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:
Milanesi, et al. v. C.R. Bard, Inc., et al.
Case No. 2:18-cv-01320

EVIDENTIARY MOTIONS OPINION & ORDER No. 20

Before the Court are Defendants' Motions to Exclude the Opinions and Testimony of Plaintiffs' Experts Ahmed El-Ghannam, Ph.D. (ECF No. 72), Robert W. Johnson (ECF No. 66), and John L. Quick (ECF No. 68), and Plaintiffs' Motion to Exclude the Opinions and Testimony of Defense Expert James M. Anderson, M.D., Ph.D. (ECF No. 81.) For the reasons below, Defendants' motion to exclude Dr. El-Ghannam (ECF No. 72) is **DENIED**, Defendants' motion to exclude Johnson (ECF No. 66) is **GRANTED**, Defendants' motion to exclude Quick (ECF No. 68) is **GRANTED IN PART AND DENIED IN PART,** and Plaintiffs' motion to exclude Anderson (ECF No. 81) is **GRANTED IN PART AND DENIED IN PART.**

I. Background[1]

Plaintiffs', Antonio Milanesi and Alicia Morz de Milanesi, case is the second bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants, C.R. Bard, Inc. and Davol, Inc. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. (ECF No. 167)

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." (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)[2] This includes Defendants' Ventralex Hernia Patch, the device implanted in Mr. Milanesi.

The Ventralex is a prescription medical device used for umbilical and small ventral hernia repairs. (ECF No. 167 at PageID #13610.) The small and medium sizes were cleared through the 510(k) premarket notification process by the Food and Drug Administration ("FDA") in 2002; the Composix Kugel was listed as a predicate device. (*Id.* at PageID #13611.) The large size was cleared via "a no 510(k) rationale based upon the 510(k) for the Composix Kugel product." (*Id.*) The Ventralex has two sides—one of polypropylene mesh and one of permanent expanded polytetrafluoroethylene ("ePTFE"). (*Id.* at PageID #13610.) The polypropylene mesh side faces the abdominal wall, encouraging tissue to grow into the mesh and thus supporting the hernia repair. The ePTFE side faces the intestines and is designed to minimize tissue attachment, such as adhesions, to the intestines and other viscera. The Ventralex also has a monofilament memory coil ring, which was made of polyethylene terephthalate ("PET") when it was implanted in Mr. Antonio. The ring is designed to help the patch "pop open" and then "lay flat" against the abdominal wall after the Ventralex is folded and inserted through the incision site during surgical repair of the hernia. (*Id.*)

Plaintiffs bring this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralex device. Ten years after the implantation of the

[2] All docket citations are to the docket in the instant case, Case No. 18-cv-1320, unless otherwise noted.

Ventralex, Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel resection. (*Id.* at PageID #13611–13.) Shortly thereafter, Mr. Milanesi suffered a high-grade post-operative small bowel obstruction that required emergency surgery. (*Id.* at PageID #13613.)

The crux of Plaintiffs' claims is that Defendants knew of the risks presented by the Ventralex device but marketed and sold the device despite these risks and without appropriate warnings. Plaintiffs point to three specific issues with the Ventralex: (1) polypropylene resin oxidatively degrades *in vivo*, (2) the ePTFE layer contracts more quickly than the polypropylene, which in combination with the too-weak memory coil ring causes the device to fold or buckle or "potato chip," leading to the exposure of the bare polypropylene to the bowel, and (3) the ePTFE layer is prone to infection. (*Id.* at PageID #13613–14.) After summary judgment, the following claims remain for trial: defective design (strict liability), failure to warn (strict liability), negligence, gross negligence, negligent misrepresentation, fraud and fraudulent misrepresentation, fraudulent concealment, loss of consortium, and punitive damages. (*Id.* at PageID #13616–37.)

The parties have filed their dispositive and *Daubert* motions, and the motions are now ripe for adjudication, including the present motion.

II. Legal Standard

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an

evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because courts are "almost always better situated during the actual trial to assess the value and utility of evidence." *Jackson v. Cnty. of San Bernardino*, 194 F. Supp. 3d 1004, 1008 (C.D. Cal. July 5, 2016) (quoting *Wilkins v. Kmart Corp.*, 487 F. Supp. 2d 1216, 1218 (D. Kan. 2007)); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975) ("A better practice is to deal with questions of admissibility of evidence as they arise."). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (quoting *Ind. Ins. Co*., 326 F. Supp. 2d at 846). The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

The burden is on the party offering the expert opinions and testimony to demonstrate "by a preponderance of proof" that the expert evidence is 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. *See Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) ("The Court [in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993),] explained that Rule 702 displays a 'liberal thrust' with the 'general approach of relaxing the traditional barriers to "opinion" testimony.'" (quoting *Daubert*, 509 U.S. at 588)); Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.").

III. Analysis

The district court's role in assessing expert testimony is a "gatekeeping" one, "screening expert testimony" so that only admissible expert testimony is submitted to the jury; its role is not to weigh the expert testimony or determine its truth. *United States v. Gissantaner*, 990 F.3d 457, 463 (6th Cir. 2021) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). Expert testimony, testimony given by "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education," is admissible 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. In this circuit, "[t]he Rule 702 analysis proceeds in three stages." *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). "First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' 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.' Third, the testimony must be reliable." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (quoting Fed. R. Evid. 702.).

First, an expert witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "[T]he 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." *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). "[T]he only thing a court

should be concerned with in determining the qualifications of an expert is 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. Int'l 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) (quoting *Mannino*, 650 F.2d at 851); *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.").

Second, expert testimony must be relevant. Expert testimony is relevant if it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir. 2015) (quoting *United States v. Freeman*, 730 F.3d 590, 599–600 (6th Cir. 2013)); Fed. R. Evid. 702(a). "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 (quoting 3 Jack B. Weinstein & Margaret A. Berger, Weinstein's Evidence ¶ 702[02], p. 702–18 (1988)). "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). This is a case-specific inquiry. *See Madej*, 951 F.3d at 370 ("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.").

Third, expert testimony must be reliable. Rule 702 provides the following general standards to assess reliability: whether "the testimony is based on sufficient facts or data," whether

"the testimony is the product of reliable principles and methods," and whether "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider "'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,'" though 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*, 527 F.3d at 529 (citations omitted); *see Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as "flexible" (quoting *Daubert*, 509 U.S. at 594)). 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.

The parties move for the exclusion of expert testimony from the following experts: Ahmed El-Ghannam, Ph.D., Robert W. Johnson, John L. Quick, and James M. Anderson, M.D., Ph.D.

A. Ahmed El-Ghannam, Ph.D.

Defendants argue that Dr. El-Ghannam's opinions on polypropylene degradation are irrelevant to this case and incorporate by reference their other arguments from their briefing on Dr. El-Ghannam in *Johns v. C.R. Bard, Inc.*, the first bellwether case in this MDL. (ECF No. 72 at PageID #3703.) Accordingly, the Court follows its previous *Daubert* opinion holding Dr. El-Ghannam's opinions are admissible except for his pore-size opinions, on which the Court reserves ruling. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md2846, 2020

WL 6603389, at *13 (S.D. Ohio Sept. 10, 2020) (Evidentiary Motions Order ("EMO") No. 6). This leaves Defendants' new argument that Dr. El-Ghannam's polypropylene opinions are irrelevant, which the Court rejects.

Dr. El-Ghannam's general polypropylene degradation opinions are relevant to this case. Plaintiffs identify a two-step mechanism of injury in all bellwether cases in this MDL, including this case. First, the polypropylene mesh's "adhesion barrier fails, and polypropylene is exposed to underlying organs to which it attaches." (ECF No. 105 at PageID #9151.) As the Court noted in its *Daubert* opinion addressing Dr. Krpata, the precise two-step mechanism of injury here is that the Ventralex buckles due to contracture, which then exposes bare polypropylene to the viscera. (ECF No. 166 at PageID #13590.) Dr. Krpata, a general and specific causation expert, opines on the first step of this mechanism, explaining that polypropylene mesh and ePTFE contract at different rates, causing buckling, and the memory recoil ring lacked sufficient rigidity to prevent the buckling. (*Id.*) He also notes that the exposure of bare polypropylene is widely known to be problematic and can cause adhesions, fistula, and erosion. (*Id.*) Dr. El-Ghannam picks up where Dr. Krpata leaves off, explaining why bare polypropylene causes such injuries. (ECF No. 219 at PageID #14987–90.) Thus, Dr. El-Ghannam's general causation opinions about polypropylene degradation are relevant.

Defendants counter that polypropylene degradation has no relation to this case, but Defendants ignore the two-step mechanism of injury described above. (ECF No. 72 at PageID #3705–06.) Moreover, no expert need supply every link in the chain of Plaintiffs' theory of the case for his opinion to be relevant. *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536456, at *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."). Thus, it is perfectly permissible for Dr. Krpata to opine on the "gross behavior" of the device, the buckling, and for Dr. El-Ghannam to opine on the "molecular and cellular" behavior of the device, specifically polypropylene degradation. (ECF No. 119 at PageID #10836; *see also* ECF No. 219 at PageID #14987.)

Defendants also argue that Dr. Krpata's conclusion that the exposure of polypropylene to viscera is problematic because porous materials stimulate tissue ingrowth is a separate issue from Dr. El-Ghannam's degradation opinion. (ECF No. 119 at PageID #10837.) This is an issue about the proper interpretation of Dr. Krpata's expert report. It is sufficient that Defendants can cross-examine both experts at trial on these issues, and then the jury can decide what Dr. Krpata meant and whether Dr. El-Ghannam's opinion is inconsistent with Dr. Krpata's opinion.

Accordingly, Defendants' motion is **DENIED**.

B. Robert W. Johnson

Defendants move to exclude Johnson's opinions related to the financial condition of their non-party parent company, Becton Dickinson. (ECF No. 66.) In *Johns*, the Court excluded Johnson's opinions on his topic for lack of relevance, explaining that the plaintiff provided no authority, state or federal, demonstrating a non-party parent company's financial condition was relevant to Defendants' ability to pay. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-1509, 2021 WL 2646771, at *3–4 (S.D. Ohio June 28, 2021) (EMO No. 12).

Plaintiffs do not provide any new or different authority on this point.[3] (ECF No. 102 at PageID #8672–74.) Accordingly, there is no justification to depart from this Court's prior ruling or to address Defendants' other grounds for excluding Johnson's testimony. Defendants' motion is **GRANTED**.

C. John L. Quick

Finally, Defendants argue that Quick's opinions and testimony should be excluded. (ECF No. 68.) They argue that Quick is unqualified to offer opinions on Defendants' Quality Management Systems ("QMS") and design controls; that his methodology is unreliable; that he cannot offer causation, MSDS, or state-of-mind opinions; that his opinions regarding Sepramesh and Ventralight ST are irrelevant; and that he conceded his lack of qualifications to offer some opinions. (*Id.* at PageID #2844–56.) Only some of Defendants' arguments regarding state-of-mind and MSDS opinions find traction, however.

1. Qualifications

Quick is qualified to offer his opinions. Most of the arguments Defendants raise regarding Quick's qualifications were raised in *Johns*, and so the Court's reasoning in *Johns* that Quick is generally qualified to offer QMS opinions applies here. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-1509, 2021 WL 2643109, at *4 (S.D. Ohio June 28, 2021) (EMO No. 9).

Defendants also argue that Quick is unqualified to offer other, non-QMS

[3] Plaintiffs cite this Court's decision *In re E.I. du Pont de Nemours & Co., C-8 Pers. Injury Litig.*, No. 2:13-md-2433, 2014 WL 1653158 (S.D. Ohio Apr. 24, 2014), but this decision provides no guidance. This opinion addresses discoverability, not admissibility. *In re E.I. du Pont*, 2014 WL 1653158, at *6.

arguments. First, they argue that Quick is unqualified to opine that Defendants failed to comply with the 510(k) application requirements from the FDA. (ECF No. 68 at PageID #2846–48.) Quick is qualified to offer opinions that in his view Defendants did not satisfy FDA 510(k) regulations, even if he has not himself drafted a 510(k) application (*id.* at PageID #28480), Quick has ample experience with QMS and other FDA regulatory compliance, including consulting (ECF No 68-2 at PageID #2941).

Next, Defendants contend Quick impermissibly opines that Defendants should have used the Premarket Approval ("PMA") process instead of the 510(k) process and on the meaning of the 510(k) process. (ECF No. 68 at PageID #2846–48.) It does not appear that Quick offers opinions that Defendants should have obtained PMA or on the meaning of the 510(k) application in contravention of Motion in Limine Orders ("MIL") No. 3 or No. 4 in *Johns*. *See generally In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605648, at *1 (S.D. Ohio Sept. 11, 2020) (prohibiting "evidence or argument regarding Bard's ability to obtain [PMA]") (MIL No. 3); *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6603657, at *7–9 (S.D. Ohio Oct. 20, 2020) (MIL No. 4) (holding no expert may opine on the meaning of the 510(k) process). Defendants provide no record citations to where Quick offers such opinions. Defendants describe one statement were Quick apparently said that the FDA lacked information that was present in a mock audit because the large Ventralex was cleared by the special 510(k) process, meaning the information was not included the more in-depth 510(k) application. (ECF No. 68 at PageID #2848.) But it is not enough that Quick "sounds a critical tone" (*id.* at PageID #2846).

2. Reliability

Next, Defendants argue that Quick follows an unreliable methodology, one where he simply reads documents, in forming his opinions. (ECF No. 68 at PageID #2848.) Defendants also argue that this amounts to an impermissible non-expert factual narrative and opinions on Defendants' state of mind. (*Id.* at PageID #2850–51.) The Court disagrees.

The Court concluded in *Johns* that Quick relied on a reliable method, identifying regulations and standards, and then reviewing records to determine if Defendants met them. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2643109, at *5 (EMO No. 9). For instance, Quick explains how an adequate QMS requires design controls and details these controls. (*E.g.*, ECF No. 68-2 at PageID #2946.) Quick then opines that Defendants' QMS on this point was deficient in relation to the Ventralex because there were inadequate design validations, verifications, reviews, etc. (*Id.* at PageID #2948, 2959–60.) Similarly, Quick determines that Defendants conducted inadequate animal testing on the ring in the Large Ventralex under International Organization for Standards ("ISO") 10993, which pertain to biocompatibility testing in animals. (*Id.* at PageID #2975–76). This is sufficiently reliable methodology.

Quick's usage of record documents is also an appropriate application of his methodology under these circumstances. "[C]ourts have held that 'an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible.'" *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605542, at *11 (S.D. Ohio Sept. 1,

2020) (quoting *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D.W. Va. Sept. 29, 2014) (collecting cases) (EMO No. 5). Defendants are correct that "[a] history without any expert analysis or other application of the expert's expertise is a factual narrative that 'should be presented to the jury directly.'" *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-01509, 2021 WL 3286439, at *6 (S.D. Ohio Aug. 1, 2021) (quoting *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1346 (S.D. Fla. 2010)) (EMO No. 15). But that is not the case here.

Defendants generally contend that Quick's reliance on internal documents is insufficient because he did not read the entire design file or other pertinent documents, such as only reading the mock FDA-483 audit report to form his opinion that Defendants' complaint handling was insufficient. (ECF No. 123 at PageID #10934–35.) Upon careful review of Quick's opinions related to the Ventralex, this argument goes to the weight, not admissibility, of Quick's opinions because the documents Quick reviewed are highly pertinent. For example, Quick reviewed the Mock FDA-483 audit that identified alleged QMS violations, and Quick confirmed his agreement with the audit while opining that the subsequent changes Defendants made to their QMS systems still fell short of compliance. (ECF No. 68-2 at PageID #2959–60.) It is unclear what information the design file contains that would render this opinion unreliable when the mock audit appears to capture all of the relevant information about Defendants' QMS.[4]

[4] In *Johns*, the Court concluded that Quick's opinions about Defendants' efforts to validate the Ventralight ST's 14-day hydrogel coating were unreliable because he did not read the entire design file or explain why the documents that he reviewed were sufficient. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2643109, at *5 (EMO No. 9). Here, it apparent that Quick's review

As for state-of-mind opinions, Defendants are partially correct. Defendants argue that Quick should not be permitted to opine on what Defendants' personnel, including its medical director, intended or wanted. (ECF No. 68 at PageID #2850–51.) Defendants point to one instance during Quick's deposition in which he said that the medical director "felt [Defendants] should be doing . . . long-term studies." (ECF No. 68-1 at PageID #2925, p. 255.) What an individual thinks or feels is not the proper subject of expert testimony. *See* Fed. R. Evid. 702. However, Quick may rely on records pertaining to the medical director's statements insofar as it forms a basis for his admissible expert QMS opinions.

Relatedly, Defendants assert that Quick opines on Defendants' corporate knowledge or state-of-mind. (ECF No. 123 at PageID#10933.) Defendants take specific issue with Quick's opinion that Defendants were "on notice" of the Ventralex issues. (*Id.*) An expert witness cannot opine on an entity's state of mind, including knowledge, motive, and intent. *E.g.*, *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) (concluding that expert testimony "on the intent, motives or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise"); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009). But as the Court clarified in *Johns*, an expert can opine on what information Defendants had in their possession and offer an opinion considering this fact, such as whether Defendants' conduct was appropriate under the circumstances from their expert perspective. *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 3286439, at *7 (EMO

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of an audit designed to measure QMS deficiencies is sufficient to demonstrate his complaint-handling opinions are reliable.

No. 15). Here, however, Plaintiffs argue that he will offer an opinion purely based on whether Defendants were on notice (ECF No. 106 at PageID #9189), which is impermissible.

Defendants also offer more general counterarguments. Defendants disagree with Plaintiffs' and Quick's characterization of the word "buckle" from Defendant' internal documents, again arguing that buckling is not a universal term and can mean different things. (ECF No. 123 at PageID #10934.) Similarly, they disagree with his interpretation of some records. (*Id.* at PageID #10935.) This is disagreement with Quick's opinions—not a sign of unreliability. (ECF No. 166 at PageID #13595.) Then Defendants argue that Quick's opinions are unreliable because he is an expert for hire. (ECF No. 123 at PageID #10933.) As before, the Court notes that "this is not [a] problem with Quick's testimony" because "Quick has decades of QMS experience, which shows that his testimony naturally flows from his own current and prior experience." *In re Davol, Inc./C.R. Bard, Inc.*, 2021 WL 2643109, at *5 n.4 (EMO No. 9). These issues are best addressed on cross-examination.

3. Causation Opinions

Next, Defendants argue that Quick is unqualified to offer opinions on a causal connection between patient complications and QMS deficiencies. (ECF No. 68 at PageID #2851.) Plaintiffs state that Quick will not offer any opinions on this topic. (ECF No. 106 at PageID #9200.) Thus, Defendants' motion is moot.

Defendants argue that this part of their motion is not moot because Quick's notation of certain QMS deficiencies via internal documents "dabble[s] in drawing connections between injuries and device characteristics." (ECF No. 123 at PageID

#10941.) But the only example Defendants point to is that Quick noted Defendants' alleged failure to follow certain QMS protocols resulted in treating patients like "test subjects" (ECF No. 68 at PageID #2851). This is not a causation statement, *i.e.*, whether QMS violations are capable of causing injuries such as Mr. Milanesi's.

4. MSDS Opinions

Defendants challenge Quick's MSDS opinions, arguing these opinions are irrelevant and impermissible corporate mind-reading, and that Quick is unqualified to offer these opinions. (ECF No. 68 at PageID #2852–54; ECF No. 123 at PageID #10940.) Plaintiffs counter that Quick's opinion is that the information in the Marlex MSDS should have triggered due diligence under proper QMS. (ECF No. 106 at PageID #9199; ECF No. 68-2 at PageID #2964–65.) Most of Quick's MSDS opinion is permissible.

Quick's opinion that the Marlex MSDS should have led to certain steps under an appropriate QMS is relevant and Quick is qualified to offer it. Contrary to Defendants' assertions (ECF No. 68 at PageID #2852), Plaintiffs' theory of defect is two-fold—the Ventralex buckled, exposing polypropylene to Plaintiffs' bowels. The MSDS opinion goes to the reasonableness of Defendants' conduct in light of information they knew or should have known regarding the risks of the polypropene. Given Quick's regulatory QMS expertise, he is qualified to offer this opinion. *Supra* Part III.C.1.

However, no expert may opine on Defendants' state-of-mind. *Supra* Part III.C.2. Moreover, no expert may rely on a factual narrative untethered from an admissible expert opinion to impute a motive to Defendants. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ----, Nos. 2:18-cv-1509, 2:18-md-2846, 2021 WL 2646797, at *7 (S.D. Ohio June 28, 2021) (EMO No. 10). For

this reason, Quick cannot opine that Defendants tried to hide their use of the polypropylene resin.

Defendants counter that the Equifax MSDS accompanying the polypropylene resin used in the Ventralex did not contain the statement as the Marlex MSDS that warned against permanent implantation in the body before the Ventralex was implanted in Mr. Milanesi in 2007 and that Quick did not actually rely on the Equifax MSDS document to reach this specific opinion. (ECF No. 123 at PageID #10937–40.) Critically, neither party attaches the document at issue. In any case, Quick's opinion is that certain information in the Marlex MSDS should have triggered certain actions with regard to all polypropylene due to the applicable FDA regulations regarding QMS. Thus, it does not matter for the sake of the admissibility of this opinion that Quick did not consider the Equifax MSDS.

5. Relevance of Sepramesh Technology and Ventralight ST Opinions

Defendants argue that Quick should not be permitted to offer his opinions on Sepramesh and the Ventralight ST. (ECF No. 68 at PageID #2854.) Plaintiffs confirm that Quick will not offer this opinion. (ECF No. 106 at PageID #9199.) This part of Defendants' motion is moot.

6. Other opinions

Defendants also point to a list of opinions that they claim Quick cannot offer because he conceded he was unqualified to offer them: advanced chemistry or engineering; the FDA's inner workings, medical device labeling, or instructions for use; hernia mesh; animal studies; biocompatibility testing; and determining which tests should

be conducted during the design and development process of hernia mesh.[5] (ECF No. 68 at PageID #2841–42.) Plaintiffs represent that Quick will not offer opinions on the FDA's inner workings and labeling, the 510(k) process, PMA preparation, and chemistry/engineering opinions. (ECF No. 106 at PageID #9200–01.) Importantly, Quick did not state that he was unqualified to offer opinions on hernia mesh, animal studies, biocompatibility testing, and which tests should be used form a QMS perspective. (*E.g.*, ECF No. 68-1 at PageID #2890–91, pp. 117–18.) Without other argumentation before the Court, it appears that Quick is qualified to offer opinions on these topics from a QMS perspective. The Court declines to go further at this time.

D. James M. Anderson, M.D., Ph.D.

Next is Plaintiffs' motion to exclude Dr. Anderson's opinions. (ECF No. 81 at PageID #5184.) Plaintiffs argue that Dr. Anderson's opinions should be excluded because his opinions pertain only to the *McCourt* case and are thus irrelevant, that he should be precluded from offering opinions on the Material Safety Data Sheets ("MSDS"), and that he is unqualified to offer surgical opinions. (*Id.* at PageID #5191–92.) These arguments were addressed in the Court's *Daubert* opinion addressing Dr. Anderson in *Johns*. First, Dr. Anderson offers relevant general opinions that polypropylene is biocompatible that are not limited to *McCourt*. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-1509, 2021 WL 2643114, at *6–7 (S.D. Ohio June 28, 2021) (EMO No. 11). Second, Dr. Anderson's opinions regarding the meaning of the MSDSs is irrelevant because it does

[5] The other five opinions that Defendants list separately are encompassed by the Court's earlier reasoning, as is the medical causation opinion that is also listed. (*See* ECF No. 68 at PageID #2841.)

not pertain to the only admissible purpose of the MSDS—Defendants' knowledge. *Id.* at *9. Third, Dr. Anderson is qualified to opine on the impact of surgical technique on the body's tissue response, and in his report and deposition he does not appear to offer an opinion about general surgery technique. *Id.* at *10.

Plaintiffs argue that Dr. Anderson does not discuss the Ventralex device or ePTFE layer, rendering his opinions irrelevant. (ECF No. 81 at PageID #5196; ECF No. 124 at PageID #10967.) Plaintiffs' theory of injury is two-fold—the Ventralex buckles, which is a failure of the adhesion barrier, here ePTFE, and this buckling causes exposure of bare polypropylene to the internal organs. Dr. Anderson's opinion addresses the second step, specifically the biocompatibility of polypropylene. *See supra* Part III.A. Moreover, he offers this opinion with regard "to the Bard Ventralight ST and other Bard devices for hernia repair containing polypropylene mesh." (ECF No. 81-2 at PageID #5264.)

For these reasons, Plaintiffs' motion is **GRANTED IN PART AND DENIED IN PART**.

IV. Conclusion

Accordingly, Defendants' motion to exclude Dr. El-Ghannam (ECF No. 72) is **DENIED**, Defendants' motion to exclude Johnson (ECF No. 66) is **GRANTED**, Defendants' motion to exclude Quick (ECF No. 68) is **GRANTED IN PART AND DENIED IN PART**, and Plaintiffs' motion to exclude Anderson (ECF No. 81) is **GRANTED IN PART AND DENIED IN PART.**

IT IS SO ORDERED.

10/26/2021
DATE

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