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. 29

Before the Court are Plaintiff's Motions to Exclude the Opinions and Testimony of Defense Experts Maureen T.F. Reitman, Sc.D. (ECF No. 97), Stephen Badylak, D.V.M., Ph.D., M.D. (ECF No. 101) and Robert D. Tucker (ECF No. 102). For the reasons that follow, Plaintiff's motions addressing Dr. Badylak (ECF No. 101) and Dr. Tucker (ECF No. 102) are **GRANTED IN PART** and **DENIED IN PART**, and Plaintiff's motion addressing Dr. Reitman (ECF No. 97) is **GRANTED IN PART**, **DENIED IN PART**, and **RESERVED 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,

[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.

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. Maureen T.F. Reitman, Sc.D.

Plaintiff challenges the opinions of Defendants' expert Dr. Maureen T.F. Reitman, Sc.D. Plaintiff's motion is largely identical to the ones filed 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. The Court adopts its prior rulings on Dr. Reitman's opinions. (*See* Case No. 18-cv-1509, Evidentiary Motions Order ("EMO") No. 8, ECF No. 425; Case No. 18-cv-1320, EMO No. 19, ECF No. 219 at PageID #14983–84.) The parties have indicated to the Court that there is ongoing discovery related to Plaintiff's manufacturing defect claim, and therefore the Court reserves ruling on Dr. Reitman's manufacturing opinions. Plaintiff raises new arguments regarding Dr. Reitman's opinions on wound healing and tissue repair.

In his motion, Plaintiff offers several examples of the biological response opinions he seeks to exclude, which largely center on scarring and wound healing. (ECF No. 97 at PageID #2401.) According to Plaintiff, the Court's ruling in *Johns* should apply here as to Dr. Reitman's wound

healing and tissue repair opinions. In *Johns*, the Court noted that "Dr. Reitman [did] not purport to opine on the body's biological response" and that she "[did] not attempt to give an opinion on the reaction of the body to polypropylene," but that her opinions were limited to the suitability and characteristics of polypropylene, about which she was "eminently qualified to opine." (Case No. 18-cv-1509, EMO No. 8, ECF No. 488 at PageID #6395.) Plaintiff claims that the Court's language amounted to a ruling that Dr. Reitman "is not to opine on the body's biological response as she does not know, and cannot talk about, the cells' response to the polypropylene or the reaction of the body to polypropylene." (ECF No. 139 at PageID #5752 (emphasis in original).) Contrary to Plaintiff's interpretation, the Court did not forbid Dr. Reitman from opining on the subject, but simply noted that she was not offering such an opinion in that case.

Plaintiff likens this case to *Salinero v. Johnson & Johnson*, in which the court determined that a chemical and biomolecular engineer was unqualified to offer opinions regarding "clinical manifestations of the body's response to implanted polypropylene mesh." *Salinero v. Johnson & Johnson*, No. 1:18-CV-23643-UU, 2019 WL 7753453, at *15 (S.D. Fla. Sept. 5, 2019). The court found him to be unqualified to opine on medical complications caused by polymer degradation because he was not a medical doctor and had not examined patients nor conducted differential diagnoses. *Id.* (citing *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4547055, at *3 (S.D.W. Va. Aug. 31, 2016)). Defendants respond that Plaintiff's arguments regarding wound healing and tissue repair do not warrant the exclusion of Dr. Reitman's opinions. (ECF No. 117 at PageID #4270.) They claim that Plaintiff is ignoring the Court's prior rulings by arguing that Dr. Reitman should not be permitted to offer opinions regarding the body's response to polypropylene, and point to the Court's rejection of a "per se rule that any opinion implicating biology or medicine must require a degree in biology or medicine." (*Id.* at PageID #4271.)

According to Defendants, Dr. Reitman's background as a materials scientist with medical device experience should allow her to "discuss the body's biological response in the context of her causation and biocompatibility opinions, which the Court has previously allowed in the two prior bellwether trials." (*Id.*) They also seek to differentiate between opinions as to the body's response to polypropylene, and opinions regarding the nature or meaning of the cell response itself. (*Id.* at PageID #4277.) According to Defendants, Dr. Reitman's qualifications as a materials scientist qualifies her to offer opinions as to the body's response to polypropylene.

In *Johns*, the Court allowed Dr. Reitman to opine that "oxidative degradation of the polypropylene could not have caused [the plaintiff's] injuries because the polypropylene did not and cannot oxidatively degrade in the body, as well as that polypropylene is a suitable material from a biocompatibility perspective." (Case No. 18-cv-1509, EMO No. 8, ECF No. 425 at PageID #22494.) Consistent with the Court's ruling in *Johns*, Dr. Reitman may testify as to the effect of implantation in the body on polypropylene, whether it is stable, and whether or when polypropylene can oxidize. These opinions are in line with Dr. Reitman's qualifications and experience in the fields of polymer science and engineering. However, her experience as a polymer scientist do not qualify her to offer opinions on wound healing and tissue response. *See Salinero*, 2019 WL 7753453 at *15; *In re: Ethicon*, 2016 WL 4547055 at *3.

B. Dr. Stephen Badylak, D.V.M., Ph.D., M.D.

Plaintiff challenges the opinions of Defendants' expert Dr. Stephen Badylak, D.V.M., Ph.D., M.D. Plaintiff asks that the Court adopt its prior rulings limiting Dr. Badylak's testimony in *Johns* and *Milanesi*, and seeks to prevent Dr. Badylak from testifying about intra-abdominal forces because such testimony would be an undisclosed opinion, Dr. Badylak is not qualified to discuss intra-abdominal forces nor an alleged lack of forces that would cause a PerFix Plug to roll

up, and Dr. Badylak gives no basis for his opinion. (ECF No. 101 at PageID #3572–73.) According to Plaintiff, during the *Milanesi* trial Dr. Badylak impermissibly testified about intra-abdominal forces, and Dr. Badylak offered no basis for his assertion that there are no forces that could remove a hernia mesh from the abdominal wall other than a surgeon trying to remove the mesh with a sharp device. (*Id.* at PageID #3578.) The plaintiffs' counsel objected to Dr. Badylak's testimony on the grounds that the proffered opinion was undisclosed and Dr. Badylak was not qualified to offer it. (*Id.*) Plaintiff here anticipates similar testimony and seeks to exclude any such opinions.

Plaintiff asks the Court to adopt its prior rulings regarding Dr. Badylak's opinions. In *Johns* and *Milanesi*, the Court ruled that no expert may testify as to the meaning of Material Safety Data Sheets ("MSDS"), and that Dr. Badylak was not qualified to testify as to the sufficiency of the Instructions for Use (IFUs) for the devices at issue. (Case No. 18-cv-1509, EMO No. 13, ECF No. 461; Case No. 18-cv-1320, EMO No. 19, ECF No. 219 at PageID #14984–85.) The Court adopts its prior rulings.

Plaintiff next argues that Dr. Badylak is unqualified to opine on forces within the body, and that any such opinions are unreliable. (ECF No. 101 at PageID #3579.) Plaintiff claims that Dr. Badylak's expertise in the field of biomaterials does not render him qualified to opine on forces within the body, and he "provides no basis, whether it be from research, knowledge, or experience, to conclude, unequivocally, that there are *no* human forces that could roll a mesh up, without surgical error or some other type of outside source." (ECF No. 101 at PageID #3579 (emphasis in original).) Plaintiff does not object to Defendants asking Dr. Badylak whether maturing, healing, or scar contracture could lead to a mesh product to deform as they did in *Milanesi*. (ECF No. 141 at PageID #5837.) However, he would object to the question of whether "contraction, movement,

fluids, or anything" could cause a similar effect. (*Id.*) Plaintiff distinguishes between "the magnitude and direction of force *needed* to detach or deform polypropylene hernia meshes" and "the magnitude and direction of force *available* in the human body." (*Id.* at PageID #5838.)

Plaintiff claims that Dr. Badylak "can point to no experiment, methodology, or basis supporting his blanket statement that [there are] '*no* forces' that could rip mesh from the abdominal wall, or here that mesh could not roll up purely by human force within the preperitoneal space." (ECF No. 101 at PageID #3580 (emphasis in original).) He concedes that if Dr. Badylak knew the amount of force that would be necessary for a PerFix Plug to roll up in the preperitoneal space, with research to support that assertion, he could offer such testimony. (*Id.*) However, Dr. Badylak cannot testify that no such force could exist inside the body at all. (*Id.*) Plaintiff also claims that any testimony regarding forces in the body would be an undisclosed opinion and therefore impermissible. (*Id.*)

Defendants respond that "no expert in this case should be wasting time discussing whether implanted mesh can 'roll up' because there is no evidence of 'rolled up' mesh in this case." (ECF No. 112 at PageID #4102.) However, if the Court permits Plaintiff to offer such an argument, then Dr. Badylak should be allowed to discuss "the *general* understanding of how tissue responds to implanted materials like polypropylene mesh and what that means for the PerFix Plug device." (*Id.*) Dr. Badylak will not offer an opinion on Plaintiff's case specifically, or on what Plaintiff's implanting surgeon did or did not do. (*Id.*) Defendants point to published literature and studies by Dr. Badylak on polypropylene implantation and tissue ingrowth, as well as studies on the importance of the strength of tissue ingrowth that he reviewed in preparing his opinion. (*Id.* at PageID #4098.) According to Defendants, these demonstrate that "Dr. Badylak has [a] reliable basis to respond to any of Plaintiff's arguments regarding contraction, deformation, folding,

migration, and any other purported host tissue responses to implantation of the PerFix Plug, which may involve or relate to the body's internal forces." (*Id.*)

The Court agrees with Defendants that Dr. Badylak has extensive experience with "internal forces, healing and tissue ingrowth" and is qualified to testify about the same. (ECF No. 112 at PageID #4105.) However, the Court agrees with Plaintiff that there is a difference between Dr. Badylak's opinions regarding the magnitude and direction of force *required* to detach or deform polypropylene hernia meshes, and the magnitude and direction of force *available* within the human body. As Plaintiff notes, Dr. Badylak has performed "peel" tests and other mechanical tests on pigs, which provide a basis to testify regarding the force required. (ECF No. 141 at PageID #5838.) However, as to blanket statements that no such forces could exist at all within the human body, Dr. Badylak has not provided a reliable basis for such opinions. As the Court ruled in *Johns*, Dr. Badylak may not "draw inferences for the jury, or speculate." (Case No. 18-cv-1509, EMO No. 13, ECF No. 461 at PageID #23460.)

C. Dr. Robert D. Tucker, Ph.D., M.D.

Plaintiff challenges the opinions of Defendants' expert Dr. Robert D. Tucker, Ph.D., M.D., and argues that Dr. Tucker, who is designated as an expert pathologist, "proffers a methodologically unsound specific causation opinion as well as improper and misleading opinions on the FDA, mesh pore size and opinions as to the MSDS." (ECF No. 102 at PageID #3585.) According to Plaintiff, Dr. Tucker is unqualified to offer specific causation opinions and his opinions are not the result of a reliable methodology. (*Id.* at PageID #3586.) Plaintiff also challenges Dr. Tucker's opinions regarding the FDA and mesh pore size. (*Id.*)

1. Qualifications

Dr. Tucker is a non-board certified pathologist and does not see, diagnose, or treat patients. (ECF No. 102-2 at PageID #3700–01.) Dr. Tucker is not a surgeon "or any other type of physician that would be qualified to diagnose and treat[] patients who present with the injuries suffered by [Plaintiff]." (ECF No. 102 at PageID #3594.) Therefore, Plaintiff argues that Dr. Tucker is not qualified to opine as to the causes of Plaintiff's symptoms and injuries. Dr. Tucker is not qualified as to opine on Plaintiff's "complex medical history" because he "has no medical expertise, experience or educational background that would permit him to diagnose or treat the litany of factors that he claims in this catch-all bucket, let alone the qualifications to opine upon how or why any one of these very different factors contributed to [Plaintiff's] chronic pain and injuries at issue here." (ECF No. 143 at PageID #5894–95.) He also argues that Dr. Tucker is unqualified to offer opinions as to nerve entrapment or whether surgical error or technique contributed to Plaintiff's injuries. (*Id.* at PageID #5895.) Defendants cite to the Court's prior ruling that Dr. Tucker is qualified to opine on the reaction of tissues to mesh devices from a pathology perspective. (ECF No. 113 at PageID #4159 (citing Case No. 18-cv-1509, EMO No. 11, ECF No. 459 at PageID #23421).) Plaintiff characterizes Defendants' reading of the Court's prior rulings as overly broad, because the Court did not find that Dr. Tucker was "qualified to look beyond the pathology to assign causation to pre-existing medical conditions for which Dr. Tucker has zero education or expertise." (*Id.* at PageID #5896.)

Consistent with its rulings in *Johns* and *Milanesi*, the Court finds that Dr. Tucker is qualified "to opine on the effect of the mesh devices on human tissues, specifically whether the tissues contained evidence of the mechanisms that caused Plaintiff's injuries or the injuries themselves, including poor tissue integration, degradation, mesh contraction, biocompatibility,

adhesions, etc." (Case No. 18-cv-1509, EMO No. 11, ECF No. 459 at PageID #23420.) Plaintiff is correct that "[p]athologists do not perform physical examinations or base their conclusions on them." *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 712 (S.D.W. Va. 2014). However, a pathologist is qualified to perform a "morphological differential diagnosis" in which he "review[s] clinical records, examine[s] explanted specimens, consider[s] possible causes of pain, and c[omes] to a diagnostic conclusion." *Id.*; *see also Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *20 (S.D.W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 529 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014). That is exactly what Dr. Tucker did here. As the Court discusses in more detail below, Dr. Tucker reviewed medical records to consider alternative possible causes of Plaintiff's pain, examined Plaintiff's histopathology, and reached a conclusion based on his observations.

2. Methodology

Plaintiff argues that Dr. Tucker does not provide an explanation or methodology for how he reached his specific causation opinions. First, he points to the lack of a differential diagnosis and argues that because Dr. Tucker did not consider other factors or causes for Plaintiff's symptoms, and his report and opinions "instead reveal[] speculative guesswork for assessing the causation." (ECF No. 102 at PageID #3596.) Plaintiff claims that Dr. Tucker does not explain in his report why and how he decided that Plaintiff's medical history played a role in his injuries, and failed to properly consider the PerFix Plug as a cause. (*Id.* at PageID #3596–97.) In Dr. Tucker's report, he stated that "it is impossible to conclude that the implanted Bard mesh products are the cause of, or even substantially contribute to, any specific symptom or complaints claimed by the Plaintiff." (ECF No. 102-1, Tucker Report at 35.) According to Plaintiff, that testimony is an

admission on Dr. Tucker's part that he "cannot rule in or rule out the causative impact of the PerFix Plug." (ECF No. 102 at PageID #3598.)

Defendants respond that Dr. Tucker "methodically details" Plaintiff's medical history, and "conducted a careful and reliable differential diagnosis, considering and ruling out potential causes, before arriving at his conclusion." (ECF No. 113 at PageID #4161–62.) Dr. Tucker referenced Plaintiff's medical records and the explanting surgeon's report, and "scrupulously consider[ed] Plaintiff's medical history, and examin[ed] the histopathology." (*Id.* at PageID #4162.) Additionally, Dr. Tucker reviewed Plaintiff's histopathology in the form of a tissue block and slides in this case, which were not available in *Johns* or *Milanesi*. (*Id.* at PageID #4152.) Differential diagnosis is "an acceptable method of determining causation." *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 261 (6th Cir. 2001). Differential diagnosis "is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Id.* at 260.

Dr. Tucker devotes several pages of his report to reviewing Plaintiff's medical history. (ECF No. 102-1, Tucker Report at 28–30.) He considered pre-existing conditions (*id.* at 32), nerve entrapment (*id.*), oxidative degradation (*id.* at 32–33), mesh pore size (*id.* at 34), and mesh contraction (*id.*) in reaching his conclusion that the PerFix Plug did not cause Plaintiff's injuries. Dr. Tucker clearly "eliminat[ed] the likely causes until the most probable one [wa]s isolated," *Hardyman*, 243 F.3d at 260, and considered the elements of the PerFix Plug as a potential cause of Plaintiff's injuries. A reliable method for a pathologist to form a case specific opinion is a morphological differential diagnosis. *See Eghnayem*, 57 F. Supp. 3d at 675 ("I have not excluded Dr. Iakovlev's specific causation opinions. Dr. Iakovlev testified that he performed a 'morphological differential diagnosis' in preparing his specific causation report for Ms.

Eghnayem, which allowed him to rule out alternative causes."); *Tyree*, 54 F. Supp. 3d at 532 ("Reviewing Dr. Trepeta's report and deposition testimony as a whole, I find that Dr. Trepeta has based his opinion in large part on reliable pathology methods—he reviewed pathology slides, considered the possible causes for the inflammation, and came to a diagnostic conclusion. Challenges to the accuracy of the diagnostic conclusion are better suited for cross-examination.") (internal citations omitted). Accordingly, the Court finds that Dr. Tucker's specific causation opinions are based on a reliable methodology.

Plaintiff also claims that Dr. Tucker's specific causation opinions are based on his "unsupported and speculative belief that Dr. Tan improperly implanted the [PerFix Plug] in a manner that entrapped the genitofemoral nerve." (ECF No. 102 at PageID #3597.) Specifically, he points to the following portion of Dr. Tucker's testimony: "I think there was nerve entrapment. Specifically, whether it was [the genitofemoral] nerve? I don't think we know. But—but it's a good bet that it's at least a branch of it." (ECF No. 102-2 at PageID #3704.) Plaintiff emphasizes the phrases "I don't think we know" and "it's a good bet" to support his assertion that Dr. Tucker's opinion regarding the cause of Plaintiff's injuries is purely speculative. (ECF No. 102 at PageID #3597.) Plaintiff also points to Dr. Tucker's testimony that he "think[s] [Dr. Tan] caught [the genitofemoral nerve]," emphasizing Dr. Tucker's use of the phrase "I think." (ECF No. 102-2 at PageID #3705–06; ECF No. 102 at PageID #3597.) Therefore, Plaintiff claims that Dr. Tucker's opinions regarding Dr. Tan's surgical technique are speculative and "[t]here is simply too great an analytical gap between the data and the opinions proffered by Dr. Tucker." (*Id.* at PageID #3598.) As the Court stated in *Johns*, "this is not a 'magic words' test, and the fact that an expert does not use absolute terms but rather couches the opinion in terms of 'can' or 'may' does not render it speculative or unreliable. In other words, the district court must assess the whole of the expert's

opinion, not isolated instances of word choice." (Case No. 18-cv-1509, ECF No. 458, EMO No. 10 at PageID #23402 (internal citations omitted).) Dr. Tucker discusses genitofemoral nerve entrapment multiple times in his report, and ultimately concludes that "the entrapment of the genitofemoral nerve, which [Dr. Tan] does not mention, produced [Plaintiff's] chronic pain." (ECF No. 102-1, Tucker Report at 32.) In considering the whole of Dr. Tucker's opinions, the Court does not agree with Plaintiff that Dr. Tucker's opinions are purely speculative.

3. FDA Opinions

Plaintiff alleges that in his report, Dr. Tucker improperly claims that other of Defendants' hernia mesh products have been deemed safe and effective by the FDA. (ECF No. 102 at PageID #3598.) He also points to Dr. Tucker's statement in his report regarding the FDA approval of Prolene suture in 1969, and claims that the opinion regarding the Prolene suture should be excluded as irrelevant in accordance with the Court's rulings in *Milanesi* and *Johns*. (*Id.* at PageID #3599; *see* Case No. 18-cv-1509, ECF No. 459, EMO No. 11 at PageID #23421; Case No. 18-cv-1320, ECF No. 274, EMO No. 24 at PageID #16819.) Additionally, any testimony suggesting that the FDA determined that the PerFix Plug, or other devices, were safe and effective would be unduly prejudicial. (ECF No. 102 at PageID #3599.)

Defendants respond that "Plaintiff's recycled motion fails to identify where Dr. Tucker has disclosed any opinions about the meaning of FDA clearance or the regulatory status of the PerFix Plug. Dr. Tucker does not intend to offer any affirmative opinions on the FDA and the 510(k) process." (ECF No. 113 at PageID #4156.) For preservation purposes, Defendants reiterate their argument in favor of admissibility of Dr. Tucker's opinions about FDA approval and clearance of the Prolene suture. (*Id.*) However, the Court's prior reasoning on this point still holds here: "Although it appears that the Prolene suture is also made of polypropylene, there is no indication

that the Prolene suture is a component part of the [PerFix Plug] or otherwise directly connected to the [PerFix Plug]." (Case No. 18-cv-1320, EMO No. 24, ECF No. 274 at PageID #16819; Case No. 18-cv-1509, EMO No. 11, ECF No. 459 at PageID #23421–22.) The Court's reasoning in *Johns* regarding FDA clearance and other polypropylene mesh devices still applies here. (*Id.*)

4. Pore Size and Testing Opinions

Plaintiff next asks the Court to exclude Dr. Tucker's opinions regarding mesh pore size as inconsistent and unreliable. According to Plaintiff, Dr. Tucker testified that "the only testing that should be conducted by a pharmaceutical device company is the testing required by the FDA." (ECF No. 102 at PageID #3600.) However, as the Court has previously ruled, "the opinion that Dr. Tucker actually offers, as opposed to Plaintiff's characterization of his opinion, is not misleading and is reliable, and he is qualified to offer it." (Case No. 18-cv-1509, EMO No. 11, ECF No. 459 at PageID #23422–24; *see also* Case No. 18-cv-1320, EMO No. 24, ECF No. 274 at PageID #16818.)

5. MSDS Opinions

Plaintiff asks the Court to adopt its prior rulings regarding Dr. Tucker's MSDS opinions. (ECF No. 102 at PageID #3601.) Defendants reiterate their earlier arguments solely for preservation purposes. (ECF No. 113 at PageID #4158.) The Court therefore adopts its previous rulings regarding Dr. Tucker's MSDS opinions. (Case No. 18-cv-1320, EMO No. 24, ECF No. 274 at PageID #16818; Case No. 18-cv-1509, EMO No. 11, ECF No. 459 at PageID #23424–25.)

IV. Conclusion

For the reasons set forth above, Plaintiff's motions addressing Dr. Badylak (ECF No. 101) and Dr. Tucker (ECF No. 102) are **GRANTED IN PART** and **DENIED IN PART**. Plaintiff's motion addressing Dr. Reitman (ECF No. 97) is **GRANTED IN PART**, **DENIED IN PART**, and

RESERVED IN PART.

IT IS SO ORDERED.

6/2/2023
DATE

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