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. 6

Bard's Motion to Exclude Dr. El-Ghannam

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 Ahmed El-Ghannam, Ph.D (ECF No. 33). For the reasons set forth below, Bard's Motion is **DENIED IN PART AND RESERVED 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 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

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

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., ECF No. 17.)

[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.)

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 motion to exclude Plaintiff's expert Dr. El-Ghannam.

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.

Plaintiff offers the testimony of Ahmed El-Ghannam, Ph.D. concerning "the design, manufacture, and application of Bard's polypropylene mesh products in the human body, and their lack of biocompatibility." (El-Ghannam Rep. at 5, ECF No. 33-1.) Dr. El-Ghannam's expertise is in the areas of biomaterials and bioengineering. According to Dr. El-Ghannam, "a biomaterial is a natural or synthetic material (such as a metal or polymer) that is implanted into living tissue, especially as part of an implantable medical device." (*Id.* at 1.) Bioengineering, which is short for biological engineering or biomedical engineering, "is the biological or medical application of engineering principles." (*Id.*) Dr. El-Ghannam's academic and professional career has focused on researching and studying the "interaction between implanted medical devices and the body, and how the body reacts to such implanted medical devices." (*Id.*) Dr. El-Ghannam describes his expertise as follows:

> As part of my academic and professional career, I have studied the reaction of the body to implantation of various materials, including polymers, and therefore I have knowledge and training that allows me to comment on the body's reactions pathologically to implantable medical devices. I also have the knowledge to analyze the structure and surface characteristics of the implant material and correlate these to the biocompatibility and toxicity to the body.

(*Id.*) Dr. El-Ghannam is currently a Professor in the Department of Mechanical Engineering and Engineering Science at the University of North Carolina at Charlotte. Dr. El-Ghannam earned a Bachelor of Science in Chemistry from Cairo University, a Master of Science in Inorganic Chemistry from Ain Shams University in Cairo and both a Master of Science-Engineering and a Ph.D. in Bioengineering from the University of Pennsylvania. Dr. El-Ghannam has taught undergraduate and graduate courses in biomedical and mechanical engineering.

Dr. El-Ghannam has worked on the design and development of medical devices and products, and has holds patents for several biomaterials, delivery systems, and formation methodologies. He has conducted research subject to peer-review and published in journals, has authored and co-authored book chapters, presented at conferences and meetings, and served as a reviewer for scientific journals and presentations.

In his expert report, Dr. El-Ghannam offers the following four opinions:

> In particular, it is my opinion to a reasonable degree of medical and scientific certainty that Bard's hernia mesh products at issue in this litigation: (1) polypropylene is not inert, and is highly susceptible to oxidative degradation, which causes a failure of the mesh in vivo leading to potentially catastrophic injuries; (2) Bard did not properly consider and account for the well-known adverse effects of repeated thermo mechanical stresses on the oxidative degradation of polypropylene; (3) Bard's polypropylene meshes lose mechanical integrity over time as they degrade, and they are no longer able to augment tissue, behave as a biocompatible device, or serve as a permanent implant; (4) the average pore size of Bard's mesh products is significantly smaller than the necessary pore size determined by medical/scientific literature and Bard's internal documents, which significantly increases the risk to the patient.

(*Id.* at 5.)

Bard moves to exclude these opinions, contending they are not relevant to this case, and that Dr. El-Ghannam lacks qualifications and a reliable basis for his general causation opinions and for his general opinions about the materials in Bard's hernia mesh devices. (Bard's Mot. to Exclude at 1, ECF No. 33).[3]

1. **Degradation Opinions**

Bard first contends that Dr. El-Ghannam's general opinions regarding polypropylene

[3] Pursuant to EMO 2, Bard has been granted leave to re-depose Dr. El-Ghannam regarding his February 10, 2020 rebuttal report, (*see* ECF No. 40-5), and to submit additional Daubert briefing based on that report and testimony. (*See* EMO 2 at 15, ECF No. 118; *see also* EMO 2-A, ECF No. 201.) Due to the ongoing COVID-19 pandemic, that deposition has not yet taken place. The instant order is based on the record currently before the Court.

degradation do not meet *Daubert*'s "fit" requirement because no expert can connect those opinions to Plaintiff's alleged injury. Bard argues that Dr. El-Ghannam does not offer any opinions specific to Plaintiff, and that Plaintiff's only case specific medical causation expert, Dr. Grischkan, does not provide the link between Plaintiff's alleged injury of omental adhesions to polypropylene degradation. (Mot. at 5-7; Reply at 3-4.) Bard's arguments are not well-taken.

Dr. El-Ghannam's opinions related to polypropylene, including his opinions that it degrades, are relevant to Plaintiff's claimed injury based on 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.). As this Court explained in EMO 5 regarding Dr. Babensee's opinions, Dr El-Ghannam's opinions are not irrelevant simply because Dr. El-Ghannam does not himself link them to Plaintiff's injuries:

> 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.

(*See* EMO 5 at 41-42, ECF No. 310); *see also 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) ("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.")

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); *see also Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 707 (S.D.W. Va. 2014) ("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."); *see also 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."). Accordingly, Bard's motion on this point is **DENIED**.

2. General Causation and Clinical Outcomes Opinions

Bard next contends that Dr. El-Ghannam lacks qualifications and a reliable basis for his general causation opinions. First, Bard argues that Dr. El-Ghannam is a not a medical doctor and has no medical training, and that his opinions about the clinical consequences related to Bard's polypropylene is unsupported and unreliable. (Mot. at 7-8.) Plaintiff, however, represents that he does not offer Dr. El-Ghannam to show "specific causation of injuries at a treating physician level." (Pl.'s Opp. at 15, ECF No. 73.) Instead, Plaintiff contends Dr. El-Ghannam will testify "as a scientist to show Defendants' polypropylene hernia mesh products involved in this litigation—including the Ventralight ST mesh—are not biocompatible, and to show the correlation between the degradation of the polypropylene mesh material and the irritation of the immune system which has manifested in the symptoms Plaintiffs suffered." (*Id.* at 14-15.)

Bard has not identified, nor has the Court found, an example of a "specific causation" opinion offered by Dr. El-Ghannam related to the cause of Plaintiff's injuries. Accordingly, the Court need not decide whether Dr. El-Ghannam is qualified to offer such an opinion, though it notes other courts have found him unqualified to do so. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 632 (S.D.W. Va. 2013), *on reconsideration in part* (June 14, 2013).

The Court does find, however, that Dr. El-Ghannam is well-qualified, based on his

knowledge, experience, and education, to provide general causation opinions regarding polypropylene and the body's reaction to that material. In another MDL involving Bard's polypropylene products, Judge Goodwin rejected similar challenges to Dr. El-Ghannam's qualifications to offer general causation opinions:

> As it relates to the issue of general causation, and as I previously stated, Dr. El-Ghannam is certainly qualified in the field of biomaterials and biomedical engineering—he is educated and his professional experience has focused in this field. In moving to exclude, Bard fails identify any particular opinion advanced by Dr. El-Ghannam that speaks to the issue of general causation outside the scope of his expertise. Instead, Bard relies upon its conclusory assertion that without a medical education or background Dr. El-Ghannam is not "qualified to draw any connection between polypropylene degradation and any alleged injury to a particular plaintiff." I disagree, Dr. El-Ghannam's experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its purported degradation and the resulting inflammatory response.

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) (internal citations omitted); *see also Chrestecky v. C.R. Bard*, 2020 WL 748182, at *9 (W.D. Tex. Feb. 14, 2020).

This Court further disagrees with Bard that Dr. El-Ghannam's general causation opinions are unreliable. Bard's argues that Dr. El-Ghannam has no knowledge of the clinical performance of the Ventralight ST and that he failed to perform a differential diagnosis. (*See* Mot. at 8-9.) Specifically, Bard contends "[w]ithout a differential diagnosis or some other method of evaluating specific cause, a disconnected opinion about general causation in unreliable." (*Id.* at 9.) But as discussed above, there is no requirement that a single expert provide both general and specific causation opinions, and Dr. El-Ghannam's failure to perform a differential diagnosis has no bearing on his general causation opinions. Dr. El-Ghannam's general opinions regarding the body's reactions to polypropylene mesh devices are sufficiently reliable, and Bard's contention that Dr. El-Ghannam did not review literature regarding the clinical performance of the

Ventralight ST specifically goes to the weight of his opinions, not their admissibility. *See Daubert*, 509 U.S. at 596. Accordingly, Bard's motion on this point is **DENIED**.

3. Materials Opinions

Bard also moves to exclude Dr. El-Ghannam's opinions regarding the materials in Bard's hernia mesh devices, arguing he lacks qualifications and a reliable basis for those opinions.

a. Qualifications

Bard first contends Dr. El-Ghannam is unqualified to offer opinions regarding the materials in the Ventralight ST because his education and experience has concentrated in bioceramics, not in polypropylene or other components of the Ventralight ST, and that his only knowledge of and experience with polypropylene has been gained through litigation. (Mot. at 10-11.)

Bard's arguments are not well-taken. Dr. El-Ghannam has extensive knowledge, education, and experience in bioengineering and with biomaterials, and he has studied the reaction of the body to the implantation of various materials, including polymers, throughout his academic and professional career. (*See* El-Ghannam Rep. at 33-1.) Judge Goodwin and others have repeatedly found Dr. El-Ghannam qualified to opine on polypropylene and his theory of degradation based on his education and experience in biomaterials generally, finding he "is well-qualified in the field of biomaterials and biomedical engineering to testifying regarding the interaction between implanted medical devices and, more specifically, the mechanisms and biologic effects of degradation of polypropylene." *In re C. R. Bard, Inc., Pelvic Repair System Products*, 2018 WL 514879 at *3; *see also In re C.R. Bard, Inc.*, 948 F.Supp.2d at 633 (finding Dr. El-Ghannam had demonstrated "sufficient knowledge of the area of polypropylene to qualify him to offer opinions on design defects."); *Chrestecky v. C.R. Bard*, 2020 WL 748182 at *10.

Moreover, Dr. El-Ghannam has experience with polypropylene specifically, and as this Court explained in EMO 5, that this experience is due to his work as an expert in other MDLs involving Bard's polypropylene devices does not warrant exclusion of his opinions, as long as the opinions are sufficiently reliable. *See Johnson v. Manitowoc Boom Trucks, Inc.,* 484 F.3d 426, 434-35 (6th Cir. 2007); *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D.W. Va. Sept. 29, 2014).

b. Reliability of Polypropylene Degradation Opinions

Bard next contends Dr. El-Ghannam's opinions regarding polypropylene degradation are based on an unreliable methodology and analysis. In forming his opinions in this case, Dr. El-Ghannam performed testing on pristine hernia mesh exemplars, including Scanning Electron Microscopy ("SEM"), Fourier Transform Infrared Spectrometry ("FTIR"), porosity analyses, Differential Scanning Calorimetry ("DSC") thermal analysis, and *in vitro* analysis of the chemical stability, mechanical integrity, and biocompatibility of the pristine exemplars in a physiological solution. (*See* El-Ghannam Rep. at 6.) Dr. El-Ghannam's analysis of the mesh devices "revealed the following issues, among many others: deformation, contraction, severe surface damages, and oxidative degradation of the polypropylene fibers in all products" and that "the polypropylene mesh degraded and cracked after immersion in physiological solution for even a short period of time, indicating the absence or lack of biocompatibility and mechanical stability inside the body." (*Id.*)

Bard contends Dr. El-Ghannam's testing methodology was "fundamentally flawed" and that his results are unreliable and incorrect. Specifically, Bard argues 1) Dr. El-Ghannam did not properly prepare his samples for analysis with DRIFTS FTIR, leading to erroneous results; and 2) Dr. El-Ghannam failed to follow ASTM standards in interpreting the DSC analysis. (Mot. at

12-17.)

Dr. El-Ghannam used FTIR to analyze the surface chemistry of Bard's mesh implants. (El-Ghannam Rep. at 18.) According to Bard, "there are multiple methods for conducting FTIR, including attenuated total reflectance ("ATR") and diffuse reflectance mode ("DRIFTS"). (Mot. at 13.) Here, Dr. El-Ghannam used DRIFTS to conduct his FTIR testing on Bard's pristine mesh products. (El-Ghannam Rep. at 18.)

Bard argues "[w]hile DRIFTS is an appropriately validated method of analysis for certain preparations of materials (e.g., samples that can be ground into a fine powder), it is not appropriate for use in the analysis of polypropylene in its bulk or extruded state." (Mot. at 13.) Bard contends "Dr. El-Ghannam failed to properly perform DRIFTS FTIR because he used a bulk piece of mesh as opposed to a powdered sample, in direct contradiction to both the FTIR machine manufacturer's recommendations and the techniques discussed in published literature." (*Id.* at 14.). According to Bard, this "improper preparation" of the material distorted the results of his testing and renders his opinions that the FTIR testing shows degradation unreliable. (Reply at 10.) Bard contends that Dr. El-Ghannam was unable to identify any literature that utilized DRIFTS for the analysis of polypropylene mesh, or that supports Dr. El-Ghannam's methods or results. (Mot. at 15.) Bard contends that "the standard and accepted methodology to analyze the chemical composition of polypropylene mesh is to apply ATR-FTIR, not DRIFTS." (Reply at 15.)

Plaintiff counters that Dr. El-Ghannam has used DRIFTS FTIR for almost thirty years to analyze "a multitude of materials in various forms and shapes" and that there is a "plethora" of peer-reviewed literature supporting the use of DRIFTS to analyze bulk polymer samples without grinding them into a powder. (Pl.'s Opp. at 27.) In response to criticisms by Bard's expert Dr.

Maureen Reitman, Dr. El-Ghannam's rebuttal report offers a thorough defense of his use of DRIFTS FTIR to analyze bulk samples in his rebuttal report. (*See* El-Ghannam Rebuttal Rep. at 1-18, ECF No. 45.) While Bard has argued that these opinions and supporting literature in Dr. El-Ghannam's rebuttal report were improper, the Court has already declined to strike that report but permitted Bard to re-depose Dr. El-Ghannam and to submit supplemental *Daubert* briefing. (*See* EMO 2 and EMO 2-A.) Due to the ongoing COVID-19 pandemic, that supplemental deposition and briefing has not been completed.

Based on the evidence currently before it, the Court finds Dr. El-Ghannam's opinions based on his FTIR testing are sufficiently reliable.[4] Dr. El-Ghannam has extensive experience performing DRIFTS FTIR, and relies on scientific literature and peer-reviewed publications throughout his rebuttal report that have used DRIFTS to analyze bulk samples of polymers, metals, and ceramics, concluding "DRIFT analysis of bulk materials is a well-known and accepted method of analysis in the scientific community. (*See* Rebuttal Rep. at 1-6.) Dr. El-Ghannam explains:

> A major reference book for FTIR Spectroscopy analysis of polymers is "Spectroscopy of Polymers," edited by Jack L. Koenig. In Chapter 3, entitled Experimental IR Spectroscopy of Polymers, it explicitly states that "Bulk polymer samples can be studied by using DRIFT." Two separate studies for bulk polymer analysis by DRIFT were quoted and four more references were cited as examples for the use of DRIFT to examine local areas of bulk samples and depth profiling

[4] Other courts have found the same. *See In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 514879, at *4 (finding Dr. El-Ghannam's use of DRIFTS method for his FTIR testing sufficiently reliable); *Chrastecky*, No. A-19-CV-1240-LY-SH, 2020 WL 748182 at *10 (same); *In Re Mentor Corp. Obtape Transobturator Sling Products Liability Litigation*, No. 4:08-MD-2004 (CDL), 2016 WL 6138253, at *7 (M.D. Ga. Oct. 20, 2016), *aff'd sub nom. Taylor v. Mentor Worldwide LLC*, 940 F.3d 582 (11th Cir. 2019) ("Dr. El-Ghannam is a well-qualified biomaterials engineer, and he used widely accepted methods to test [polypropylene device]–such as electron microscope examination, FTIR test, and gas chromatography/mass spectrometry analysis.").

> of the surface, and to analyze the interface between organic and inorganic materials.
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> Many other peer-reviewed publications in the scientific literature have used DRIFT to analyze bulk samples of polymers, metals and ceramics. In other words, DRIFT has been properly used for decades to analyze all kinds of materials in a wide variety of shapes other than particles. For example, Kubo, et al., employed DRIFT to analyze carbon fibers derived from the polymer blend fibers of hardwood kraft lignin (HKL) and polypropylene (PP). The polypropylene used in Kubo's study was an isotactic polypropylene similar to the kind of polypropylene used to make Bard's meshes.

(*Id.* at 1, 4) (internal citations omitted). Dr. El-Ghannam thus relies on the principles set forth in this literature regarding bulk polymers and on his experience with biomaterials generally to apply DRIFTS FTIR to the specific bulk polymer here—polypropylene. Bard's arguments that these articles do not specifically relate to polypropylene mesh can be addressed through "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" rather than through exclusion." *Daubert*, 590 U.S. at 596; *see also Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 561 (8th Cir. 2014) ("As long as the expert's testimony is supported by relevant scientific literature, it should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded by the court at the outset.") (citing *Daubert*, 509 U.S. at 590, 596).

Bard next contends Dr. El-Ghannam's assessment of the DSC data in his report lacks a sufficiently reliable basis. (Mot. at 15-17.) Dr. El-Ghannam used DSC—differential scanning calorimeter—to determine the thermal properties and transitions of Bard's mesh devices. (*See* El-Ghannam Rep. at 19.) A different lab, the Polymer Center of Excellence, performed the DSC tests, and Dr. El-Ghannam analyzed the data provided by the Center in forming his opinions. Dr. El-Ghannam states his analysis was performed in accordance with "ATSM D3418-08 Standard

Test Method for Transition Temperatures of Polymers by Differential Scanning Calorimetry[.]" (*Id.*)

Bard contends, however, that Dr. El-Ghannam failed to follow this standard's guidelines in reaching his results and identifying the onset of melting and "multiple melting points." For example, Bard argues that the standards define the "onset of melting" at a specific point, but that Dr. El-Ghannam identified the onset of melting at a point that is inconsistent with the ASTM standard. (*See* Mot. at 15-16.) Bard further argues Dr. El-Ghannam "identifies multiple melting points during the first heating of samples that were not identified by Polymer Center for Excellence, or which are not in fact present on the data." (*Id.* at 17.) For example, Bard contends Dr. El-Ghannam identifies four melting points for the polypropylene in the Ventralight ST, but that the actual data shows only one melting point. (*Id.*) Similarly, Dr. El-Ghannam identifies "multiple melting points" in the first heat cycle, but according to Bard, the ATSM standard states the second heat, not the first, should be used to identify melting points and that those points were not present in the data for the second heat cycle. (*Id.*) Bard concludes Dr. El-Ghannam's interpretation of the results directly conflict with the ATSM requirements. (*Id.*)

Bard's arguments are not well-taken. While Bard frames its argument as an issue of the reliability of Dr. El-Ghannam's methodology, Bard is challenging the validity of Dr. El-Ghannam's conclusions regarding the melting points observed in the DSC data. This Court's reliability inquiry focuses "solely on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 595; *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[.]"). Bard's arguments about the validity of Dr. El-Ghannam's conclusions and deviations from the ASTM standards is an issue of weight,

not admissibility, and can be addressed on cross-examination and through Bard's own experts.

Moreover, Plaintiff contends that Dr. El-Ghannam has explained why he disagrees with some of the definitions in the ATSM standards, and that his conclusions regarding the onset of melting are "based on a review of the textbooks and scientific literature, which he teaches in his polymer class" and his identification of "multiple melting points" is "well-documented and supported in the scientific and medical literature, as noted in Dr. El-Ghannam's expert report and supplemental expert report." (Pl.'s Opp. at 33-34.)

On this point, Bard argues that this literature was not timely served, and that Dr. El-Ghannam failed to produce all of the underlying materials he received from the Polymer Center of Excellence relating to the specimens he submitted for DSC testing, include the pristine Bard hernia mesh devices and "unidentified 'medical grade' polypropylene." (Reply at 14-15.) It is the Court's understanding that this information was provided in Dr. El-Ghannam's supplemental report, and his rebuttal report, and that the Court declined to strike this information from the record. (*See* EMO 2 at 12-15.) Bard will have an opportunity to question Dr. El-Ghannam regarding this information during his supplemental deposition.

c. Reliability of Manufacturing Process and Pore Size Opinions

Finally, Bard argues Dr. El-Ghannam's opinions regarding Bard's manufacturing processes and the pore size of Bard's devices are unreliable. (Mot. at 17-20.)[5] Dr. El-Ghannam offers opinions regarding Bard's manufacturing process of the hernia mesh products at issue in

[5] Bard repeats its arguments Dr. El-Ghannam is unqualified to offer these opinions, but this Court has already found Dr. El-Ghannam qualified to opine as to the polypropylene and degradation even though he is "is neither a textile engineer nor did he review the necessary documents to understand how the process is conducted." *See also In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 514879, at *5; *Chrastecky*, 2020 WL 748182 at *10-11 (same).

this litigation. According to Dr. El-Ghannam, these products are subjected to thermal and mechanical stresses during the manufacturing process that damage the mesh and cause it to degrade. (*See, e.g.,* El-Ghannam Rep. at 36-66, 121-124, 138.) For example, Dr. El-Ghannam opines:

> Both mechanical stress and heat will independently break the plastic sheet due to the disruption to the integrity of the molecular structure. This same structural disruption can be seen in the polymer, namely polypropylene, fibers contained in Bard's hernia mesh implants. The structural disruption to the mesh is likely caused during the manufacturing process as the polymers are subjected to adverse mechanical stresses during, for example, knitting, and subjected to both mechanical stresses and heat during the thermal forming and setting procedures as well as the thermal sealing of the edges.

(*Id.* at 36) He concludes "[t]he damage to the surface of Bard's polypropylene meshes, in my expert opinion, are more likely than not created by Bard's storage and/or manufacturing processes." (*Id.* at 49.)

According to Bard, Dr. El-Ghannam's opinion "that Bard's manufacturing processes cause pristine mesh devices to degrade, has nothing to do with the Ventralight ST—let alone Plaintiff's Ventralight ST—and to the extent it relates to other products, is unsupported by the relevant literature and based on his faulty FTIR testing." (Mot. at 19.) Specifically, Bard contends that at Dr. El-Ghannam's deposition, he was unable to tie these opinions to the Ventralight ST device or identify any documents relevant to the Ventralight ST device manufacturing process. (*Id.* at 18.) Bard further argues that "[n]o published literature, let alone any cited by Plaintiff, shows degradation in pristine polypropylene mesh," and that the only basis for Dr. El-Ghannam's opinion is his unreliable testing. (Reply at 18.)

This Court disagrees. As Plaintiff explains, Dr. El-Ghannam's opinions that the degradation observed in the pristine mesh implants is due to the thermo-mechanical stresses applied during the manufacturing process are based on Dr. El-Ghannam's experience, education,

and training, as well as his review of Bard's internal documents and his FTIR testing on pristine mesh devices, including the Ventralight ST. (*See* Pl.'s Opp. at 35-38.)

Dr. El-Ghannam reviewed numerous internal Bard documents related to its manufacturing process to the Ventralight ST, and he has previously studied degradation in different materials, including in another MDL involving Bard's polypropylene products.[6] Dr. El-Ghannam relies on literature throughout his report with respect to the methods he used to test Bard's pristine mesh devices and the principles of the effect of heat and other stresses on the surface of the mesh and degradation of mesh fibers. (*See, e.g.*, El-Ghannam Rep. at 36-51.) Dr. El-Ghannam explains the results of the testing conducted on Bard's pristine mesh devices in this case support his opinions:

> FTIR analyses of pristine (untouched) Bard meshes confirmed the oxidation and showed characteristic bands for carbonyl groups indicating the oxidation of the pristine implant materials. The oxidation of the pristine Bard polypropylene fibers is maximized by the high surface area of the fibers, the groves and cavities on the damaged surfaces and by the spreading of debris and particulate matter attached to the surface. The fibers of the mesh showed longitudinal cracks along the axis of the fiber that more likely than not enhance diffusion of the oxygen into the bulk of the fiber. The wide distribution of polymeric debris and the torn thin sheets partially attached to the fibers would have a similar effect on increasing the oxidative degradation of the polymer.
>
> The effect of applying high heat and stresses during knitting, thermal seal of the edges and heat forming of the mesh resulted in deterioration of the crystalline structure as confirmed by the DSC analyses of the pristine Bard meshes (polypropylene implants).

(*Id.* at 138.)

In arguing no literature confirms Dr. El-Ghannam's opinion, Bard is again contending

[6] Bard again contends it has not had an opportunity to cross-examine Dr. El-Ghannam regarding information related to his prior mesh work that was included in his rebuttal report, (*see* Reply at 17), but as explained above, Bard will have that opportunity at Dr. El-Ghannam's supplemental deposition.

that its disagreement with Dr. El-Ghannam's conclusions—that there is evidence of degradation in Bard's pristine mesh—is a basis for excluding his opinions. *Daubert*, 509 U.S. at 595 (holding the focus under Role 702 "must be solely on principles and methodology, not on the conclusions they generate."). Bard's arguments regarding the accuracy of Dr. El-Ghannam's conclusions or his reliance on certain Bard documents 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 evidence." 508 U.S. at 596.

The Court therefore finds Dr. El-Ghannam's opinions regarding Bard's manufacturing processes are sufficiently reliable. *See In re C.R. Bard, Inc.*, 948 F.Supp.2d at 636 (admitting Dr. El-Ghannam's manufacturing process opinions relating to temperature because he "explained adequately and with sufficiently reliable basis in his deposition testimony and supplemental report, the effects of subjecting the polypropylene material in the Avaulta mesh to the heat during the manufacturing process."); *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 514879, at *5; *Chrastecky v. C. R. Bard, Inc.*, No. A-19-CV-1240-LY-SH, 2020 WL 748182, at *10.[7]

Bard also contends Dr. El-Ghannam's pore size opinions are unreliable because of his "failure to design a measurement protocol, the variability in his measurement technique and

[7] These courts did not permit Dr. El-Ghannam to testify regarding the "knitting process of the mesh process" as part of his manufacturing process, but Bard has not separately raised issues specific to Dr. El-Ghannam's knitting process opinions here.

results, and his utter lack of a meaningful review of Bard's internal documents[.]" (Mot. at 21.) Dr. El-Ghannam offers opinions regarding the pore size of Bard's hernia mesh products, including that "the average pore size of Bard's mesh products is significantly smaller than the necessary pore size determined by medical/scientific literature and Bard's internal documents, which significantly increases the risk to the patient." (El-Ghannam Rep. at 5.)

The Court is not persuaded that Dr. El-Ghannam's pore size opinions, based on his Scanning Electron Microscopy ("SEM") analysis are unreliable. However, as Bard points out, Dr. El-Ghannam's report contains the results of his analysis on certain Bard hernia mesh products, such as the Perfix Plug, 3D Max, and Ventralex, but not the Ventralight ST. (*See id.* at 72-80.) While pages 163-72 of Dr. El-Ghannam's report contains results from his SEM analysis of other aspects of the Ventralight ST, that section is silent as to pore size.

Plaintiff offers that Dr. El-Ghannam's report contains information "specifically related to the alleged pore size of the Ventralight ST mesh. See, e.g., Ex. 1 at 6-7, and Appendix 2 at 22-25." (Pl.'s Opp. at 41.) At his deposition, Dr. El-Ghannam represented that he did measure pore size for the Ventralight ST, and that the results were in the appendix to his report:

> Q: You did not measure the pore size of the Ventralight, did you?
> A. I did.
> Q. Okay. And what was it?
> A. I have the figure in here in front of me.
> Q. Okay. Then tell me what the average pore size was for the Ventralight or the pore size --
> A. I have to go to the text.
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> ***
>
> THE WITNESS: I'm sorry, [Ms. Moberg], what was the page that we were reading before that has the table?
> MS. MOBERG: Seventy-three.
> THE WITNESS: Seventy-three, okay. I really can't see the table for the Ventralight, but the scanning electro-microscope in my appendix in here is showing my measurements for the length and width of the pores.

BY MS. MOBERG:
Q. On the Ventralight?
A. On the Ventralight ST and it's not really different from the others and I can look at the image and tell you what is the smallest pore size if you are interested. It's about 107-microns, that's the smallest pore size.
Q. What is 107-microns in millimeters?
A. That's 0.107 millimeter.
Q. And you are sure that's the Ventralight product?
A. This is Ventralight ST, yes.

(*See* El-Ghannam Dep. at 278:22-280:12, ECF No. 33-2.) Based on the Court's review of the docket, the images to which Dr. El-Ghannam may be referring appears to be located in the appendices of the report filed with Plaintiff's opposition brief under the heading "Sample #3 SEM analysis of Pristine Ventralight ST." (*See* ECF No. 73-4 at PAGEID#4972, 5018-19.) But these images contain no explanation or notations, and without more, the Court is left to guess as to the significance of this analysis. The Court is not finding Dr. El-Ghannam's pore size opinions unreliable or unsupported at this stage. Given some confusion in the record, the Court does note that Dr. El-Ghannam will have to provide further foundation, in the upcoming supplemental deposition or in *voir dire*, before his pore size testing of the Ventralight ST may be given to the jury. Accordingly, the Court reserves ruling on the relevance and reliability of Dr. El-Ghannam's pore size opinions pending further explanation from Dr. El-Ghannam regarding these opinions at trial. Bard's Motion is otherwise **DENIED**.

IV.

For the reasons set forth above, Bard's Motion is **DENIED IN PART AND RESERVED IN PART**.

IT IS SO ORDERED.

9-10-2020
DATE

EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE