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. 28

Before the Court are Defendants' Motions to Exclude the Opinions and Testimony of Plaintiff's Experts Ahmed El-Ghannam, Ph.D. (ECF No. 90), Julia Babensee, Ph.D. (ECF No. 91), and Jimmy Mays, Ph.D. (ECF No. 92). For the reasons that follow, Defendants' motion addressing Dr. El-Ghannam (ECF No. 90) is **DENIED IN PART** and **RESERVED IN PART**, and Defendants' motions addressing Dr. Babensee (ECF No. 91) and Dr. Mays (ECF No. 92) are both **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. Ahmed El-Ghannam, Ph.D.

Defendants challenge the opinions of Plaintiff's expert Dr. Ahmed El-Ghannam, Ph.D. Defendants filed their motion in part to preserve their prior arguments regarding Dr. El-Ghannam's opinions and adopt the arguments they offered in the first two bellwether trials, *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 previous rulings holding that Dr. El-Ghannam's opinions are admissible except for his pore size opinions, on which the Court reserves ruling. (*See* Case No. 18-cv-1509, Evidentiary Motions Order ("EMO") No. 6, ECF No. 328; Case No. 18-cv-1320, EMO No. 20, ECF No. 220 at PageID #14997–99.)

In addition to the arguments presented in *Johns* and *Milanesi*, Defendants present three new arguments regarding Dr. El-Ghannam's specific causation opinions. First, they argue that Dr. El-Ghannam is not qualified to opine on specific causation because he is a biomedical engineer and "does not possess a medical degree and is not a clinician, medical doctor, or general surgeon."

(ECF No. 90 at PageID #1203.) Second, they argue that Dr. El-Ghannam's specific causation opinions are unreliable because he did not conduct a differential diagnosis. (*Id.*) Third, they argue that Dr. El-Ghannam's specific causation opinions should be excluded as cumulative because Plaintiff has already disclosed Dr. David Grischkan as a specific causation expert. (*Id.*)

As to Defendants' first argument, the Court previously detailed Dr. El-Ghannam's qualifications and expertise in EMO No. 6 in *Johns*. (Case No. 18-cv-1509, ECF No. 328 at PageID #17838–39.) As Plaintiff points out, Dr. El-Ghannam's testimony "is not offered as a treating physician but rather as a scientist to show that Defendants' polypropylene hernia mesh products involved in this litigation—including the PerFix Plug mesh—are not biocompatible, and to show the correlation between the degradation of the polypropylene mesh material and the irritation of the immune system which has manifested in the symptoms Plaintiff[] suffered." (ECF No. 123 at PageID #4771.) The Court has previously found Dr. El-Ghannam "well-qualified, based on his knowledge, experience, and education, to provide general causation opinions regarding polypropylene and the body's reaction to that material." (Case No. 18-cv-1509, EMO 6, ECF No. 328 at PageID #17841–42.) The same reasoning applies here as to his specific causation opinions. Dr. El-Ghannam is qualified to offer an opinion regarding polypropylene and Plaintiff's body's reaction.

Although the Court noted in *Johns* that Dr. El-Ghannam's specific causation opinions were excluded in another polypropylene mesh case (*id.* at PageID #17841), the circumstances of that case differ from the circumstances here. In that case, "[n]othing in [Dr. El-Ghannam's] expert report . . . suggest[ed] that he [was] offering an opinion that any of the particular bellwether plaintiffs was injured by the [mesh product at issue] that was implanted in them." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 632 (S.D.W. Va. 2013). The Court went on to distinguish the

circumstances in that case from a case in which a biomaterials expert's testimony was found to have been properly admitted when he had "personally observed the plaintiff's explanted product and explained in detail how he arrived at the conclusion." *Id.* at n. 17 (citing *Thrope v. Davol, Inc.*, No. 07-1842ML, 2011 WL 470613, at *25 (D.R.I. Feb. 4, 2011)).

Defendants claim that Dr. El-Ghannam's case specific opinions are unreliable because he did not perform a differential diagnosis. (ECF No. 90 at PageID #1209–10.) In response, Plaintiff points to *Chrastecky v. C. R. Bard, Inc.*, another case in in which Defendants argued that Dr. El-Ghannam's specific causation opinions were unreliable because they were not the product of a differential diagnosis. The court offered the following analysis as to Dr. El-Ghannam's specific causation opinions in that case:

> Bard ignores the fact that Plaintiffs retained Dr. El-Ghannam not as a medical expert, but as a biomedical and bioengineering expert to opine regarding the interaction between Plaintiff's mesh implant and her body. Bard also fails to mention that Dr. El-Ghannam actually examined and analyzed the mesh at issue before forming his opinions: "I removed the tissue around the failed implant taken from [Plaintiff] and analyzed the mesh samples using scanning electron microscopy ('SEM'), Fourier transform infrared spectroscopy ('FTIR') and Differential Scanning Calorimetry ('DSC')." Dkt. No. 90-7 at p. 5. On examination, Plaintiff's tissue showed signs of degradation and migration.
>
> Dr. El-Ghannam testified that according to his experience analyzing hundreds of Bard mesh devices, as well as his reading of pertinent medical literature, degrading mesh migrates from the implantation site into other areas of the body and other organs. *See* Dkt. No. 90-11 at p. 38-39. He found that Plaintiff's tissue contained degraded mesh particles that had migrated from the mesh into the surrounding tissue. *Id.* at p. 134-135. He noted that the literature is "full of data" confirming the migration of mesh particles into other parts of the body, and opined that due to his observations and analysis, Plaintiff experienced the same complications. *Id.* at 38-39.
>
> The Court finds that Dr. El-Ghannam has established an adequate foundation for his testimony. The Court further finds that Bard's criticisms of Dr. El-Ghannam's specific causation opinions go to the weight of his testimony, not to its admissibility. *See Fair v. Allen*, 669 F.3d 601, 607 (5th Cir. 2012) ("[T]he basis of an expert's opinion usually goes to the weight, not the admissibility, of the testimony."); *Priddy*, 2018 WL 662500, at *2 (finding that Bard's suggested other

> possible alternative causes affect the weight, not the admissibility of the expert's testimony).

Chrastecky v. C. R. Bard, Inc., No. A-19-CV-1240-LY-SH, 2020 WL 748182, at *9–10 (W.D. Tex. Feb. 14, 2020). Similar to *Chrastecky*, in this case Dr. El-Ghannam "actually examined and analyzed the mesh at issue before forming his opinions." *Id.* at *9. He made findings based specifically on his observations and testing he performed on Plaintiff's explanted mesh. He provided a detailed explanation of his analysis of Plaintiff's explanted mesh, including how he prepared and handled the materials, the methodology for the testing he performed, and the reasons for his conclusions. (El-Ghannam Report, Case No. 18-cv-1509, ECF No. 33-1.) He reviewed Mr. Stinson's medical records in addition to his own pathological findings and SEM images. (ECF No. 123 at PageID #4778.) Therefore, the Court finds that Dr. El-Ghannam has a reliable basis for his specific causation opinions.

Lastly, Defendants argue that Dr. El-Ghannam's specific causation opinions should be excluded under Rule 403 as redundant and needlessly cumulative. *See* Fed. R. Ev. 403 ("The court may exclude relevant evidence if its probative value is substantially outweighed by a danger of . . . needlessly presenting cumulative evidence."). According to Defendants, the opinions of Plaintiff's case specific medical expert, Dr. Grischkan, render Dr. El-Ghannam's specific causation opinions redundant. (ECF No. 90 at PageID #1210.) However, Dr. Grischkan is testifying from the perspective of a hernia surgeon, whereas Dr. El-Ghannam offers opinions from the perspective of a biomedical engineer. Their opinions are neither identical nor needlessly cumulative, and the Court declines to exclude Dr. El-Ghannam's opinions as duplicative under Rule 403.

B. Dr. Julia Babensee, Ph.D.

Defendants challenge the opinions of Plaintiff's expert Dr. Julia Babensee, Ph.D. They

argue that the following opinions should be excluded: 1) opinions specific to this case, including on pain or any other clinical complications; 2) opinions on pore size, weight, and layers of the polypropylene mesh in the PerFix Plug; 3) general causation opinions regarding contraction, migration, mesh configuration, and pain; 4) opinions on safer alternative designs to the PerFix Plug; and 5) opinions on Material Safety Data Sheets for the Marlex polypropylene resin. Defendants argue that the opinions should be excluded because Dr. Babensee is not qualified to offer these opinions, lacks a reliable basis for these opinions, and/or these opinions do not fit the issues in this case.

1. Case Specific Opinions

In *Johns* and *Milanesi*, the Court concluded that "without consideration of alternative causes, Dr. Babensee's specific causation opinion is unreliable." (Case No. 18-cv-1320, EMO No. 23, ECF No. 273 at PageID #16800; Case No. 18-cv-1509, EMO No. 5, ECF No. 310 at PageID #16813.) Defendants argue that Dr. Babensee's specific causation opinions should likewise be excluded in this case because she did not consider potential alternative causes for Plaintiff's injuries. (ECF No. 91 at PageID #1233–34.) Plaintiff disagrees, and argues that a different ruling is warranted in this case. Dr. Babensee did not review histology slides of the plaintiffs' explanted mesh in *Johns* and *Milanesi*, but she did evaluate pathology materials specific to Mr. Stinson. (ECF No. 121 at PageID #4557.) Plaintiff claims that a differential diagnosis was not necessary because Dr. Babensee is not a clinician, and that the "morphological differential diagnosis" performed by Dr. Babensee is a sufficient foundation for her specific causation opinions. *See Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 712 (S.D.W. Va. 2014) ("Morphology is the study of human tissue and morphological findings provide basis for clinical symptoms. In preparing his expert report specific to [the plaintiff], [the expert] reviewed [the plaintiff's] clinical

records and examined two specimens of her explanted mesh to make morphological findings that explain her symptoms.") (internal citations omitted).

Plaintiff claims that Dr. Babensee performed a morphological differential diagnosis. However, "merely claiming that an expert used differential diagnosis is alone insufficient to satisfy the reliability inquiry under *Daubert*." *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 678 (6th Cir. 2011) (internal citation omitted). Calling an expert's conclusion a differential diagnosis "does not by itself answer the reliability question," and if an expert does not reliably rule out alternative causes "the court must exclude the ultimate conclusion reached." *Id.* (quoting *Tamraz v. Lincoln Elec. Co.,* 620 F.3d 665, 674 (6th Cir.2010)). This applies not only to a clinical differential diagnosis by a medical professional, but to a morphological differential diagnosis. *See Eghnayem*, 57 F. Supp. 3d at 712. "The core of differential diagnosis is a requirement that experts at least consider alternative causes." *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 179 (6th Cir. 2009) (internal citation omitted). Contrary to Plaintiff's assertion that the Court excluded Dr. Babensee's specific causation opinions in *Johns* and *Milanesi* because she had not reviewed the plaintiffs' histopathology, Dr. Babensee's failure to consider potential alternative causes was no small part of the Court's reasoning in excluding her specific causation opinions. (*See* Case No. 18-cv-1509, EMO No. 5, ECF No. 310 at PageID #16812–13; Case No. 18-cv-1320, EMO No. 23, ECF No. 273 at PageID #16800.) Consistent with its rulings in *Johns* and *Milanesi*, the Court finds that without consideration of alternative causes, Dr. Babensee's specific causation opinion is unreliable.

2. Pore Size, Weight, and Migration Opinions

Defendants claim that "Dr. Babensee's opinions on pore size, weight, and migration of the polypropylene mesh in the PerFix Plug are beyond her qualifications, unreliable, and lack fit for

this case." (ECF No. 91 at PageID #1237.) In *Johns* and *Milanesi*, the Court considered and denied challenges to Dr. Babensee's qualifications to offer opinions about pore size. (Case No. 18-cv-1509, EMO No. 5, ECF No. 310 at PageID #16802–03; Case No. 18-cv-1320, EMO No. 23, ECF No. 273 at PageID #16800–01.) Defendants offer no reason why the Court should rule differently as to Dr. Babensee's qualifications, and the Court therefore finds that Dr. Babensee is qualified to testify regarding pore size.

Defendants go on to argue that Dr. Babensee's pore size, shape, and mesh weight opinions are unreliable because she has not personally studied whether large pore mesh devices are safer or result in fewer complications. (ECF No. 91 at PageID #1241.) However, as the Court explained in EMO No. 23, "experts with appropriate expertise may review scientific literature to form their opinions, meaning an expert need not perform tests for his opinion to be reliable." (Case No. 18-cv-1320, ECF No. 273 at PageID #16798.) The Court reiterates its conclusion that "[c]oupled with her education and training in biomaterials science, [Dr. Babensee's analysis of assembled data] is sufficient to convey reliability." (*Id.* at PageID #16799.) If Defendants take the position that Dr. Babensee's opinions are weak because she has not performed her own testing, that goes to the weight of her testimony, not its admissibility. *Daubert*, 509 U.S. at 596 ("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.").

Additionally, Defendants contend that Dr. Babensee could not explain how an inadequate pore size or increased mesh weight leads to increased inflammation, excessive fibrosis, and "meshoma" formation. (ECF No. 91 at PageID #1239.) In her report, Dr. Babensee details that the overlapping layers of mesh in the PerFix Plug inhibit effective integration, and the increase in weight "is going to cause even more of an inflammatory response and fibrosis." (ECF No. 91-3,

Babensee Report at 18.) She states that "[t]his can lead to a ball of inflammatory tissue/fibrosis or a meshoma or plugoma with many layers of polypropylene mesh throughout." (*Id.* at 18–19.) Dr. Babensee also opines that small pore polypropylene mesh does not properly integrate into the tissue and adds to "the inflammatory process, the fibrotic process, entrapment of nerves and pain" associated with Defendants' small pore mesh products "particularly intended for groin hernias." (*Id.* at 12–13.) Defendants have previously argued that Dr. Babensee did not connect her pore size opinions to an increased risk of complications. In both *Johns* and *Milanesi*, the Court rejected Defendants' relevance and fit arguments and concluded that Dr. Babensee's opinions on pore size helped to explain why exposure to bare polypropylene could be harmful, which is a central theory in this MDL. (Case No. 18-cv-1509, EMO No. 5, ECF No. 310 at PageID #16805–07; Case No. 18-cv-1320, EMO No. 23, ECF No. 273 at PageID #16801–02.) The Court adopts the same reasoning in this case.

Defendants also argue that the Court should exclude Dr. Babensee's opinion that the shape of the PerFix Plug predisposes the device to migrate within the body. Defendants claim that Plaintiff's explanting surgeon Dr. Radke testified that the PerFix Plug had not migrated, and that the PerFix Plug performed as expected. (ECF No. 91 at PageID #1240; ECF No. 91-6 at PageID #1679, 1682.) Defendants also point to Dr. Babensee's testimony that she did not see any evidence of migration or erosion in Plaintiff's case. (ECF No. 91 at PageID #1240; ECF No. 91-4 at PageID #1608.) Plaintiff states that "[t]o the extent that no migration occurred in Plaintiff Stinson's case, as noted above he will not be eliciting testimony on the topic," and asks the Court to reserve judgment on the issue as it did in *Milanesi*. (ECF No. 121 at PageID #4561, 4563.) The Court therefore reserves ruling on Dr. Babensee's migration opinions.

3. Contraction and Mechanical Mismatch Opinions

Defendants attack Dr. Babensee's contracture opinions as beyond her qualifications, unreliable, and lacking fit for this case. (ECF No. 91 at PageID #1242–43.) The Court finds that her contracture opinions lack fit for this case, and therefore will not address Defendants' arguments regarding reliability or her qualifications. Dr. Babensee opines that contracture of the PerFix Plug's onlay mesh "strangulates the spermatic cord and cuts off blood supply, causing pain and ischemic necrosis." (ECF No. 91-3, Babensee Report at 19.) In arguing that Dr. Babensee's contraction opinions are admissible, Plaintiff points to the Court's ruling that her contraction opinions were admissible in *Milanesi*. (ECF No. 121 at PageID #4562–63.) Plaintiff addresses Defendants' reliability and qualifications arguments but does not address whether Dr. Babensee's contraction opinions fit with the specific facts of this case, and does not dispute Defendants' contention that there is no evidence of erosion of the spermatic cord or ischemic necrosis in this case. In Dr. Grischkan's report, he claims to have observed the PerFix Plug eroding into the spermatic cord in his practice (ECF No. 93-4 at PageID #2061), but he does not opine that Plaintiff suffered that complication. Nor does he opine that Plaintiff suffered from ischemic necrosis. Plaintiff points to no other evidence and makes no argument that that his PerFix Plug eroded into the spermatic cord or that he experienced ischemic necrosis. Therefore, Dr. Babensee's contracture opinions lack fit and are not admissible.

Defendants also argue that Dr. Babensee's "mechanical mismatch" opinions are inadmissible. Defendants point to the Court's prior rulings excluding expert opinions about alleged risks of devices that did not result in injury, and claim that the Court should therefore exclude Dr. Babensee's opinion that a "mechanical mismatch" between polypropylene mesh and tissue in the area of the hernia can cause excessive inflammation and fibrosis as lacking fit to

Plaintiff's injuries. (ECF No. 91 at PageID #1242; ECF No. 133 at PageID #5618.) Dr. Babensee's report explains that:

> [T]here is a mechanical mismatch between stiff polypropylene mesh material and the tissue in the area where the hernia occurs, particularly the case for the inguinal location. The mechanical properties of the mesh predispose it not to be integrated. The inelasticity of the polypropylene mesh prevents it from conforming to the surrounding tissue to allow for cellular infiltration and stabilization, and as such, makes it a mechanical irritant. . . . The compliance mismatch between the device and the tissue results in micromotion that can be a further inflammatory stimulus in the host response against the foreign body, resulting in inflammation, fibrosis around the mesh region and contraction of the implant site. These complications may be seen grossly as fibrosis, which is evident around the mesh.

(ECF No. 91-3, Babensee Report at 12.) Although Plaintiff does not address Defendants' mechanical mismatch argument, Dr. Babensee's mechanical mismatch opinions relate to "fibrosis around the mesh region." Plaintiff does claim excessive fibrosis and scarring as part of his injuries. (ECF No. 121 at PageID #4550, 4557.) Therefore, Dr. Babensee's mechanical mismatch opinions do not lack fit in this case.

Defendants also ask the Court to exclude Dr. Babensee's opinions that "the forces in the inguinal region are greater than those in other areas of the body [because] she is not an expert in anatomy and physiology, and she relies on literature discussing pelvic mesh, an entirely different product." (ECF No. 91 at PageID #1243.) Defendants claim that she does not attempt to quantify the forces, or to integrate the theory with the facts of this case. However, as the Court stated in *Milanesi*, "attack[s on] the strength of the literature that Dr. Babensee relied on in forming her opinions, [and] that she did not [perform testing] herself . . . go to the weight of her opinion, not its admissibility." (Case No. 18-cv-1320, ECF No. 273, EMO No. 23 at PageID #16799.)

4. Safer Alternative Design Opinions

In *Johns* and *Milanesi*, the Court allowed Dr. Babensee's alternative design opinions. (Case No. 18-cv-1509, ECF No. 310, EMO No. 5 at PageID #16809–11; Case No. 18-cv-1320,

ECF No. 273, EMO No. 23 at PageID #16804–05.) However, Defendants argue that "the issues [in this case] differ markedly from the [first] two bellwether cases with respect to safer alternative designs." (ECF No. 91 at PageID #1244.) Under Maine law, "[i]n actions based upon defects in design, negligence and strict liability theories overlap in that under both theories the plaintiff must prove that the product was defectively designed thereby exposing the user to an unreasonable risk of harm. Such proof will involve an examination of the utility of its design, the risk of the design and the feasibility of safer alternatives." *Stanley v. Schiavi Mobile Homes, Inc.*, 462 A.2d 1144, 1148 (Me. 1983) (internal citations omitted). According to Defendants, any evidence of a proposed safer alternative design would have to show that the design would have avoided Plaintiff's injuries, was reasonably available, and that the benefits outweighed any risks. (ECF No. 91 at PageID #1244–45.) Defendants are correct that Plaintiff must demonstrate the feasibility of any alternative designs or products. *See Stanley*, 462 A.2d 1148. However, as the Court held in DMO No. 7, "whether Plaintiff's proposed alternative designs would have prevented his injuries is a question for the jury." (ECF No. 225 at PageID #9122.) That question, and the question of whether a proposed alternative's benefits outweigh its risks, go to the weight of Dr. Babensee's testimony, not its admissibility.

Defendants again raise the argument that because Dr. Babensee has not done any testing on proposed alternative devices, her opinions are unreliable. (ECF No. 91 at PageID #1245.) However, as the Court has explained above, this argument goes to the weight of Dr. Babensee's opinions, not their admissibility.

5. Material Safety Data Sheets ("MSDS") Opinions

The Court has previously held in this MDL that MSDS may only be used to show whether "Defendants had notice of the risks of inserting polypropylene-based materials . . . into the human

body," and they may not be used to prove the truth of the matter asserted. (Case No. 18-cv-1320, Motions *in Limine* ("MIL") Order No. 32, ECF No. 308 at PageID #17377.) In *Milanesi*, the Court excluded Dr. Babensee's MSDS opinions based on its ruling that MSDS could only be used as evidence of notice. Plaintiff does not oppose the same result here. (ECF No. 121 at PageID #4566.) The Court sees no reason to depart from its prior ruling.

C. Dr. Jimmy Mays, Ph.D.

Defendants challenge the opinions of Plaintiff's expert Dr. Jimmy Mays, Ph.D. Defendants filed their motion in part to preserve their arguments regarding Dr. Mays's opinions and adopt the arguments they offered in *Johns* and *Milanesi*. Accordingly, the Court follows its previous opinions. Dr. Mays may not offer state-of-mind opinions or provide a factual history unless he applies his expertise to contextualize, analyze, and interpret the history, or he relies on the record to reach an admissible expert opinion. (*See* Case No. 18-cv-1509, EMO No. 10, ECF No. 458; Case No. 18-cv-1320, EMO No. 19, ECF No. 219 at PageID #14985–90.)

In addition, Defendants ask the Court to exclude any "state of the art" opinion regarding the PerFix Plug because it is an undisclosed opinion, and because Dr. Mays is not qualified to offer such an opinion. During the *Milanesi* trial, defense expert Dr. Maureen Reitman testified that the hernia mesh device at issue was "state of the art." (Case No. 18-cv-1320, ECF No. 403 at PageID #21902.) The plaintiffs offered Dr. Mays as a rebuttal expert to Dr. Reitman's "state of the art" testimony. The Court concluded that in providing the testimony, Dr. Mays was not going beyond what was stated in his report and it was "classic rebuttal." (Case No. 18-cv-1320, ECF No. 406 at PageID #22528.) The Court declines to preemptively rule on the admissibility of potential rebuttal testimony outside the context of trial. The Court therefore reserves ruling on Dr. Mays's state of the art opinions.

IV. Conclusion

For the reasons set forth above, Defendants' Motion to Exclude the Opinions and Testimony of Dr. El-Ghannam (ECF No. 90) is **DENIED IN PART** and **RESERVED IN PART**; Defendants' Motion to Exclude the Opinions and Testimony of Dr. Babensee (ECF No. 91) is **GRANTED IN PART**, **DENIED IN PART**, and **RESERVED IN PART**; and Defendants' Motion to Exclude the Opinions and Testimony of Dr. Mays (ECF No. 92) 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