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 OPINION & ORDER NO. 30

Defendants' Motion *in Limine* ("MIL") No. 9 and Plaintiffs' MILs No. 13 & No. 18

Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi and Defendants C.R. Bard, Inc. and Davol, Inc. filed various MILs to exclude evidence in this case. Now before the Court are (A) Defendants' MIL No. 9 to Exclude Evidence and Argument Concerning "Medical Grade" Polypropylene (ECF No. 191), (B) Plaintiffs' MIL No. 13 to Exclude Testimony or Argument From Defendants' Witnesses or Counsel Regarding the Purported Safety of Polypropylene Mesh Devices Generally and the Irrelevant Evidence of the Explanter's Use of the Ventralex Device (ECF No. 207), and (C) Plaintiffs' MIL No. 18 to Prohibit Defendants, Their Counsel, or Witnesses From Stating That the Risks of Polypropylene are the Same Regardless of Amount or Placement (ECF No. 201). For the reasons that follow, the Court **DENIES** Defendant's MIL No. 9, **GRANTS IN PART** and **DENIES IN PART** Plaintiffs' MIL No. 13, and **DENIES AS MOOT** Plaintiffs' MIL No. 18.

I. Background[1]

The Milanesis' case will be tried as the second bellwether selected from thousands of cases in this multidistrict litigation ("MDL") titled *In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, 2:18-md-2846. 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.)

Plaintiffs bring this action to recover for injuries sustained as a result of the implantation of the Ventralex Large Hernia Patch, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. 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.

The relevant facts here are that 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. Shortly thereafter, Mr. Milanesi suffered a high-grade post-operative small bowel obstruction that required emergency surgery. Mr. Milanesi had the Ventralex Large Hernia Patch implanted ten years earlier to repair a hernia.

[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.) All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

II. Standards

"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. Analysis

A. Defendants' MIL No. 9

Both parties agree that a similar issue was before this Court in the first bellwether case, *Johns v. C. R. Bard, Inc., et al.*, Case No 2:18-cv-01509. The Court denied Defendants' motion to exclude evidence of "medical grade" polypropylene. (Case No 2:18-cv-01509, MIL Order No. 2, ECF No. 331 at PageID #17885.) At the September 3, 2020 MIL hearing in *Johns*, the Court noted that the phrase "medical grade" polypropylene had been used before in Defendants' internal documents. (Case No 2:18-cv-01509, ECF No. 322 at PageID #17269.) The Court stated that "[t]he defense can certainly argue that there's a lack of standards . . . [whether] it's safer, what sort of testing was done, all those things are fair game to discredit that phrase, but I'm going to leave that to the jury to decide if there's any significance." (*Id.* at PageID #17269–70.) The same reasoning applies here, and the Court adopts its prior ruling in *Johns*.

B. Plaintiffs' MIL No. 13

1. Purported Safety and Efficacy of Polypropylene Mesh Devices

Plaintiffs first argue that Defendants should not be permitted to introduce testimony or arguments that polypropylene mesh devices are generally safe and effective. (Pls' MIL 13, ECF No. 207.) Plaintiffs claim that "such broad testimony is unreliable, lacks evidentiary basis, does not prove or disprove any of the claims in this case, and will only mislead the jury, confuse the issues, waste the Court's time, and provoke an unfair prejudice that substantially outweighs any potential probative value from its admission. (*Id.* at PageID #14786.) Plaintiffs allege that testimony regarding the purported safety and efficacy of polypropylene mesh amounts to an implied endorsement by the medical community at large.

In response, Defendants argue that testimony regarding the "decades-long history of polypropylene mesh" is directly relevant to Plaintiffs' claims. (Defs' Mem. in Opp., ECF No. 224 at PageID #15033.) Defendants point out that one of Plaintiffs' main theories is that polypropylene mesh should not be used in implantable medical devices. (*Id.* at PageID #15034.) This Court agrees. Plaintiffs' case centers on the alleged harm caused by the polypropylene side of the Ventralex coming into contact with Mr. Milanesi's bowel. The history of polypropylene mesh is part of Defendants' "story." *Old Chief v. United States*, 519 U.S. 172, 189 (1997). If Plaintiffs intend to argue that polypropylene mesh products are not safe for use, Defendants must be allowed to rebut those claims. The Court has limited the manner in which Defendants may argue the safety of polypropylene mesh in its other MIL Orders, for example excluding testimony that polypropylene mesh is the "gold standard" for hernia repairs (MIL Order No. 18, ECF No. 285 at PageID #16894), but the Court declines to broadly exclude any testimony or argument claiming that polypropylene mesh is safe or effective. This portion of Plaintiffs' motion is denied.

2. Dr. Caluda's Use of the Ventralex

Plaintiffs ask the Court to exclude testimony or arguments related to the explanting surgeon's use of the Ventralex in his practice. (Pls' MIL 13, ECF No. 207.) The explanting surgeon, Dr. Caluda, is not designated as an expert witness in this case. Plaintiffs argue that as a fact witness, "any testimony from Dr. Caluda regarding his usage of the Ventralex patch would be irrelevant to the issues in this case of which Dr. Caluda has actual knowledge, *i.e.* the removal of [Mr. Milanesi's] mesh." (*Id.* at PageID #14790.) Plaintiffs claim that "[t]he only way such information would be relevant would be if the Defendants sought to elicit testimony or create an inference that Dr. Caluda holds opinions about the safety or efficacy of the Ventralex patch." (*Id.*)

In response, Defendants concede that Dr. Caluda is not a designated expert, but argue that his experience is a probative fact "because it provides important context for Dr. Caluda's testimony and Plaintiffs' expected mischaracterization of such testimony." (Defs' Mem. in Opp., ECF No. 224 at PageID #15035.) Defendants claim that Plaintiffs treated Dr. Caluda as an expert by having him review the implant operative report before his deposition and by asking standard of care questions about implant procedure. (*Id.* at PageID #15035–36.) Defendants next argue that Dr. Caluda's observations about the Ventralex that he removed from Mr. Milanesi makes the extent of his experience with the Ventralex relevant. (*Id.* at PageID #15037.) Finally, Defendants argue that because Dr. Caluda recommended another hernia repair with synthetic mesh for Mr. Milanesi, Dr. Caluda's experience with the Ventralex is at issue. (*Id.* at PageID #15036–37.)

This Court disagrees with Defendants' contentions regarding Dr. Caluda's experience with the Ventralex. Both parties agree that Dr. Caluda has not been designated as an expert witness who opines that the Ventralex is generally safe or unsafe. Dr. Caluda's observations of the state of Mr. Milanesi's specific Ventralex patch upon removal do not open the door to his general use

of the Ventralex throughout his career as a surgeon. If Dr. Caluda were to offer testimony regarding the overall safety and efficacy, or lack thereof, of the Ventralex patch, then his use of the Ventralex in connection with other patients may be relevant. However, Dr. Caluda's case-specific opinions regarding Mr. Milanesi's explant surgery do not invite broad evidence regarding other instances of his use of the Ventralex throughout his career. This portion of Plaintiffs' motion is granted.

C. Plaintiffs' MIL No. 18

Plaintiffs ask the Court to exclude any statements that the risks of polypropylene are the same regardless of amount or placement. (Pls' MIL 18, ECF No. 201.) However, no expert witnesses on either side have opined that the amount of polypropylene in the Ventralex played a role in Mr. Milanesi's injuries. Additionally, as Plaintiffs recognize in their Motion, both Plaintiffs' and Defendants' experts agree that different surgical techniques and different hernia mesh placements come with their own risks. (*Id.* at PageID #14707.) Defendants do not claim that any and all hernia mesh placements carry identical risks; as their response states, "there is no dispute that surgical technique can present different risks and benefits[.]" (Defs' Mem. in Opp., ECF No. 252 at PageID #15816.) In their Motion, Plaintiffs acknowledge that none of Defendants' experts "ha[s] opined that the risks posed by polypropylene implanted in the human body are the same regardless of mesh type, amount, or placement." (Pls' MIL 18, ECF No. 201 at PageID #14709.) Plaintiffs state that "'the bowel must not come into contact with an adhesion-inducing material such as polypropylene.'" (*Id.* at PageID #14708 (quoting ECF No. 63-1 at PageID #1090).) This is consistent with Defendants' response, which states "polypropylene mesh may adhere to bowel or other internal organs when there is direct contact." (Defs' Mem. in Opp., ECF

No. 252 at PageID #15817.) There does not appear to be any disagreement between the parties on this issue, therefore Plaintiffs' Motion is moot.

IV. Conclusion

For the reasons set forth above, the Court **DENIES** Defendants' MIL No. 9 (ECF No. 191), **GRANTS IN PART** and **DENIES IN PART** Plaintiffs' MIL No. 13 (ECF No. 207), and **DENIES AS MOOT** Plaintiffs' MIL No. 18 (ECF No. 201).

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.

12/9/2021
DATE

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