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. 7

Plaintiff's Motions to Exclude Dr. Novitsky and Dr. Renton

This matter is before the Court on Plaintiff Steven Johns' Motion to Exclude the Opinions and Testimony of Defense Expert Yuri William Novitsky, M.D., F.A.C.S. (ECF No. 51) and Motion to Exclude the Opinions and Testimony of Defense Expert David B. Renton, M.D. (ECF No. 98). For the reasons set forth below, Plaintiff's Motions are **GRANTED IN PART AND DENIED IN PART**.

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.)

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.)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Bard's allegedly defective Ventralight ST. In 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

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

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 original device and implanted another Ventralight ST. (Grischkan Supp. Rep. at 9.) Plaintiff was diagnosed with another hernia within the diastasis recti in April 2019 and underwent a third surgery that month to repair the hernia, but the second Ventralight ST device was not removed. (*Id.*)[2]

Plaintiff contends the omental adhesions discovered in his second surgery were a result of the failure of the ST coating on the Ventralight ST, (*id.*), and asserts claims under Utah law for, *inter alia*, failure to warn and design defect to recover for those injuries. (*See* Amend. Compl.,

[2] As set forth in this Court's DMO 1 and EMO 5, the parties dispute whether Plaintiff's hernia actually recurred in 2016, and whether Plaintiff's alleged current pain is due to his currently implanted Ventralight ST. This Court has held, however, that Plaintiff may not pursue claims related to his alleged 2016 recurrent hernia, current pain, and need for future surgeries. (*See* DMO 1 at 25, ECF No. 309.)

ECF No. 17.)

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 Plaintiff's motions to exclude Bard's experts Dr. Novitsky and Dr. Renton.

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. Qualifications

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*, 951 F.3d at 374 (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. Yuri William Novitsky, M.D., FACS

Bard offers Dr. Novitsky for "general opinions related to hernia repair, the Ventralight ST (from an end user physician perspective), and case-specific causation opinions as it relates to Plaintiff." (Bard's Opp. to Pl.'s Mot. to Exclude at 5, ECF No. 70.) Dr. Novitsky is a Board-certified general surgeon with a specialized focus on minimally invasive surgery and hernia repair. Since 2018, Dr. Novitsky has been a Professor of Surgery at the Columbia University College of Physicians and Surgeons in New York as well as the Director for the Columbia Hernia Center at Columbia University Medical Center. Dr. Novitsky is a member of numerous medical and surgical associations and committees, is a journal reviewer for several peer-reviewed medical and scientific journals, and has authored and co-authored numerous books, book chapters, and medical and scientific journal articles. In addition, Dr. Novitsky has conducted studies and research focusing on prosthetics and techniques used in hernia repair, including hernia mesh products.

Plaintiff contends some of Dr. Novitsky's opinions should be excluded or limited for two reasons. First, Plaintiff contends Dr. Novitsky is not qualified to "render an opinion regarding defects—or the lack thereof—in design, warning, and function of the Bard Ventralight ST mesh" because he "has neither a background in designing or creating warning labels related to mesh products nor in biomedical engineering; and he does not design mesh products." (Pl.'s Mot. to Exclude at 3, ECF No. 51.)

Second, Plaintiff argues "Dr. Novitsky's opinions regarding risk factors for the recurrence of Plaintiff Johns' diastasis are inadmissible, as the factors are unrelated to his adhesion injuries and will not aid the jury in understanding the evidence or determining the facts in issue." (*Id.* at 3.)

1. Lack of Qualifications for Defect Opinion

Plaintiff contends that Dr. Novitsky is not qualified to offer expert testimony concerning engineering, biomedical engineering, or biomechanics and cannot opine on defects in design, warning, and function. He argues Dr. Novitsky's report is not limited to surgical opinions, and moves to exclude the following opinion in Dr. Novitsky's report:

> Based on my personal and continued use of the Ventralight ST, I consider this to be an excellent product and in no way defective in design, warning, or function.

(Novitsky Rep. at 7, ECF No. 51-1.) Plaintiff argues this opinion is based solely on Dr. Novitsky's surgical expertise, and that he has no experience in biomedical engineering or in preparing applications to the FDA for medical device approvals that would qualify him to provide opinions regarding the design, warning, and function of Bard's mesh products. (*See* Mot. at 6-8.) In addition to arguing Dr. Novitsky is unqualified to offer such an opinion, Plaintiff contends this opinion is an inadmissible legal conclusion. (*Id.* at 8.)

A witness can be qualified as an expert "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Dr. Novitsky has used "a variety of coated and uncoated mesh products" throughout his career. (Novitsky Rep. at 6.) He has used polypropylene mesh products in over 1,500 ventral hernia repairs, (*id.*), and has used the Ventralight ST approximately 400 times. (Novitsky Dep. at 61:9-15, ECF No. 70-2.) Dr. Novitsky has also written and presented on the Ventralight ST at conferences and seminars. (*Id.* at 61:24-62:13, 90:14-20, 127:6-128:18.) Dr. Novitsky's knowledge of and experience with hernia mesh devices, and specifically with the

Ventralight ST, qualifies him to opine on the design and function of the device from the perspective of a hernia surgeon and end-user of the device. *See 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) (finding physician qualified to offer opinions regarding design of mesh product based on his "extensive experience" with pelvic organ prolapse and using mesh to treat that condition, in addition to "direct experience" with defendants' product as a consultant); *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 613 (S.D.W. Va. 2013), *on reconsideration in part* (June 14, 2013) (finding doctor qualified to opine on product design, testing, and materials because his "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders qualifies him to render opinions on such issues, notwithstanding his lack of expertise in the particular areas of product design or biomaterials"); *Franco v. Boston Sci. Corp.*, Case No. 2:12-cv-02748, 2016 WL 3248505, at *26 (S.D.W. Va. Jun. 13, 2016) (finding doctor qualified to opine generally as to the safety and efficacy of products at issue based on his thirty-four years of surgery experience and use of polypropylene mesh devices, including specific product at issue).

And as this Court found with respect to Dr. Grischkan's warning opinions, Dr. Novitsky may, as an experienced hernia surgeon, testify as to the risks he perceives that the Ventralight ST poses to patients and whether those risks were disclosed on the product's warnings. (*See* EMO 5 at 31-23, ECF No. 310); *see also Huskey*, 29 F. Supp. 3d at 719-20 (finding urologist qualified to render opinion as to completeness of manufacturer's warning and whether any inaccuracies or omissions could deprive or mislead as to the risks and benefits of the product); *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 . . .").

The specific opinion challenged here that the Ventralight ST is "in no way defective in design, warning, or function" is inadmissible, however. (*See* Novitsky Rep. at 7.) Under Federal Rule of Evidence 704, "[a]n opinion is not objectionable just because it embraces an ultimate issue." Fed. R. Evid. 704(a). "Nonetheless, a witness may not testify to a legal conclusion." *Hyland v. HomeServices of Am., Inc.*, 771 F.3d 310, 322 (6th Cir. 2014); *Killion v. KeHE Distributors, LLC*, 761 F.3d 574, 593 (6th Cir. 2014); *see also Babb v. Maryville Anesthesiologists P.C.*, 942 F.3d 308, 317-18 (6th Cir. 2019) ("[T]here is a 'subtle,' but 'nonetheless important' distinction between 'opin[ing] on the ultimate question of liability' (impermissible), and 'stating opinions that suggest the answer to the ultimate issue or that give the jury all the information from which it can draw inferences as to the ultimate issue' (permissible).") (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1353 (6th Cir. 1994)). Words with complex legal meaning may not be used by a witness.

Bard offers no defense of this specific opinion, other than to say Plaintiff never asked Dr. Novitsky about it during his deposition, and that Dr. Novitsky is a "world-renowned hernia surgeon and researcher" who "can say, as a physician who uses it, that the Ventralight ST is a safe and effective medical device based on his experience." (Bard's Opp. at 6.)

As discussed above, Dr. Novitsky may offer opinions related to the design, warnings, and functions of the Ventralight ST from the perspective of a hernia surgeon that may help the jury determine whether the Ventralight ST is defective in design or warning under Utah law. But the Court finds that Dr. Novitsky's specific opinion that the device "is in no way defective" is an impermissible legal conclusion. *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No.

MDL 2187, 2018 WL 4220602, at *3 (S.D.W. Va. Sept. 5, 2018) ("[A]n expert may not offer expert testimony using 'legal terms of art,' such as 'defective,' 'unreasonably dangerous,' or 'failure to warn.'") (quoting *Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008)); *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 4220671, at *4 (S.D.W. Va. Sept. 5, 2018) (excluding expert's opinion that Bard failed to adequately warn physicians and patients as an improper legal conclusion); *see also Hyland*, 771 F.3d at 322 (affirming exclusion of expert's opinion that a price-fixing "conspiracy" likely existed in real estate market as improper legal conclusion while permitting experts to testify as to "all the other aspects of the real estate market").

This opinion "'usurp[s] . . . the role of the trial judge in instructing the jury as to the applicable law [and] the role of the jury in applying that law to the facts before it.'" *In re E. I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d 897, 914 (S.D. Ohio 2015) (quoting *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 547 (S.D.N.Y. 2004); *see also Babb*, 942 F.3d at 317-18 (explaining courts generally exclude expert testimony "for stating a 'legal conclusion' only when the witness explicitly testifies, in 'specialized' legal terminology, that a defendant violated (or did not violate) the law."). Moreover, such an opinion "creates a danger of unfair prejudice, confusion [of] the issues, and misleading of the jury, and therefore, warrants exclusion under Federal Rule of Evidence 403." *Id.*

Relatedly, Dr. Novitsky may not 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 ("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.").

Accordingly, Plaintiff's motion on this specific opinion is **GRANTED IN PART AND DENIED IN PART**.

2. **Relevance of Other Risk Factors**

Plaintiff also seeks to exclude Dr. Novitsky's opinions regarding risk factors for the recurrence of Plaintiff Johns' diastasis, arguing these opinions are unrelated and irrelevant to Plaintiff's clamed injuries. Dr. Novistky opines that "[t]he central issue of this case involves plaintiff's recurrence of his diastasis/hernia." (Novitsky Rep. at 11.) He states that it his opinion "to a reasonable degree of medical certainty that [Plaintiff's] diabetes and obesity were major risk factors for breakdown of [Plaintiff's] diastasis repair." (*Id.* at 10.)

Plaintiff contends that these opinions are irrelevant "because the recurrence of Plaintiff's diastasis is not an injury ever alleged in this case" and that "[t]he jury will be deciding only whether Defendants' mesh product failed to prevent or reduce adhesions and resultant complications," not whether the device "caused or contributed to Plaintiff's diastasis recurrence." (Mot. at 9.)

But Plaintiff's adhesions were not the only injury he once claimed in this case. Plaintiff had previously argued that his "second hernia originated from complications to [his] abdominal wall caused by adhesions that formed as a result of the Ventralight ST Mesh that was used in [his] first surgery." (Pl.'s Opp. to Bard's Mot. for Summary Judgment at 10, ECF No. 165 (citing Grischkan Dep. at 886:4-887:8).)

Bard offers Dr. Novitsky to opine that Plaintiff needed surgery in 2016 because his

diastasis recurred, and that diabetes and obesity were major risk factors for breakdown of the diastasis repair. According to Bard, it is "undisputed" that Plaintiff had a diastasis that was repaired in three separate operations, twice after recurring, and that "the diastasis and the hernia repair using the Ventralight ST are interconnected." (Bard's Opp. at 8.) According to Dr. Novitsky, "Plaintiff's 2016 reoperation (the alleged complication) was because Plaintiff's implanting physician used an inappropriate technique for an obese patient with a hernia within a large diastasis recti—not because of adhesions." (*Id.* at 9.) Bard contends:

> Dr. Novitsky opines that Plaintiff needed a reoperation because Plaintiff's diastasis recurred. *Id.* Dr. Novitsky further opines that the cause of this recurrence was likely Plaintiff's comorbidities, including diabetes, in addition to the incorrectly chosen technique. Exhibit 2, Novitsky Dep. at 228:3-229:13. In other words, Dr. Novitsky opines that Plaintiff's complications had nothing to do with the Ventralight ST, but instead were caused by other factors. This opinion is completely relevant to Bard's defense and will not confuse a jury.

(*Id.*) Bard further contends that Dr. Novitsky's opinion related to the diastasis is relevant as a rebuttal to Plaintiff's expert Dr. Grischkan's regarding the cause of Plaintiff's complications and the need to reoperate. (*Id.*)

In light of the Court's recent decisions on Dr. Grischkan's opinions and Bard's motion for summary judgment, the Court finds that Dr. Novitsky's opinions regarding diastasis risk factors are not relevant to the issues in this case. In EMO 5, this Court excluded Dr. Grischkan's opinions that Plaintiff's adhesions caused his hernia to recur in 2016, (*see* EMO 5 at 21-23), and therefore held in DMO 1 that Plaintiff could only proceed to trial on his claim for adhesions. (*See* DMO 1 at 24-25.) Because the jury will not be deciding whether the Ventralight ST caused Plaintiff's alleged 2016 hernia—or his diastasis—to recur, testimony regarding risk factors for either a hernia recurrence or for a diastasis recurrence will not "assist the trier of fact to understand the evidence or determine a fact in issue." 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. Moreover, Dr. Novitsky testified that the risk factors he identifies for a diastasis recurrence—diabetes and obesity—are not risk factors for adhesions. (*See* Novitsky Dep. at 225:7-14, 294:17-24.) Because there is no "fit" between Dr. Novitsky's testimony regarding diastasis risk factors and the issues in this case, Dr. Novitsky's testimony on this point is not relevant.

This is not to say that Dr. Novitsky—or any other expert—may not mention these recurrences at all. Plaintiff's diagnoses and surgical history is important to understanding the full context for his first surgery when the first Ventralight ST was implanted and his second surgery when the adhesions were discovered and the first Ventralight ST removed and will be helpful to the jury.[3] But testimony regarding risk factors for injuries other than Plaintiff's adhesions do not fit the issues in this case. Additionally, based on the Court's rulings regarding the relevant injuries in this case and the scope of Dr. Grischkan's opinions, Dr. Novitsky may not offer opinions regarding the second Ventralight ST device currently implanted in Plaintiff or Plaintiff's third surgery in April 2019, or any opinions regarding Plaintiff's current pain or future complications.

Plaintiff's motion on this point is therefore **GRANTED**.

B. David B. Renton, M.D.

Dr. Renton is a board-certified surgeon whom Bard disclosed as "both a general and

[3] *Cf. Old Chief v. United States*, 519 U.S. 172, 189 (1997) ("People who hear a story interrupted by gaps of abstraction may be puzzled at the missing chapters, and jurors asked to rest a momentous decision on the story's truth can feel put upon at being asked to take responsibility knowing that more could be said than they have heard. A convincing tale can be told with economy, but when economy becomes a break in the natural sequence of narrative evidence, an assurance that the missing link is really there is never more than second best.")

case-specific expert in the Johns case." (Bard's Opp. at 1, ECF No. 127.) For the past 10 years, Dr. Renton has served as the Chief of Surgery at The Ohio State University Wexner Medical Center East Hospital, where he is also an Associate Professor of Surgery. Dr. Renton attended medical school at Louisiana State University New Orleans, completed a surgical residency at UAB Birmingham, and trained in a fellowship in Minimally Invasive Surgery at Ohio State before teaching for several years at the University of South Carolina. Dr. Renton has performed over a thousand hernia repair surgeries using synthetic mesh, including over two hundred just last year, and has used the Ventralight ST for several years.

Plaintiff contends Dr. Renton's opinions regarding the cause of Plaintiff's injuries and whether the Ventralight ST is defective are inadmissible. Specifically, he opines: "In no way do I consider the Ventralight ST defective in any regard." (Renton Rep. at 10-11, ECF No. 98-1.) Plaintiff argues that Dr. Renton is not qualified to offer this opinion because he "has zero experience in the design of products such as the Ventralight ST and has performed no testing to support his theories." (Pl.'s Mot. to Exclude at 2, ECF No. 98.) With respect to Plaintiff, Dr. Renton expresses his disagreement with Dr. Grischkan's conclusions and opinions, and then concludes: "There is simply no evidence that the Ventralight ST implant failed, was defective or otherwise did not do what it was intended to do." (Renton Rep. at 15.) Plaintiff contends this opinion "is rank speculation based on nothing more than his *ipse dixit*," and that his opinions are "irrelevant and unreliable." (*Id.*)

1. Qualifications Regarding Defect and Design Opinions

Plaintiff first contends Dr. Renton is unqualified to offer expert testimony on the defectiveness of the Ventralight ST or its design. Specifically, Plaintiff argues Dr. Renton is not qualified to provide an opinion that the Ventralight ST is not defective, to testify about the

physical properties of the Ventralight ST, or to testify as to the adequacy of the IFU. (Mot. at 6.)

In his report, Dr. Renton describes the design of the Ventralight ST and explains that he has "used this product for a few years now, and have had excellent success when intra-abdominal placement of mesh is needed to repair my patient's hernia." (Renton Rep. at 10.) He then opines "[i]n no way do I consider the Ventralight ST defective in any regard" before explaining how mesh is used in hernia repairs. (*Id.* at 10-11.)

Plaintiff contends that because Dr. Renton is not an engineer or chemist and has never designed a medical device, he has no experience that would qualify him to comment on the design of the mesh. (Mot. at 6-7.) Plaintiff further contends that Dr. Renton is not qualified to testify about the physical properties of the Ventralight ST, such as pore size, weight, and tensile strength, and how it behaves in the body, including opinions related to absorption rates, degradation, and inflammatory responses. (*Id.* at 7-8). Bard argues Dr. Renton's "expertise and experience as a surgeon and someone who has used the Ventralight ST and related devices make him qualified to offer these opinions." (Bard's Opp. at 4.) Bard contends Dr. Renton is not testifying as an engineer or biochemist, but as an "experienced surgeon and end-user regarding the safety and efficacy of the very device that is the subject of the case." (*Id.* at 7-8.) Bard's arguments are well-taken.

As the Court has found with respect to both Dr. Novitsky and Dr. Grischkan, Dr. Renton is qualified to offer opinions regarding the design and function of the Ventralight ST based on his knowledge and extensive experience performing hernia repair surgeries and using mesh products, including the Ventralight ST. *See In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 4220602, at *4; *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 613; *Franco*, 2016 WL 3248505, at *26. Moreover, courts have held 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 at 612 (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).

Dr. Renton does not purport to offer opinions as a chemist or biomaterials expert, but instead offers opinions "how mesh works in the body from a surgical perspective and why we use it in cases." (*See* Renton. Dep. at 121:3-6, ECF No. 98-2.) 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).

Plaintiff's arguments, such as Dr. Renton's lack of knowledge of the scientific literature evaluating the chronic inflammation of synthetic meshes, (*see* Mot. at 7), goes to the weight or

credibility of his testimony, not admissibility. *See 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[.]"); *see also Daubert*, 508 U.S. at 596 ("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.").

But as with Dr. Novitsky, Dr. Renton may not opine that he does not consider to be "defective." (*See* Rep. at 10-11.) Such an opinion is an impermissible legal conclusion that "usurps" the jury's role in applying the law to the facts and risks misleading and confusing the jury. *See* Fed. R. Evid. 403; *In re E. I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d at 914.

Plaintiff also contends Dr. Renton is unqualified to offer opinions regarding the adequacy of the Ventralight ST's IFU and technique guide. Dr. Renton opines "the Ventralight ST and Technique guides are adequate to apprise physicians of the potential complications and adverse events that can occur when the product is implanted for hernia repair." (Renton Rep. at 10.) Plaintiff contends Dr. Renton has no experience drafting IFUs and is not at a regulatory expert. (Mot. at 10.). According to Plaintiff, Dr. Renton has no knowledge of the requirements for IFUs, and that his basis for his opinion is "inadmissible *ipse dixit*." (*Id.* at 11.)

Consistent with this Court's prior holdings, Dr. Renton may not testify as to the adequacy of the warnings from a regulatory or legal perspective. *See also Wise*, 2015 WL 521202 at *14; *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 4220671 at *5.

But Dr. Renton is qualified to testify, as an experienced hernia surgeon, as to the risks he

perceives that the Ventralight ST poses to patients and whether those risks were disclosed on the product's warnings. (*See* EMO 5 at 31-23); *see also 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); *see also Wise*, 2015 WL 521202 at *14; *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625 at *11. Accordingly, Plaintiff's motion on this point is **GRANTED IN PART and DENIED IN PART**.

2. Reliability and Relevance of Causation Opinions

Plaintiff next moves to exclude Dr. Renton's opinions regarding the cause of Plaintiff's injuries, arguing his opinions are unreliable and irrelevant. (*See* Mot. at 11.) Dr. Renton offers opinions regarding all three of Plaintiff's surgeries and both Ventralight ST devices used in those surgeries, opining "[t]he devices did not fail and there is no indication they were the cause of Mr. John's recurrence or other complaints," (Renton Rep. at 14), and that "[t]here is simply no evidence that the Ventralight ST implanted failed, was defective or otherwise did not do what it was intended to do." (*Id.* at 15.)

Although not specifically raised by Plaintiff, the Court finds that many of Dr. Renton's opinions are not relevant to the issues in this case in light of this Court's rulings in EMO 5 and DMO 1 regarding Plaintiff's injuries. For example, Dr. Renton offers opinions regarding the currently implanted Ventralight ST used in the October 2016 surgery and Plaintiff's April 2019 surgery, including opinions related to the procedure for performing an open diastasis repair as conducted in that third surgery. (*See* Rep. at 13-15.) Because Plaintiff cannot pursue claims for current pain and future complications related to the currently implanted Ventralight ST, Dr. Renton's opinions regarding that device and the procedures used in Plaintiff's third surgery will

not "assist the trier of fact to understand the evidence or determine a fact in issue," Fed. R. Evid. 702, and are not relevant.

Relatedly, this Court has determined that Plaintiff may not pursue claims that adhesions caused Plaintiff's hernia to recur in 2016, and Plaintiff has offered no other evidence of the cause of his alleged recurrent hernia or allege the Ventralight ST caused his diastasis recurrence. The jury will be deciding whether the Ventralight ST caused Plaintiff's adhesions discovered in the October 2016 surgery, not whether the Ventralight ST caused either Plaintiff's alleged recurrent hernia or his recurrent diastasis. Much like Dr. Novitsky, Dr. Renton's opinions regarding the cause of Plaintiff's diastasis recurrence, including the opinions that Ventralight ST devices did not cause the diastasis to recur, are "not relevant, and ergo, non-helpful." *Daubert*, 509 U.S. at 591.

Many of Dr. Renton's opinions fall within this category. For example, Dr. Renton offers the following opinions in response to Plaintiff's expert, Dr. Grischkan:

> I have reviewed the report of Dr. Grischkan in this case and disagree with his conclusions and opinions. The primary reason for my disagreement is I do not believe that his argument addresses the issue at the heart of this case. Adhesions form in the abdomen during any procedure, regardless of whether mesh is placed or not. I can say, of my experience, most of the bowel obstructions I have operated on during my career were due to adhesive disease in patients who had never had mesh. **While adhesions are a consequence of intra-abdominal procedures, this is not the chief complaint of this case. The patient is stating that the mesh failed, causing a recurrence of his diastasis.** Adhesions were not the cause of the diastasis recurrence or any other alleged complications in the patient. I will again state that while the diastasis the patient had before the initial operation recurred, with the size mesh used during the first and second operation, the hernia that was in the middle of the diastasis was still covered, and had little chance of causing the patient harm in the future. I do not think the second two operations were necessary, as stated in his surgeon's deposition, "[t]he typical course of treatment for a diastasis recti is no treatment at all." Jensen Dep, 41:18-19. There is simply no evidence that the Ventralight ST implanted failed, was defective or otherwise did not do what it was intended to do.

(Renton Rep. at 15) (emphasis added). Dr. Renton also opines:

> In his deposition, Dr. Jensen stated that he did not believe Mr. Johns's first or second Ventralight ST implantation failed, nor did he believe either to be defective. *See* Jensen Dep., 82:12-23. He further opined that neither device was the cause of Plaintiff's complaints and alleged injuries. Jensen Dep., 82:12-23. I agree with Dr. Jensen's opinions regarding the Ventralight ST. The devices did not fail and there is no indication they were the cause of Mr. Johns's recurrence or other complaints.
>
> The patient in question here was probably out of danger of their hernia after the first operation. Their diastasis returned, but their hernia was covered, and no visceral contents could get through it anymore. In this sense, there is no mesh failure here. The mesh was intact, in position, and un-altered. **I do not believe the diastasis came back due to a failure of the mesh product, it was a failure in technique and judgment**.

(*Id.* at 14-15) (emphasis added).

Dr. Renton's opinions focus on Plaintiff's diastasis recurrence and both Ventralight ST devices generally, and therefore are largely irrelevant to the main issue in this case—whether the first Ventralight ST caused Plaintiff's adhesions. It is not clear whether Dr. Renton's opinions that the mesh "was intact, in position, and un-altered," (Renton Rep. at 15), and that "there is no indication they were the cause of Mr. Johns's . . . other complaints" (*id.* at 14) relates to Plaintiff's adhesions injuries and his first Ventralight ST device. Dr. Renton only references Plaintiff's adhesions in the content of explaining his disagreement with Dr. Renton that Plaintiff's "chief complaint" is his diastasis recurrence, not his adhesions. (*See* Renton Rep. at 15.)

While Dr. Renton may not offer opinions regarding the cause of Plaintiff's diastasis recurrence or the second Ventralight ST device, Dr. Renton may offer criticisms of Dr. Grischkan's opinions regarding Plaintiff's adhesion injuries. Dr. Renton may also offer certain opinions opinions regarding Plaintiff's diagnoses and surgical history, such as describing the first and second surgeries and the condition and position of the first Ventralight ST device. (*See* Renton Rep. at 12-13.) As discussed above with Dr. Novitsky, these facts are important to

understanding the context for Plaintiff's first surgery when the first Ventralight ST was implanted and his second surgery when the adhesions were discovered and the device removed.

With these limitations, many of Plaintiff's arguments that Dr. Renton's opinions are unreliable appear moot. For example, Plaintiff contends Dr. Renton admits "he did not consider whether certain alleged defects with the mesh caused [Plaintiff's] injuries," (Mot. at 13), and that he "failed to conduct relevant literature searches related to some of the primary issues involved in this case and failed to even consider numerous likely causes of Plaintiff's injuries (such as degradation, chronic inflammation, a recurrent hernia, other pitfalls associated with the Ventralight ST mesh, etc.), which is necessary to perform an adequate differential diagnosis." (Mot. at 15.) The Court need not consider whether Dr. Renton performed a reliable differential diagnosis in reaching his opinions regarding the cause of Plaintiff's diastasis recurrence because that opinion is irrelevant and inadmissible.

As a defense expert, however, Dr. Renton need not conduct a differential diagnosis in order to rebut Dr. Grischkan's testimony. *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-01564, 2017 WL 6350554, at *3 (S.D.W. Va. Dec. 12, 2017) ("[A]s a defense specific causation witness, [the expert] need not conduct a differential diagnosis. Instead, she is tasked with giving testimony that affects the weight and potentially the admissibility of the plaintiffs' specific causation expert. So long as the defense specific causation expert's opinion is a product of her specialized knowledge or training and is reliably grounded, it should be admissible to rebut the plaintiffs' specific causation expert."); *Yang v. Smith*, 728 S.E.2d 794, 800 (Ga. Ct. App. 2012) (refusing to exclude defendant's specific causation expert testimony where that testimony did not identify an injury's specific cause because the defendant had no burden to prove the specific cause of the injury); *see also Goodrich v. John Crane, Inc.*, No.

4:17CV9, 2018 WL 4677773, at *9 (E.D. Va. Sept. 28, 2018).

Dr. Renton's relevant opinions are based on his knowledge and experience as a hernia surgeon and his review of the medical records, including the postoperative reports, and Dr. Jensen's deposition testimony. Dr. Renton "need not taken an additional step and prove that another alternative cause caused [Plaintiff's] injury; causation is the plaintiffs' burden." *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 WL 6350554 at *3.

And although Plaintiff contends Dr. Renton disregarded certain facts in these records and misinterpreted Dr. Jensen's testimony, courts will "generally permit testimony based on allegedly erroneous facts when there is some support for those facts in the record." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008). "[A]lthough "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert,' *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997), a court must be sure not 'to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other.' Fed.R.Evid. 702 advisory committee's note, 2000 amend." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008).[4]

Clearly the parties dispute many of the facts in this case, including whether Plaintiff's hernia recurred and was repaired during the October 2016 surgery, and whether Dr. Jensen observed that the device failed. Plaintiff's concerns appear to relate to Dr. Renton's opinions

[4] *See* Fed. R. Evid. 702 Advisory Committee's Notes ("When facts are in dispute, experts sometimes reach different conclusions based on competing versions of the facts. The emphasis in the amendment on 'sufficient facts or data' is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other.")

regarding the cause of Plaintiff's diastasis recurrence, but to the extent they exist with Dr. Renton's admissible opinions, Plaintiff can address these issues through "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" instead of exclusion. *Daubert*, 509 U.S. at 596.

Finally, Plaintiff contends Dr. Renton's opinions are unreliable because he relies on his own "anecdotal experience." (*See* Mot. at 18.) But it is "well-established that experience-based testimony satisfies Rule 702 admissibility requirements." *In re E. I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d at 902 (citing *Kumho Tire Co., Ltd.*, 526 U.S. at 141, 119 S.Ct. 1167; *United States v. Poulsen*, 543 F.Supp.2d 809, 811-12 (S.D. Ohio 2008)). "Thus, an expert who intends to provide experience-based testimony or an experience-based opinion may well assist the trier of fact in understanding the evidence and/or in determining a fact in issue." *Id.* Dr. Renton's experience as a hernia surgeon and his use of the Ventralight ST are a reliable basis for his opinions in this case, and Plaintiff has not identified any specific "anecdotal" opinion—such as a guess as to his patient's complication rates—that would be unreliable. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4582231, at *3 (S.D.W. Va. Sept. 1, 2016) (excluding surgeon's opinion regarding his patients' estimated complication rates derived "entirely from mental estimates and not from accumulated data or patient records" as unreliable.)[5]

Accordingly, Plaintiff's motion on these points is **GRANTED IN PART** and **DENIED IN PART**.

[5] The Court notes there is a pending motion *in limine* regarding Dr. Renton's prior use of polypropylene mesh under Federal Rules of Evidence 401, 402, and 403. (*See* Pl.'s Mot. *in Limine* No. 21, ECF No. 244.)

IV.

For the reasons set forth above, Plaintiff's Motions are **GRANTED IN PART AND DENIED IN PART**.

IT IS SO ORDERED.

9-11-2020
DATE

EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE