**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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

**Case No. 2:18-md-2846**

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

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

# EVIDENTIARY MOTIONS OPINION AND ORDER No. 23

Now before the Court is Defendants' Motion to Exclude the Testimony of Plaintiffs' Expert Julia Babensee, Ph.D. (ECF No. 64.) For the reasons below, Defendants' motion is **GRANTED IN PART, DENIED IN PART, DENIED IN PART AS MOOT, AND RESERVED 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 PageID #1–2.)[2] This includes Defendants' Ventralex Hernia Patch, the device implanted in

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

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

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

## II. Legal Standard

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because courts are "almost always better situated during the actual trial to assess the value and utility of evidence." *Jackson v. Cnty. of San Bernardino*, 194 F. Supp. 3d 1004, 1008 (C.D. Cal. July 5, 2016) (quoting *Wilkins v. Kmart Corp.*, 487 F. Supp. 2d 1216, 1218 (D. Kan. 2007)); *accord Sperberg v. Goodyear Tire & Rubber Co.*,

519 F.2d 708, 712 (6th Cir. 1975) ("A better practice is to deal with questions of admissibility of evidence as they arise."). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (quoting *Ind. Ins. Co*., 326 F. Supp. 2d at 846). The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

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

## III. Analysis

The district court's role in assessing expert testimony is a "gatekeeping" one, "screening expert testimony" so that only admissible expert testimony is submitted to the jury; its role is not to weigh the expert testimony or determine its truth. *United States v. Gissantaner*, 990 F.3d 457, 463 (6th Cir. 2021) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). Expert testimony, testimony given by "[a] witness who is

qualified as an expert by knowledge, skill, experience, training, or education," is admissible if:

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

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

First, an expert witness must be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "[T]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question." *Madej v. Maiden*, 951 F.3d 364, 370 (6th Cir. 2020) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). "[T]he only thing a court should be concerned with in determining the qualifications of an expert is whether the expert's knowledge of the subject matter is such that his opinion will likely assist the trier of fact in arriving at the truth. The weight of the expert's testimony must be for the trier of fact." *Mannino v. Int'l Mfg. Co.*, 650 F.2d 846, 851 (6th Cir. 1981). A party's expert need only meet the "'minimal qualifications' requirement—not one who could teach a graduate seminar on the subject." *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 377 (6th Cir. 2014) (quoting *Mannino*, 650 F.2d at 851); *see*

*also Dilts v. United Grp. Servs., LLC*, 500 F. App'x 440, 446 (6th Cir. 2012) ("An expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact.").

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

Third, expert testimony must be reliable. Rule 702 provides the following general standards to assess reliability: whether "the testimony is based on sufficient facts or data," whether "the testimony is the product of reliable principles and methods," and whether "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)–(d). To evaluate reliability of principles and methods, courts consider "'testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community,'" though these "factors 'are not dispositive in every case' and should be applied only 'where they are reasonable measures of the

reliability of expert testimony.'" *In re Scrap Metal*, 527 F.3d at 529 (citations omitted); *see Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) (describing these factors as "flexible" (quoting *Daubert*, 509 U.S. at 594)). The objective of the reliability requirement is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152.

Defendants challenge the opinions of Dr. Julia Babensee, Ph.D. They argue that (A) Dr. Babensee is unqualified to offer buckling opinions and that these opinions are unreliable, (B) she is unqualified to offer case-specific opinions, (C) she is unqualified to opine on mesh pore size and that these opinions are irrelevant and unreliable, (D) her polypropylene degradation opinions are irrelevant and unreliable, (E) she is unqualified to offer her contraction, migration, and pain opinions, which are irrelevant and unreliable, (F) her safer alternative design opinions are inadmissible, (G) her Material Safety Data Sheet ("MSDS") opinions are inadmissible, and (H) her corporate state-of-mind opinions, parroted opinions, and disclaimed opinion are inadmissible. Defendants' motion is denied except as to Dr. Babensee's case-specific and MSDS opinions, on which Defendants' motion is granted; her corporate intent, parroted and disclaimed opinions, on which Defendants' motion is denied as moot; and her migration opinion, on which the Court reserves judgment.

**A. Buckling and contraction opinions**

Defendants urge the Court to exclude Dr. Babensee's buckling opinions about the Ventralex device because her opinions are irrelevant, are beyond her qualifications, and are unreliable. (ECF No. 64 at PageID #1457–59; ECF No. 120 at PageID #10847–49.) Dr. Babensee opines that the Ventralex buckled because ePTFE and polypropylene contract a different rates and

that the too-thin PET ring increased the chances of buckling. (ECF No. 64-2 at PageID #1557.) Dr. Babensee's opinions are relevant, she is qualified to offer them, and they are reliable.

Dr. Babensee's buckling opinions are relevant. Dr. Babensee opines on the capacity of the Ventralex to buckle, which is a general causation opinion that supports Plaintiffs' theory of injury in this case. Plaintiffs' theory of injury is that the Ventralex buckled, exposing Mr. Milanesi's bowels to bare polypropylene. Defendants counter that Dr. Babensee does not offer opinions that fit with Dr. Krpata's specific causation opinions because she did not opine that the Ventralex poses *increased* risks of buckling and complications compared to other devices and does not tie her PET ring opinion to Dr. Krpata's specific causation opinion. (ECF No. 64 at PageID #1457–58; ECF No. 120 at PageID #10848.) As the Court has clarified before, Dr. Krpata's causation opinions are not limited to comparative risk assessments across devices. (ECF No. 166 at PageID #13584.) Dr. Babensee's PET ring opinion is also consistent with Dr. Krpata's opinion that the too-thin PET ring contributes to the buckling of the Ventralex device, which was the specific cause of Mr. Milanesi's injuries. (ECF No. 64-1 at PageID #1488–89, 1495–1501.)

Dr. Babensee is qualified to offer her buckling opinions. In *Johns v. C.R. Bard*, the first bellwether case in this MDL, the Court concluded that Dr. Babensee was qualified to offer opinions related to polypropylene due to her experience, education, and training in biomaterial science. *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 *19–20 (S.D. Ohio Sept. 1, 2020) (Evidentiary Motions Order ("EMO") No. 5). The Court emphasized her general expertise with medical devices and implantable biomaterials and concluded that this permitted her to offer hernia mesh polypropylene opinions even if she did not have specific experience with polypropylene hernia mesh. *Id.* Dr. Babensee does not have specific experience with polypropylene, ePTFE, or PET,

as Defendants point out (ECF No. 120 at PageID #10847), but her biomaterial and medical implantable device expertise provides a foundation for Dr. Babensee's opinions and her expertise will assist the jury. *See Dilts*, 500 F. App'x at 446 ("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.").

Finally, Dr. Babensee's buckling 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). 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) (concluding that an expert's failure to perform tests personally goes to weight not admissibility). 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)). Moreover, "[t]rained experts commonly extrapolate from existing data." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). In her report, Dr. Babensee cites scientific literature that supports her contracture and PET opinions. (ECF No. 64-2 at PageID #1557.) Coupled with her education and training biomaterials science, this is sufficient to convey reliability.

Defendants' arguments to the contrary are unconvincing. They attack the strength of the literature that Dr. Babensee relied on in forming her opinions, that she did not test for buckling or contraction herself, and that she lacks experience with polypropylene, ePTFE, PET, and hernia mesh outside of litigation. (ECF No. 64 at PageID #1458–49, 1464–65.) Defendants also argue that she did not opine as to the degree of contraction, how contraction is affected by polypropylene and ePTFE sewn together, etc. (*Id.* at PageID #1464.) These arguments go to the weight of her opinion, not its admissibility. Additionally, expert testimony is not typically excluded as unreliable expert-for-hire opinions if "a proposed expert's testimony flows naturally from his own current or prior research (or field work)," 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. Babensee is a biomaterials and biomedical engineer who studies medical implants, and so her testimony flows from her work. Defendants also argue that two circuit courts, the Eleventh Circuit, *Olmo v. Davol, Inc.*, 710 F. App'x 861 (11th Cir. 2018) (per curiam), and the 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 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. Babensee relies on scientific literature as well as her own experience. (*See* ECF No. 166 at PageID #13584–88.)

**B. Case-specific opinions**

Defendants argue that Dr. Babensee is unqualified to offer opinions that Mr. Milanesi's "infected hernia mesh and small bowel fistula were due to the Bard Ventralex mesh implanted into Mr. Milanesi" and that this opinion is unreliable. (ECF No. 64 at PageID #1459–60.) In *Johns*, the Court concluded in part that without "consideration of alternative causes, Dr. Babensee's specific causation opinion is unreliable." *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6605542, at *25 (collecting cases) (EMO No. 5). Dr. Babensee did not consider potential alternative causes. (ECF No. 64-7 at PageID #1709–10.) The same reasoning requires exclusion of Dr. Babensee's case-specific opinion here. Defendants also address her qualifications and whether this opinion is pertinent under Florida law (ECF No. 64 at PageID #1459–60), but the Court does not address these issues because it is unnecessary to do so.

**C. Mesh pore size opinions**

Next, Defendants contend that Dr. Babensee is unqualified to opine about the pore size of polypropylene mesh and that her opinions are unreliable and irrelevant. (ECF No. 64 at PageID #1461–62.) Dr. Babensee opines that Defendants' devices "lack biocompatibility because of a lack of effective pore size to support appropriate tissue integration," *i.e.*, that the pore size was too small and that this contributed to device stiffness. (ECF No. 64-2 at PageID #1542–45.) She also concludes that the small pore size led to infections by harboring bacteria. (*Id.* at PageID #1556.) The Court held in *Johns* that Dr. Babensee is qualified to offer this opinion, *In re Davol, Inc./C.R.*

*Bard, Inc*, 2020 WL 6605542, at *20 (EMO No. 5), and Defendants provide no reason why the Court should reconsider this determination. This leaves relevance and reliability, and Dr. Babensee's pore-size opinions clear both hurdles.

Dr. Babensee's pore-size opinions are relevant. As this Court has explained before, Plaintiffs' theory of injury is two-fold—the Ventralex buckled, exposing bare polypropylene to Mr. Milanesi's bowel, which then caused his injuries. Dr. Babensee's pore-size opinions explain why the exposure of bare polypropylene of Defendants' Ventralex device is dangerous and capable of causing injury. Defendants argue that Dr. Babensee does not tie her pore-size opinion to her buckling opinion (ECF No. 64 at PageID #1461), but this is inaccurate. In her report, Dr. Babensee explains that a small pore size leads to inappropriate tissue integration and that coupled with degradation, this can lead to bunching and movement of the device, *i.e.*, buckling. (ECF No. 64-2 at PageID #1542–43.) Moreover, Dr. Babensee's infection-based opinion is relevant because it explains why the exposure of bare polypropylene is dangerous, which is aligns with Plaintiffs' two-step theory of injury.

Defendants also assert that Dr. Babensee's pore-size opinions are irrelevant considering Plaintiffs' injuries and Dr. Krpata's specific-causation opinion. (*Id.*at PageID #1461.) Dr. Krpata opines that "the [Ventralex] device does not perform as intended, and instead encounters a buckling effect, thereby exposing bare polypropylene to the bowel. Bare polypropylene cannot be exposed directly to the bowel, as devastating adverse reactions can occur such as erosion into the viscera, infection, fistula, sepsis, and even death." (ECF No. 63-1 at PageID #1097.) He concludes that this buckling was the cause of Mr. Milanesi's injuries. (*Id.* at PageID #1108.) Dr. Babensee's opinions explain why exposure to polypropene is deleterious and are thus relevant. (*See* ECF No. 219 at PageID #14987–90.) Relatedly, Defendants contend that Dr. Babensee does not connect

her pore-size opinions to any increased risks of complications. Again, Dr. Krpata's specific causation opinion—the source of Defendants' continued emphasis that Plaintiffs must demonstrate the Ventralex poses increased risks than other hernia mesh devices—is not limited to a comparative risk opinion; it is a general causation opinion. (ECF No. 166 at PageID #13584.) For this reason, Dr. Babensee's opinions do not need to address comparative risks to be relevant.

Her opinions are also reliable. Dr. Babensee relies on scientific literature in her area of expertise to form these opinions. (ECF No. 64-2 at PageID #1542–45, 1556.) This are sufficient indicia of reliability. *Supra* Part III.A. Defendants counter that her opinions "were developed solely for litigation" and that she relies on selective literature. Because Dr. Babensee is a biomaterials expert, her pore-size opinions are not so suspect that they lack the typical indicia of reliability. *Id.* The remainder of Defendants' arguments are fodder for cross-examination. *Id.*

**D. Polypropylene degradation opinions**

Then, Defendants challenge the admissibility of Dr. Babensee's polypropylene degradation opinions on the basis that they are irrelevant and unreliable. Defendants raise the same arguments as those in relation to her pore-size opinions: polypropylene degradation is not at issue and Dr. Babensee's opinions are unreliable because her opinions are litigation-driven. (ECF No. 64 at PageID #1462–63.) These arguments are unpersuasive for the reasons *supra*: Dr. Babensee's polypropylene degradation opinions are relevant because they explain why exposure to bare polypropylene is problematic, and Defendants' reliability concerns go to the weight of Dr. Babensee's opinions and are thus properly addressed on cross-examination. *Supra* Parts III.A & C.

**E. Contraction, migration, and pain opinions**

Defendants attack Dr. Babensee's contraction, migration, and pain opinions based on her

qualifications and the relevance and reliability of these opinions. (ECF No. 64 at PageID #1462–63.) Again, the Court held earlier in this MDL that Dr. Babensee is qualified to offer these opinions, *In re Davol, Inc./C.R. Bard, Inc*, 2020 WL 6605542, at *20 (EMO No. 5), and Defendants provide no explanation for why the Court should reconsider this holding here. The Court also resolved the arguments that Defendants raised with regard to contracture in Part III.A of this opinion, *supra*. Thus, relevance and reliability are all that remain. Dr. Babensee's pain opinions are relevant and reliable, but the Court cannot address her migration opinion at this time.

Dr. Babensee's pain opinions are relevant and reliable. Mr. Milanesi claims that his Ventralex caused him pain ten years after implantation, leading to his 2017 surgery to remove the Ventralex, and after his 2017 surgeries, including the removal of the Ventralex and the emergency bowel obstruction surgery. (ECF No. 103 at PageID #8786.) Thus, Dr. Babensee's opinions are relevant. Dr. Babensee's opinions are reliable for the same reasons as discussed above. *Supra* Part III.A. Defendants argue that Dr. Babensee's pain opinions are about chronic pain, which Mr. Milanesi does not claim, and that Dr. Caluda testified that Mr. Milanesi's Ventralex performed as expected, undercutting Dr. Babensee's pain opinions. (ECF No. 64 at PageID #1464; EC No. 120 at PageID #10852.) Dr. Babensee does not only discuss chronic pain but also pain generally from degradation, pore size, etc. (ECF No. 64-2 at PageID #1539, 1542–43.) Moreover, Defendants' interpretation of the evidence, which includes more heavily weighing parts of Dr. Caluda's testimony and inferring that it pertains to pain, is solely the province of the jury.

As to migration, it is unclear what migration opinions—if any—Dr Babensee will offer. In her report, she only addresses migration in relation to the PerFix Plug device and in relation to another bellwether plaintiff. (ECF No 64-2 at PageID #1549, 1567–68.) Neither Plaintiffs nor Defendants identify a migration opinion from Dr. Babensee in the record that pertains to this case,

and Defendants do not develop their argument challenging the reliability of the migration opinion. Plaintiffs state that "Dr. Babensee can also discuss the mechanism that leads to migration of polypropylene. To the extent that no migration occurred in Mr. Milanesi's case, Plaintiffs will not be eliciting testimony on that topic." (ECF N. 103 at PageID #8786–87.) There is no indication what mechanism to which Plaintiffs are referring. In short, the argument on this issue is too sparse for the Court to meaningfully address this issue. The Court therefore declines to address the migration opinion without the benefit of more thorough consideration and thus reserves judgment on this opinion.

**F. Safer alternative design opinions**

Defendants move to exclude Dr. Babensee's safer alternative design opinions, arguing that they are irrelevant because "there is no indication that Florida law permits discussion of what would amount to completely different products used in different ways or products that are 'safer' in ways irrelevant to the claimed defect." (ECF No. 64 at PageID #1466.) The Court rejects Defendants' unsupported assessment of Florida law and concludes that Dr. Babensee's opinions are relevant.

First, Florida law. Defendants do not provide legal authority for their assertion that Florida courts have concluded as a matter of law that some alternative designs amount to different devices, nor do they provide any other explanation; they only provide the perfunctory statement above. (*Id.*; ECF No. 120 at PageID #10853–54.) In any case, the Court disagrees with Defendants' unsupported assessment of Florida law. In *Aubin v. Union Carbide Corp.*, the Florida Supreme Court declined to require evidence of a reasonable alternative design to demonstrate a design defect under strict liability as set forth in the Restatement (Third) of Torts: Products Liability § 2 but noted that a plaintiff could introduce such evidence. 177 So.3d 489, 511 (Fla. 2015). The Third

Restatement notes that "[a]ssuming that a court concludes that sufficient evidence on this issue has been presented, the issue is then for the trier of fact." Restatement (Third) of Torts: Products Liability § 2 cmt. f (Am. L. Inst. 1998). Simply put, whether Dr. Babensee's proposed alternative designs are too dissimilar in form and function to the Ventralex to be a reasonable alternative design is an issue for the jury.

Second, relevance. Dr. Babensee provides a variety of alternative designs that specifically address issues with polypropylene degradation. (ECF No. 64-2 at PageID #1558–61.) Her opinions are therefore relevant.

**G. MSDS opinions**

Next, Defendants argue that Dr. Babensee's MSDS opinions should be excluded. (ECF No. 64 at PageID #1467–68.) Dr. Babensee's MSDS opinions are inadmissible. In her report, Dr. Babensee described the statements in MSDSs that polypropylene is not suitable for permanent human implantation, stated that the resins can oxidize in response to oxygen or strong oxidizing agents, and recounted Defendants' efforts to obtain the resin. (ECF No. 64-2 at PageID #1545–48.) In her deposition, she opined that the MSDS "demonstrated concerns about incompatibility." (ECF No. 103-5 at PageID #8954, p. 330.) She also stated that MSDSs are "also for people using the materials afterwards . . . not just for the people who are handling it." (*Id.* at PageID #8955, p. 334.) Dr. Babensee's opinions speak to the meaning of the MSDS, *i.e.*, that it presented safety concerns. This opinion is inadmissible. *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 * 4–5 (S.D. Ohio Oct. 20, 2020) (holding the MSDS is only admissible as evidence of notice) (Motions in Limine Order ("MIL") No. 4).

Plaintiffs argue that this Court permitted Dr. Babensee to offer this opinion in in *Johns*.

(ECF No. 103 at PageID #8782.) In *Johns*, the Court denied Defendants' *Daubert* motion attacking Dr. Babensee's qualifications to offer MSDS opinions. *In re Davol, Inc/C.R. Bard, Inc.*, 2020 WL 6605542, at *22 (EMO No. 5). However, the Court stated that this holding was "[s]ubject to the pending motions in limine regarding the admissibility of evidence related to MSDS filed by both parties." *Id.* Subsequently, the Court held that the MSDS was only admissible as evidence of Defendants' notice of the risks presented by polypropylene. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at * 4–5 (MIL No. 4). Thus, the Court's earlier *Daubert* opinion on Dr. Babensee does not allow her to offer her MSDS opinions.

**H. Corporate state-of-mind, parroted, and disclaimed opinions**

Finally, Defendants argue that Dr. Babensee should not be permitted to offer opinions on Defendants' corporate state of mind, to parrot another expert's opinion, or to offer disclaimed opinions. (ECF No. 64 at PageID #1468–69.) Defendants argue that Dr. Babensee will not offer any such opinions. (ECF No. 103 at PageID #8789–90.) Thus, Defendants' motion is moot. Defendants seek a preemptory, follow-the-law order, which this Court has consistently declined to issue. *E.g.*, *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6605542, at *17.

Defendants contend that their concern about Dr. Babensee parroting another expert's opinion "is not a mere hypothetical concern" because Dr Babensee has reviewed Plaintiffs' other expert's reports and cites Dr El-Ghannam's analyses from other litigation. (ECF No. 64 at PageID #1469.) This is speculation. Defendants identify no portion of Dr. Babensee's report or testimony that actually presents this problem. Dr. Babensee is permitted to "to base an opinion on another expert witness for a point of expert knowledge not personally possessed." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ----, 2021 WL 2646797, at *5 (S.D. Ohio June 28, 2021) (citations omitted) (EMO No. 10). Without any showing that she

is in fact parroting those expert's opinions, the Court declines to go further this time.

## IV. Conclusion

For these reasons, Defendants' motion to exclude Dr. Babensee's opinions and testimony (ECF No. 64) is **GRANTED IN PART, DENIED IN PART, AND DENIED IN PART AS MOOT, AND RESERVED IN PART**.

**IT IS SO ORDERED.**

**11/2/2021**
**DATE**

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