

**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:

Johns v. CR Bard et al.,
Case No. 2:18-cv-1509

MOTION IN LIMINE OPINION AND ORDER No. 9

Plaintiff Steven Johns and defendants C.R. Bard, Inc. and Davol, Inc. filed various motions in limine to exclude evidence in this case. Now before the Court is Plaintiff's Motion in Limine No. 10 (ECF No. 241) and Defendants' Motion in Limine No. 20 (ECF No. 12164).

I. Background¹

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation, alleging "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." (No. 2:18-md-02846, ECF No. 1 at PageID #1-2.)² This includes the Ventralight ST, the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs. (ECF No. 309 at PageID #16717.) The Food and Drug Administration cleared it for use through the premarket notification § 510(k) process in 2010 and later cleared it for use with the Echo

¹ The Court assumes that the parties and other interested readers are familiar with the history of this case. For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order. (ECF No. 309.)

² Unless otherwise noted, record citations are to the docket for this case, No. 18-cv-01509.

Positioning System in 2011. It is a multicomponent device made of a mesh, which consists of polypropylene, polyglycolic acid (“PGA”) fibers, and a bioresorbable coating called “Sepra Technology” (“ST”). The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment and thus supports the hernia repair. (*Id.*)

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Defendants’ allegedly defective Ventralight ST device. Plaintiff claims that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body and that the PGA fibers created an increased inflammatory response. (*Id.*) The crux of Plaintiff’s claims is that the ST coating on Ventralight ST devices resorbs too quickly. This leads to the exposure of bare polypropylene to internal organs and tissues, increasing the risk of potential complications. Plaintiff alleges that this occurrence led to omental adhesions after his laparoscopic hernia repair surgery in 2015. The adhesions were diagnosed during a subsequent laparoscopic surgery in October 2016 by Plaintiff’s implanting surgeon. (*Id.* at PageID #16740, 16746.)³ After summary judgment, the following claims remain for trial: design defect, under negligence and strict liability theories; failure to warn, under negligence and strict liability theories; breach of express warranty; breach of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. (*Id.* at PageID #16727–65.) Now, various motions in limine and other evidentiary motions are ripe for adjudication.

This opinion addresses two motions in limine that the Court considered during the August 27, 2020 hearing: Plaintiff’s Motion in Limine No. 10 (ECF No. 241) and Defendants’ Motion in Limine No. 20 (ECF No. 224). In his motion, Plaintiff moves for the exclusion of evidence

³ The Court granted Defendants’ motion for summary judgment on Plaintiff’s other alleged injuries because Plaintiff failed to demonstrate a material fact dispute regarding causation. (ECF No. 309 at PageID #16740.)

regarding a number of subjects, including that adhesions occur in all abdominal surgeries; that diabetes, prediabetes, or elevated A1C causes adhesions; that obesity causes adhesions; and that Plaintiff and others are predisposed to forming adhesions. (ECF No. 241 at PageID #13024–25.) The Court granted part of this motion, reserving judgment on the diabetes and obesity issues. (ECF No. 330 at PageID #17882.) Because the Court did not to address the predisposition portion of Plaintiff’s motion (*id.*), the Court addresses it here as well. The Court also reserved judgment on Defendants’ motion, which seeks exclusion of reference to C-8 and the *In re Du Pont de Nemours & Co. C-8 Personal Injury Litigation*. (*Id.* at PageID #17883.)

II. Legal 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 Motion in Limine No. 10

In his motion, Plaintiff argues that evidence establishing that diabetes, prediabetes, elevated A1C, obesity, and certain predispositions cause adhesions should be excluded as irrelevant and/or prejudicial. (ECF No. 241 at PageID #13029–31.) Defendants clarify that they do not seek to introduce evidence that diabetes, prediabetes, elevated A1C, and obesity cause

adhesions, but to introduce evidence that these factors are risk factors for hernia reoccurrence and other complications, such as poor healing after surgery, recurrent diastasis, and infection. (ECF No. 266 at PageID #14131–32.) However, they do intend to introduce evidence that predispositions may cause adhesions, alleging that “[t]his is basic medical knowledge.” (*Id.* at PageID #14133.)

Several problems arise in relation to this evidence. First, it is clear from the record that Defendants have yet to show that Plaintiff was ever diagnosed with diabetes, prediabetes, or elevated A1C. The Court highlighted this during the hearing on this motion, concluding that Defendants would need to establish this diagnosis via witness testimony. (ECF No. 311 at PageID #16852.) If Plaintiff does not have any of these conditions, evidence related to these conditions is irrelevant. Moreover, Defendants explain that they do not intend to introduce this evidence to show diabetes and related ailments cause adhesions, but instead that they cause hernia and diastasis recurrence and other complications, such as poor healing and infection. (ECF No. 266 at PageID #14131.) The only injury left in Plaintiff’s case after summary judgment is his adhesions. Therefore, this evidence is irrelevant on this ground as well.

Evidence of Plaintiff’s obesity and high Body Mass Index, which is undisputed by Plaintiff (ECF No. 241 at PageID #13031), is similarly irrelevant based on this record. Defendants intend to introduce this evidence to prove an alternate cause of recurrence and other complications (ECF No. 266 at PageID #14131), but these injuries are no longer part of this case.

Finally, Defendants’ assertion that some patients are predisposed to adhesions suffers from a similar problem—it is unclear what, if any, predisposition Plaintiff has to adhesions. Defendants provide no record citation that indicates that Plaintiff was diagnosed with a predisposition. (ECF

No. 266 at PageID #14133.) It should be obvious that for evidence about genetic predispositions to be relevant, Plaintiff must have a genetic predisposition.

For these reasons, the remaining part of Plaintiff's motion is granted. No party may address these topics without prior approval. The Court notes that it is willing to revisit these rulings because its summary judgment opinion and order was issued after the briefing was completed and the hearing was held. However, it will only consider additional arguments related to diabetes and genetic predispositions if Defendants intend to introduce witness testimony that Plaintiff was diagnosed with these conditions.

B. Defendants' Motion in Limine No. 20

In their motion, Defendants argue that reference to C-8 and the *In re Du Pont de Nemours & Co. C-8 Personal Injury Litigation* should be excluded. (ECF No. 224 at PageID #12164.) Plaintiff responds that he would only introduce any evidence related to C-8 and the *In re Du Pont de Nemours* litigation in the event that his expert Dr. Fedoruk must explain the basis for his expert testimony. (ECF No. 293 at PageID #16085–86.) Dr. Fedoruk was an expert in the C-8 litigation and his opinions in this case about the Marlex Material Safety Data Sheet (“MSDS”) are based in part on his knowledge of the C-8 MSDS. (*Id.* at PageID #16086.) During the hearing on this motion, the Court reserved judgment because it was uncertain if the need to introduce this evidence would ever arise. (ECF No. 211 at PageID #16860.)

At this point, the Court denies Defendants' motion. Defendants and Plaintiff clarified during the hearing that they had no intention to ask Dr. Fedoruk about the C-8 MSDS. (*Id.* at PageID #16858–60.) In the event that the need to reveal Dr. Fedoruk's specific knowledge related to the C-8 MSDS arises, the Court will address the issue in the context of trial. No party may address this issue without prior court approval.

IV. Conclusion

For the reasons set forth above, the remainder Plaintiff's Motion in Limine No. 1 (ECF No. 241) is **GRANTED IN PART** and Defendants' Motion in Limine No. 20 (ECF No. 224) is **DENIED**.

IT IS SO ORDERED.

1/5/2020
DATE

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