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. 34

Before the Court is Defendants' Motion to Exclude Additional Opinions of Plaintiff's Expert Dr. David Grischkan, M.D., F.A.C.S. (ECF No. 302.) For the reasons that follow, Defendants' Motion is **GRANTED IN PART** and **DENIED IN PART**.

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 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

[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.

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.*) 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. The Court addressed the admissibility of Dr. Grischkan's opinions in his original report in Evidentiary Motions Order ("EMO") No. 26 (ECF No. 227).

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 Antitrust Litig.*, 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

Defendants challenge the additional opinions of Plaintiff's expert Dr. David Grischkan, M.D., F.A.C.S. (ECF No. 302.) Following Plaintiff's May 2023 surgery, the court permitted the parties to supplement their experts' reports based on the new information from the May 2023 surgery. (*See* Case No. 18-md-2846, ECF No. 763.) Defendants now seek to exclude the new opinions of Plaintiff's medical expert. Defendants argue that (1) Dr. Grischkan's supplemental report includes new opinions that go beyond the bounds of the limited new discovery; (2) Dr. Grischkan's general causation opinions are unreliable and/or lack fit; and (3) Dr. Grischkan's specific causation opinions are unreliable and lack fit. (ECF No. 302.)

A. Supplementation Under Rule 26

Defendants first argue that much of Dr. Grischkan's report is not a proper supplement, and it includes opinions that are new or are different from the opinions offered in his original report. (ECF No. 302 at PageID # 10737.) Additionally, the new opinions are based on information that was available to Dr. Grischkan prior to his original report, and these opinions do not clarify or correct opinions in his original report as permitted by Rule 26 of the Federal Rules of Civil Procedure. (*Id.*) For example, Defendants point to Dr. Grischkan's new opinions on Plaintiff's 2017 explant surgery. (*Id.* at PageID #10738.) Dr. Grischkan testified that these opinions were based on the explanting surgeon's 2017 operative report. (ECF No. 302-2 at PageID #10846–47.) Defendants characterize these opinions as an "impermissible revision of [Dr. Grischkan's] earlier

report" rather than a proper supplementation. (ECF No. 302 at PageID #10738 (quoting *McNamee v. Nationstar Mortgage, LLC*, No. 14-1948, 2021 WL 4355549, at *5 (S.D. Ohio Sept. 24, 2021)).)

Plaintiff responds that, in light of the new information, it was necessary for Dr. Grischkan to review all records, including ones that predate his original report, "to show that [Plaintiff's] recent complaints can be traced back to the PerFix Plug." (ECF No. 317 at PageID #11579.) The Court agrees. Dr. Grischkan may use information previously available to him as a basis for his opinions on Plaintiff's new injuries. However, Dr. Grischkan may not offer new opinions regarding alternative courses of treatment for Dr. Tan in 2015 and Dr. Radke in 2017, and regarding Plaintiff's older injuries. Such opinions are beyond the limited scope of the new discovery. Dr. Grischkan also cannot offer new opinions regarding the possibility of pre-explant nerve entrapment or neuroma.

Dr. Grischkan offers an opinion in his supplemental report ruling out the possibility of radiculopathy as a cause of Plaintiff's chronic pain, and Defendants argue that this is a new and undisclosed opinion. However, Plaintiff points out that Dr. Grischkan did consider radiculopathy or radiculitis in his original report and at his 2020 deposition, and then ruled it out as a cause of Plaintiff's pain. (ECF No. 317 at PageID #11583.) To the extent that Dr. Grischkan's radiculopathy opinions are in line with the opinions in his original report and deposition, they are admissible.

Defendants challenge Dr. Grischkan's "upregulation" opinions, and point out that in his prior deposition he testified that he was not familiar with the concept of "upregulated pain." (ECF No. 302 at PageID #10739.) Plaintiff argues that these opinions are necessary to rebut the upregulation opinions of Defendants' experts, but as Defendants note, the concept of "upregulated pain" was included in Dr. Pomerants's original expert report. (*See* ECF No. 103-1 at PageID

#3789 ("Certain patients' pain responses are elevated because of their central sensitization or upregulation of pain. Mr. Stinson's post-operative complaints are more likely than not pre-existing and caused by the numerous prehernia surgery repair traumas, surgeries, injuries, and complaints, including his pre-existing spinal pathology, including bulging discs, as well as his chronic pain syndromes.") (internal citation omitted).) Therefore, Dr. Grischkan's upregulation opinions are inadmissible.

B. General Causation Opinions

a. "Hostile Environment" Opinions

Defendants challenge Dr. Grischkan's general causation opinions as lacking fit and a reliable methodology. They claim that he has "put forth no reliable evidence that explanted polypropylene mesh in general, or the PerFix Plug in particular, can cause" issues like chronic pain or injuries to the bladder, prostate, and epididymis years after explant. (ECF No. 302 at PageID #10741.) His general causation opinions, Defendants contend, presume that responses to implanted mesh continue and progress well after explant. (*Id.* at PageID #10742.) According to Defendants, the case reports and studies on which he relies are distinguishable and are an unreliable basis for his opinions. (*Id.*) Defendants also take issue with Dr. Grischkan's reliance on his own experience, without any database or documentation, in forming his opinions. (*Id.* at PageID #10744.) Defendants therefore conclude that Dr. Grischkan should be precluded from offering these causation opinions at trial.

Plaintiff responds that Defendants have mischaracterized Dr. Grischkan's general causation opinions. Dr. Grischkan opines that "the chronic inflammatory response to the PerFix Plug implant (during the time that it was in place) created a 'hostile environment' and scar tissue 'that prevented the flat polypropylene Bard Mesh from adhering/incorporating to the floor of the

hernia canal, thereby allowing mesh to invade the spermatic cord,' and exacerbated the compression of the nerves." (ECF No. 317 at PageID #11586 (quoting ECF No. 302-1 at PageID #10757–58; ECF No. 302-2 at PageID #10819).) According to Plaintiff, Dr. Grischkan's opinion that excessive fibrosis, also referred to as a "hostile environment," is based on his own experience with hernia repair, as well as "the medical and scientific concepts and evidence in the published literature included in his expert reports." (*Id.* at PageID #11587.) Plaintiff points to Dr. Grischkan's deposition in which he testified about "hundreds" of his own cases in which he has observed excessive fibrosis, and his general statement that his opinions are based on the literature and materials he reviewed. (*Id.* at PageID #11588 (citing ECF No. 302-2 at PageID #10846, 10848, 10850).) Plaintiff also highlights the studies and case reports cited in Dr. Grischkan's supplemental report and deposition in support of the opinions. (*Id.* at PageID #11588–90.)

As this Court has ruled, Dr. Grischkan may rely on his own experience to inform his conclusions. (ECF No. 227, EMO No. 26.) "[I]t is well-established that experience-based testimony satisfies Rule 702 admissibility requirements." (Case No. 18-cv-1509, ECF No. 329, EMO No. 7 at PageID #17879 (internal quotation omitted).) Defendants argue that Dr. Grischkan cannot base his opinions on his personal experience which is "not documented or discoverable." (ECF No. 302 at PageID #10741.) However, the Court has rejected this argument—most recently, as it pertained to Defendants' own medical expert. (ECF No. 306, EMO No. 33 at PageID #10895.) As the Court explained, the "exact basis and extent of his opinions based on his [experience] with patients may be drawn out during cross-examination." (*Id.* at PageID #10895–96 (citing Case No. 18-cv-1320, ECF No. 272, EMO No. 22 at PageID # 16787).) Defendants point out that Dr. Grischkan did not seek out studies on the subject of the efficacy of a second mesh hernia repair after the explant of a prior mesh device (*see* ECF No. 302-2 at PageID #10821), and this is "fertile

grounds for cross-examination" (ECF No. 227, EMO No. 26 at PageID #9153 (citing Case No. 18-cv-1320, ECF No. 166, EMO No. 17 at PageID #13589)).

Defendants argue that case reports on which Dr. Grischkan relies are inapposite because they relate to mesh migration. (ECF No. 333 at PageID #12645.) They point out that Dr. Grischkan's migration opinions have been excluded, which is true. (ECF No. 227, EMO No. 26 at PageID #9167–69.) However, Dr. Grischkan does not cite these reports to support a migration opinion. Instead, he relies on the reports to support his opinions regarding "re-repair[s] that fail as a result of the hostile environment created by the original mesh." (ECF No. 317 at PageID #11590.) He acknowledged that the case reports deal with mesh migrations, but opines that the reports "represent[] unincorporation of a second mesh resulting in migration." (ECF No. 302-2 at PageID #10844.) As the Court has explained previously, Defendants may raise on cross-examination their contention that Dr. Grischkan's opinions should be afforded less weight because the case reports involve issues such as mesh migration and laparoscopic surgery. (ECF No. 227, EMO No. 26 at PageID #9155.)

b. Bladder, Prostate, and Epididymis Opinions

Defendants also argue that Dr. Grischkan's general causation opinions as they relate to issues with the bladder, prostate, and epididymis are unreliable. They argue that Dr. Grischkan has "identified no publication purporting to describe an inflammatory response to an implanted mesh that continued after explant and then led to bladder, prostate, or epididymis complications." (ECF No. 302 at PageID #10742.) Plaintiff argues that these opinions are based on "clinical experience, case reports, and relevant scientific literature." (ECF No. 317 at PageID #11591.)

As Defendants point out, Dr. Grischkan offers no basis for his opinions specific to prostate, epididymis, and bladder issues. In his supplemental report Dr. Grischkan begins with an

explanation, including supporting citations, about how polypropylene can generally cause inflammation and foreign body reactions. (ECF No. 302-1 at PageID #10761.) However, he does not cite to any supporting literature or to his own experience when he links that inflammation to the bladder and prostate. (*Id.*) Dr. Grischkan conceded that he did not know of any literature that described an enlargement of the prostate due to a hernia repair (ECF No. 302-2 at PageID #10828), inflammation of the bladder absent adherence to or migration into the bladder (*id.* at PageID #10849), or epididymitis related to a mesh plug absent migration into the scrotum (*id.* at PageID #10832). Accordingly, Dr. Grischkan's opinions related to bladder, epididymis, and prostate issues are not reliable and therefore not admissible.

C. Specific Causation Opinions

Defendants argue that without reliable general causation evidence, Dr. Grischkan's specific causation opinions on Plaintiff's post-explant groin pain and bladder, prostate, and epididymis issues are inadmissible. (ECF No. 302 at PageID # 10744–45.) They claim that his differential diagnosis is flawed, and even if that were not the case, it "cannot make up for the missing reliable evidence of general causation." (*Id.* at PageID #10745.)

a. Mesh Failure to Incorporate Opinions

Defendants dispute the reliability of Dr. Grischkan's opinion that the position of the Bard Mesh as seen in the May 2023 surgery is because of its failure to incorporate into the tissue due to inflammation and fibrosis caused by the PerFix Plug. (ECF No. 302 at PageID #10745.) Defendants point to Dr. Grischkan's testimony that he is not aware of any literature "that describes a lack of tissue incorporation when a mesh is placed after a prior mesh is explanted," and said that the "closest [he] c[ould] come would be his personal experiences with cases "where [he has] seen mesh placed on top of another mesh." (ECF No. 302-2 at PageID #10822.) Defendants claim that

the surgeon who performed the May 2023 surgery testified that the second mesh device, the Bard Mesh, was incorporated into the tissue. (ECF No. 302-4 at PageID #10746.) Plaintiff points out, however, that Dr. Jacobus testified that the Bard Mesh had failed to incorporate correctly and had moved. (ECF No. 317 at PageID #11599.) Accordingly, Dr. Grischkan's failure to incorporate opinions are admissible.

b. Bladder, Urinary, and Prostate Opinions

The Court determined above that Dr. Grischkan's general causation opinions as to bladder, prostate, and epididymis injuries are unreliable and therefore inadmissible. Plaintiff argues that his specific causation opinions are nonetheless admissible because a single expert does not need to opine on both general and specific causation, and points to "numerous other experts in this case . . . who will also opine as to general and specific causation in this case." (ECF No. 317 at PageID #11599–600.) However, Plaintiff does not point to any other general causation expert opinions regarding bladder, prostate, and epididymis issues, and without a general causation opinion, Dr. Grischkan's bladder, prostate, and epididymis specific causation opinions are inadmissible. *See Buck v. Ford Motor Co.*, 810 F. Supp. 2d 815, 827 (N.D. Ohio 2011) ("'[P]roof of general causation [is] a prerequisite to proving specific causation.'") (quoting *In re Bausch & Lomb Contact Lens Solution Prods. Liab. Litig.,* 2010 WL 1727807 *1 (D.S.C. April 6, 2010), *aff'd sub nom. Fernandez-Pineiro v. Bausch & Lomb, Inc.*, 429 F. App'x 249 (4th Cir. 2011)).).

c. Future Pain and Recurrence Opinions

In his supplemental report and his deposition testimony, Dr. Grischkan opines that Plaintiff will experience groin pain in the future. (ECF No. 302-1 at PageID #10767; ECF No. 302-2 at PageID #10841.) Defendants point to the Court's order in the first bellwether trial, *Johns v. C.R. Bard, Inc., et al.*, excluding Dr. Grischkan's opinions as to the cause of the plaintiff's pain and

need for future surgeries as "based on pure speculation." (Case No. 18-cv-1509, ECF No. 310, EMO No. 5 at PageID #16792.)

Plaintiff attempts to distinguish Dr. Grischkan's future pain opinions in this case by explaining that the opinions are based on "an extensive review of [Plaintiff's] recent medical records and deposition testimony." (ECF No. 317 at PageID #11601.) The Court agrees that these opinions are distinguishable from the ones excluded in *Johns*. In *Johns*, the Court's decision was based on the fact that "[t]he only basis for Dr. Grischkan's opinion that Plaintiff is currently experiencing pain . . . and that such pain is attributable to the currently implanted mesh, is a phone call between Dr. Grischkan and Plaintiff." (Case No. 18-cv-1509, ECF No. 310, EMO No. 5 at PageID #16792.) The Court noted that the opinions at issue were "not based on a review of any medical records or surgical history." (*Id.*) In contrast, Dr. Grischkan's opinions here are based Plaintiff's recent medical records and the findings from his May 2023 surgery. (ECF No. 302-1 at PageID #10766–67.) Unlike in *Johns*, Dr. Grischkan's opinions here are not "based on pure speculation," and are admissible.

IV. Conclusion

For the reasons set forth above, Defendants' Motion to Exclude Additional Opinions of Plaintiff's Expert Dr. David Grischkan, M.D., F.A.C.S. (ECF No. 302), is **GRANTED IN PART** and **DENIED IN PART**.

IT IS SO ORDERED.

10/24/2023
DATE

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