UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

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

EVIDENTIARY MOTIONS OPINION AND ORDER No. 21

Before the Court are Defendants' Motions to Exclude the Testimony of Plaintiffs' Experts John A. Morrison, M.D. (ECF No. 67) and Kenneth Rudo, Ph.D. (ECF No. 70). For the reasons below, Defendants' motion addressing Dr Morrison (ECF No. 67) is **GRANTED IN PART AND DENIED IN PART** and their motion addressing Dr. Rudo (ECF No. 70) is **GRANTED.**

I. Background[1]

Plaintiffs', Antonio Milanesi and Alicia Morz de Milanesi, case is the second bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants, C.R. Bard, Inc. and Davol, Inc. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (Case No. 2:18-md-02846, ECF No. 1 at

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

PageID #1–2.)[2] This includes Defendants' Ventralex Hernia Patch, the device implanted in Mr. Milanesi.

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

Plaintiffs bring this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralex device. Ten years after the implantation of the Ventralex, Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel resection. (*Id.* at PageID #13611–13.) Shortly thereafter, Mr. Milanesi suffered a high-grade post-operative

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

small bowel obstruction that required emergency surgery. (*Id.* at PageID #13613.)

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

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

II. Legal Standard

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because courts are "almost always better

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

The burden is on the party offering the expert opinions and testimony to demonstrate "by a preponderance of proof" that the expert evidence is admissible. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001). Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility. *See Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000) ("The Court [in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993),] explained that Rule 702 displays a 'liberal thrust' with the 'general approach of relaxing the traditional barriers to "opinion" testimony.'" (quoting *Daubert*, 509 U.S. at 588)); Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("A review of the case law after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.").

III. Analysis

The district court's role in assessing expert testimony is a "gatekeeping" one, "screening expert testimony" so that only admissible expert testimony is submitted to the

jury; its role is not to weigh the expert testimony or determine its truth. *United States v. Gissantaner*, 990 F.3d 457, 463 (6th Cir. 2021) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). Expert testimony, testimony given by "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education," is admissible if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In this circuit, "[t]he Rule 702 analysis proceeds in three stages." *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2016). "First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529 (6th Cir. 2008) (quoting Fed. R. Evid. 702.).

First, an expert witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "[T]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). "[T]he only thing a court should be concerned with in determining the qualifications of an expert is whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert's testimony must be for the trier of fact." *Mannino v. Int'l*

Mfg. Co., 650 F.2d 846, 851 (6th Cir. 1981). A party's expert need only meet the "'minimal qualifications' requirement—not one who could teach a graduate seminar on the subject." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (quoting *Mannino*, 650 F.2d at 851); *see also Dilts v. United Grp. Servs., LLC*, 500 F. App'x 440, 446 (6th Cir. 2012) ("An expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.").

Second, expert testimony must be relevant. Expert testimony is relevant if it will "help the trier of fact to understand the evidence or to determine a fact in issue." *Bradley v. Ameristep, Inc.*, 800 F.3d 205, 208 (6th Cir. 2015) (quoting *United States v. Freeman*, 730 F.3d 590, 599–600 (6th Cir. 2013)); Fed. R. Evid. 702(a). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (quoting 3 Jack B. Weinstein & Margaret A. Berger, Weinstein's Evidence ¶ 702[02], p. 702–18 (1988)). "This requirement has been interpreted to mean that scientific testimony must 'fit' the facts of the case, that is, there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000) (citing *Daubert*, 509 U.S. at 592). This is a case-specific inquiry. *See Madej*, 951 F.3d at 370 ("Whether an opinion 'relates to an issue in the case' or helps a jury answer a 'specific question' depends on the claims before the court.").

Third, expert testimony must be reliable. Rule 702 provides the following general standards to assess reliability: whether "the testimony is based on sufficient facts or data," whether "the testimony is the product of reliable principles and methods," and whether "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider "'testing, peer review, publication,

error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community,'" though these "factors 'are not dispositive in every case' and should be applied only 'where they are reasonable measures of the reliability of expert testimony.'" *In re Scrap Metal*, 527 F.3d at 529 (citations omitted); *see Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as "flexible" (quoting *Daubert*, 509 U.S. at 594)). The objective of the reliability requirement is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

Defendants challenge the opinions of Dr. John A. Morrison, M.D. and Dr. Kenneth Rudo, Ph.D. on qualifications, reliability, and relevance grounds.

A. John A. Morrison, M.D.

Dr. Morrison is general surgeon offered by Plaintiff as a general-causation expert. (ECF No. 107 at PageID #9378.) Defendants challenge eight types of opinions offered by Dr. Morrison: opinions that rely on Material Safety Data Sheets ("MSDSs"), as well as opinions on polypropylene mesh degradation, mesh contraction, mesh placement, mesh weight and pore size, mesh surface roughening, alternatives to polypropylene, FDA regulations, and product warnings. (ECF No. 67 at PageID #2040–56.) These challenges rest on relevance, Dr. Morrison's qualifications, and reliability. (*Id.*) Dr. Morrison's opinions are admissible with the exception of his MSDS, intraperitoneal onlay mesh implantation ("IPOM") placement, and polyvinylidene difluoride ("PVDF") opinions.

1. MSDS

Defendants take issue with part of Dr. Morrison's report that cites an MSDS, specifically

language that polypropylene is unsuitable for permanent implantation. (ECF No. 67 at PageID #2046–47.) They contend that he is unqualified to opine on this issue and that it is irrelevant to the case. (*Id.* at PageID #2047.) The Court agrees that he cannot reference or quote the MSDS.

In this MDL, polypropylene MSDSs are only admissible as evidence of Defendants' notice as to the risks presented by polypropylene. *In re Davol, Inc./C.R. Bard, Inc.*, *Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6603657, at *5 (S.D. Ohio Oct. 20, 2020) (Motions In Limine Order ("MIL") No. 4). In his report, Dr. Morrison cites the Marlex MSDS and explains that "polypropylene manufacturers later warned Bard and all other purchasers of their Marlex polypropylene that the polypropylene should not be permanently implanted in the human body or come in contact with internal bodily fluids or tissue." (ECF No. 67-3 at PageID #2440 (footnote omitted).) This testimony does not go to Defendants' notice, however. Moreover, no expert can opine on the mindset of corporations or entities because such opinions "have no basis in any relevant body of knowledge or expertise." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004); *see also In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, No. 2:18-cv-1509, 2021 WL 2643114, at *8 (S.D. Ohio June 28, 2021) (Evidentiary Motions Order ("EMO") No. 11).

2. Relevance

Defendants argue that Dr. Morrison's opinions on mesh degradation, mesh placement, mesh weight and pore size, surface roughening, and alternatives to polypropylene mesh are irrelevant to this case. (ECF No. 67 at PageID #2040–44, 2048–52, 2054–55.) These opinions are relevant.

Dr. Morrison's opinions on mesh degradation, surface roughening, mesh weight, pore size, and polypropylene alternatives are relevant. Plaintiffs identify a two-step

mechanism of injury in all bellwether cases in this MDL, including this case. First, the polypropylene mesh's "adhesion barrier fails, and polypropylene is exposed to underlying organs to which it attaches." (ECF No. 105 at PageID #9151.) As the Court noted in this case, the precise two-step mechanism of injury here is that the Ventralex buckles due to contracture, which then exposes bare polypropylene to the viscera. (ECF No. 166 at PageID #13590.) Dr. Krpata, a general and specific causation expert, opines on the first step of this mechanism, explaining that polypropylene mesh and ePTFE contract at different rates, causing buckling, and that the memory recoil ring lacked sufficient rigidity to prevent the buckling. (*Id.*) He also notes that the exposure of bare polypropylene is widely known to be problematic and can cause adhesions, fistula, and erosion. (*Id.*) Dr. Morrison's general opinion then explains why bare polypropylene is problematic via degradation and surface roughening, and that lighter weight meshes with smaller pores or meshes made of a different material altogether, PVDF, is more suitable. (ECF No. 67-3 at PageID #2439, 2443–45, 2459–60.) These opinions support Plaintiffs' design defect claim, and thus Dr. Morrison's opinions are relevant.[3] (*See* ECF No. 219 at PageID #14987–90; ECF No. 562 at PageID #7251-52.)

Plaintiffs also demonstrate that Dr. Morrison's IPOM mesh placement opinion is relevant. Plaintiffs identify a portion of Dr. Morrison's report in which he explains the risks of implanting a mesh via IPOM, which includes adhesions and bowel obstructions—the types of injuries that

[3] Defendants argue that Plaintiffs intend to use Dr. Morrison's surface roughening opinion to support their manufacturing defect claims. (ECF No. 67 at PageID #2051–52.) It is unclear how Plaintiffs intend to use this opinion. (*See* ECF No. 107 at PageID #9387.) The gist of Plaintiffs' response is that it is a true geometric statement that roughening increases surface area. (*Id.*) The Court dismissed Plaintiffs' manufacturing defect claim (ECF No. 167 at PageID #13617–20), and so the Court assumes that Plaintiffs intend to use the surface roughening opinion to support their design defect claim.

Mr. Milanesi suffered. (ECF No. 67-3 at PageID #2460.) There is a "connection" between this opinion and "the disputed factual issues in the case." *Pride*, 218 F.3d at 578.

3. Qualifications

Next, Defendants contend that Dr. Morrison is unqualified to offer opinions on mesh degradation, mesh contraction, mesh weight and pore size, mesh surface roughening, FDA regulations and product warnings, and alternatives to polypropylene. (ECF No. 67 at PageID #2040–46, 2049–56.) These opinions can be sorted as those pertaining to mesh and those regarding FDA regulations. For his mesh opinions, Defendants assert that Dr. Morrison is unqualified because he is not an expert in biomaterials, design, chemistry, or engineering. (*Id.* at PageID #2040–45, 2050.) And for his FDA opinions, Defendants argue that Dr. Morrison has no experience drafting warnings and "he would not change the substantive language of the warnings but only make them more prominent." (*Id.* at PageID #2053–54.) Dr. Morrison is qualified to offer his opinions.

Dr. Morrison is qualified to opine on the characteristics of polypropylene based on his extensive experience with treating hernia patients, particularly performing hernia repairs with polypropylene mesh devices and explanting the devices. (ECF No. 67-3 at PageID #2436–38.) Many courts have concluded that "a surgeon's 'extensive experience with performing mesh implant and explant surgeries can qualify him or her to opine on how the product reacts inside the body.'" *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605542, at *6 (S.D. Ohio Sept. 1, 2020) (collecting cases) (EMO No. 5). This includes "[s]urgeons without pathology expertise or experience in polymer science or biomaterials," so long as they "testify as to 'mesh degradation on a large scale, focusing on the ways a polypropylene mesh product can change after implantation in the human

body,'" *id.* (quoting *Wilkerson v. Bos. Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *20 (S.D.W. Va. May 5, 2015)), as opposed to "what's happening on the molecular level," *Wilkerson*, 2015 WL 2087048, at *20. In addition to opinions about the mesh's reaction to the body, courts have likewise concluded that surgeons are qualified to opine on a mesh device's effect on the body. *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2018 WL 3575936, at *3 (S.D.W. Va. July 24, 2018). Thus, Dr. Morrison is qualified to offer his opinions as to polypropylene degradation, contraction, porosity, and surface roughening of mesh, as well as the risks posed to patients by these characteristics. *E.g.*, *id.* (considering "degradation, inertness, weight, porosity, and cut"). For similar reasons, Dr. Morrison is also qualified to opine on the suitability of alternative materials in hernia mesh devices so long as he considers the large-scale effects on the body and the mesh.

Dr. Morrison is also qualified to opine on whether the Ventralex's Instructions for Use ("IFUs") disclose those risks in a helpful manner based on his experience as a hernia surgeon. Plaintiffs represent that Dr Morrison will not offer other FDA or regulatory opinions, and so Defendants' motion on this topic is moot. (ECF No. 107 at PageID #9387.) As for Dr. Morrison's IFU opinions, he stated in his report that the information disclosed to surgeons in the IFU is "minimal" and "with little about the long-term complications" being discussed by . . . [the] product monograph." (ECF No. 67-3 at PageID #2461.) He testified at his deposition that he "would probably make the warning far more prominent." (ECF No. 67-2 at PageID #2318, p. 140.) He has extensive specialized experience in hernia repairs and uses mesh products in his repairs. (ECF No. 67-3 at PageID #2436–38.) In this MDL, the Court has found this type of experience—even without specific experience using the Ventralex—is sufficient to qualify an expert to opine on the sufficiency of the IFUs in warning of the risks of polypropylene from the perspective of the end

user. *In re Davol, Inc.*, 2020 WL 6605542, at *16 (EMO No. 5). And Dr. Morrison's expert report and testimony as a general causation expert need not provide a specific-causation connection to this case for Plaintiff's design defect claims or failure to warn claim, such as by providing an opinion that any change to the IFU would have changed Plaintiff's implanting surgeon's decision to use the Ventralex. Therefore, this opinion is admissible.

4. Reliability

Finally, Defendants contend that Dr. Morrison's opinions on polypropylene mesh degradation, contraction, weight and pore size, surface roughening, and alternatives to polypropylene are unreliable. (ECF No. 67 at PageID #2040–46, 2049–52, 2055.) They argue primarily that Dr. Morrison relied only on the feel and appearance of mesh and scientific literature and that he did not perform his own research or testing. (*Id.* at PageID #2042.) Dr. Morrison's opinions are reliable except for his opinion that PVDF is a better alternative to polypropylene.

Expert opinions founded in peer-reviewed literature and the expert's own experience are usually sufficiently reliable. *E.g.*, *In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 724 (N.D. Ohio 2011); *see also Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 522–23 (S.D.W. Va. 2014); *In re Ethicon, Inc.*, *Pelvic Repair Sys. Prods. Liab. Litig.*, Nos. 2:12-MD-02327, No. 2327, 2014 WL 186872, at *7 (S.D.W. Va. Jan. 15, 2014). An expert is permitted to rely on academic literature, despite not conducting testing and research himself, if these studies are within his area of expertise. *In re E.I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig.*, 337 F. Supp. 3d 728, 743 (S.D. Ohio 2015) (citations omitted); *see also Buck v. Ford Motor Co.*, 810 F. Supp. 2d 815, 844 (N.D. Ohio 2011) (reviewing published studies); *In re Davol, Inc., C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ----, Nos. 2:18-cv-1509, 2:18-md-2846, 2021 WL 2646797, at *5 (S.D. Ohio June 28, 2021) (EMO No. 10).

Dr. Morrison's opinions regarding the characteristics of polypropylene, specifically degradation, contraction, weight, porosity, and surface roughening of mesh, are reliable opinions. Dr. Morrison relies on his own observations, experience, and peer-reviewed scientific articles and studies. (*E.g.*, ECF No. 67-3 at PageID #2443–44.) Moreover, Dr. Morrison is a veteran hernia surgeon with mesh experience (*id.* at PageID #2438), meaning the scientific literature he relies on is within his area of expertise. He also visually and tactilely observed explanted meshes. Dr. Morrison's polypropylene mesh opinions are thus sufficiently reliable.

However, Dr. Morrison's opinion that PVDF is a better alternative to polypropylene is unreliable. Dr. Morrison opines that PVDF is a safer material than polypropylene, but he does not reference his own experience, expertise, or cite to any supporting literature. (ECF No. 67-3 at PageID #2441–42.) In his deposition, he clarified that he has no experience with PVDF and has never used it, and that he was simply reiterating the opinion of European surgeons. (ECF No. 67-2 at PageID #2303–04, pp. 79–82.) This falls short of "intellectual rigor" required of expert opinions. *Kumho Tire Co.*, 526 U.S. at 152. Dr. Morrison lacks a reliable basis for his opinion that PVDF is a suitable alternative, and thus the opinion is inadmissible.

Defendants offer a number of counterarguments, none of which persuades this Court that Dr. Morrison's other polypropylene mesh opinions are unreliable. Defendants argue that Dr. Morrison's personal observations are unreliable (ECF No. 67 at PageID #2042), but they provide no support for this contention. It is unclear why visual and tactile comparisons of an explanted hernia mesh device by hernia surgeon are inherently unreliable, particularly when Dr. Morrison's mesh opinions are supported by scientific literature. At best this is an issue of weight, not admissibility, of expert testimony. The same goes for Dr. Morrison's statement that he does not consider himself to be part of the scientific debate about polypropylene. (ECF No. 67 at

PageID #2042.)

Defendants also argue that because Dr. Morrison cannot name the additives in the Ventralex or provide any specific Ventralex opinions as to contracture, his opinions about the degradation and contracture of polypropylene are unreliable. (ECF No. 67 at PageID #2042, 2045.) Dr. Morrison offers general causation, not specific causation, opinions. Accordingly, his general polypropylene opinions are not unreliable for these reasons Defendants also contend that Dr. Morrison did not account for the possibility that scar tissue, not the mesh, contracts and that he did not review internal documents regarding the design or manufacture of Defendants' devices. (*Id.* at PageID #2046; ECF No. 114 at PageID #10736.) But these are issues of weight, not admissibility of his general causation opinion

Defendants assert that Dr. Morrison relies on opinions from the pathologists in his practice that there is an increased inflammatory response, as opposed to his own personal experience, which makes his mesh weight and pore-size opinions unreliable. (ECF No. 67 at PageID #2050.) Dr. Morrison relies on his patient's pathology results, his patients' reports of pain, and ample scientific literature in forming these opinions. (ECF No. 67-3 at PageID #2443–45, 2459–60; ECF No. 67-2 at PageID #2351, pp. 271–72.) This is enough to satisfy *Daubert*.

B. Kenneth Rudo, Ph.D.

Plaintiffs offer Dr. Rudo's opinion on the toxicological effects of perfluorooctanoic acid ("PFOA"), which he opines is found in ePTFE meshes. (ECF No. 110 at PageID #10346–47.) Defendants argue that Dr. Rudo's opinions and testimony should be excluded because he is unqualified to offer these opinions and because his opinions are irrelevant and unreliable. (ECF No. 70 at PageID #3425.) The Court agrees that Dr. Rudo's opinions are irrelevant and thus inadmissible.

Dr. Rudo's opinions about PFOA are irrelevant because they lack a connection to Plaintiffs' theory of injury or the injuries themselves. Plaintiffs' case revolves around three mechanisms causing injury: the buckling of the mesh due to the differential contracture of ePTFE and polypropylene, polypropylene exposure to bowls or other viscera, and infection related to ePTFE. Nothing in Plaintiffs' response or Dr. Rudo's report demonstrates a connection to these alleged failures in the Ventralex device. Nor do Plaintiffs demonstrate a connection between Dr. Rudo's opinions and Plaintiffs' injuries. Dr. Rudo opines that PFOA causes a litany of issues, spanning from adverse reproductive and developmental effects to cancer. (ECF No. 70-1 at PageID #3482.) Mr. Milanesi claims none of these issues as injuries.

Plaintiffs argue that Dr. Rudo's opinions are relevant to Defendants' manufacturing process and their "flagrant disregard for the public's health and safety," to Defendants' lack of testing the ePTFE layer, and to rebut MSDS opinions. (ECF No. 110 at PageID #10353–56.) But this assertion does not demonstrate that Dr. Rudo's opinion are admissible. Dr. Rudo's PFOA opinion is inadmissible character evidence, *i.e.*, propensity evidence enticing the jury to infer that because Defendants were careless in one aspect of testing, they were careless with regard to the relevant aspects of the creation and marketing of the Ventralex. *See* Fed. R. Evid. 404(b)(1). In effect, Plaintiffs are arguing that because Defendants did not test for PFOA appropriately, all of their other testing of the ePTFE is insufficient. This is impermissible. Moreover, there is no occasion for Plaintiffs to rebut any opinion about the polypropylene manufacturer's motivations to include the Medical Application Causation statement in the MSDS because any expert opinion on an entity's motivations is inappropriate. Fed. R. Evid. 702. And finally, Dr. Rudo's PFOA opinion raises serious concerns of unfair prejudice under Federal Rule of Evidence 403.

Accordingly, Dr. Rudo's opinions are inadmissible because they are irrelevant, and

Defendants' motion is granted.

IV. Conclusion

For these reasons, Defendants' motion to exclude Dr. Morrison's opinions and testimony (ECF No. 67) is **GRANTED IN PART AND DENIED IN PART**, and Defendants' motion to exclude Dr. Rudo's opinions and testimony (ECF No. 70) is **GRANTED**.

IT IS SO ORDERED.

11/2/2021
DATE

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