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-1320

EVIDENTIARY MOTIONS ORDER No. 17

Defendants C.R. Bard, Inc. and Davol, Inc. seek to exclude the opinion and testimony of Plaintiffs', Antonio Milanesi and his wife Alicia Morz De Milanesi, expert David Krpata, M.D. (ECF No. 63.) For the reasons set forth below, Defendants' motion is **DENIED**.

I. Background

Plaintiffs' case is the second bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)[1] Plaintiffs raise Florida law claims against Defendants based on the implantation of Defendants' Ventralex Hernia Patch in Mr. Milanesi. (ECF No. 15 at PageID #88–93.)

The Ventralex is a prescription medical device used for umbilical, or navel, and small

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

ventral hernia repairs. (ECF No. 57-1 at PageID #419.) The mesh has two sides—one made of polypropylene mesh and one with a permanent expanded polytetrafluoroethylene ("ePTFE") layer. (*Id.* at PageID #418.) The polypropylene mesh side faces the abdominal wall, encouraging tissue to grow into the mesh and thus supporting the hernia repair. (*Id.*; ECF No. 57-2 at PageID #437.) The ePTFE side faces the intestines and is designed to be smooth with "sub-micronal porosity," minimizing tissue attachment, such as adhesions, between the intestines and other viscera and the Ventralex. (ECF No. 57-1 at PageID #418; ECF No. 57-2 at PageID #437.) The Ventralex also has a memory coil ring, also called a monofilament ring, which was made of polyethylene terephthalate ("PET") when it was implanted in Mr. Milanesi. (ECF No. 57-5 at PageID #651.) The ring is designed to help the patch "pop open" and then "lay flat" against the abdominal wall when the Ventralex is folded and inserted through the incision site during surgical repair of the hernia. (ECF No. 57-1 at PageID #418, 422.) This feature of the Ventralex is helpful for umbilical hernia repairs because the "pop open" feature allows for a smaller surgical incision, shorter surgeries, and less implanted foreign matter, which is considered advantageous because these hernias tend to be smaller in size. (ECF No. 57-2 at PageID #437.)

The Ventralex comes in three sizes: small, medium, and large. (*Id.*) The small and medium sizes were cleared through the 510(k) premarket notification process by the Food and Drug Administration ("FDA") on July 16, 2002.[2] (ECF No. 57-5 at PageID #653–56.) Defendants listed the Composix Kugel Mesh as the predicate device. (*Id.* at PageID #656.) The large size was subsequently brought to market via "a no 510(k) rationale based upon the 510(k) for the Composix Kugel product." (ECF No. 57-8 at PageID #673.) A no-510(k) rationale is when a

[2] The 510(k) premarket approval process has been described previously in this MDL in *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 *7–8 (S.D. Ohio Oct. 20, 2020) (MIL No. 4).

510(k) application does not need to be submitted because the manufacturer has made changes that do not "significantly affect the safety or effectiveness of the device." (ECF No. 57-9 at PageID #675–76 (citation omitted).) In their surgical "Technique Guide," Defendants recommend selecting a Ventralex size "that is approximately twice the size of the hernia defect to provide sufficient coverage." (ECF No. 57-1 at PageID #419.)

Mr. Milanesi underwent a surgical repair for an approximately two-centimeter umbilical hernia on July 11, 2007. (ECF No. 57-13 at PageID #857.) Dr. Karanbir Gill, Mr. Milanesi's implanting surgeon, decided to use a large Ventralex for the repair. (*Id.* at PageID #858.) Dr. Gill considered a non-mesh, or primary, repair, but elected to use the Ventralex because there was "undue tension" on the primary repair when he initially attempted it. (*Id.*)

In April 2016, about ten years after his surgery, Mr. Milanesi experienced abdominal pain, swelling, and lack of appetite. (ECF No. 57-15 at PageID #881, pp. 66–67.) His primary care provider Dr. Miguel Gutierrez-Diaz, M.D., diagnosed him with a periumbilical, or around the navel, hernia and an incisional hernia. (ECF No. 57-16 at PageID #910.) Dr. Guiterrez-Diaz referred him to a surgeon, Dr. Michael J. Caluda, M.D. (*Id.* at PageID #912.) On May 25, 2017, Dr. Caluda diagnosed Mr. Milanesi with a recurrent entrapped ventral hernia and recommended prompt surgery. (ECF No. 57-18 at PageID #942.)

The next day, Dr. Caluda performed surgery on Mr. Milanesi. (ECF No. 57-19 at PageID #945.) He wrote in his operative notes that he had discovered not an entrapped hernia, but "purulent material" and "[a] loop of the small bowel was densely adherent to the overlying mesh and an erosion of the bowel was evident into an abscess cavity involving a portion of the mesh, which had turned to expose the polypropylene to the bowel at some point, causing an area of adherence." (*Id.*) In his deposition, Dr. Caluda clarified that he had found a fistula, "or an

abnormal connection between the intestine and other structure," which eroded into the subcutaneous space through the abdominal wall, and an infection in an abscess cavity. (ECF No. 57-17 at PageID #931.) Dr. Caluda clarified, "[t]here was definitely an opening in the abdominal wall fascia which could be construed as a recurrent hernia but more accurately should be described as part of the infectious process in the small intestinal fistula which had eroded from the abdominal cavity into the subcutaneous space." (ECF No. 87-2 at PageID #7760, pp. 36–37.) He excised the infected Ventralex from Mr. Milanesi's abdominal wall and resected the bowel, removing nine centimeters of Mr. Milanesi's small intestine. (*Id.* at PageID #6671, pp. 42–45.) Dr. Caluda described the explanted Ventralex as "firm," "not pliable," and in a "buckling" shape. (*Id.* at PageID #6672, pp. 46–47.)

Several days later, on June 1, 2017, Mr. Milanesi returned for emergency surgery because he had a high-grade post-operative small bowel obstruction. (ECF No. 57-20 at PageID #947.) This obstruction was caused by "adhesions in the right lower quadrant." (*Id.*) The adhesions were removed. (*Id.*)

Afterwards, Mr. Milanesi developed a recurrent incisional abdominal wall hernia near his previous surgery sites. (ECF No. 87-1 at PageID #6662.) He had "at least two areas of herniation extending laterally from the umbilicus in each direction." (*Id.*) The hernia defects were two and three centimeters. (*Id.*) Both Dr. Caluda and a surgeon from whom Mr. Milanesi sought a second opinion recommended surgical repair. (*Id.* at PageID #6663.) It does not appear that Mr. Milanesi has had this surgery.

The crux of Plaintiffs' claims are 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. First, they argue that

polypropylene resin oxidatively degrades *in vivo*. (ECF No. 87 at PageID #6591–92.) Defendants were aware of these risks because the Material Safety Data Sheet for polypropylene noted that the material should not be used for human implantation because it can oxidize in the body. (*Id.* at PageID #6592.) Second, Plaintiffs contend that 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."[3] (*Id.* at PageID #6594–95.) The buckling leads to some of the Ventralex patch pulling away from the abdominal wall and curving in toward the bowel, exposing the bare polypropylene side of the Ventralex to the bowel. (*Id.* at PageID #6598–99.) Plaintiffs explain that Defendants knew about this issue due to the Composix Kugel device recall for broken memory coil rings but opted to use the same size rings in the Ventralex device despite this knowledge and despite the fact that more buckle-resistant options were available. (*Id.* at PageID #6596–97.) Third, Plaintiffs argue that the ePTFE layer was prone to infection due to the ePTFE layer's small pore size, which is big enough for bacteria to grow in but too small for white blood cells to enter to intercept the bacteria. (*Id.* at PageID #6600–01.) This risk was known by Defendants' employees, as illustrated by their internal documents. (*Id.*)

The parties have now filed their dispositive and *Daubert* motions, and the motions are now ripe for adjudication, including the present motion to exclude the opinions and testimony of Dr. David Krpata.

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.*

[3] The technical name of this double-curved shape is a hyperbolic paraboloid. A popular potato chip packaged in tubes and horseback-riding saddles have the same shape.

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, 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 v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). 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 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 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.

Defendants challenge Dr. Krpata's general causation, general design defect, specific causation, warning, and allegedly disclaimed opinions. Dr. Krpata's opinions are admissible, and the Court will not address opinions that Dr. Krpata does not offer or those that Plaintiffs do not intend to offer. While Defendants do not challenge Dr. Krpata's qualifications, the Court will begin with those.

A. Qualifications

Dr. Krpata is qualified as an expert by knowledge, skill, experience, training, or education. Dr. Krpata is a board-certified general surgeon at the Cleveland Clinic and

an Assistant Professor of Surgery at the Cleveland Clinic Lerner College of Medicine in Cleveland, Ohio, and has published over seventy-five peer reviewed manuscripts and written over ten book chapters. (ECF No. 63-1 at PageID #1083.) During his residency training in general surgery at University Hospitals Case Medical Center in Cleveland, Ohio, Dr. Krpata did two years of dedicated research with a focus on abdominal wall hernias, after which he completed a one-year fellowship in abdominal wall reconstruction at the Cleveland Clinic. (*Id.*) Dr. Krpata's primary focus in his clinical practice is hernia surgery, specifically cases of complex abdominal wall reconstruction and hernia mesh infections. (*Id.* at PageID #1084.) Dr. Krpata has repaired over 1,000 hernias and has implanted a variety of mesh products and has removed approximately 300 pieces of hernia mesh. (*Id.*) Although he had practice implanting Ventralex and other mesh products containing ePTFE during his training, he has never used Ventralex or other ePTFE products in his time as a staff surgeon. (*Id.*)

B. General causation

Defendants argue that Dr. Krpata's general causation opinion is that the Ventralex poses an increased risk of causing injuries compared to other mesh devices, and that this opinion is unreliable. (ECF No. 63 at PageID #1058.) Dr. Krpata does not offer a comparative risk opinion, however, and the general causation opinion that he offers is reliable.

It is necessary to pinpoint first what opinions Dr. Krpata offers. Defendants argue that Dr. Krpata offers the opinion that the Ventralex poses an increased risk of contracture and folding over, which then causes an increased risk of certain injuries. (ECF No. 63 at PageID #1058.) Plaintiffs characterize Dr. Krpata's opinions as typical general causation

opinions, or those about whether the Ventralex design causes injury. (ECF No. 108 at PageID #9550 61.) By the Court's reading of Dr. Krpata's report and deposition testimony, he did not offer a comparative risk or rate opinion; at most, he simply responded to opposing counsel's questioning that addressed such comparative opinions.

Dr. Krpata offers typical general causation opinions in his report. Dr. Krpata concludes that ePTFE contracts leading to buckling and causing injuries. (ECF No. 63-1 at PageID #1096–1101.) The substance of these opinions read as general causation opinions, not as comparative risk opinions. Dr. Krpata mentions "increased risk" in his headings, but it is clear that he does not mean an increased risk compared to other devices. (*Id.*) Importantly, he does not make comparisons to other devices, specifically or broadly, in his report. (*See id.*) And Plaintiffs do not offer his opinion as evidence of comparative risk. (ECF No. 108 at PageID #9560–61.) With this in mind, the Court proceeds to consider whether Dr. Krpata's general causation opinions are reliable.

"Experts are permitted wide latitude in their opinions, including those opinions not based on firsthand knowledge. An expert is able to base an opinion on another expert witness for a point of expert knowledge not personally possessed." *In re E.I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig.*, 337 F. Supp. 3d 728, 743 (S.D. Ohio 2015) (citating cases); *see also Buck v. Ford Motor Co.*, 810 F. Supp. 2d 815, 844 (N.D. Ohio 2011) (reviewing published studies). Thus, 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. *E.g.*, *Monsanto Co. v. David*, 516 F.3d 1009, 1015 (Fed. Cir. 2008); *Buck*, 810 F. Supp. 2d at 844 ("However, 'the process of analyzing assembled data while using experience to interpret the data is not illicit; an expert need not actively conduct his or her own tests to have a valid methodology.'" (quoting *Phillips v.*

Raymond Corp., 364 F.Supp.2d 730, 743 (N.D.Ill.2005))); *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); *cf. Clay v. Ford Motor Co.*, 215 F.3d 663, 668–69 (6th Cir. 2000) (failure to test goes to weight not admissibility). Moreover, "[t]rained experts commonly extrapolate from existing data." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). And "[a]n expert is permitted to draw a conclusion from a set of observations based on extensive and specialized experience." *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 190 (S.D.N.Y. 2009) (quoting *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, MDL No. 1358 (SAS), No. M21-88, 2008 WL 1971538, at *6 (S.D.N.Y. May 7, 2008)).

Dr. Krpata's general causation opinion is reliable. To reach his conclusion that the Ventralex buckles due to contracture, he relies on the Novitsky *et al.* study that notes the high contraction rate of ePTFE compared to other device materials, the Tollens *et al.* article that observes the buckling phenomena, and the Berrevoet *et al.* article that addressed the buckling and shrinkage of the device. (*Id.* at PageID #1097–1101.) Dr. Krpata also relied on his personal observations as a hernia surgeon explanting devices. (*Id.* at PageID #1097.) Although no one study has specifically considered whether the Ventralex buckles because ePTFE contracts at a higher different rate than polypropylene, Dr. Krpata is permitted to extrapolate from these studies and his own experience to conclude that the Ventralex buckles because ePTFE contracts more than polypropylene, causing the well-observed buckling effect. Indeed, this is what experts are often hired to do.

Defendants' arguments to the contrary are unpersuasive. First, they turn back to

their characterization of Dr. Krpata's testimony as one of comparative risks or rates, arguing that "[t]here cannot be a causal connection between the design of the Ventralex and an injury if the same outcome can occur at the same rate with any hernia mesh device, regardless of the design." (ECF No. 63 at PageID #1059.) In medical device litigation, general causation is whether a device is "capable of causing . . . the plaintiff's alleged injury." *Madej*, 951 F.3d at 370; *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 676–77 (6th Cir. 2011). Whether other devices are more or less capable of causing certain injuries than the Ventralex does not speak to the Ventralex's capability of the same. The definition of general causation focuses on capacity, and this focus on capacity necessarily contemplates that all devices may be capable of causing an injury.

Second, Defendants argue that two circuit courts, the Eleventh Circuit, *Olmo v. Davol, Inc.*, 710 F. App'x 861 (11th Cir. 2018) (per curiam), and Seventh Circuit, *Robinson v. Davol, Inc.*, 913 F.3d 690 (7th Cir. 2019), have rejected Plaintiffs' buckling general causation theory because the experts in those cases relied mostly on their personal experience, which they could not quantify, and lacked any scientific support. (ECF No. 63 at PageID #1062.) This is not the case here. Dr. Krpata relies on scientific literature as well as his own experience. *Cf. Olmo v. Davol, Inc.*, No. 13-62260-CIV-COHN/SELTZER, 2017 WL 1367231, at *4 (S.D. Fla. Apr. 7, 2017) (concluding an expert's opinion was unreliable when he summarily stated his personal observations and he did not also rely on other data or scientific studies), *aff'd*, 710 F. App'x 861 (11th Cir. 2018) (per curiam); *Robinson v. Davol, Inc.*, 913 F.3d 690 (7th Cir. 2019).

Next, Defendants argue the studies that Dr. Krpata relies on do not measure contracture of ePTFE in ePTFE and polypropylene devices and that the focus of the

studies is recurrence, not any of the injuries in this case. (ECF No. 121 at PageID #10867–68.) In other words, Defendants argue that Dr. Krpata extrapolates too much from the studies on which he relies to form his opinion. An expert may certainly stretch his reliance on scientific literature too far, rendering his opinion "connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146. Put differently, the connection between the data and the opinion cannot be "speculative." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010). In *Tamraz*, for instance, an expert's opinion that the plaintiff's parkinsonism was caused by manganese was too speculative because the expert assumed that the disease was triggered by plaintiff's genetics (which were not tested) and exposure to welding fumes (which he assumed contained manganese). *Id.* at 670–71.

Here, Dr. Krpata's conclusions are not too far drawn as in *Tamraz*. There is no question that the Ventralex contains ePTFE and that there is scientifically sound research that ePTFE contracts more than materials like polypropylene. Moreover, the scientific literature has expressly noted that the Ventralex buckles. True, no study has expressly set out to determine whether this differential contracture causes the buckling, but Dr. Krpata draws these conclusions from multiple peer-reviewed studies. His conclusions are not so far removed from the literature that the Court would call his opinions his *ipse dixit*. Defendants' suggestion that ePTFE may behave differently when attached to polypropylene and that no study has expressly studied the buckling phenomenon (ECF No. 121 at PageID #19868) go to issues of weight suitable for cross-examination, not

admissibility.[4]

Defendants relatedly assert that Dr. Krpata's reliance on the Novitsky *et al.* paper is misplaced because the study actually undercuts Dr. Krpata's differential contracture opinion. (ECF No. 121 at PageID #10866–67.) Defendants argue that the study measured ePTFE-only devices, polypropylene-only devices, and the Composix Kugel, which has an ePTFE and polypropylene side like the Ventralex. (ECF No. 111 at PageID #10599.) The study, Defendants contend, showed high contracture for the ePTFE-only devices but not from the Composix device, which would weaken Dr. Krpata's theory. (*Id.*) That Dr. Krpata chose to draw certain inferences from Novitsky *et al.* to explain the buckling phenomena of the Ventralex even though the study contained other results that suggested a contrary conclusion does not show a lack of reliability. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 531–32 (6th Cir. 2007) ("The question of whether [an expert's] opinion is accurate in light of his use of [certain] data goes to the weight of the evidence, not to its admissibility[.]"). This is fertile grounds for cross-examination, but it does not show that Dr. Krpata's opinion is unreliable.

Finally, Defendants counter that Dr. Krpata does not connect his opinion that the Ventralex buckles due to contracture to the injuries at issue—primarily Mr. Milanesi's bowel erosion and fistula. (ECF No. 121 at PageID #10867.) Defendants do not raise this argument with regard to adhesions. Defendants are correct that the studies that Dr. Krpata relied on did not measure bowel erosion or fistula, nor does Dr. Krpata discuss the

[4] Plaintiffs argue that the Berrevoet *et al.* study does in fact measure the buckling effect, as opposed to reoccurrence. (ECF No. 108 at PageID #9552–53.) This does not wash. Berrevoet clearly notes hernia recurrence in addition to buckling, and that a confirmed lack of hernia defect was made at the time of implant, not subsequent surgery. (ECF NO. 108-6 at PageID #9661.)

risk of injury from the buckling in much detail besides noting in his personal experience that ePTFE meshes result in fistulas. (ECF No. 63-2 at PageID #1220, p. 316.) However, Dr, Krpata need not supply every link in the chain of Plaintiffs' theory of the case for his opinion to be relevant. *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536456, at *3 (S.D.W. Va. Aug. 30, 2016) ("A single expert need not provide all the pieces of the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case."). The mechanism of Plaintiffs' theory of injury is the buckling caused by contracture, thus exposing bare polypropylene to the viscera, and Dr. Krpata's opinion addresses the first step of this mechanism. Dr. Krpata briefly notes that bare polypropylene causes adhesion, fistula, and erosion into the viscera (ECF No. 63-1 at PageID #1093, 97), but other experts opine on polypropylene degradation and its effects, including the injuries in this case. (*See, e.g.*, ECF No. 64-2 (expert report of Dr. Babensee); ECF No. 105 at PageID# 9146 (discussing Dr. El-Ghannam's report regarding this case).[5]

C. General design defect opinions

Next, Defendants challenge what they describe as Dr. Krpata's general design defect opinions. Dr. Krpata opines that the Ventralex buckles due to contracture and that this buckling is exacerbated by a weak memory recoil ring. (ECF No. 63 at PageID #1063–71.) Part of Dr. Krpata's theory of defect is also that the Ventralex is designed in a way that leads to "unavoidable technical errors" during insertion, such as that the ring

[5] Defendants raised this argument for the first time in their reply brief, meaning that Plaintiffs have not yet had an opportunity to respond. Though the ability of the Court to revisit issues raised in a motion in limine indicates that arguments are not forfeited when they are not raised in the party's main brief, fairness counsels waiting until both parties have been heard in all meaningful respects before excluding evidence.

cannot completely unfurl during implantation and cannot withstand contracture. (ECF No. 63-1 at PageID #1101.) Defendants primarily argue that Dr. Krpata's general design defect opinion with regard to the unavoidable technical errors is irrelevant and that his other general design defects lack reliable scientific support and are not based on sufficient facts or data. (ECF No. 121 at PageID #10872, ECF No. 63 at PageID #1063, 1066.) Dr. Krpata's opinions are relevant and reliable because they have sufficient scientific support and are based on sufficient facts or data.

1. Relevance

Defendants argue that Dr. Krpata's opinion that the design of the Ventralex causes unavoidable technical error is irrelevant because there is no connection between the opinion and Mr. Milanesi's case and because Dr. Krpata's opinion focuses on the state of the art after the pertinent time period. Neither argument is convincing.

First, Defendants assert that there is no record evidence connecting this opinion to the facts of Mr. Milanesi's case. (ECF No. 121 at PageID #10873.) It is true that neither Dr. Krpata nor Mr. Milanesi's implanting surgeon, Dr. Gill, opined that there was an error during implantation. However, the point of this design defect opinion is that the error is inherent to the Ventralex, and hence "unavoidable." Indeed, the nature of the unavoidable technical error identified by Berrevoet *et al.* is that when a surgeon folds the Ventralex and inserts it in the small incision and then attempts to clear any possible adhesions under the fascia and around the incision, the surgeon cannot assess whether the Ventralex has properly sprung open and whether all adhesions have been cleared. (ECF No. 108-6 at PageID #9663.) Because Mr. Milanesi received the Ventralex device, the unavoidable-technical-error design defect opinion is relevant to this case. *See In re Standard Jury*

Instructions in Civil Cases—Report No. 13-01 (Prods. Liab.), 160 So.3d 869, 874 (Fla. 2015) (mem.) (describing a design defect as "defective because of a design" and defining manufacturing defect as a defect "different from its intended design").

Second, Defendants assert that a defective design must be considered defective at the time of manufacture, and that because the study in Berrevoet *et al.* was not conducted until after Mr. Milanesi's surgery, Dr. Krpata's unavoidable-technical-error opinion based on that study is inadmissible. (ECF No. 121 at PageID #10873.) Florida law provides that "[i]n an action based upon defective design, brought against the manufacturer of a product, the finder of fact shall consider the state of the art of scientific and technical knowledge and other circumstances that existed at the time of manufacture, not at the time of loss or injury." Fla. Stat. § 768.1257. Succinctly put, evidence about state of the art technology is restricted to evidence of what the state of the art was at the time of manufacture. *Sta-Rite Indus. v. Levey*, 909 So.2d 901, 904 (Fla. Dist. Ct. App. 2004) (discussing whether technology was available at the time of product design); *Eghnayem v. Bos. Sci. Corp.*, No. 1:14–cv–024061, 2016 WL 4051311, at *4 (S.D. Fla. Mar. 17, 2016). Dr. Krpata's opinion relying on the Berrevoet *et al.* study is simply not state-of-the-art evidence. For example, the study does not suggest that the ring in the Ventralex was not the best technology available, nor does it point to an alternative type of design that was not feasible at the time. *Sta-Rite Indus.*, 909 So.2d at 904 (alternate design); *Eghnayem*, 2016 WL 4051311, at *4–5 (technology available). The study only contends that the technology in the Ventralex at the time it was manufactured contains a defect—the weak ring. The Florida statute does nothing to prevent Dr. Krpata from relying on scientific literature studying the Ventralex that identifies a defect, which

necessarily will be published after the Ventralex was manufactured. *Kaufman v. Wyeth, LLC*, No. 1:02–CV–22692, 2011 WL 10483576, at *6 (S.D. Fla. Aug. 15, 2011) (explaining that the Florida statute allows a device manufacturer "to show that its design of the product was state-of-the-art and, therefore, not defective since it complied with the best known and available technology").

2. Reliable scientific support

This challenge to Dr. Krpata's design defect opinions is a more typical challenge to general causation. As explained above, the issue is whether the Ventralex was capable of causing Mr. Milanesi's injuries. This inquiry requires consideration of whether the defects, the injury-causing mechanisms, of the Ventralex are capable of occurring. For this reason, the Court's above analysis is applicable here; Dr. Krpata relied on scientific literature and his own personal experience to conclude that the Ventralex buckled due to contracture. *Supra* Part III.A. And Dr. Krpata's opinion that the memory recoil ring is too weak to resist buckling and leads to "unavoidable technical errors," that the ring cannot completely unfurl during implantation, finds support in the Berrevoet *et al.* study. (ECF No. 63-1 at PageID #1101.) Defendants argue that Berrevoet *et al.* "did not make any observations of the ring" or "of changes in the body after implantation" "as it relates to Dr. Krpata's 'buckle' theory." (ECF No. 121 at PageID #10871.) This is an iteration of their earlier argument that no study has yet to specifically test Dr. Krpata's theory. Dr. Krpata is permitted to extrapolate from scientific research, given his expertise in this area, to conclude that a weak ring would contribute to the inability of the Ventralex to withstand buckling. *Supra* Part III.A. Although the authors did not specifically test the strength of the ring, they still observed during the course of the study that the ring appeared to be too

weak. (ECF No. 108-6 at PageID #9659–63.) Moreover, this was not a casual observation—the authors of the study went so far as to recommend to Bard that the ring should be reinforced. (*Id.* at PageID #9663.)

Defendants offer a number of counterarguments. They again focus on Dr. Krpata's comparative risk opinion about buckling and contracture (*id.* at PageID #1063–64), which has already been considered. *Supra* Part III.A. Defendants also contend that Dr. Krpata did not consider that all devices contract to some degree after implantation and that the force of contracture would have been sufficient to peel the mesh from the abdominal wall. (*Id.* at PageID #1064–65.) This does not demonstrate that Dr. Krpata's opinions lack scientific support, only that there are weaknesses to Dr. Krpata's theory that can be addressed at trial. Defendants also argue Dr. Krpata's ring opinions that rely on Berrevoet *et al.* are unreliable because the study population was small, as were the number of cases that saw buckling of the Ventralex. (ECF No. 121 at PageID #10874.) These critiques go to the weight of Dr. Krpata's opinion, not whether it is reliable enough to be admitted during trial.

3. Sufficient facts and/or data

Next, Defendants argue that Dr. Krpata's general opinions on defective design, specifically that the Ventralex is prone to buckle, are not based on sufficient facts or data. (ECF No. 63 at PageID #1066.) In support of this argument, Defendants point to Dr. Krpata's reliance on Defendants' internal documents, documents created after Mr. Milanesi's surgery, documents addressing the Composix Kugel, and audit documents. (*Id.* at PageID #1067–71.) Despite these arguments, the Court concludes that Dr. Krpata's opinions are based on sufficient facts and data.

Internal documents. Experts are often permitted to consider "internal documents, and other medical and scientific literature." *Trevino v. Bos. Sci. Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at *19 (S.D.W. Va. May 19, 2016); *see, e.g.*, *Hosp. Auth. of Metro. Gov't of Nashville & Davidson Cnty. v. Momenta Pharms., Inc.*, 333 F.R.D. 390, 402 (M.D. Tenn. 2019). And as this Court has explained, "an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible." *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 *11 (S.D. Ohio Sept. 1, 2020) (quoting *Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *4 (S.D.W. Va. Sept. 29, 2014)) (Evidentiary Motions Order ("EMO") No. 5). As discussed *supra*, Dr. Krpata relies on his review of scientific and medical literature and his personal experience in addition to his review of Defendants' internal documents to formulate his buckling opinions. *See In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187, 2018 WL 4220602, at *4 (S.D.W. Va. Sept. 5, 2018) (explaining an expert may rely on "internal documents to develop and reinforce his opinions"). This is sufficient.

Defendants contend that Dr. Krpata misinterprets the meaning of their internal documents. (*Id.* at PageID #1067–68 & n.8.) For example, one document allegedly addressed a pre-market model of the Ventralex (*id.* at PageID #1067) and the documents do not use the term "buckle" to refer to the same phenomenon as Dr. Krpata—the potato-chipping Ventralex (ECF No. 121 at PageID #10881). The usefulness of pre-market model information and the information that can be drawn from these internal documents is a matter of Dr. Krpata's interpretation, and ultimately the jury. "It is not the district

court's role under *Daubert* to evaluate the correctness of facts underlying an expert's testimony." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 856 (Fed. Cir. 2010) (concluding that an expert's reliance on the defendants' internal documents, along with other data, constituted sufficient data). During cross-examination, Defendants will be able to assess whether Dr. Krpata understood the context of the internal documents.

Defendants also argue that Dr. Krpata has no experience reviewing corporate documents, specifically an internal memorandum. (ECF No. 63 at PageID #1067–68; 1070–71.) At the most, the internal documents are scientific documents and at the least are correspondence. Given Dr. Krpata's medical training and experience, it is unclear how additional or different experience reviewing corporate documents would aid his interpretation of these documents. *See In re C.R. Bard, Inc.*, 2018 WL 4220602, at *4 (noting an expert's qualifications on the subject matter of the internal documents).[6] Defendants do not explain what training or education Dr. Krpata lacks to be qualified of reading and pulling information from these documents.

Defendants then insist that Dr. Krpata did not follow a reliable methodology in reviewing these internal documents because the documents were cherry-picked by Plaintiffs' counsel. (*Id.* at PageID #1067–68; 1070–71.) But as this Court has concluded before in response to this argument, this goes to the weight of Dr. Krpata's testimony, not its admissibility. And "'[w]here the reliability of the evidence is in dispute, it is more appropriate for a judge to admit the evidence than to keep it from the fact-finder because

[6] Defendants argue that Dr. Krpata inappropriately relies on a study addressing contracture of ePTFE and an email to conclude that ePTFE contracts more than polypropylene. (ECF No. 63 at PageID #1068.) As explained earlier, Dr. Krpata permissibly extrapolates from scientific literature addressing this topic. *Supra* Part III.A. That Dr. Krpata also cites to the email is an issue for cross-examination.

"[v]igorous 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."'" *Little Hocking Water Ass'n, Inc.*, *v. E.I. du Pont de Nemours & Co.*, 90 F. Supp. 3d 746, 752 (S.D. Ohio 2015) (quoting *Daubert*, 509 U.S. at 596).

Last on this point, Defendants argue that Dr. Krpata cannot rely on internal documents to offer a state-of-mind opinion. (ECF No. 63 at PageID #1070.) Dr. Krpata does not appear to rely on any internal documents to offer state-of-mind opinions, nor do Defendants identify any specific documents. Accordingly, there is no need to reach this issue.

Postdated documents. Next, Defendants argue that Dr. Krpata cannot rely on any documents postdating Mr. Milanesi's implantation surgery. (ECF No. 63 at PageID #1068.) Defendants specify that the documents "would not have been available to Bard in 2007 and cannot therefore provide a basis for what Bard did or did not know at the time, or what should or should not have been in the Ventralex IFU in 2007." (*Id.* at PageID #1068–69.) But Dr. Krpata cannot offer an opinion on Defendants' knowledge in the first place. *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (holding that experts cannot offer testimony about a corporation's knowledge); *see also In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004). And as explained earlier, an expert may rely on information postdating the manufacture or implant of a device so long as the information does not suggest that the state of the art was more advanced at the time of manufacture or implant. *Supra* Part III.A.1. Defendants must do more than simply point to postdated documents and research.

Documents considering unrelated devices. Defendants also assert that Dr. Krpata

cannot rely on documents addressing devices that are unrelated to the Ventralex. (ECF No. 63 at PageID #1068.) The documents that Defendants claim are unrelated to the Ventralex are those pertaining to the Composix Kugel ring breaks. (ECF No. 63 at PageID #1069.) Defendants understate the connection between the Ventralex and the Composix Kugel. The Composix Kugel is the predicate device for the Ventralex under the FDA's 510(k) process. (ECF No. 57-5 at PageID #656.) Therefore, when Defendants filed their 510(k) application for the Ventralex, they pointed to the Composix Kugel as the device to which the Ventralex is substantially equivalent, justifying a 510(k) premarket submission as opposed to the more rigorous Premarket Approval. *See 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 *7 (S.D. Ohio Oct. 20, 2020) (Motions in Limine Order ("MIL") No. 4); Premarket Notification 510(k), U.S. Food & Drug Administration, https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k (last updated Mar. 13, 2020). As Dr. Krpata points out in his report while quoting Defendants' 510(k) application, "the Composix Kugel Patch products have the same design and materials as the proposed large Ventralex Patch," including the memory recoil ring and excepting the Ventralex's positioning straps. (ECF No. 63-1 at PageID #1098.) Dr. Krpata offers an opinion that the ring in the Ventralex was too weak, and whether a ring bends or breaks are both questions about ring strength. This is sufficient for relevance. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-1509, 2:18-md-2846, 2021 WL 2643107, at *4 (S.D. Ohio June 28, 2021) (relying on a device's predicate status to determine relevance) (MIL No. 12). Accordingly, Dr. Krpata's reliance on these documents does not render his opinion regarding ring strength unreliable.

Audit documents. Defendants next claim that Dr. Krpata's reliance on Defendants' audit

renders his opinions unreliable because he lacks the appropriate experience to review the documents and fails to show how the documents support his design defect theory. (ECF No. 63 at PageID #1070.) Dr. Krpata opines that the Ventralex's memory recoil ring "contributes to the buckling of the device." (ECF No. 63-1 at PageID #1098.) He points to the external and internal audits to show that design specifications for the rings inadequately addressed buckling. (*Id.* at PageID #1099.) It is apparent that Dr. Krpata relies on the failure of the design specifications to account for the ring strength to support his conclusion that the inadequate strength of the memory recoil ring contributed to its defective design. Defendants provide no reason why Dr. Krpata is unqualified to read and draw information from the audits in forming his opinion. Defendants point to Dr. Krpata's deposition as evidence of his lack of pertinent experience with audits (*id.*), but Dr. Krpata only admitted that he had no experience conducting mock audits himself (ECF No. 63-2 at PageID #1242, p. 405). This provides no basis for Defendants' argument.

D. Specific causation opinions

Defendants contest Dr. Krpata's specific causation opinions for Plaintiffs' design defect claim, *i.e.,* that the Ventralex caused Plaintiffs' injuries in this case. (ECF No. 63 at PageID #1071.) Defendants argue that Dr. Krpata gave deposition testimony negating his specific causation opinion, that his differential diagnosis is unreliable, and that his other specific-causation opinions are unreliable and irrelevant. (*Id.* at PageID #1071– 72, 1076.)[7] The Court disagrees.

First, Defendants argue that Dr. Krpata's deposition testimony that another device may not have prevented Mr. Milanesi from developing a fistula negates Dr. Krpata's

[7] Defendants argue that the risk-utility test applies to design defect claims under Florida law. (ECF No. 1071 & n.10.) It is unnecessary to reach this question on this *Daubert* motion, so the Court reserves its judgment on this issue.

opinion that the Ventralex actually caused Mr. Milanesi's fistula. (*Id.* at PageID #1072.) During his deposition, Dr. Krpata declined to provide a figure of risk comparison between the Ventralex and other devices, specifically regarding the risk of fistula. (ECF No. 63-2 at PageID #1194, p. 212–13.) Defendants state that under Florida law, this means Dr. Krpata's opinion does not aid the jury (ECF No. 63 at PageID #1072), which the Court presumes refers to Defendants' assertion that "[t]here cannot be a causal connection between the design of the Ventralex and an injury if the same outcome can occur at the same rate with any hernia mesh device." (ECF No. 63 at PageID #1059.) Defendants repeat their argument that Dr. Krpata must show that the Ventralex presents increased risks in relation to other devices, which the Court rejected. *Supra* Part III.A.

Next, Defendants argue that Dr. Krpata's specific causation opinion is unreliable because his differential diagnosis is not reliable. (ECF No. 63 at PageID #1072.) A differential diagnosis is a sufficiently reliable specific-causation opinion "when a doctor: '(1) objectively ascertains . . . the nature of the patient's injury'; '(2) "rules in" . . . causes of the injury using a valid methodology'; and '(3) engages in "standard diagnostic techniques by which doctors normally rule out alternative causes" to reach a conclusion as to which cause is most likely.'" *United States v. Davis*, 970 F.3d 650, 660 (6th Cir. 2020) (quoting *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 179 (6th Cir. 2009)). To satisfy the third prong, the expert "must provide a reasonable explanation" for his conclusion that an alternative cause "'was not the sole cause'" of the plaintiff's injury. *Best*, 563 F.3d at 179 (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 758 n.27 (3d Cir. 1994)). Defendants claim that Dr. Krpata did not adequately rule out Dr. Gill's operative decision to use a large-sized Ventralex because he did not give a reasonable

explanation. (*Id.* at PageID #1073–74.) This is not supported by Dr. Krpata's testimony.

During his deposition, Dr. Krpata gave a reasonable explanation of why he ruled out that Dr. Gill's choice of patch size caused Mr. Milanesi's injuries. Dr. Krpata explained that three centimeters of overlap by a mesh patch on either side of a defect is the standard from the American Hernia Society and that to achieve that degree of overlap for Mr. Milanesi, Dr. Gill should have selected the large Ventralex patch. (ECF No 63-2 at PageID #1255–56, pp. 457–58.) Dr. Krpata clearly reiterated that Dr. Gill's choice of patch did not cause Mr. Milanesi's injuries. (*Id.* at PageID #1256, p. 460.) Dr. Krpata's explanation demonstrates that he adequately ruled out the size of patch while forming his specific causation opinion.

None of Defendants' arguments to the contrary is persuasive. Defendants argue that Dr. Krpata does not offer a reasonable explanation, only a statement that he disagrees with Defendants' size guide, which indicates that a small- or medium-sized Ventralex was most appropriate based on the size of Mr. Milanesi's defect. (ECF No. 63 at PageID #1075.) It is true that Dr. Krpata disagrees with these guidelines, but Defendants ignore his explanation on redirect. Defendants also point to a litany of complications from using a Ventralex patch that is bigger than they recommend. (*Id.* at PageID #1073–74.) This simply shows that Defendants disagree with Dr. Krpata and that there is room for disagreement regarding the proper selection of patch size. This is insufficient to render his opinion unreliable, and this issue is best saved for trial.[8]

[8] Defendants filed a supplemental brief addressing the proprietary of Plaintiffs relying on James Keegan's deposition regarding the meaning of the size recommendations in the IFU when Keegan had not yet been fully deposed. (ECF Nos. 140, 143.) Defendants admit that Keegan's deposition "does not affect the admissibility of Dr. Krpata's challenged opinions (ECF No. 121 at PageID #10886 n.16). Accordingly, there is no need to address this issue at this time.

Defendants also contend that Dr. Krpata is unqualified due to his lack of experience with using the Ventralex, rendering his differential diagnosis unreliable. (ECF No. 63 at PageID #1074–76; ECF No. 121 at PageID #10855.) As an initial matter, Dr. Krpata's qualifications do not speak to the reliability of his opinions; they are separate considerations under *Daubert*. *Supra* Part III. Regardless, Dr. Krpata is qualified to offer his specific causation opinions. Dr. Krpata is a hernia surgeon; he completed a one-year fellowship in abdominal wall reconstruction and specializes in "managing cases of complex abdominal wall reconstruction, mesh infections, and chronic groin pain after inguinal hernia repairs. (ECF No. 63-1 at PageID #1083.) He has repaired over 1,000 hernias in his career and has implanted synthetic, biologic, and bioabsorbable mesh devices, including the Ventralex mesh. (ECF No. 63-1 at PageID #1084.) Dr. Krpata has also explanted approximately 300 devices, most which he estimates at least had one component of ePTFE in it. (*Id.*) True, Dr. Krpata has not used the Ventralex or an ePTFE based mesh since his surgical training. (*Id.*) But Dr. Krpata certainly has the qualifications that "provide a foundation for" Dr. Krpata to opine on whether the size of Mr. Milanesi's Ventralex could be ruled out as a cause of his injury, specifically that three centimeters of overhang is preferred in hernia repair surgeries. *Madej*, 951 F.3d at 370 (quoting *Berry*, 25 F.3d at 1351). That Dr. Krpata does not regularly use the Ventralex speaks to the weight of his testimony, but not its admissibility under *Daubert*. *Mannino*, 650 F.2d at 851 ("[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.").

Finally, Defendants aver that Dr. Krpata's "case-specific opinion on defective

design is not reliable." (ECF No. 63 at PageID #1076.) It is unclear what a "case-specific opinion" is other than specific causation —whether this Ventralex device caused Mr. Milanesi's injuries. Defendants claim that Dr. Krpata does not sufficiently connect the defects that he discusses to Mr. Milanesi's device, specifically that the mere fact that Ventralex was "not flat" is insufficient. (*Id.*) Dr. Krpata has already offered a sufficient specific causation opinion by offering a reliable differential diagnosis. (ECF No. 63-1 at PageID #1109.) Defendants also point to a variety of other surgical errors that Dr. Gill could have made, such as bowel contact at the time of surgery. (ECF No. 63 at PageID #1076.) This possible cause should be analyzed along with the rest of Dr. Krpata's differential analysis. Dr. Krpata concluded that Dr. Gill did not make any surgical errors based on his review of the operative report, which he could assume would include any significant events or complications. (ECF No. 63-1 at PageID #1108.) This is sufficient.

Defendants focus on the fact that Dr. Krpata expressed during his deposition that he does not generally agree with the intraperitoneal approach to surgical hernia repair using ePTFE and polypropylene meshes, as with the Ventralex device. (ECF No. 63 at PageID #1077.) Defendants argue that this "fundamental[ ]" disagreement means that Dr. Krpata cannot deliver a reliable opinion regarding the risks and benefits of the Ventralex device. (*Id.*) That Dr. Krpata has a professional opinion that the Ventralex and the surgery used to implant it is objectionable does not render his opinions unreliable. Defendants even urge the Court to consider that "every other physician to testify in this case . . . agreed that there were benefits to the Ventralex." (*Id.*) Disagreement with an expert "is not grounds for exclusion." *North v. Ford Motor Co.*, 505 F. Supp. 2d 1113, 1118 (D. Utah 2007). This is very clearly an issue of the weight of Dr. Krpata's opinions

and testimony for the jury—not one of a reliability and thus admissibility for this Court. Defendants may draw out Dr. Krpata's professional biases for the jury's consideration, but what Defendants present to the Court in support in this argument falls much too short of demonstrating that Dr. Krpata's opinions lack reliability.

E. Warning opinions

Next, Dr. Krpata's warning opinions. Defendants argue that Dr. Krpata is unqualified to opine whether a warning was adequate, that his warning opinions are unreliable, and his opinions are irrelevant. (ECF No. 63 at PageID #1077–79.) Dr. Krpata is qualified to offer his warning or IFU opinions, which are both reliable and relevant.

First, qualifications. Dr. Krpata is qualified to offer his warning or IFU opinions. It is well-established in this MDL "that experts may offer opinions about whether the warnings sufficiently apprised medical doctors of the risks of the [device at issue] from the vantage point of the end-user" if the expert opining has "some on-point experience, such as conducting hernia surgeries with mesh devices." *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 2643110, at *5 (S.D. Ohio June 28, 2021) (EMO No. 13). Defendants argue that Dr. Krpata is unqualified because he was not practicing in 2007 and does not use the Ventralex himself. (ECF No. 63 at PageID #1078.) This goes to the weight of Dr. Krpata's testimony, however, not its admissibility. *In re Davol, Inc.*, 2020 WL 6605542, at *16 ("Bard's contention that Dr. Grischkan has never used the product goes to the weight of Dr. Grischkan's opinion, rather than admissibility.") (EMO No. 5). Defendants appear to frame this argument as one against Dr. Krpata offering an opinion about the legal adequacy of the IFU (ECF No. 63 at PageID #1077), which is improper.

In re Davol, Inc., 2021 WL 2643110, at *5 (EMO No. 13). But Dr. Krpata was clear in his deposition that he intended to offer his "opinion as a surgeon who is an intended end user," not a legal or regulatory sufficiency opinion. (ECF No. 63-2 at PageID #1208, p. 267.)

Next, reliability and relevance. Defendants again focus on Dr. Krpata's usage of the word "increase" in his report, arguing that Dr. Krpata cannot offer his IFU opinion because he initially failed to support his increased-risk-of-contracture theory. (ECF No. 63 at PageID #1078.) They also assert that because Dr. Krpata cannot give a comparative rate of risks or injuries between the Ventralex and other devices, any IFU opinion would be unhelpful to the jury. (*Id.* at PageID #1078–79.) As stated before, Dr. Krpata does not offer comparative-risk opinions in his report, even if he did so on cross-examination during his deposition. *Supra* Part III.A. The Court also finds that Dr. Krpata's IFU opinions are useful to the jury. He states that "[t]he IFU informs the surgeons that the listed complications are 'possible' and fails to inform the surgeon that certain adverse reactions are at an increased probability due to the design of the device." (ECF No. 63-1 at PageID #1104.) This information is certainly helpful to the jury, even without a comparative rate of risks.

Defendants resurrect their argument that Dr. Krpata's opinions are unreliable insofar as they rely on studies published after the manufacture and distribution of Mr. Milanesi's Ventralex. (ECF No. 121 at PageID #10875.) Florida law requires that a particular risk be "known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." *Ferayornia v. Hyundai Motor Co.*, 711 So.2d 1167, 1172 (Fla. Dist. Ct.

App. 1998) (quoting *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 558–59 (Cal. 1991)). But again, this does not translate to a per se rule against any evidence postdating the events of this case. *Supra* Part III.B.2. Defendants do not identify anything particular about the conclusions drawn in Berrevoet *et al.* and Tollens *et al.* articles that were neither known nor knowable in the relevant timeframe.[9]

Defendants also reiterate their summary judgment arguments regarding Plaintiffs' failure to warn claim. They argue that Dr. Krpata's IFU opinions are irrelevant because under Florida law, the inquiry is whether the manufacturer warned of the risk of injury, not the specific defects, or mechanism in a device that allegedly causes the injury. (ECF No. 121 at PageID #10886.) Dr. Krpata opines that the Ventralex IFU does not address the buckling of the device, which he concludes can lead to patient bowel exposure to bare polypropylene. (ECF No. 63-1 at PageID #1104.) Defendants also argue that Plaintiffs lack evidence of proximate cause. (ECF No. 121 at PageID #10887.) Defendants raise the same arguments regarding Dr. Krpata's IFU opinion, albeit with a handful of more recent citations, and general lack of causation in their motion for summary judgment. (*Compare id.* at PageID #10886–87 *with* ECF No. 57 at PageID #401–408 (arguing that "Plaintiffs cannot establish an inadequacy by pointing to the omission of a hypothetical mechanism for injury, like 'buckling' or 'differential contracture'").) Accordingly, the Court reserves its

[9] Defendants also argue that Dr. Krpata does not offer an IFU opinion that pertains to "unavoidable technical failures," and that Plaintiffs attempt to put words in Dr. Krpata's mouth and connect Dr. Krpata's IFU opinion to the two aforementioned studies. (ECF No. 121 at PageID #10876.) The Court disagrees with Defendant's characterization of Plaintiffs' briefing. There is no mention of unavoidable technical errors in Plaintiffs' IFU section (ECF No. 108 at PageID #9567–69) and in the instances where Plaintiffs reference the studies and/or unavoidable technical errors alongside the IFU, they do so while addressing their design defect arguments (*e.g.*, *id.* at PageID #5555). Accordingly, the Court gives no opinion on this matter.

judgment on these arguments for its adjudication of Defendants' motion for summary judgment.[10] *Jackson*, 194 F. Supp. 3d at 1008 (explaining that a motion in limine should not be "used as a substitute for a motion for summary judgment").

Finally, Defendants argue that Dr. Krpata cannot offer state-of-mind opinions in relation to the Ventralex's IFU. (ECF No. 121 at PageID #10887.) Defendants point to Dr. Krpata's report where he states that "Bard downplays those risks [of the Ventralex] by predicating the listing [of risks] with "possible complications include" and then listing them without any additional information indicating to the surgeon the degree, likelihood, or mechanism of failure associated with the risk." (ECF No. 63-1 at PageID #1104.) Defendants insist that Dr. Krpata will offer this as a state-of-mind opinion based on his unwillingness to back away from the word "downplays" during his deposition. (ECF No. 121 at PageID #10887.) The Court is unconvinced that Dr. Krpata's use of the word "downplay" on its own conveys Defendants' corporate intent or state of mind. In response to defense counsel's question whether Dr. Krpata was referring to Defendants' state of mind by using the word "downplay," Dr. Krpata replied that he was "speaking as a surgeon who has reviewed the internal documents that were provided that if the company is aware that there's an issue and it's not getting reported on an IFU with the potential adverse reaction, I would be concerned." (ECF No. 63-2 at PageID #1245, p. 414.) He went on to explain that he would still be concerned "whether or not I know if [Defendants] were aware or not aware." (*Id.* at p. 415.) At this time, it does not appear that Dr. Krpata will offer an otherwise inadmissible corporate state-of-mind opinion, and

[10] On a minor note, Defendants argue that Dr. Krpata cannot testify in relation to what Dr. Gill would have done with a different IFU. (ECF No. 63 at PageID #1079.) Plaintiffs do not appear to dispute this and argue that Dr. Krpata acknowledged during his deposition that Dr. Gill must be the one to offer such an opinion. (ECF No. 108 at PageID #9568–69.)

so the Court declines to exclude this portion of his report and testimony.

F. Disclaimed opinions & unoffered opinions

Defendants conclude by arguing that any opinions that Dr. Krpata expressly disclaimed should be excluded and that Dr. Krpata should not be permitted to testify regarding topics he did not opine upon. (ECF No. 63 at PageID #1079.) Plaintiffs agree, contending that any Court order excluding such opinions is unnecessary because they recognize that an attempt to elicit such opinions is improper. (ECF No. 108 at PageID #9569.) Accordingly, the Court will not decide a non-existent dispute.

IV. Conclusion

For the reasons set forth above, Defendants' Motion to Exclude the Testimony of Plaintiffs' Expert David Krpata M.D. (ECF No. 63) is **DENIED**.

IT IS SO ORDERED.

10/5/2021
DATE

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