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:
Stinson v. Davol, Inc., et al.
Case No. 2:18-cv-01022

EVIDENTIARY MOTIONS OPINION & ORDER No. 27

Before the Court are Plaintiff's Motions to Exclude the Opinions and Testimony of Defense Experts Donna-Bea Tillman, Ph.D. (ECF No. 98), Kimberly A. Trautman, M.S. (ECF No. 99), and James M. Anderson, M.D., Ph.D. (ECF No. 100), and Defendants' Motion to Exclude the Opinions and Testimony of Plaintiff's Expert John L. Quick (ECF No. 95). For the reasons that follow, Plaintiff's motions addressing Dr. Tillman (ECF No. 98), Ms. Trautman (ECF No. 99), and Dr. Anderson (ECF No. 100) are **GRANTED IN PART AND DENIED IN PART**, and Defendants' motion addressing Mr. Quick is **GRANTED**.

I. Background[1]

Plaintiff's case is the third bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants. 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 defendants' polypropylene hernia mesh products can lead to complications when

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case. (Dispositive Motions Order ("DMO") No. 7, ECF No. 225.) All docket citations are to the *Stinson* case, 2:18-cv-1022, unless otherwise noted.

implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

The relevant facts here are that in 2015 Plaintiff underwent a right inguinal hernia repair with an Extra-Large PerFix Plug mesh, a product manufactured by Defendants. In 2017, Plaintiff underwent exploratory surgery to determine if he had a recurrent hernia or nerve entrapment because of chronic pain in his right groin area. The explanting surgeon, Dr. Radke, noted extensive scarring and found "a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle." (ECF No. 89-22 at PageID #1134.) Dr. Radke removed the mesh, which he described as "slow going and extremely difficult" because of the significant scarring. (*Id.*) Dr. Radke then repaired the hernia with another of Defendants' products, Bard Marlex Mesh. (*Id.*) Even after the explant surgery, Plaintiff claims to have continuing chronic pain and other complications.

The crux of Plaintiff's claims is that Defendants knew of certain risks presented by the PerFix Plug device but marketed and sold the device despite these risks and without appropriate warnings, causing Plaintiff's injuries. Plaintiff alleges that the polypropylene in the PerFix Plug degrades after implantation, which enhances the chronic inflammatory response in the body. (ECF No. 124 at PageID #4826.) Plaintiff also claims that the inflammation and resulting fibrosis are exacerbated by the PerFix Plug's shape, weight, and pore size. Plaintiff also claims that the PerFix Plug is susceptible to migration and has a high incidence of chronic pain. (*Id.*) According to Plaintiff, Defendants downplayed the rate and severity of complications caused by the PerFix Plug, even when faced with reports of negative outcomes, which created an unreasonable risk of significant and permanent harm to patients. (*Id.*)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of the PerFix Plug, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. After summary judgment, the following claims remain for trial: design defect, failure to warn, negligence, breach of express warranty, and breach of implied warranty; the Court has reserved judgment on Plaintiff's claims for manufacturing defect, certain damages, and claims related to his current Bard Mesh implant.

II. Legal Standard

Evidentiary rulings are made subject to the district court's sound discretion, *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019), including the admissibility of expert testimony, *United States v. Dunnican*, 961 F.3d 859, 875 (6th Cir. 2020). 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 v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993).

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*] 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.").

The district court's role in assessing expert testimony is a "gatekeeping" one, ensuring 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*, 509 U.S. at 597). Expert testimony, *i.e.*, 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 at 529 (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 J. Weinstein & M. 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. *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.

III. Analysis

A. Dr. Donna-Bea Tillman, Ph.D.

Plaintiff challenges the opinions of Defendants' expert Dr. Donna-Bea Tillman, Ph.D. He seeks to exclude her opinions regarding 1) the meaning of Material Safety Data Sheets ("MSDS"), 2) whether Defendants complied with quality management standards ("QMS") and regulations when designing and manufacturing the PerFix Plug, and 3) any testimony related to the FDA's hernia mesh website. The plaintiffs filed similar motions in the first two bellwether cases, *Johns v. C.R. Bard, Inc., et al.*, Case No. 18-cv-1509, and *Milanesi, et al. v. C.R. Bard, Inc., et al.*, Case No. 18-cv-1320. In both cases, the Court granted the plaintiffs' motions as to the meaning of MSDS and the FDA's hernia mesh website, and denied the motions as to the FDA's quality system regulations. (Case No. 18-cv-1509, Evidentiary Motions Order ("EMO") No. 9, ECF No. 457 at PageID #23387–89; Case No. 18-cv-1320, EMO No. 24, ECF No. 274 at PageID #16814–16.) The parties have not presented a convincing reason for the Court to depart from its prior rulings.

Therefore, Plaintiff's Motion (ECF No. 98) is **GRANTED IN PART AND DENIED IN PART**. Dr. Tillman's MSDS and FDA website opinions are inadmissible, but her opinions regarding the FDA's quality systems regulations are admissible.

B. Kimberly A. Trautman, M.S.

Plaintiff challenges the opinions of Defendants' expert Kimberly A. Trautman, M.S. He seeks to exclude or limit Ms. Trautman's opinions regarding 1) whether Defendants have been in acceptable regulatory standing with respect to their inspectional history under the pertinent FDA regulations for their polypropylene mesh products, and 2) whether the FDA considers Defendants' products to be safe. The plaintiffs filed similar motions in the first two bellwether cases. In *Johns*, the Court allowed Ms. Trautman to testify regarding whether Defendants were in compliance with QMS regulations during the design and manufacture of the device at issue in that case, the Ventralight ST, and excluded Ms. Trautman's opinions as to non-Ventralight ST compliance opinions and the FDA's beliefs. (Case No. 18-cv-1509, EMO No. 9, ECF No. 457 at PageID #23389–92.) In *Milanesi*, the Court adopted its prior ruling in *Johns*. (Case No. 18-cv-1320, EMO No. 24, ECF No. 274 at PageID #16816.) Plaintiff here makes the same arguments, and the Court's previous rulings on Ms. Trautman's testimony apply. Ms. Trautman is qualified to offer her opinions, but she cannot opine on the FDA's beliefs. Therefore, Plaintiff's Motion (ECF No. 99) is **GRANTED IN PART AND DENIED IN PART**.

C. Dr. James M. Anderson, M.D., Ph.D.

Plaintiff challenges the opinions of Defendants' expert Dr. James M. Anderson, M.D., Ph.D. Plaintiff asks that the Court adopt its previous rulings in *Johns* and *Milanesi*, specifically as to the following:

First, Plaintiff seeks to prevent Dr. Anderson from testifying as to specific causation in

Plaintiff's case. (ECF No. 100 at PageID #3421.) Defendants agree that Dr. Anderson will not offer specific causation testimony (ECF No. 111 at PageID #3944–45), which Plaintiff acknowledges (ECF No. 140 at PageID #5832). Accordingly, this argument is moot.

Second, Plaintiff seeks to prevent Dr. Anderson from referring to Mr. McCourt as a plaintiff in this MDL.[2] (ECF No. 100 at PageID #3421.) Defendants agree that Dr. Anderson will not do so (ECF No. 111 at PageID #3944–45), therefore this argument is also moot.

Third, Plaintiff seeks to prevent Dr. Anderson from opining as to the mindset of the pathologist who created Mr. McCourt's pathology slides. (ECF No. 100 at PageID #3421.) In *Johns*, the Court held that Dr. Anderson's "opinions about the mindset of the pathologist who created Mr. McCourt's pathology slides and the inferences he draws from those opinions are unreliable here." (Case No. 18-cv-1509, EMO No. 11, ECF No. 459 at PageID #23427.) The Court adopts its prior ruling on this issue.

Fourth, Plaintiff seeks to exclude Dr. Anderson's testimony or opinions regarding MSDS. (ECF No. 100 at PageID #3421–22.) As the Court held in *Johns* and *Milanesi*, Dr. Anderson's opinions regarding the meaning of the MSDS are irrelevant because they do not pertain to the only admissible purpose of the MSDS—Defendants' knowledge. (Case No. 18-cv-1509, EMO No. 11, ECF No. 459 at PageID #23431; Case No. 18-cv-1320, EMO No. 20, ECF No. 220 at PageID #15008–09.) The Court adopts that ruling here.

Fifth, Plaintiff argues that Dr. Anderson should not offer any "surgery opinions" because he is not a surgeon. (ECF No. 100 at PageID #3422.) As the Court has previously held, Dr. Anderson "is qualified to opine on the impact of surgical technique on the body's tissue response,

[2] Dr. Anderson reviewed histopathology slides from plaintiff Thomas McCourt in another bellwether case, *McCourt v. C.R. Bard, Inc., et al.* (Case No. 18-cv-1011). (ECF No. 111 at PageID #3944–45.)

and in his report and deposition he does not appear to offer an opinion about general surgery technique." (Case No. 18-cv-1320, EMO No. 20, ECF No. 220 at PageID #15009; *see also* Case No. 18-cv-1509, EMO No. 11, ECF No. 459 at PageID #23433.)

In addition, Plaintiff seeks to exclude Dr. Anderson's general causation opinions as unreliable. According to Plaintiff, Dr. Anderson's isolated examination of Mr. McCourt's medical records "provides no meaningful support for any opinion on general causation—and particularly with respect to the alleged malfunctioning of a PerFix [P]lug, a product Mr. McCourt didn't have." (ECF No. 100 at PageID #3422.) Plaintiff also argues that a sample size of one is insufficient and requires too large an analytical leap in this cause, and points to the differences in human physiology between patients. (*Id.* at PageID #3422–23 (citing *Am. Honda Motor Co. v. Allen*, 600 F.3d 813, 818 (7th Cir. 2010).) In support of his argument, Plaintiff cites to *Sanchez v. Boston Scientific Corp.* In *Sanchez*, the court found that an expert's "testing of merely one or two samples [of polypropylene pelvic mesh] lack[ed] reliability." *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *8 (S.D.W. Va. Sept. 29, 2014). Because of the differences in physiologies between patients and the "jump[] from a Ventralight ST to a PerFix Plug," Plaintiff claims that Dr. Anderson's general causation opinions are unreliable and therefore must be excluded. (ECF No. 100 at PageID #3425.) Plaintiff further claims that Dr. Anderson's written report "pertains only to *McCourt* and any other plaintiff who had Ventralight ST, like the plaintiff in *Johns*," but then states that Plaintiff does not seek to exclude Dr. Anderson's opinions as to "what he has read in the literature" or "relevant opinions about the nature of certain chemicals." (ECF No. 140 at PageID #5831.)

Defendants respond that Dr. Anderson does not "base his general opinions about the PerFix Plug, wound healing, and tissue reaction to polypropylene mesh solely on the review of the slides

of another plaintiff implanted with a Ventralight ST." (ECF No. 111 at PageID #3937.) They claim that Dr. Anderson's opinions instead rely on decades of personal research, hundreds of publications, and his review of countless histopathology slides looking at the response to polypropylene and other implants. (*Id.* at PageID #3938.) The Court previously ruled that Dr. Anderson offers relevant general opinions in his report, such as his opinions that polypropylene is biocompatible. (*Id.* at PageID #3945.) Moreover, "Dr. Anderson's general causation opinions about the PerFix Plug, wound healing, and tissue reaction to polypropylene mesh have nothing to do with Mr. McCourt's pathology." (*Id.*) Defendants contend that if Plaintiff "wishes to challenge Dr. Anderson's methodology to arrive at case-specific opinions about Mr. McCourt that he would offer in that case, any such challenge would need to be made in the *McCourt* case, not in this one." (*Id.* at PageID #3949.)

Plaintiff argues that Dr. Anderson should not be permitted to testify as to Mr. McCourt's slides; however, Defendants state that Dr. Anderson's general causation opinions in this case "have nothing to do with Mr. McCourt's pathology." (ECF No. 111 at PageID #3945.) Therefore, Plaintiff's arguments regarding Mr. McCourt's slides are moot. Additionally, the Court has already rejected arguments that Dr. Anderson's opinions relate only to Mr. McCourt, and held that "Dr. Anderson offers relevant general opinions in his report, *i.e.* opinions that are not limited to Mr. McCourt," including general opinions that polypropylene is biocompatible. (Case No. 18-cv-1509, ECF No. 459 at PageID #23425; Case No. 18-cv-1320, ECF No. 220 at PageID #15009.) Therefore, Plaintiff's Motion (ECF No. 100) is **GRANTED IN PART AND DENIED IN PART**.

D. John L. Quick

Defendants challenge the opinions of Plaintiff's expert John L. Quick. According to Defendants, Mr. Quick's opinions regarding product development quality controls only relate to

certain of Defendants' product lines, and the PerFix Plug is not one of those product lines. Therefore, Defendants argue, Mr. Quick's opinions lack fit in this case and should be excluded. (ECF No. 95.)

In *Johns* and *Milanesi* the Court found that Mr. Quick was qualified to offer his opinions on Defendants' QMS and design controls. (Case No. 18-cv-1509, EMO No. 9, ECF No. 457 at PageID #23383–84; Case No. 18-cv-1320, EMO No. 20, ECF No. 220 at PageID #15000–01.) The Court's reasoning in its prior opinions applies here, and Mr. Quick is qualified to offer his opinions. The Court also addressed the reliability of Mr. Quick's methods, finding that Mr. Quick employed "a reliable method, identifying regulations and standards, and then reviewing records to determine if Defendants met them." (*Id.* at PageID #15002.) However, in *Johns* the Court determined that although Mr. Quick's methodology was sound, his application of the method in that specific case was unreliable. (Case No. 18-cv-1509, EMO No. 9, ECF No. 457at PageID #23385–86.) In *Johns*, Mr. Quick's opinions addressed the QMS in place for devices other than the device at issue, the Ventralight ST, and addressed the status of Defendants' QMS prior to the development of the Ventralight ST, its components, or a predicate device. (*Id.* at PageID #23382.) The Court held that such opinions were "inadmissible character evidence because [they were] being used to show that earlier inadequacies in the QMS show[ed] inadequacies in the QMS in place at the time the Ventralight ST was designed and manufactured." (*Id.*)

The Court's reasoning in *Johns* applies here. Mr. Quick's report does not discuss the PerFix Plug at all, nor does it address Defendants' QMS when the PerFix Plug was developed in the early 1990s. Mr. Quick's report discusses other devices and the status of Defendants' QMS in the mid-2000s, which Plaintiff purports to use to "show that [later] inadequacies in the QMS show inadequacies in the QMS in place at the time the [PerFix Plug] was designed and manufactured."

(*Id.*) Therefore, the Court again finds that Mr. Quick's opinions are impermissible character evidence and therefore inadmissible.

Plaintiff attempts to link Mr. Quick's opinions about other devices and later QMS to the PerFix Plug by pointing to an email from Roger Darois, a former vice president of research and advanced technology that Mr. Quick cited in his report. Plaintiff claims that Mr. Darois admitted that "the problems . . . identified in FDA and private audits occurring between 2006–2008[] extended to all of Davol's 'older products,' which would have included the PerFix Plug." (ECF No. 119 at PageID #4318.) This assertion appears to rely on an email in which Mr. Darois wrote that "[n]one of Defendants' older products have user needs defined." (ECF No. 119-3 at PageID #4411.) However, Defendants argue that Plaintiff's interpretation of the email is misleading. (ECF No. 132 at PageID #5605.) During the *Milanesi* trial, Mr. Darois was asked about the email in question and testified that while there was not a specific user needs document, "[t]here were user needs identified in several of the projects which you could certainly look at different reports and see them." (Case No. 18-1320, ECF No. 398 at PageID #20886.)

The Court agrees with Defendants that a line in an email from Mr. Darois, which he later clarified at the *Milanesi* trial, is not sufficient to support Plaintiff's contention that Mr. Quick's report, which discusses neither the PerFix Plug or Defendants' QMS at the time the PerFix Plug was developed, is admissible in this case. Therefore, Defendants' Motion (ECF No. 95) is **GRANTED**.

IV. Conclusion

For the reasons set forth above, Plaintiff's motions addressing Dr. Donna-Bea Tillman (ECF No. 98), Kimberly A. Trautman (ECF No. 99), and Dr. James M. Anderson (ECF No. 100) are **GRANTED IN PART AND DENIED IN PART**. Defendants' motion addressing John L.

Quick (ECF No. 95) is **GRANTED**.

IT IS SO ORDERED.

4/11/2023
DATE

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