable, that there could be dense adhesions attached to the second Ventralight ST mesh that was implanted in October 2016," (Original Rep. at 9-10, ECF No. 31-1), and that the failure of the ST coating "may still lead to these injuries since the condition of the second Ventralight ST mesh currently implanted is unknown." (*Id*. at 12.) Dr. Grischkan completed a supplemental report on February 3, 2020 detailing a November 2019 phone call with Plaintiff, where Plaintiff complained of "left-side abdominal pain near the location of the second Ventralight ST mesh implant." (Grischkan Supp. Rep. at 10.) Based on this call, Dr. Grischkan opines:

> This information merely confirms my opinion that the Ventralight ST mesh is flawed and increased the risk and severity of complications to Mr. Johns. As mentioned above, it is highly likely that either there are already dense adhesions to the second Ventralight ST mesh, which has led to Mr. Johns' current abdominal pain, or the pain is caused by residual adhesions related the to the first Ventralight ST mesh. Based on my knowledge and experience explanting meshes with bioresorbable coatings, including the Ventralight ST, as well as my review of the medical literature, Bard's documents, and the medical records and depositions in this case, it is my opinion to a reasonable degree of medical certainty that the second Ventralight ST mesh is flawed and will cause Mr. Johns to suffer from additional injuries related to the mesh, such as chronic pain or the demand for subsequent surgeries.

(Grischkan Supp. Rep. at 10.) As explained in Evidentiary Motions Order ("EMO") No. 1, this Court declined to strike Dr. Grischkan's opinions regarding Plaintiff's current pain under Rule

26. (*See* EMO 1, ECF No. 117.) Bard questioned Dr. Grischkan regarding these opinions at his second deposition on February 14, 2020. Bard was also granted leave to re-depose Plaintiff regarding his physical complaints since his May 2019 deposition, to submit a supplemental expert report from one of its experts addressing Dr. Grischkan's supplemental expert report and Plaintiff's deposition testimony, and to supplement its briefing on its pending *Daubert* and summary judgment motions. (*Id*. at 11-12). Due to the ongoing coronavirus (COVID-19) pandemic, Bard has not yet re-deposed Plaintiff or submitted any of the additional reports or briefing.

Based on the evidence before this Court, Dr. Grischkan's opinions regarding Plaintiff's current pain are based on speculation rather than a valid methodology. First, it is not clear Dr. Grischkan "objectively ascertain[ed], to the extent possible, the nature of the patient's injury[.]" *See Best*, 563 F.3d at 179 (citing *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994) ("A physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness and . . . should . . . determine that a patient is ill and what illness the patient has contracted.")). The only basis for Dr. Grischkan's opinion that Plaintiff is currently experiencing pain (or at least was in November 2019), and that such pain is attributable to the currently implanted mesh, is a phone call between Dr. Grischkan and Plaintiff. Unlike his opinions regarding Plaintiff's omental adhesions and 2016 surgery, Dr. Grischkan's opinion at issue here is not based on a review of any medical records or surgical history. Dr. Grischkan has not examined Plaintiff, and he did not know whether Plaintiff is currently under any medical care or had seen any health care professionals about that pain. (Grischkan Dep. 594:16-595:22.) At the time of his deposition, Dr. Grischkan had not reviewed any recent medical records or imaging relating to Plaintiff's left-side pain, and he testified there is no

mention of this pain in any records since the Ventralight ST was implanted in October 2016. (Grischkan Dep. 490:22-491:4, 604:10-605:3, 914:18-20.) Other than Dr. Grischkan's report and deposition testimony, Plaintiff has offered no evidence of Plaintiff's current condition or updated medical records.[3]

Furthermore, Dr. Grischkan's opinion as to the source of that pain is unclear. His report states that he believes "*either* there are already dense adhesions to the second Ventralight ST mesh, which has led to Mr. Johns' current abdominal pain, or the pain is caused by residual adhesions." (Grischkan Supp. Rep. at 10.) At deposition, Dr. Grischkan continued to say it was either adhesions to the mesh or residual adhesions, or both, as well as adhesions to the bowel. (Grischkan Dep. 607:7-24, 610:11-614:6, 615:11-616) (emphasis added). For example, Dr. Grischkan testified:

> Q. Okay. More likely than not, you will testify there's a current, undiagnosed adhesion to bowel?
>
> A. Yes.
>
> Q. And which part of the Ventralight ST is touching it? Is it the polypropylene side that was placed against the fascia or is it whatever is left over after absorption on the visceral side?
>
> A. It would be a result of the early resorption of the hydrogel, and that would then cause the attachments of the structures in the vicinity. If it happens to be exclusively omentum, you'll get the omental adhesions, as we saw in the October, 2016 surgery. But you can just as easily have the intestines, the small intestine, involved in that, as well.
>
> Q. Is that in the middle of the patch, on the side, top, bottom? Can you give us any details?

[3] The Court further notes that at his second deposition, Dr. Grischkan opined that he would recommend Plaintiff to be "seen at least twice a year by a surgeon, not an internist, and probably have some kind of an imaging once a year for the first maybe two or three years that I would monitor him to see if there any thickening of that area or and evidence for any bowel loops that are beginning to dilate." (Grischkan Dep. 888:18-889:21). As noted above, Plaintiff has presented no evidence that he has undergone any of the kind of imaging or diagnostic testing Dr. Grischkan recommends.

> A. Well, it's my Expert opinion that the entire patch now is caked with adhesions --
>
> Q. And – I'm sorry.
>
> A. -- probably -- with high probability that the intestines would be involved, as well.
>
> ***
>
> Q. Okay. Either/or, which one is most likely, as you sit here today, that it's both of them?
>
> A. Either one could be involved. And more than likely, in my experience, it would be both. You'd have some part of the mesh attached with omentum, and another part, the bowel attached.

(*Id*. at 610:11-614:6) (objections omitted).

Dr. Grischkan's basis for concluding the currently implanted Ventralight ST caused these complications is essentially that because one device already failed, the second device was likely to fail as well:

> Q. So what is the mechanism that you think may be at play here involving the Ventralight ST?
>
> A. Well, clearly the first Ventralight ST that was explanted in 2016 was plastered with omental adhesions, dense adhesions that the doctor described as having to do a lengthy, time-consuming dissection. There's no reason not to believe, and the probability is significant that he has the same adhesions at this point.

(*Id*. at 607:7-17) (objection omitted).[4]

Although Dr. Grischkan appears to have considered other causes, (*see id*. at 619:21-620:25 ("Q. What have you considered as alternative causes for the left-sided abdominal pain

[4] *See also* Grischkan Dep. at 624:8-12 ("But the probability, again, because of the evidence from the first Ventralight, is that the second one will have the exact, same result as the first ST. There's no reason to think it would be different."); *id*. at 622:19-24 (". . . because we know with the first ST there was plastering of that omentum into that Ventralight. Why wouldn't that happen again with the second one if we already know that it happened with the first one?").

that he hasn't told anybody about, other than you? A. I don't have any idea what would be the other causes. He doesn't have diverticulitis, that I know of. He's never had any direct trauma to the abdominal wall from any major injuries, lacerations, so . . . ")), there is "too great an analytical gap between the data and the opinion proffered" for this Court to admit Dr. Grischkan's opinions. *See Joiner*, 522 U.S. at 146.

Dr. Grischkan's opinion regarding the need for future surgeries is likewise based on pure speculation:

> Q. Do you have a time course in mind here before how long you think it will be until he'll need an explant or some sort of intervention to address the possibility of bowel obstruction?
>
> A. I can tell you he will need additional surgery in the future, I just can't give you a timeline.
>
> Q. You think 100 percent he will or 51 percent? Where are you on this?
>
> A. There's no specific number. But it's more probable than not that he will need additional surgery.

(Grischkan Dep. 619:6-20) (objections omitted).

No studies or patient histories are mentioned by Dr. Grischkan. No tests were conducted, and no studies were referenced. The conclusions reached by Dr. Grischkan all flow from complaints by Plaintiff of abdominal pain. He testified further:

> Q. And do you have an opinion as to whether or not a future surgery in Mr. Johns' case will be required?
>
> A. I do.
>
> Q. And what is that opinion?
>
> A. Based on my experience, extensive experience treating hernias and redoing hernias, that it is more probable than not that he will end up needing additional surgery whether for chronic pain or for the potential of a bowel obstruction.

(*Id*. at 888:18-890:9) (objection omitted). As the Sixth Circuit has recognized, it makes no

difference that Dr. Grischkan testified that "it is more probable than not" Plaintiff will need a future surgery. *See Tamraz,* 620 F.3d at 671 ("Whatever Dr. Carlini understood by 'with a reasonable degree of medical certainty,' the phrase—the conclusion by itself—does not make a causation opinion admissible."). "The '*ipse dixit* of the expert' alone is not sufficient to permit the admission of an opinion." *Id*. (quoting *Joiner,* 522 U.S. at 146. No matter how good Dr. Grischkan's credentials may be, he is "'not permitted to speculate.'" *Id*. (quoting *Goebel v. Denver & Rio Grande W. R.R. Co.,* 215 F.3d 1083, 1088 (10th Cir.2000)). Dr. Grischkan's speculative opinions as to the cause of Plaintiff's current pain and need for future surgeries is therefore inadmissible. Bard's motion on this point is **GRANTED**.

iii. Relevance

Bard contends Dr. Grischkan's opinions are not helpful or relevant to the issues in this case because "Dr. Grischkan cannot say there was any tangible injury to Plaintiff" and because "Dr. Grischkan cannot opine that another design of the Ventralight ST or even another product for the same surgery would not have prevented the injury claimed here." (Mot. at 11-13.)

Bard's arguments are not well-taken. Dr. Grischkan identifies a tangible injury to Plaintiff—"significant omental adhesions to the entire Ventralight ST mesh" that required "lengthy arthrosopic [sic] lysis of the dense omental adhesions from the prior mesh implant" and the surgical excision of the mesh "with blunt, sharp, and electrocautery dissections." (Grischkan Supp. Rep. at 9.) Dr. Grischkan testified that the adhesions made the surgery more complex and resulted in "longer anesthesia, longer operative time and exposure to increased risks" which also "increases the cost of the procedure[.]" (Grischkan Dep. at 886:18-888:11.) Moreover, Dr. Grischkan's causation opinion is relevant to whether a defect in the Ventralight ST caused Plaintiff's injuries, an element of Plaintiff's products liability claims under Utah law.

Moreover, Dr. Grischkan did not admit that a different product or alternative design "would not have changed the outcome" for Plaintiff, as Bard contends. (*See* Mot. at 12.) Rather, Dr. Grischkan testified that he did not have an opinion about how the Ventralight ST and/or ST Coating could have been designed differently to last longer. (Grischkan Dep. at 312:15-313:6.) Dr. Grischkan did testify, however, that a composite or ePTFE mesh would have avoided Plaintiff's injuries. (*Id*. at 60:16-61:9, 76:1-77:23.) At his second deposition, Dr. Grischkan elaborated on several safer alternative designs that could have avoided Plaintiff's injuries, such as a "dual mesh, which is perfectly safe when exposed to the intestines, it does not cause the obstruction and fistulozation that polypropylene does" in addition to "composite mesh, composite being PTFE on one side and a polypropylene on the side facing the fascia." (*Id*. at 897:12-24.)

Bard contends this opinion was not disclosed in either of Dr. Grischkan's reports and should be excluded. (Reply at 4.) The Court notes, however, that Bard has not moved to strike this opinion under Rule 26 in the sixth months since Dr. Grischkan's deposition as it has done with other opinions—including those of Dr. Grischkan—Bard claimed were untimely, or otherwise explained how it was surprised or prejudiced by this opinion. (*See* Mot. to Strike El-Ghannam, ECF No. 40; Mot. to Strike Grischkan, ECF No. 48.) Dr. Grischkan first indicated that he had opinions relating to safer alternatives at his January 21 deposition during cross examination by Bard's counsel (Grischkan Dep. at 60:16-61:9, 76:1-77:23), and he elaborated on these opinions during re-direct examination by Plaintiff's counsel during his second deposition. (*Id*. at 897:12-24.) Bard's counsel then had another opportunity to cross-examine Dr. Grischkan regarding these opinions. (*Id*. at 898:11-899:21.) Due to the ongoing COVID-19 pandemic, this trial has been delayed several times and is currently scheduled to begin in January 2021, several

months from now and almost a year after Dr. Grischkan provided these opinions. Both parties have had ample time to prepare for trial and to request leave to conduct additional discovery and briefing when necessary. The Court is therefore not inclined to exclude Dr. Grischkan's opinions regarding alternative designs solely on the grounds they were not disclosed in his reports. Moreover, Bard's arguments that Dr. Grischkan's opinions "are not safer, feasible alternative designs under Utah law," (*see* Reply at 4), is an issue of substantive Utah law, not Rule 702. Bard's motion on this point is **DENIED**.

2. Warnings Opinions

Bard also contends Dr. Grischkan is not qualified to offer opinions regarding warnings and the Ventralight ST Instructions for Use ("IFU") because he lacks relevant experience. (Mot. at 15-17.) Dr. Grischkan offers the following regarding Bard's IFUs:

> According to Bard's Instructions For Use ("IFU") for the Ventralight ST Mesh with Echo Positioning System, the ST coating is intended to separate and minimize tissue attachment from the underlying organ surfaces to the polypropylene. Additionally, according to the IFU, the ST coating "is resorbed from the site in less than 30 days."

(Grischkan Supp. Rep. at 5.) Dr. Grischkan then opines:

> As a surgeon specializing in hernia repairs for over thirty years, it is my opinion that a reasonable surgeon would interpret the IFU that accompanies the Ventralight ST mesh to mean that the product is safe to insert intraperitoneally. Additionally, Bard's marketing brochure for the Ventralight ST specifically states that the ST coating "resorbs within 30 days providing visceral protection during the critical healing period." Unfortunately, the true facts regarding the performance and safety of this device are far from what the IFU and Bard's physician educational materials imply. In fact, Bard failed to disclose in any of its educational materials the ST Coating could be completely absent in seven days or less. The importance of the due diligence studies is that they provide no support for Bard's implication that any part of the ST Coating is present for more than 14 days, which Bard itself has recognized is not enough time for reperitonealization. With the loss of any part of the protective ST Coating during the critical healing period, dense adhesions can develop between the intestines and the bare polypropylene causing severe injuries to the internal organs, such as bowel obstruction and fistulization.

> The Ventralight ST IFU also fails to mention other potential complications that surgeons should be aware of in order to perform a proper risk-benefit analysis. The risk of intestinal obstruction resulting from the early loss or delamination of this protective barrier is conspicuously absent. Additionally, Bard fails to mention in its IFU other pertinent complications such as significant shrinkage, chronic pain and stiffness with the use of this mesh.

(*Id*. at 5-6.)

Bard does not disagree that surgeons can offer opinions about IFUs from the vantage of the end users of the relevant products. Instead, Bard contends Dr. Grischkan's lack of specific experience with the Ventralight ST, absorbable barrier products, or robotic hernia repairs renders him unqualified to opine as to the adequacy of the Ventralight ST's IFUs. (*See* Mot. at 16)

This Court disagrees. The only case on which Bard relies is unpersuasive. There, the court found a physician was unqualified to opine on the adequacy of warnings for a radioactive contrast dye used in the plaintiff's neurosurgery because he was "not himself a neurosurgeon and has never, in the course of his professional practice, ever dealt with the medical decision that faced [the treating physician] here." *Lareau v. Page*, 840 F. Supp. 920, 932-33 (D. Mass. 1993).

Unlike the physician in *Lareau*, Dr. Grischkan has specialized in the repair of abdominal wall and inguinal hernias for over thirty years and has "extensive experience working with prosthetic material, having implanted and explanted many varieties of mesh, including synthetics, biologics, and composites" such as "uncoated and coated polypropylene meshes, ePTFE, compressed PTFE, polyester and synthetic absorbable meshes as well as meshes derived from human and porcine dermis (biologic)." (Grischkan Supp. Rep. at 1.) While Dr. Grischkan lacks specific experience with the Ventralight ST device, his significant experience as a hernia surgeon, and his experience with mesh generally, makes him qualified to opine on the IFUs here. *See Dilts*, 500 F. App'x at 446 ("An expert's lack of experience in a particular subject matter

does not render him unqualified so long as his general knowledge in the field can assist the trier of fact."). As an experienced hernia surgeon, Dr. Grischkan may testify as to the risks he perceives that the Ventralight ST poses to patients and whether those risks were disclosed on the IFU. *Huskey*, 29 F. Supp. 3d at 719-20 (finding urologist qualified to qualified to render opinion as to completeness of manufacturer's warning and whether they inaccuracies or omissions could deprive or mislead as to the risks and benefits of the product) (citing *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, at *11 (E.D.Pa. June 20, 2000)); *see also Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *5, *14 (S.D.W. Va. Feb. 7, 2015); *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . ."). Bard's contention that Dr. Grischkan has never used the product goes to the weight of Dr. Grischkan's opinion, rather than admissibility.

Dr. Grischkan may not, however, testify as to the adequacy of the warnings from a regulatory or legal perspective. *See Wise*, 2015 WL 521202, at *14 ("Dr. Raybon has no demonstrated experience in the requirements for product labeling, and as such, he may not testify as to what the Avaulta label should or should not have included under the law."); *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 4220671, at *5 (S.D.W. Va. Sept. 5, 2018) ("A doctor who has no background in the requirements of an IFU is not qualified to opine that it 'adequately and appropriately' warns of the risks merely because he personally knows about or has observed risks in his practice.")

Additionally, consistent with the Court's holding above, Dr. Grischkan may not testify as

to how the ST coating resorbs too quickly or the science behind the resorption rate, including statements such as "the true facts regarding the performance and safety of this device are far from what the IFU and Bard's physician educational materials imply" and that "[t]he importance of the due diligence studies is that they provide no support for Bard's implication that any part of the ST Coating is present for more than 14 days, which Bard itself has recognized is not enough time for reperitonealization." (Grischkan Supp. Rep. at 6.) However, Dr. Grischkan may testify that he views there to be a risk of adhesions due to the ST coating and whether that risk is disclosed in the IFU.

Bard also contends that Dr. Grischkan's opinions as to the Ventralight ST's IFU are not relevant because Plaintiff's implanting surgeon, Dr. Jensen, testified he did not recall using or relying on the IFU. (Mot. at 16.) But as set forth in this Court's opinion regarding Bard's motion for summary judgment, an issue of fact exists as to whether Dr. Jensen reviewed and relied on the Ventralight ST's IFU. Dr. Grischkan's opinions regarding IFUs are relevant to the issues in this case. Bard's motion on this point is **DENIED**.

3. Disclaimed Opinions and Other Experts' Opinions

Bard also seeks an order prohibiting Dr. Grischkan from offering opinions that he did not disclose in his Rule 26 report and that he "disclaimed" at his deposition. (Mot. at 17-18.) For example, Dr. Grischkan testified that he would not offer opinions regarding manufacturing defects, compliance with FDA regulations, Material Safety Data Sheets, etc. (*Id*. at 17.) Plaintiff represents that "[t]o the extent Dr. Grischkan actually disclaimed any opinions in his deposition, Plaintiff does not intend to have Dr. Grischkan contradict his deposition testimony." (Pl.'s Opp. at 24.)

Bard is, in essence, "requesting an order instructing Plaintiff to follow the law." *Carte v. Loft Painting Co.*, No. 2:09-CV-178, 2011 WL 2020731, at *2 (S.D. Ohio May 24, 2011); *see also Ohio A. Philip Randolph Inst. v. Smith*, No. 1:18CV357, 2019 WL 428371, at *3 n.4 (S.D. Ohio Feb. 4, 2019). The Court declines to issue such an order at this time. If Plaintiff or his experts, including Dr. Grischkan, attempt to offer at trial any opinions not properly disclosed or that that were previously disclaimed, the Court will address any objections to those opinions at the time.

Similarly, Bard contends that if the Court limits Dr. Grischkan's opinions, "then Plaintiff's other expert witnesses should be limited to the same topics, because without Dr. Grischkan's causation opinions, general opinions on other subjects would not fit the facts of the case." (Mot. at 18; *see also* Reply at 3.) Bard "respectfully requests that it treat them in accordance with Federal Rule of Evidence 104(b) and require that Plaintiff first prove relevance to the claimed injuries in this case before any expert is permitted to offer general opinion testimony." (Mot. at 19.)

Bard is correct that Rule 702 requires there be a "fit" between expert testimony and the issues in the case, and that expert testimony that "does not relate to any issue in the case is not relevant and ergo, nonhelfpul." *Daubert*, 509 U.S. at 591. The Court will address the "fit" of other experts' opinions on a witness-by-witness basis as it rules on Bard's challenges to those opinions. But the Court will not, at this time, order exclusion of unidentified general experts' opinions based on its rulings on Dr. Grischkan's opinions. If at trial, Bard believes a specific expert's opinions are not relevant to the issues in this case, Bard may so object and the Court will address the objection at that time. Bard's motion on this point is **DENIED**.

B. Julia Babensee, Ph.D.

Plaintiff offers Dr. Babensee as an expert "in host responses to implanted biomaterials, including Defendants' polypropylene mesh implanted in humans." (Pl.'s Opp. to Bard's Mot. to Exclude at 3, ECF No. 137.) Dr. Babensee is a biomedical engineer and has served as an Associate Professor of biomedical engineering at the Georgia Institute of Technology since 1999. Dr. Babensee has a B.A. Sc. and a Ph.D from the Department of Chemical Engineering and Applied Chemistry from the University of Toronto. From 1996 to 1999, Dr. Babensee was a post-doctoral fellow in the Department of Bioengineering at Rice University, associated with the Baylor College of Medicine, Houston, Texas. At Georgia Tech, Dr. Babensee supervises the research of undergraduate students, doctoral graduate students, and post-doctoral fellows, and teaches undergraduate and graduate students in bioengineering and biomedical engineering.

According to Dr. Babensee:

> I am trained and have extensive experience in the *in vitro* and *in vivo* assessment of various aspects of the host response to biomaterials, including the inflammatory and immune responses. I have extensive experience in the examination and interpretation of histological samples prepared from biomaterial-tissue explants. I do this on a regular basis in my teaching, research, and review of peer manuscripts and grant proposals. I am research active and my research program focuses on understanding host responses to combination products— combinations of biomaterial and biological components—for example, in a tissue-engineered construct. I have my own lab at Georgia Tech, in which "the Babensee Laboratory is focused on defining design criteria for new biomaterials with improved host responses through a fundamental understanding of the *in vivo* failure mechanisms of current biomaterials."

(Babensee Rep. at 2.) Dr. Babensee's research has been funded by the NIH and other organizations. She has served as an editor of various journals, authored dozens of peer-reviewed articles, papers, and book chapters, and presented her research at conferences.

Dr. Babensee offers the following "general opinion" that it is her "professional biomedical opinion that the most concerning aspect of the Bard Bellwether Products is their lack

of biocompatibility." (*Id*. at 7.) Dr. Babensee attributes the incompatibility with human tissue to several factors, and states that while the Bard Bellwether Products share commonalities, "each product has various additional components, materials, and/or geometric designs that are unique to each product and act to compound the incompatible nature of the products." (*Id*. at 8.) Dr. Babensee concludes:

> It is my opinion that the Bard Bellwether Products were not suitable for implantation in the human body because of the polypropylene mechanical mismatch, degradation of the polypropylene, chronic inflammatory response, hyper-fibrotic reaction, lack of adequate tissue ingrowth, encapsulation, and micro-motion. I further find that the failure of the adhesive barrier subjects the visceral organs to all the deleterious consequences of polypropylene. Material incompatible for inclusion in a device is also demonstrated with the co-knitted PGA fibers of the Ventralight ST mesh, exposing the body to its pro-inflammatory degradation environment and revealing the underlying polypropylene mesh.

(*Id*. at 38.) Dr. Babensee provides the following opinion regarding Plaintiff specifically:

> **d.) Steven Johns**
>
> Mr. Steven Johns was implanted in 2015 with a Bard Ventralight ST product to treat recurrent ventral hernia. On October 4, 2016, he was required to have an explant surgery to remove the mesh to be able to repair his recurrent hernia. Adhesions were noted to the omentum throughout the mesh which needed to be severed for removal of the mesh. No bowel injury was noted. It is my opinion that Mr. Johns' recurrent hernia and mesh adhesion to the omentum was due to the Bard Ventralight ST mesh implanted into him.

(*Id*. at 37.)

Bard argues "[m]any of Dr. Babensee's opinions do not fit the issues in this case, are offered outside of her area of non-litigation expertise, and/or are derived from an unreliable methodology" and moves to exclude Dr. Babensee's opinions regarding pore size, polypropylene degradation, safer alternative designs, Material Safety Data Sheets, and causation. (Bard's Mot.

to Exclude at 1, ECF No. 112.)[5]

1. Opinions regarding Polypropylene, Degradation, and Pore Size

Bard contends Dr. Babensee is not qualified "to offer any opinions as to degradation, contraction, pore size, tissue response, mechanical mismatch, or other properties of medical devices containing polypropylene, and they should be excluded." (Mot. at 6.) Bard argues that Dr. Babensee's expertise is in chemical engineering and applied chemistry, and that she has no experience with polypropylene or medical devices outside of litigation. (*Id*. at 6-11.)

Bard's arguments are not well-taken. The Court notes that Bard previously made similar, if not identical, arguments regarding Dr. Babensee's lack of qualifications in another MDL involving Bard's polypropylene mesh products. Judge Goodwin rejected those arguments and found Dr. Babensee was qualified to render opinions related to polypropylene:

> A review of Dr. Babensee's curriculum vitae and deposition testimony reveals that while her education was in chemical engineering and applied chemistry, her postdoctoral work and research have focused in the area of biomaterials and biomedical engineering. One of her areas of research is host responses to implantable biomaterials, and she has previously studied implantable materials generally. In short, while Dr. Babensee may not have background or experience in the specific area of polypropylene or with medical devices specifically, she is qualified to testify as to the host response to the Avaulta mesh products because of her general background and experience in the area of studying implantable materials in the human body and studying the effects thereof. Moreover, because she studies the interaction between implanted materials and human tissue, she necessarily has experience studying what happens to the implanted materials and human tissue. Accordingly, she is qualified to testify as to the theory of degradation in polypropylene. In sum, I **FIND** that Dr. Babensee is qualified to render opinions related to polypropylene.

[5] As with Dr. Grischkan, Bard asks this Court for an order prohibiting Dr. Babensee from opinions she conceded she would not offer. The Court declines to issue such an order at this time, but again states that if Dr. Babensee attempts to offer at trial any opinions not properly disclosed or that that were previously disclaimed, the Court will address any objections to those opinions at the time.

In re C.R. Bard, Inc., 948 F. Supp. 2d 589, 641-42 (S.D.W. Va. 2013), *on reconsideration in part* (June 14, 2013) (internal citations omitted).

For the same reasons, this Court finds Dr. Babensee is qualified to offer opinions related to polypropylene and the theory of its degradation with respect to Bard's Ventralight ST device based on her "knowledge, skill, and experience." Fed. R. Evid. 702. Dr. Babensee's training and experience has focused on the *in vitro* and *in vivo* assessment of host responses to biomaterials, including examining and interpreting histological samples prepared from biomaterial-tissue explants. Her research has focused on host responses to "combination products—combinations of biomaterial and biological components" and she has her own lab at Georgia Tech that studies "design criteria for new biomaterials with improved host responses through a fundamental understanding of the *in vivo* failure mechanisms of current biomaterials." (Babensee Rep. at 2.) As Judge Goodwin found, because Dr. Babensee "studies the interaction between implanted materials and human tissue, she necessarily has experience studying what happens to the implanted materials and human tissue." *In re C.R. Bard, Inc.*, 948 F.Supp.2d at 642; *see also Wise*, 2015 WL 521202, at *9 (finding biomaterials expert qualified to offer opinions on the effect of polypropylene mesh on the body because "[c]learly, as a biomedical engineer, Dr. Brennan has extensive education and experience in biomaterials generally—which includes polymers—as well as knowledge of how these materials respond when implanted in the human body."). Dr. Babensee is qualified to testify regarding the biocompatibility of polypropylene, including the theory of degradation and pore size.[6]

[6] Although Dr. Babensee was not permitted to offer opinions regarding pore size in *In re C.R. Bard* due to her failure to disclose those opinions in her Rule 26 report, this Court finds the same knowledge and experience that qualifies Dr. Babensee to testify regarding polypropylene and degradation qualifies her to testify as to how the product's pore size affects its biocompatibility. (*See* Babensee Rep. at 12-15.)

Notably, Bard does not argue Dr. Babensee has no experience with polypropylene or medical devices. Instead, Bard argues Dr. Babensee is not qualified because "she has no background or experience with polypropylene outside of her work as an expert witness for plaintiffs in personal injury litigation." (Mot. at 6-9.)

Bard is correct that the Sixth Circuit "views with special caution expert testimony prepared solely for purposes of litigation, rather than flowing from an expert's line of scientific or technical work." *Simmons v. Novartis Pharms. Corp.* (*In re Aredia & Zometa Prod. Liab. Litig.)*, 483 F. App'x 182, 190 (6th Cir. 2012) (citing *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 434–35 (6th Cir.2007)); *Johnson*, 484 F.3d at 435 (holding that a "quintessential expert for hire" need not be "accorded a presumption of unreliability, but the party proffering the expert must show some objective proof . . . supporting the reliability of the expert's testimony."); *Simmons*, 483 F. App'x at 190 (excluding expert's opinion as unreliable because "it was not derived from scientifically valid principles but rather relied exclusively on the scientific literature provided by Plaintiff's counsel" and the expert "made no attempt to verify this information, such as doing his own research for other articles, and then drawing an independent conclusion.").

But the fact that Dr. Babensee's experience with polypropylene is due to her work as an expert in other mesh MDLs does not warrant automatic exclusion of her opinion. *See Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D.W. Va. Sept. 29, 2014) ("[W]ith respect to the arguments that certain experts' testimony is litigation driven, I note that an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion"); *see Daubert v. Merrell Dow Pharm., Inc.* ("*Daubert II* "), 43 F.3d 1311, 1317 (9th Cir. 1995) ("That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an

eleemosynary gesture."). As long as Dr. Babensee's opinions are sufficiently reliable, they will not be excluded simply because they arose during litigation. *See Sanchez*, 2014 WL 4851989. Critically, Bard does not argue that Dr. Babensee's opinions regarding the biocompatibility of the polypropylene in Bard's devices, including her opinions on degradation and pore size, are unreliable under Rule 702.

Bard does, however, argue that Dr. Babensee's opinions relating to pore size and polypropylene degradation are not relevant to this case. According to Bard, none of Plaintiff's experts or treating physicians has opined that Plaintiff suffered any injury because of the Ventralight ST's pore size or any purported degradation of that mesh. Because Dr. Babensee did not review Plaintiff's explanted Ventralight ST explanted or histopathology materials from Plaintiff, she "cannot begin to connect any general opinions on pore size for the Ventralight ST or on polypropylene degradation to anything that happened in Plaintiff[.]" (Mot. at 4.) Bard posits "[w]ithout a link between Dr. Babensee's general opinions and the claimed injuries and issues in this case, having Dr. Babensee opine about issues with pore size and purported degradation of polypropylene would only serve to confuse the jury and prejudice Bard." (*Id*. at 4-5.)

Bard's arguments are not well-taken. While there "must be a connection between the scientific research or test being offered and the disputed factual issues in the case in which the expert will testify," *Pride*, 218 F.3d at 578, Bard is incorrect that Dr. Babensee's opinions are irrelevant because Dr. Babensee does not link them to Plaintiff's specific injuries herself. "A single expert need not provide all the pieces of the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4536456, at *2–3 (S.D.W. Va. Aug. 30, 2016) (denying motion

to exclude expert's degradation and toxicity opinion despite expert's inability to connect them to plaintiffs' injuries because his testimony was "a relevant step towards establishing general causation.")

Moreover, Dr. Babensee's opinions related to the biocompatibility of polypropylene, including her opinions on pore size and degradation, are relevant to Plaintiff's claimed injury in light of Dr. Grischkan's opinions that Plaintiff's adhesions were caused by exposure to bare polypropylene due to failure of the ST coating. (Grischkan Supp. Rep. at 11-12.) Dr. Babensee's report contains an extensive discussion of the biocompatibility of the Ventralight ST device in general and each of its components, including the polypropylene, the ST coating, and the PGA layer. (Babensee Rep. at 21-26.) Dr. Babensee explains how the failure of the ST coating affects the biologic system:

> The Bellwether Products intended to treat ventral hernias in this litigation are placed inside the abdominal cavity, designed and intended in many cases for intraperitoneal placement, in other words, placed next to the bowel with no tissue layers to protect the internal organs or the viscera from the dangerous effects of polypropylene. Therefore, when the supposed adhesive barrier fails or otherwise allows for polypropylene to adhere to the bowel, the end result is catastrophic. Adhesions to visceral organs occur where the inflammatory response to the polypropylene mesh results in fibrosis that now involves the internal organ.

(*Id*. at 21.) She further opines:

> [T]hat the failure of the adhesive barrier subjects the visceral organs to all the deleterious consequences of polypropylene. Material incompatible for inclusion in a device is also demonstrated with the co-knitted PGA fibers of the ST mesh exposing the body to the pro-inflammatory degradation environment and revealing the underlying polypropylene mesh.

(*Id*. at 38.) Thus, Dr. Babensee's opinions regarding degradation and pore size fit the issues in this case. As is often the case, a single expert cannot opine on both specific and general causation. The plaintiff is typically required to produce at least two experts—one on general, and the other on specific causation. There is no rule that a single expert is required or that one expert

cannot rely on another's opinion. To the extent Bard believes that Plaintiff cannot prove specific causation, they can argue that at trial. *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *20 (S.D.W. Va. July 8, 2014) ("[S]imply because Dr. Klosterhalfen's opinions are limited to general causation does not mean they are not helpful to the jury. If Ethicon believes the plaintiffs cannot establish that the TVT–O caused Ms. Edwards's injuries, it can address this issue at trial."); *See Huskey*, 29 F.Supp.3d at 707 ("Ethicon is incorrect that Dr. Rosenzweig's general causation testimony —that the TVT–O mesh can degrade, fray, or lose particles—should be excluded under Rule 702 simply because the plaintiffs might fail to carry their burden as to specific causation—that Ms. Huskey was injured by the TVT–O mesh."). Bard's motion on this point is **DENIED**.

2. <u>Opinions Regarding Material Safety Data Sheets ("MSDS")</u>

Bard also contends Dr. Babensee is not qualified to offer opinions regarding MSDS sheets, and that her opinions are unreliable. (Mot. at 11, 15.) In her report, Dr. Babensee references MSDS for the brands of polypropylene resin from which the Ventralight ST device and other bellwether products were made. (Babensee Rep. at 15-18.) This Court agrees that Dr. Babensee is not an expert in MSDS and does not have experience drafting MSDS. However, the references to MSDS Bard seeks to exclude do not appear to opine on the adequacy of the MSDS from a regulatory perspective or speculate as to the manufacturers' intent behind the statements:

> The starting material from which these Bard polypropylene mesh products were manufactured contained a "MEDICAL APPLICATION CAUTION" in the Material Safety Data Sheet ("MSDS") stating "Do not use this [ ] material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." The MSDS for the polypropylene also warned of the "Incompatibility With Other Materials" stating that the material "may react with oxygen and strong oxidizing agents, such as chlorates, nitrates, peroxides, etc."

> In addition, the manufacturer of the polypropylene material used to manufacture some the Bard Bellwether Products, Phillips Sumika, provided to its customers a written "Technical Service Memorandum," which warned that strong oxidizing agents "can chemically attack Marlex polypropylene causing degradation of the resin." The Memorandum further warned that the material "can be attacked by some strong mineral acids, halogens and oxygen. The effect of strong oxidizing agents is an attack on the polymer chain resulting in eventual embrittlement of the resin." The polypropylene, which contains bonded hydrogen atoms and tertiary carbon atoms in its chain, reacts with these oxidizing agents or with oxygen in several ways, causing the chain to break and the polymer to become brittle. This action can be promoted by high temperatures, light or mechanical stress." Inflammatory cells that respond to a foreign material by releasing agents to destroy the foreign entity such as reactive oxygen species, which for the devices used here causes their degradation following implantation.

(*Id*. at 15-16) (internal citations omitted). Instead, as Dr. Babensee explained at her deposition, she relied on these documents because they "demonstrated concerns about incompatibility of these starting materials being used in devices that were implanted in people" and were warning "against using the products made of these resins and warning about specifically degradation by oxidative environment," which are further support for her opinion regarding degradation of polypropylene mesh. (Dep. of Babensee 330:15-21, 331:21-332:12.)[7] To the extent Bard disagrees with her conclusion, they may cross-examine her to that effect. Subject to the pending motions *in limine* regarding the admissibility of evidence related to MSDS filed by both parties (*see* Bard Motion *in Limine* No. 2, ECF No. 175, Plaintiff Motion *in Limine* No. 2, ECF No. 234), Bard's motion on this point is **DENIED**.

[7] *See In re Bos. Sci. Corp. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2326, 2018 WL 2440235, at *3 (S.D.W. Va. May 30, 2018) (denying motion to exclude expert's statement that did not comment on the adequacy or relevancy of the MSDS, but merely "relies on it in forming his opinion that 'the polypropylene mesh material was never intended to be implanted permanently in human bodies.'"); *see also Wise*, 2015 WL 521202, at *11 (finding expert who was qualified to opine as to polypropylene and degradation could offer opinions that included references to the MSDS and biocompatibility testing).

3. Opinions Regarding Safer Alternative Design

Bard next argues Dr. Babensee's opinions relating to safer alternative designs do not fit the issues in this case and are unreliable. (Mot. at 5, 13.) Bard agrees that Utah law requires evidence of a "safer, alternative design" for Plaintiff's design defect claim (*see* Bard's Mot. for Summary Judgment at 12, ECF No. 29), but contends that Dr. Babensee's opinions are irrelevant because none of her proposed alternatives would be indicated for intraperitoneal placement or offers lower risks of adhesions. In essence, Bard seeks to exclude Dr. Babensee's opinions because Bard believes Dr. Babensee's proposed alternatives are insufficient as a matter of law. Whether Dr. Babensee's proposed alternatives are sufficient is an issue of substantive Utah law, not Rule 702. The Court therefore finds that Dr. Babensee's opinions are relevant to the issues in this case.

Bard further contends Dr. Babensee's opinions on alternative design are unreliable, arguing "her theory has not been tested, cannot be tested (as there are no products on the market that embody all of the qualities she seeks in a safer design), and does not appear in any peer-reviewed scientific literature." (Mot. at 13-15.) Bard's arguments are not well-taken.

First, as set forth in this Court's opinion on Bard's motion for summary judgment, the Court is not convinced Utah law requires Plaintiff's proposed safer alternative design be a single, specific product already on the market embodying all of the qualities Dr. Babensee has identified. Utah law requires the plaintiff in a design defect action to prove "the practicability of a safer design" by coming forward with evidence that "'there was an alternative, safer ... design [for the device], practicable under the circumstances, [that] was [technically] feasible' and that would have prevented the accident that allegedly caused the injury[.]" *Tingey v. Radionics,* 193 F. App'x 747, 756 (10th Cir. 2006) (citing *Allen v. Minnstar, Inc.*, 8 F.3d 1470, 1479 (10th

Cir.1993)). Dr. Babensee acknowledged that there was not one product that had all of the recommended characteristics, but testified that "some of the major issues that I identify are reasons for lack of biocompatibility can be addressed by using a product that has some of these features . . . and that may be sufficient to address and make the device more biocompatible." (Babensee Dep. at 265:17-266:15.)

Second, Dr. Babensee identifies several alternative designs for Bard's polypropylene mesh products, including "a mesh product that had larger pores (to get effective porosity of at least 1 mm), more elasticity to the polymer, used a more appropriate resorbable polymer, and/or was biologic in primary composition." (Babensee Rep. at 28.) She provides specific alternatives for each component of the Ventralight ST device and examples of products on the market incorporating those alternative designs. For example, she opines:

> Additional considerations for a safer, feasible alternative product would be to use medical grade polypropylene and anti-oxidant addition to polypropylene or coating with an oxygen free radical scavenger. Another approach undertaken by Dr. S. Badylak and colleagues has been to add a coating of the polypropylene mesh with a extracellular matrix (ECM) such as porcine dermal or urinary bladder ECMs to attenuate the extent of the foreign body reaction, with constructive remodeling (e.g. fewer FBGCs and more blood vessels) through an effect on the macrophage phenotype from pro-inflammatory M1 to alternatively activated M2. One such device is produced by Cook Biotech, named Zenapro® Hybrid Repair Device which combines a large pore lightweight polypropylene mesh sandwiched between two layers of porcine small intestinal submucosa –layers that are known to stimulate tissue ingrowth, remodeling and vascularization. Another approach has been the coating of the polypropylene mesh with an angiogenic co-polymer containing methacrylic acid (MAA) which improved the tissue reaction to the mesh with more vascular structures and less fibrosis.
>
> Bard also designed, developed and marketed a product that was fully biologic, XenMatrix®AB,187 comprised solely of noncrosslinked porcine acellular dermal matrix bioprosthetic. It is expected that as with other noncrosslinked extracellular matrix-derived devices, the host would constructively remodel this matrix to achieve more physiologic tissue which is vascularized and not fibrotic.
>
> Alternate devices include coating of a lightweight polypropylene mesh (28 g/m2) with a large pore size (3.8 mm) with a different resorbable polymer that would not

> result in an acidic environment from its degradation products, such as
>
> poliglecaprone, in the UltraPro device by Ethicon (weight after coating is 55 g/m2).
>
> In the Phasix mesh, Bard took the approach of a fully degradable device for hernia repair in the preparation of a poly-4-hydroxybutyrate (P4HB) polymeric mesh which would provide immediate short-term support, similar to a traditional nonresorbable mesh, but provide an absorbable scaffold that enables the abdominal wall to remodel to host tissue over a resorption time of 12-18 months post implantation.

(*Id*. at 29-30.) Dr. Babensee cites to literature and studies in support of each proposed alternative, and has even studied and consulted on several of the proposed component materials. (*See* Babensee Dep. at 271:1-16.) The Court therefore finds Dr. Babensee's opinions regarding safer alternative designs sufficiently reliable. *See In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 186872, at *7 (S.D.W. Va. Jan. 15, 2014) (declining to exclude as unreliable expert's opinion that "mesh made of polyvinylidene fluoride, or PVDF, was a feasible alternative design to Ethicon's TVT" based on expert's reliance on academic articles and studies showing PVPF does not degrade like polypropylene and shows little signs of cracking, inflammation, or scar formation). Bard's motion on this point is **DENIED**.

4. <u>Opinions Regarding Causation</u>

Finally, Bard argues Dr. Babensee is not qualified to offer causation opinions because she "has scant pathology training" and because she is not a medical doctor. (Mot. at 9, 12.) This Court again notes that Judge Goodwin previously rejected similar arguments regarding Dr. Babensee's qualifications, finding that "[a] review of Dr. Babensee's expert report, curriculum vitae and deposition testimony reveals that she is qualified to render causation opinions in this matter based on her experience in pathology." *In re C.R. Bard, Inc.*, 948 F. Supp. at 642; *see also In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 514879, at

*3 (S.D.W. Va. Jan. 23, 2018) (finding biomaterials expert qualified based on experience and review of scientific literature to provide general causation opinions relating to polypropylene, including its purported degradation and resulting inflammatory response, despite lack of medical degree or background); *see also id.* at *4 ("Bard next argues that Dr. El-Ghannam is not qualified to render an expert opinion on the degradation of the specific material at issue, polypropylene. As stated above, I disagree. Dr. El-Ghannam is well-qualified in the field of biomaterials and biomedical engineering to testify regarding the interaction between implanted medical devices and, more specifically, the mechanisms and biologic effects of degradation of polypropylene."); *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *9 (S.D.W. Va. Feb. 7, 2015) (finding biomedical engineer's opinions on the effect of polypropylene mesh on the human body sufficiently reliable because "[i]n discussing inflammation and degradation, Dr. Brennan cites multiple peer-reviewed articles and refers to his own testing of explant samples.")

Dr. Babensee is well-qualified based on her knowledge, education, and experience as a biomaterials scientist to offer general opinions of the biological effects of the Ventralight ST mesh on the human body. And although Dr. Babensee may also be qualified to offer opinions as to the cause of Plaintiff's injuries,[8] the Court agrees with Bard that Dr. Babensee's specific causation opinions in this case are not sufficiently reliable. Dr. Babensee offers the following with opinion as to Plaintiff:

> Mr. Steven Johns was implanted in 2015 with a Bard Ventralight ST product to treat recurrent ventral hernia. On October 4, 2016, he was required to have an

[8] *See In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 186872, at *22 (S.D.W. Va. Jan. 15, 2014) (finding biomedical engineer with significant experience in medical devices qualified to provide medical opinions based on his examination of "hundreds" of explanted meshes and education in foreign body response and tissue inflammation); *but see In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4547055, at *3 (S.D.W. Va. Aug. 31, 2016) (finding chemical engineer unqualified to offer opinions on medical complications that may be caused by polymer degradation despite experience with implantable biomedical materials and polypropylene devices).

> explant surgery to remove the mesh to be able to repair his recurrent hernia. Adhesions were noted to the omentum throughout the mesh which needed to be severed for removal of the mesh. No bowel injury was noted. It is my opinion that Mr. Johns' recurrent hernia and mesh adhesion to the omentum was due to the Bard Ventralight ST mesh implanted into him

(Babense Rep. at 37.)

Dr. Babensee admitted, however, that she did not review histology slides of Plaintiff's explanted mesh. (Babensee Dep. at 341:14-16, 342:20-22.) Dr. Babensee testified that without this histology, she had no direct evidence of inflammation, fibrosis, or polypropylene degradation in Plaintiff. (*Id*. at 344:13-345:5.) Although Dr. Babensee reviewed some of Plaintiff's medical records, (*id*. at 76:14-21; 77:7-18; 321:1-7), she admits she did not consider other potential causes of Plaintiff's injuries or otherwise conduct a reliable differential diagnosis (*id*. at 136:4-9.) "The core of differential diagnosis is a requirement that experts at least consider alternative causes." *Best*, 563 F.3d at 179. Without a review of histology slides or consideration of alternative causes, Dr. Babensee's specific causation opinion is unreliable. *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 675–76 (S.D.W. Va. 2014) ("In addition to not reviewing any of the plaintiffs' pathology specimens, Dr. Trepeta has not conducted a differential diagnosis in reaching his conclusion that Ms. Nunez and Ms. Betancourt's pain resulted from the Pinnacle . . . Dr. Trepeta, without reviewing the pathology specimens or performing a differential diagnosis, cannot support his specific causation opinions with a scientific basis."); *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *24 (S.D.W. Va. Sept. 29, 2014) (excluding pathologist's specific causation opinion as unreliable when expert did not examine pathology slides and failed to consider alternative causes for plaintiff's symptoms, instead inferring without any scientific basis or reasoning that her symptoms "'appear to correlate with the mesh.'"). Bard's motion on this point is **GRANTED**.

IV.

For the reasons set forth above, the Court **GRANTS IN PART AND DENIES IN PART** Bard's Motions.

IT IS SO ORDERED.

9/1/2020
DATE

***s*/Edmund A. Sargus, Jr.**
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE