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 v. C.R. Bard*,**
Case No. 2:18-cv-01320

MOTIONS *IN LIMINE* ORDER NO. 19

Defendants' Motion *in Limine* ("MIL") No. 23

Before the Court for consideration is Defendants' MIL No. 23 to exclude evidence regarding polypropylene degradation (ECF No. 195[1]), which is opposed by Plaintiffs (ECF No. 269). For the reasons that follow, the Court **DENIES** Defendants' Motion.

I.[2]

On July 11, 2007, Plaintiff Antonio Milanesi underwent surgery to repair a primary umbilical hernia. During this surgery, Dr. Karanbil Gill repaired the hernia using a Bard Ventralex Hernia Patch (size Large). On May 26, 2017, approximately ten years after this initial surgery, Mr. Milanesi was diagnosed with a recurrent entrapped hernia with the possibility of a delayed mesh infection, requiring immediate surgery.

During the emergency surgery, Mr. Milanesi's surgeon, Dr. Michael Caluda recognized

[1] [1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case *Milanesi v. C.R. Bard*, Case No. 2:18-cv-01320. (ECF No. 167.)
[2] All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

that there was not a hernia recurrence, but instead there was an infected hernia mesh with erosion of the mesh into the small bowel. Dr. Caluda found that a loop of 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.

Dr. Caluda testified that the Ventralex Hernia Patch had "buckled" and was "not pliable" but was "firm." (Nov. 4, 2019 Dep. of Michael J. Caluda, M.D. at 46–47 ("Caluda Dep."), attached as Ex. B to Pls.' Opp'n to Defs.' Mot. for Summ. J.).) The reviewing pathologist described the mesh as "distorted." (*Id.*) (quoting Caluda Dep. at 43–47).) In the explant procedure, Dr. Caluda had to surgically remove nine centimeters (3.54 inches) of Mr. Milanesi's small bowel. (*Id.*)

After spending several days in the hospital after this surgery, Mr. Milanesi was released and had to return immediately to the hospital for another emergency surgery to correct a high-grade bowel obstruction due to complications from the May 26, 2017 mesh removal surgery. Mr. Milanesi now suffers from complex focal wall ventral hernias in his abdomen due to the damage caused by these 2017 surgeries. (*Id.*) More specifically, Mr. Milanesi was diagnosed with a "recurrent incisional hernia" described as at least two areas of herniation extending laterally from the umbilicus in each direction. Dr. David Krpata, Plaintiffs' expert surgeon, has opined that Mr. Milanesi's recurrent hernias are due to the weakening of the abdominal wall as a result of the two surgeries in 2017. (*Id.*)

Mr. Milanesi asserts claims under Florida law for, among other things, design defect and failure to warn. Plaintiffs bring this case to recover for the damages that they have suffered, and continue to suffer, because of Defendants' defective Ventralex Hernia Patch. Plaintiff contends

that the Ventralex Hernia Patch fails because the polypropylene becomes exposed to the visceral tissues—this occurs when the device folds inward toward the bowel because expanded polytetraflouroethylene (ePTFE) contracts at a faster rate than polypropylene. Mr. Milanesi alleges that as a result of being implanted with Defendants' Ventralex device, which contains polypropylene, he suffered from dense bowel adhesions, inflammation, infection, erosion, fistula(s), and pain, among others, because the defective Ventralex mesh deformed or "buckled," contracted/shrunk, and became stiff/rough while implanted in Mr. Milanesi.

II.

Defendants move *in limine* for exclusion of polypropylene degradation evidence under Federal Rules of Evidence 402 and 403. "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 "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). 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." *Ind. Ins. Co*., 326 F. Supp. 2d at 846; *see also Koch*, 2 F. Supp. 2d at 1388 ("[A] court is almost always better situated during the actual trial to assess the value and utility of evidence."). 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.

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. "Irrelevant evidence is" inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Evidentiary rulings are made subject to the district court's sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*, 295 F.3d 565, 576 (6th Cir. 2002) ("In reviewing the trial court's decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.").

III.

Defendants ask for exclusion of "evidence and argument regarding Plaintiffs' theory that the polypropylene mesh in the Ventralex Hernia Patch degrades." (Defs' MIL No. 23 at 1, ECF No. 195.) Defendants argue:

> Plaintiffs intend to present the same theory in this case as the plaintiff did in [the first bellwether trial] *Johns*, utilizing largely the same witnesses, that

> polypropylene mesh degrades and that degradation can lead to injuries to some patients. However, degradation has nothing to do with Mr. Milanesi's injury in this case, which Plaintiffs' allege occurred because the Ventralex large created an increased risk of bowel erosion due to the purported phenomenon of "buckling."
>
> However, despite Plaintiffs' repeated attempts to create one, there is no link between Mr. Milanesi's claimed injury and degradation. It is undisputed that when bare polypropylene mesh is exposed to the bowel it presents a risk of possible injury. This is because polypropylene mesh is a porous material designed to encourage tissue ingrowth, not because it is degrading. And, just as in *Johns*, Plaintiffs' case specific causation expert does not contend that Mr. Milanesi was injured by polypropylene mesh degrading. Indeed, Plaintiffs have ***no evidence*** that connects alleged polypropylene degradation to the claimed injuries in this case.

Id. at 1–2

Plaintiff responds:

> Defendants assert that no evidence exists that suggest degradation or oxidization caused Plaintiff Milanesi's injuries, and therefore, Defendants conclude, the evidence is irrelevant and should be excluded. But there is evidence that oxidative degradation contributed to Plaintiff Milanesi's injuries. Plaintiffs argue that the Ventralex shrinkage and contraction was the result of, in part, degradation and oxidation.
>
> Moreover, the buckling caused the mesh to expose the polypropylene side of the mesh to be exposed to the visceral and vital organs. Polypropylene should not be exposed to the vital organs because it degrades and oxidizes. (ECF No. 87, 27-28.) Accordingly, this information is relevant and probative. Indeed, as this Court has repeatedly recognized, "Plaintiffs' theory of injury is twofold— the Ventralex buckled, *and polypropylene was exposed to Mr. Milanesi's bowl*, causing his injuries." *See, e.g.,* EMO No. 19, *Milanesi* ECF No. 219 at PAGEID#14987 (emphasis added).

(Pls' Mem. in Opp. to Defs' MIL No. 23, ECF No. 269.) This Court agrees.

Plaintiffs have put forth expert testimony and opinions about polypropylene degradation and its relevance to the Milanesi case, which this Court has considered under *Daubert* and Federal Rule of Civil Procedure 702, issuing Evidentiary Motions Orders ("EMOs").

In EMO No. 19, the Court explained:

> Defendants argue that Plaintiffs do not sufficiently connect Dr. Mays's polypropylene degradation opinions to Mr. Milanesi's injuries. (ECF No. 71 at PageID #3568.) True, Dr. Krpata in his specific causation analysis did not reference degradation. However, his specific causation opinion is that polypropylene exposure at least in part caused the injuries. As Defendants explain, Dr. Mays's opinion is that all polypropylene degrades and causes injury. (ECF No. 71 at PageID #3569.) Specifically, he opines that polypropylene is not suitable for permanent implantation because it degrades. (ECF No.71-1 at PageID #3591.) Nothing in Dr. Krpata's opinion forecloses this explanation for why polypropylene exposure is problematic.

(ECF NO. 219 at PAGEID #14988-89.)

Additionally, in EMO No. 20, the Court stated:

> Dr. El-Ghannam's general polypropylene degradation opinions are relevant to this case. Plaintiffs identify a two-step mechanism of injury in all bellwether cases in this MDL, including this case. First, the polypropylene mesh's "adhesion barrier fails, and polypropylene is exposed to underlying organs to which it attaches." (ECF No. 105 at PageID #9151.) As the Court noted in its *Daubert* opinion addressing Dr. Krpata, the precise two-step mechanism of injury here is that the Ventralex buckles due to contracture, which then exposes bare polypropylene to the viscera. (ECF No. 166 at PageID #13590.) Dr. Krpata, a general and specific causation expert, opines on the first step of this mechanism, explaining that polypropylene mesh and ePTFE contract at different rates, causing buckling, and the memory recoil ring lacked sufficient rigidity to prevent the buckling. (*Id*.) Healso notes that the exposure of bare polypropylene is widely known to be problematic and can cause adhesions, fistula, and erosion. (*Id*.)
>
> Dr. El-Ghannam picks up where Dr. Krpata leaves off, explaining why bare polypropylene causes such injuries. (ECF No. 219 at PageID #14987–90.) Thus, Dr. ElGhannam's general causation opinions about polypropylene degradation are relevant. Defendants counter that polypropylene degradation has no relation to this case, but Defendants ignore the two-step mechanism of injury described above. (ECF No. 72 at PageID #3705–06.)

ECF NO. 220 at PAGEID #14998.

Moreover, in EMO No. 23, the Court held that Plaintiffs' biomaterial expert, Dr. Babensee, offered admissible opinions that polypropylene degradation opinions are relevant because they explain why exposure to bare polypropylene is problematic. (ECF No. 273.)

Finally, the probative value of this relevant evidence is not "substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Thus, this relevant evidence is not excludable under Rule 403.

IV.

Based on the foregoing, and for the reasons stated in this Court's EMO 19 (ECF No. 219), 20 (ECF No. 220), and 23 (ECF No. 273) regarding Defendants' Motions to Exclude Dr. Mays (ECF No. 71), Dr. El-Ghannam (ECF No. 72), and Dr. Babensee (ECF No. 64), Defendants' Motion *in Limine* No. 23 to exclude evidence regarding polypropylene degradation is **DENIED** (ECF No. 195).

As with all *in limine* decisions, this ruling is subject to modification should the facts or circumstances at trial differ from that which has been presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

12/2/2021
DATE

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