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 OPINION AND ORDER No. 22

Before the Court are Plaintiffs' Motions to Exclude the Opinions and Testimony of Defense Expert Witnesses Zachary L. Gleit, M.D., F.A.C.S. (ECF No. 74) and George Kevin Gillian, M.D. F.A.C.S. (ECF No. 77). For the reasons below, Plaintiffs' motions are **GRANTED IN PART AND DENIED IN PART.**

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.

Plaintiffs challenge the opinions of Dr. Zachary L. Gleit, M.D., F.A.C.S. and Dr. George Kevin Gillian, M.D., F.A.C.S.

A. Zachary L. Gleit, M.D., F.A.C.S.

Dr. Gleit is a hernia surgeon offered by Defendants to respond to Plaintiffs' buckling theory and to provide alternate theories of causation. (ECF No. 95 at PageID #7878; *see also* ECF No. 95-1 at PageID #7910–12.) Dr. Gleit offers opinions specific to this case, including opinions that pertain to the Ventralex device and Mr. Milanesi's injuries. (ECF No. 95-1 at PageID #7907–10.) Plaintiffs challenge the reliability of Dr. Gleit's opinions that the implanting surgeon selected a Ventralex that was "too large" and "too floppy; that the implanting surgeon, Dr. Karanbir Gill, used poor technique and obesity contributed to Mr. Milanesi's complications; that there is no support for Plaintiffs' buckling theory; and that other devices and procedures would have caused the same outcome. (ECF No. 74 at PageID #3942–50.) Except for Dr. Gleit's opinions that other devices and procedures would have caused the same outcome, Dr. Gleit's opinions are reliable.

1. Size opinions

Plaintiffs argue that Dr. Gleit's opinion that Dr. Gill selected a large Ventralex that was "too large" and "too floppy" is unreliable because Dr. Gleit does not cite to specific experience, literature, or documents. (ECF No. 74 at PageID #3942.) Plaintiffs also challenge Dr. Gleit's interpretation of the Ventralex's Technique Guide. (*Id.*) Dr. Gleit's opinions are reliable, and Plaintiffs' arguments amount to mere disagreement with his conclusions.

As this Court has concluded before, "it is 'well-established that experience-based testimony satisfies Rule 702 admissibility requirements." *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 6605612, at *13 (S.D. Ohio Sept. 11, 2020) (quoting *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d 897, 902 (S.D. Ohio 2015)) (Evidentiary Motions Order ("EMO") No. 7). Dr. Gleit's opinion is sufficiently reliable because it draws on his personal experience as a hernia surgeon and explains how he arrived at his conclusions, making his opinion more than an *ipse dixit*. He explains that a hernia mesh patch that is too large is challenging to place through a small incision. (ECF No. 95-1 at PageID #7909.) He continues that in his experience, a small opening makes it difficult for the patch to lay flat and to work through a small hole without a line of sight. (*Id.* at PageID #7907.) This is compounded by the fact that the mesh is only anchored at the margins of the hernia defect, which is in the middle of the patch. (*Id.* at PageID #7908.) Dr. Gleit also explains that design choices, such as the memory coil ring, attempt to address these issues, but that there are trade-offs in selecting a mesh like this, and that for this reason, a patch that is not too large should be selected. (*Id.* at PageID #7907–08.) To support his opinion, he notes the Ventralex's Instructions for Use ("IFU") that says a patch should be selected that is twice the size of the hernia defect. (*Id.* at 7910.) After explaining all of this, he concludes

that Mr. Milanesi was a victim of these trade-offs because the Ventralex was too large; his hernia defect was two centimeters, but Dr. Gill selected an eight-centimeter patch. (*Id.* at PageID #7910, 7912.) In other words, instead of picking a patch twice the size, Dr. Gill picked a patch four times the size of Mr. Milanesi's hernia.

Plaintiffs counter that these opinions contradict the IFU, do not rely on internal documents, and are contrary to some published literature. (ECF No. 74 at PageID #3943–46.) The IFU notes that a hernia patch should be selected that is twice the size of the defect, but also explains that the objective is sufficient coverage—as Plaintiffs emphasize. (*Id.* at 3944.) Whether the appropriate interpretation of the IFU emphasizes the recommendation that the patch be twice the size of the defect or the purpose behind the recommendation, sufficient coverage, is an issue of fact for the jury. As for the fact that Dr. Gleit did not review certain internal materials, this goes to the weight of Dr. Gleit's opinions, not their reliability. Finally, Dr. Gleit did not ignore contrary scientific evidence, which would make his opinion unreliable. *See Sanchez v. Bos. Sci. Corp.*, 2:12-cv-05762, 2014 WL 4851989, at *11 (S.D.W. Va. Sept. 29, 2014). In his deposition, Dr. Gleit explained his disagreement with the articles Plaintiffs identify. (*E.g.*, ECF No. 95-2 at PageID #7930, pp. 178–81.)

Plaintiffs also argue that Dr. Gleit lacks sufficient knowledge and training to convey an experienced-based opinion with the requisite degree of reliability under *Daubert*. (ECF No. 130 at PageID #11321.) Primarily, Plaintiffs assert that Dr. Gleit's experience using the Ventralex ST, the device most closely related to the Ventralex, is insufficient. (*Id.*) The Ventralex is the same as the Ventralex ST except that the Ventralex ST's barrier is resorbable while the Ventralex's is permanent ePFTE. (ECF No. 95-4 at PageID #7963.) The Ventralex ST comes in the same three sizes and has a similar memory recoil ring. (*Id.* at PageID #7963, 7979.) This is a sufficient degree

of similarity to such that Dr. Gleit's size-based opinion is reliable for *Daubert* purposes. Plaintiffs may interrogate the differences between the two devices during cross-examination, but this is not enough to show that Dr. Gleit's opinion unreliable.

2. Implanting surgical technique and obesity opinions

Plaintiffs then argue that Dr. Gleit's opinions that Dr. Gill's poor implantation technique caused the Ventralex to buckle and that Mr. Milanesi's "body habitus" contributed to his complications are unreliable. (ECF No. 74 at PageID #3946.) Both opinions are reliable.

Plaintiffs assert that Dr. Gleit's opinion that Dr. Gill did not clear the omentum and "sweep" around the implantation site for adhesions is speculation because he provides no affirmative evidence. (ECF No. 74 at PageID #3946.) Plaintiffs point to Dr. Gill's testimony that he performed these tasks. (*Id.*at PageID #3947.) However, Dr. Gleit relied on Dr. Gill's operative report, which did not note that Dr. Gill cleared the omentum and swept for adhesions. (ECF No. 74-6 at PageID #4082.) This is not an issue of whether an expert opinion is reliable but whether Dr. Gill's testimony or his operative report is more credible, and hence whether Dr. Gill or Dr. Gleit is more credible. These are issues for the jury only. Moreover, Dr. Gleit's interpretation of the operative report is not a mere supposition; it is a conclusion that he drew based on the document itself and his own surgical experience. *Cf. McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 801 (6th Cir. 2000) ("[T]he expert's conclusions regarding causation must have a basis in established fact and cannot be premised on mere suppositions. An expert's opinion, where based on assumed facts, must find some support for those assumptions in the record.").

Next, Plaintiffs urge that Dr. Gleit's opinion that Mr. Milanesi's body habitus, *i.e.,* his obesity, contributed to his complications is unreliable. (ECF No. 74 at PageID #3946). "An 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)). The key question is whether the expert's opinion "rests on a reliable foundation." *Daubert*, 509 U.S. at 597. Dr. Gleit's extensive experience as a hernia surgeon and the fact that he is testifying from an experiential perspective provides such a foundation. He has performed thousands of hernia repairs and the majority of repairs use mesh over the course of more than twenty years. (ECF No. 74-6 at PageID #4076, 4086.)

He also clearly explains the basis for his opinion. Dr. Gleit opines that it is unlikely that the patch buckled due to contracture as Plaintiffs argue because "[p]olypropylene becomes incorporated into the abdominal wall within weeks to months after implantation, and the healing process is mostly complete after 3 months. Thus, the fistula that formed in Mr. Milanesi 10 years after mesh implantation was likely the result of adhesions that had started years earlier." (ECF No. 74-6 at PageID #4082.) He went on, "[i]n my opinion, it is most likely that the mesh patch was poorly positioned from the start. Mr. Milanesi's obese body habitus and the choice of an over-sized patch likely contributed to the difficulty in positioning it, as has been previously noted." (*Id.*) Dr. Gleit explains that "[p]eople who are obese do tend to have fatty deposits in their abdomen, in particular the umbilical ligament, which can make it more difficult to ensure that the mesh is lying flat against the abdominal wall." (ECF No. 95-2 at PageID #7940, p. 319; *see also* ECF No. 74-6 at PageID #4079–80.) For these reasons, this opinion is reliable.

Plaintiffs argue that Dr. Gleit did not examine Mr. Milanesi and does not cite to records qualifying or quantifying the layer of fat on Mr. Milanesi's abdomen. (ECF No. 130 at PageID #11324.) However, it is undisputed that Mr. Milanesi was obese at the time of his implantation

surgery. Dr. Gleit's opinion is that obesity presents inherent risks during implantation. (ECF No. 74-6 at PageID #4079–80.) This is sufficient. These issues can be addressed during Dr. Gleit's cross-examination, as well as Dr. Gill's examination.

Plaintiffs next contend that the Court's previous rulings about irrelevant risk factors including obesity, is applicable here. (ECF No 74 at PageID #3948.) In *Johns v. C.R. Bard, Inc.*, the first bellwether case in this MDL, the Court held that evidence of the plaintiff's obesity was irrelevant because the evidence went to an injury no longer in the case. *In re Davol, Inc/C.R. Bard, Inc.*, 2020 WL 6605612 at *7 (EMO No. 7); *In re Davol, Inc/C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, 511 F. Supp. 3d 804, 808 (S.D. Ohio 2021) ("Evidence of Plaintiff's obesity and high Body Mass Index, which is undisputed by Plaintiff, is similarly irrelevant based on this record. Defendants intend to introduce this evidence to prove an alternate cause of recurrence and other complications, but these injuries are no longer part of this case." (citations omitted)) (Motions in Limine Order ("MIL") No. 9). Here, body habitus goes to the causation of injuries still at issue in this case.

Finally, Plaintiffs argue that Dr. Gleit's opinion is unreliable because he is an expert for hire. (ECF No. 74 at PageID #3947.) When "a proposed expert's testimony flows naturally from his own current or prior research . . . then it may be appropriate for trial judge" to admit the testimony, which is "in line with the notion that an expert who testifies based on research he has conducted independent of litigation 'provides important, objective proof that the research comports with the dictates of good science.'" *Johnson v Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 435 (6th Cir. 2007) (quoting *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1317 (9th Cir. 1995)). Dr. Gleit is board-certified general surgeon with an emphasis on hernia repairs. (ECF No. 74-6 at PageID #4076.) This is enough to demonstrate that Dr. Gleit is not the type

of patent expert for hire that would show his opinions unreliable.

3. Buckling theory opinions

Next, Plaintiffs argue that "Dr. Gleit lacks the experience, expertise, and scientific rigor to refute the fact that the Ventralex patch 'buckles' after implantation." (ECF No. 74 at PageID #3948.) But Plaintiffs do not develop any argument that Dr. Gleit's opinions fail to satisfy Rule 702. Instead, they argue that because "[t]he scientific and medical evidence shows that the Ventralex clearly 'buckled' in this case," Dr. Gleit's opinions are unreliable. (*Id.* at PageID #3950.) The Court disagrees.

Plaintiffs misconstrue Dr. Gleit's opinion and identify only sources of disagreement, not unreliability. Dr. Gleit does not deny that Mr. Milanesi's Ventralex explant was buckled. (ECF No. 74-6 at PageID #4083.) Instead, he attacks Dr. Krpata's opinion that the cause of this buckling was the differential contracture of polypropylene and ePTFE. (*Id.*) Moreover, Plaintiffs identify only areas of disagreement. They survey deposition testimony and studies, arguing that Dr. Gleit ignores the evidence showing the Ventralex buckled. (ECF No. 74 at. at PageID #3949–50.) But Dr. Gleit reviewed these studies, as noted *supra*, Part III.A.1; he simply disagrees with them. Moreover, Dr. Gleit considered evidence that the Ventralex buckled in accordance with Plaintiffs' theory of injury—differential contracture—and explained why he rejected it. (ECF No. 74-6 at PageID #4082–83.) Disagreement with an expert's conclusions does not translate to unreliable conclusions.

4. Other device and procedure opinions

Finally, Plaintiffs argue that Dr. Gleit's opinions that other devices or procedures would have caused the same outcome are unreliable. (ECF No. 74 at PageID #3950.) Dr. Gleit concludes that "[i]t is important to note that any device can be associated with an increased risk of

complication if improperly implanted. In particular, any mesh device can be associated with bowel adhesions, erosion, and fistulization, and this risk is increased with poor implantation technique or choice of mesh type or size." (ECF No. 74-6 at PageID #4083.) He also opines that "there is no reliable evidence that Ventralex poses a higher risk of remote complications like fistula formation compared to other available mesh implants, particularly when placed via the intra-peritoneal approach chosen by the implanting surgeon." (*Id.* at PageID #4082.) Dr. Gleit's outcome and comparative risk opinions are unreliable, but his other opinions are not.

In *Johns*, the Court granted in part and denied in part the plaintiff's motion in limine seeking exclusion of other products or procedures that would have caused the same complications in the plaintiff. *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 6605648, at *2 (S.D. Ohio Sept. 11, 2020) (MIL No. 3). Specifically, "Bard [could] not introduce evidence . . . that other devices or procedures would have caused the same outcome for Plaintiff." *Id.* During the hearing on the motion, the Court explained that such a conclusion "borders into speculation," but that "it's fair to say if the surgeon believes this could have caused, could have exposed him to the same risk." (No. 18-cv-1509, ECF No 345 at PageID #18605.) In other words, evidence about outcomes is speculative but evidence of differential risk is not. Thus, to the extent Dr. Gleit's opinion veers into speculating about outcomes, his opinion is inadmissible.

Dr. Gleit's opinion that any device improperly implanted can increase risks of complications is not excluded under this previous opinion and is reliable. Dr. Gleit does not speculate about the outcome of hypothetical procedures. Instead, he opines that these devices expose patients like Mr. Milanesi to the same risks posed by the Ventralex. His lengthy experience as a hernia surgeon provide a suitable foundation.

On the other hand, Dr. Gleit's opinion that there is no reliable evidence that the Ventralex poses an increased risk of complication is unreliable. The only support Defendants identify as relied upon by Dr. Gleit for this opinion are studies noting low rates of complications for the Ventralex. (ECF No. 74-6 at PageID #4082–83.) Dr. Gleit does not cite studies addressing other devices' risks that could serve as point of comparison between the Ventralex and other devices. He also does not point to his own experience to explain the differences in risks posed by other devices in comparison to the Ventralex.[3] (*See* ECF No. 166 at PageID #13584.) Defendants counter that this evidence is relevant to showing whether the Ventralex was state of the art at the time of Mr. Milanesi's implantation surgery. (ECF No. 95 at PageID #7899.) But relevance is not the same as reliability; these are distinct concerns under *Daubert* and the Federal Rules of Evidence.

B. George Kevin Gillian M.D., F.A.C.S.

Dr. Gillian is a general surgeon with a specialty in hernia repairs, and Defendants offer his opinions and testimony to "provide general and case-specific opinions including on causation and lend a surgeon's perspective to various pieces of the record that Plaintiffs intend to rely upon at trial. (ECF No. 94 at PageID #7441; *see also* ECF No. 77-5 at PageID #4528.) Plaintiffs challenge Dr Gillian's opinions that they characterize as FDA or regulatory opinions; gold standard, risk-benefit, and legal opinions; Material Safety Data Sheet ("MSDS") opinions; patient outcome opinions; opinions about Dr. Gill's surgical technique; and irrelevant risk factor opinions. (ECF No. 77 at PageID #4418–27.) Dr. Gillian may offer his risk-benefit, patient outcomes, and obesity

[3] 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 No. 141.) The Court did not rely on Keegan's testimony while evaluating the reliability of Dr. Gleit's opinions. Accordingly, there is no need to address this issue at this time.

risk factor opinions, but he cannot offer his FDA, gold standard, legal, MSDS, and other risk factor opinions.

1. FDA or regulatory opinions

Plaintiffs challenge Dr. Gillian's opinions in which explains the role of the FDA and the 510(k) clearance. (ECF No. 77 at PageID #4419.) Plaintiffs identify three specific opinions: (1) polypropylene mesh has been "cleared" by the FDA "as safe and effective, and has a demonstrated track record of successful outcomes in a significant number of hernia repairs over many decades" (ECF No. 77-5 at PageID #4532); (2) the 510(k) process denotes safety and efficacy; and (3) a product that has FDA clearance need not be classified as medical grade or receive further clearances (*id.* at PageID #2551–52). These opinions are inadmissible.

No expert may offer opinions about the meaning of the 510(k) process, meaning Dr. Gillian's opinions as to meaning of FDA clearance and the 510(k) process, the process by which FDA clearance is given, are inadmissible. *E.g.*, *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2846, 2:18-cv-1509, 2021 WL 2643114, at *5 (S.D. Ohio June 28, 2021) (EMO No. 11); *see also 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 *8 (S.D. Ohio Oct. 20, 2020) (MIL No. 4).

Dr. Gillian's opinion about further FDA classification is also inadmissible. He opines that "[i]t is my understanding that a product with polypropylene that is cleared for use by the FDA, or appropriately released to the market in adherence with FDA regulations, does not require any further designation prior to being used by surgeons, and thus need not be classified as 'medical grade' or receive any further clearances." (ECF No. 77-5 at PageID #4552.) Defendants argue that this opinion is appropriate because he is opining from the vantage point of a surgeon end-user

of the device, meaning "it would not be his expectation, as a surgeon, that a device would need further classification of 'medical grade.'" (ECF No. 94 at PageID #7452.) Defendants do not demonstrate why this perspective is relevant. The perspective of the end user is relevant to Plaintiffs' failure to warn claims because the issue is whether the warning was adequate for the end user. *E.g.*, *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 * 16 (S.D. Ohio Sept. 1, 2020) (EMO No. 5). But Defendants' compliance with FDA regulations goes to Plaintiffs' design defect claims, which focuses on the reasonableness of Defendants' conduct. Dr. Gillian's opinion does not speak to Defendants' conduct.[4]

2. Gold standard, risk-benefit, and legal opinions

Plaintiffs contend that Dr. Gillian should not be permitted to offer his opinion that polypropylene is the gold standard for hernia repair, that polypropylene presents a risk-benefit ratio favorable to patients, that the IFU adequately advises implanting surgeons, and that Mr. Milanesi's injuries were not caused by a defect or issue with the Ventralex device. (ECF No. 77 at PageID #4420–21.) Defendants acknowledge the Court's previous rulings excluding references to polypropylene as the "gold standard" and legal conclusions, such as the legal or regulatory adequacy of the warnings in the IFU and causation. (ECF No. 94 at PageID #7448–49.) Accordingly, Dr. Gillian cannot offer those opinions. *See In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6605648, at *2 (gold standard) (MIL No. 3); *In re Davol, Inc/C.R. Bard, Inc.*, 2020 WL 6605612 at *6 (legal conclusions) (EMO No. 7). However, Dr. Gillian may offer opinions from

[4] Defendants contend that this is not an opinion about regulatory compliance (*id.*), and so the Court does not treat it as such. If the opinion were one of regulatory compliance, Dr. Gillian would not be permitted to opine on whether the Ventralex required further clearance because it is a legal issue.

the vantage point of the end user, a hernia surgeon, that the IFUs sufficiently apprise surgeons of the risks. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6605542, at * 16 (EMO No. 5). The only remaining issue is Dr. Gillian's risk-benefit opinions, which the Court concludes he may offer.

Plaintiffs argue that Dr. Gillian's risk-benefit ratio opinion is not relevant to this case and would confuse and mislead the jury because he considered all polypropylene introduced to the market to form this opinion. (ECF No. 77 at PageID #4420; ECF No. 131 at PageID #11395.) Dr. Gillian opines that "the significant benefits of Bard's hernia mesh products far outweigh any purported risks." (ECF No. 77-5 at PageID #4533.) He explains the shortcomings of previous repair methods, incorporating a discussion of technique, and noting that despite trade-offs, "the risk/benefit ratio [of the Ventralex] was unequivocally in their patients' favor to use the mesh." (*Id.* at PageID #4593–42.) Dr. Gillian's opinion is relevant and poses little risk of confusing the jury.

Expert testimony is relevant if it "will assist the trier of fact to understand the evidence or to determine a fact in issue." *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 529 (quoting Fed. R. Evid. 702.). At issue in this case is whether the Ventralex was defectively designed. Under Florida law, a plaintiff may present evidence under the risk-utility test or consumer expectations test to prove a design defect. *Aubin v. Union Carbide Corp.*, 177 So.3d 489, 511 (Fla. 2015). The Ventralex is a polypropylene hernia mesh device, and so Dr. Gillian's opinion about the risks and benefits of polypropylene in hernia mesh devices will aid the jury in assessing whether a design defect existed in this case.

Plaintiffs argue that Dr. Gillian does not limit his opinion to umbilical hernia meshes, ePTFE/polypropylene meshes, etc. (ECF No. 131 at PageID #11397.) Plaintiffs' arguments go to the weight, not admissibility, of Dr. Gillian's testimony and are best addressed on

cross-examination. Vigorous cross-examination will also eliminate any risk of jury confusion on the scope and weight of Dr. Gillian's opinions.

Plaintiffs also contend that even without use of the phrase "gold standard," Dr. Gillian's risk-benefit ratio opinions are an end-run around this Court's motion in limine opinion excluding use of the phrase gold standard. (ECF No. 131 at PageID #11397.) Plaintiffs are mistaken. The Court previously held in this MDL that arguments that a device was the gold standard is inadmissible. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6605648, at *2 (MIL No. 3). The Court reasoned that that "the phrase gold standard is an aggregate almost survey conclusion as if they've taken a poll." (No. 18-cv-1509, ECF No. 345 at PageID #18604–05.) This ruling was narrow and focused on the specific connotation of the phrase "gold standard." Dr. Gillian's risk-benefit ratio opinions do not raise the same issues.

3. MSDS opinions

Plaintiffs next challenge Dr. Gillian's MSDS opinions, arguing that he is unqualified to give these opinions and these opinions are unreliable. (ECF No. 77 at PageID #4421.) The Court agrees these opinions are inadmissible, but for different reasons. 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.*, 2020 WL 6603657, at *5 (MIL No. 4). Dr. Gillian opines that surgeons do not rely on the information in MSDSs and that he "would not expect any medical device manufacturer, including Bard, to include a MSDS that was issued by a raw material manufacturer in their packaging for their device." (ECF No. 77-5 at PageID #4555–56.) This is not an opinion about notice. In any case, no expert can opine on the mindset of corporates 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., 2021 WL 2643114, at *8 (EMO No. 11).

4. Patient outcome opinions

Then, Plaintiffs argue that Dr. Gillian should not be able to offer his opinions that he has not had to remove a Ventralex from one of his patients or seen a patient suffer recurrence with the Ventralex, and that he and his patients have been satisfied with the repairs and outcomes. (ECF No. 77 at PageID #4422.) Plaintiffs assert that Dr. Gillian is speculating because most general surgeons do not have substantial or longitudinal follow up with their patients. (*Id.*) The only speculation here is Plaintiffs', however. Plaintiffs provide no factual basis for their assertion that Dr. Gillian does not conduct sufficient follow-up with his patients that would render his experiential opinion unreliable. Dr. Gillian may testify on the basis of his experience, which it appears he has done. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6605612, at *13 (quoting *In re E.I. du Pont de Nemours & Co.*, 345 F. Supp. 3d at 902) (EMO No. 7). The exact basis and extent of his opinions based on his follow-up with patients may be drawn out during cross-examination.

Plaintiffs counter that Dr. Gillian's opinion amounts to an opinion that he has a 100% success rate and a 0% complication rate, and that the opinion is unreliable because Dr. Gillian did not have a tracking system or another methodology in place. (ECF No. 131 at PageID #11401.) As the Court reads Dr. Gillian's opinion, it is not one of complication rates but the absence of certain events. However, Plaintiffs' point in well-taken; any opinion that the lack of patients coming to Dr. Gillian with post-operative issues translates to a certain complication rate would be unreliable. But at this time, it does not appear that Dr Gillian offers this opinion.

5. Opinions about Dr. Gill's surgical technique

Plaintiffs argue that Dr. Gillian cannot opine that Dr Gill used "poor [surgical] technique," *i.e.*, that Dr. Gill did not clear adhesions around the hernia or performed a finger sweep. (ECF No.

77 at PageID #4425–26.) The reasoning for Dr. Gleit's same opinion is applicable here; Dr. Gillian may rely on the operative report to reach his opinion. *Supra* Part III.A.2. Plaintiffs argue that "it is common practice for medical providers to chart by exception, meaning that standard procedures, such clearing and sweeping, would not be documents. (ECF No. 131 at PageID #11403.) First, Plaintiffs do not provide a record citation to this proposition. Moreover, this does not change the Court's decision because the issue is still one of interpretation of the operative report. There is support in the record for Dr. Gillian's opinion, and it is up to the jury to weigh the evidence and expert witness testimony.

6. Irrelevant risk factor opinions

Plaintiffs challenge Dr. Gillian's opinions about risk factors for hernia complications, including general risk factors, such as obesity, smoking, coughing, retching, heavy lifting, and diabetes, and risk factors specific to Mr. Milanesi, such as a history of prostatitis, purulent urethritis, sexual issues, anxiety, depression, obesity, hypertension, dyslipidemia, esophageal reflux, and diabetes. (ECF No. 77 at PageID #4427.) Plaintiffs argue that some of Dr. Gillian's opinions on general risk factors consider factors Mr. Milanesi did not have and that Dr. Gillian's did not connect the factors that Mr. Milanesi does have to his injuries in this case. (*Id.*) Defendants do not address any factors but obesity in their briefing. As to his obesity opinions, the Courts prior reasoning for Dr. Gleit applies here. Dr. Gillian may opine that obesity is a complicating factor during implantation and there is a nexus between his opinion and Mr. Milanesi's case because he was obese at the time of implantation. *Supra* Part III.A.2. Defendants do not specifically address Mr. Milanesi's other risk factors, such as anxiety, nor can the Court find opinions in Dr. Gillian's report that these factors contributed to his injuries. Thus, Defendants cannot offer testimony from Dr. Gillian regarding these risk factors.

IV. Conclusion

For these reasons, Plaintiffs' motion to exclude Dr. Gleit's opinions and testimony (ECF No. 74) is **GRANTED IN PART AND DENIED IN PART**, and Plaintiffs' motion to exclude Dr. Gillian's opinions and testimony (ECF No. 77) is **GRANTED IN PART AND DENIED IN PART**.

IT IS SO ORDERED.

11/2/2021
DATE

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