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:
***Stinson v. Davol, Inc., et al.*,**
Case No. 2:18-cv-01022

MOTIONS IN LIMINE OPINION & ORDER NO. 47

Plaintiff's Motions *in Limine* ("MIL") No. 13, 18, 19, 21, 22

Plaintiff Aaron Stinson and Defendants C.R. Bard, Inc. and Davol, Inc. filed various MILs to exclude evidence in this case. Now before the Court are (A) Plaintiff's MIL No. 13 to Exclude Testimony or Argument Regarding the Purported Safety of Polypropylene Mesh Devices Generally and Evidence of Treating Physicians' Use or Opinions of Polypropylene Mesh Devices, Including the PerFix Plug (ECF No. 172); (B) Plaintiff's 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. 173); (C) Plaintiff's MIL No. 19 to Prohibit Defendants, Their Counsel, or Witnesses From Stating That "All Doctors" Know of the Risks of Injuries Suffered by Mr. Stinson (ECF No. 175); (D) Plaintiff's MIL No. 21 to Prohibit Evidence or Argument Regarding Pain or Inflammation in Non-Hernia Surgeries (ECF No. 174); (E) Plaintiff's MIL No. 22 to Exclude Evidence, Argument, or Suggestion That Proof of a Feasible and Safer Alternative Device is an Element of the PerFix Plug's Design Defect Claim (ECF No. 176).

I. Background[1]

Plaintiff's case will be tried as the third 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.)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of an Extra-Large PerFix Plug hernia mesh device, 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: design defect, failure to warn, negligence, breach of express warranty, and breach of implied warranty; the Court has reserved judgment on Plaintiff's claims for manufacturing defect, certain damages, and claims related to his current Bard Mesh implant.

The relevant facts here are that in 2015 Plaintiff underwent a right inguinal hernia repair with an Extra-Large PerFix Plug mesh, a product manufactured by Defendants. In 2017, Plaintiff underwent exploratory surgery to determine if he had a recurrent hernia or nerve entrapment because of chronic pain in his right groin area. The explanting surgeon, Dr. Radke, noted extensive

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case. (Dispositive Motions Order ("DMO") No. 7, ECF No. 225.) All docket citations are to the *Stinson* case, 2:18-cv-1022, unless otherwise noted.

scarring and found "a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle." (ECF No. 89-22 at PageID #1134.) Dr. Radke removed the mesh, which he described as "slow going and extremely difficult" because of the significant scarring. (*Id.*) Dr. Radke then repaired the hernia with another of Defendants' products, Bard Marlex Mesh. (*Id.*) Even after the explant surgery, Plaintiff claims to have continuing chronic pain and other complications.

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. Plaintiff's MIL No. 13

A similar issue was before the Court in the second bellwether trial in this MDL, *Milanesi, et al. v. C.R. Bard, Inc., et al.* (Case No. 18-cv-1320). The Court ruled that the purported safety and efficacy of polypropylene mesh devices was part of Defendants' "story," and that "[i]f Plaintiffs intend to argue that polypropylene mesh products are not safe for use, Defendants must be allowed to rebut those claims." (Case No. 18-cv-1320, MIL Order No. 30, ECF No. 303 at PageID #17326.) The same reasoning applies here, and that portion of Plaintiff's motion is denied.

In *Milanesi*, the Court granted the plaintiffs' request to exclude evidence of the explanting surgeon's use of the device at issue because the surgeon was only serving as a fact witness, and was only testifying as to his observations of the state of the plaintiff's explanted mesh. (*Id.* at PageID #17327–28.) The implanting and explanting surgeons in this case are also serving only as fact witnesses and not expert witnesses. However, as Defendants point out, the motion in *Milanesi* dealt only with the explanting surgeon, whereas Plaintiff's motion here pertains to both the implanting (Dr. Tan) and explanting (Dr. Radke) surgeons. Dr. Tan's use of polypropylene mesh is directly relevant in this case because she is the one who selected the PerFix Plug and implanted the device. Her testimony as to why she chose the PerFix Plug and that it was her "first-line" product for hernia repairs for many years is relevant as to Plaintiff's failure to warn and causation claims.

Dr. Radke's testimony in this case differs from Dr. Caluda's testimony in *Milanesi*. During Plaintiff's explant surgery, Dr. Radke believed that he was removing a "sheet [of flat mesh] that had pulled loose or something of that sort," and did not know until his deposition that it was actually a 3D plug-shaped mesh. (ECF No. 89-21 at PageID #1130.) In his operative report he described the mesh as a "rolled up" and "balled up area of mesh" (ECF No. 89-22 at PageID #1134), whereas after he learned that the device was a PerFix plug, he said that would "explain some of what [he] saw" during the explant surgery (ECF No. 89-21 at PageID #1130). He also testified that he did not recall ever having explanted a mesh plug device. (*Id.* at PageID #1128.) Therefore, while Dr. Radke is not an expert, his experience with polypropylene mesh can be used to explain his operative report and observations regarding Plaintiff's case. Plaintiff's motion is **GRANTED IN PART** and **DENIED IN PART**.

B. Plaintiff's MIL No. 18

This issue was also before the Court in *Milanesi*. The Court denied the motion as moot because no expert witnesses on either side had opined that the amount of polypropylene in the device played a role in the plaintiff's injuries, and because both parties' experts agreed that different hernia mesh placements come with their own risks. (Case No. 18-cv-1320, MIL Order No. 30, ECF No. 303 at PageID #17328–29.) In their response to Plaintiff's motion, Defendants argue that the same result is warranted here because none of their experts has opined that the risks of polypropylene implanted in the body are the same regardless of amount or placement. (ECF No. 207 at PageID #7825.) This case differs because Plaintiff's experts do allege that the amount of polypropylene in the PerFix Plug increases the risks of complications. To the extent that Plaintiff offers evidence and testimony that the amount of polypropylene in the PerFix Plug can lead to complications, Defendants are entitled to present a defense. Accordingly, Plaintiff's motion is **DENIED IN PART** and **DENIED IN PART AS MOOT**.

C. Plaintiff's MIL No. 19

This issue was before the court in *Milanesi* and in the first bellwether trial, *Johns v. C.R. Bard, Inc., et al.* (Case No. 18-cv-1509). The Court granted the motion, and reasoned that:

> Certainly part of this case is medical practice and procedure. I would not let a witness get on the stand and talk about what all doctors know. There are other ways to do that that would be admissible evidence, and that would be what training did you receive, what are the procedures in the hospital where you practice, are you familiar with other hospital practices, et cetera. You know how to do it. But we're not bringing a doctor on to give a survey of other doctors. That's my only concern. This really has to do with the framing more than it does with the substance.

(Case No. 18-cv-1320, MIL Order No. 26, ECF No. 296; Case No. 18-cv-1509, ECF No. 311 at PageID #16855.) The same analysis applies here, and the Court adopts its prior rulings. Plaintiff's motion is **GRANTED**. Defendants may not present testimony or argument purporting to speak

on behalf of all doctors or the entire medical community. Pursuant to Rule 602, Defendants' witnesses may only speak to matters of which they have personal knowledge.

D. Plaintiff's MIL No. 21

Plaintiff seeks to exclude evidence regarding the risks of pain or inflammation, complications allegedly suffered by Plaintiff, in non-hernia surgeries. The Court dealt with a similar issue in *Johns*, when the plaintiff in that case moved to exclude evidence regarding adhesions occurring in non-hernia surgeries. The Court granted the motion in part and held that Defendants could present evidence of adhesions occurring in hernia surgeries, but not in other non-hernia surgeries. (Case No. 18-cv-1509, MIL Order No. 1-A, ECF No. 330 at PageID #17882.) In a MIL hearing, the Court reasoned:

> I am not in any way limiting your adducing testimony about adhesions in [hernia] surgeries, but I don't want to be talking about other types of surgery. This case is complicated enough for a jury. You can certainly explain when muscles are operated upon and sutured together, that adhesions are common or whatever you think the testimony will bear from your experts, but I don't want us to delve into any other types of surgery that will need explanation and that won't shed a whole lot of light[.]

(Case No. 18-cv-1509, ECF No. 311 at PageID #16848.) The same reasoning applies here. Plaintiff's motion is **GRANTED IN PART** and **DENIED IN PART**.

E. Plaintiff's MIL No. 22

Plaintiff has filed a motion to exclude "evidence, argument, or suggestion" that he must offer proof of a feasible and safer alternative design as a part of his design defect claim. (ECF No. 176.) The Court agrees with Defendants that this is not a proper use of a motion *in limine*. (ECF No. 192.) Plaintiff's motion does not ask to exclude evidence, but seeks an interpretation of Maine's design defect law. Further, the Court has already determined in DMO No. 7 that proof of

a feasible alternative design is required under Maine law. (ECF No. 225 at PageID #9119–22.) Plaintiff's motion is **DENIED AS MOOT**.

IV. Conclusion

For the reasons set forth above, Plaintiff's MIL No. 13 (ECF No. 172) is **GRANTED IN PART** and **DENIED IN PART**; Plaintiff's MIL No. 18 (ECF No. 207) is **DENIED IN PART** and **DENIED IN PART AS MOOT**; Plaintiff's MIL No. 19 (ECF No. 175) is **GRANTED**; Plaintiff's MIL No. 21 (ECF No. 174) is **GRANTED IN PART** and **DENIED IN PART**; and Plaintiff's MIL No. 22 (ECF No. 176) is **DENIED AS MOOT**.

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.

6/6/2023
DATE

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