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. 34

Defendants' Motion *in Limine* ("MIL") No. 12

Defendants C.R. Bard, Inc. and Davol, Inc. filed a Motion *in Limine* to Exclude Evidence and Argument Concerning Medical Device Reports ("MDRs") and Complaints Related to Patients Other Than Plaintiff Antonio Milanesi (Defs' MIL No. 12, ECF No. 192), which was opposed by Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi (ECF No. 258). For the reasons that follow, the Court **DENIES** Defendants' Motion.

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

[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.

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. The Ventralex hernia patch has two sides—one of polypropylene mesh and one of permanent expanded polytetrafluoroethylene ("ePTFE"). (ECF No. 167 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. Milanesi. 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.*)

In Defendants' MIL No. 12, they move to exclude under Federal Rules of Evidence 401, 403, and 802 all evidence and argument concerning MDRs and complaints related to patients other than Mr. Milanesi.

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."). Hearsay is an out-of-court statement offered for the truth of the matter asserted. Fed. R. Evid. 801(a), (c). Unless a statement falls within an exception or exclusion set forth by the Federal Rules of Evidence, federal statute, or Supreme Court precedent, hearsay is inadmissible. Fed. R. Evid. 802.

III. Analysis

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, where Defendants moved to exclude all evidence related to MDRs and complaints related to patients other than the plaintiff. The Court denied the motion. In addressing Defendants "substantial similarity" argument, the Court concluded:

> Prior accidents or incidents "must be 'substantially similar' to the one at issue before they will be admitted into evidence." *Rye v. Black & Decker Mfg. Co.*, 889 F.2d 100, 102 (6th Cir. 1989). Typically, this requires "that the accidents must have occurred under similar circumstances or share the same cause." *Id.* Evidence of

prior incidents may demonstrate that a defendant was on notice or had knowledge of the risks giving rise to the incident. *E.g.*, *Koloda v. Gen. Motors Parts Div., Gen. Motors Corp.*, 716 F.2d 373, 375–76 (6th Cir. 1983). When introduced to demonstrate notice or knowledge, "a lesser degree of similarity [than substantial similarity] is required provided the accident would have tended to warn the defendant." *Surles ex. rel. Johnson v. Greyhound Lines, Inc.*, 474 F.3d 288, 298 (6th Cir. 2007) (quoting *Bryan v. Emerson Elec. Co., Inc.*, 856 F.2d 192, 1988 WL 90910, at *5 (6th Cir. 1988) (unpublished table decision)) (upholding district court's application of the "lesser degree of similarity" on abuse-of-discretion review); *Mahaney el rel. Estate of Kyle v. Novartis Pharms.*, 835 F. Supp. 2d 299, 312 (W.D. Ky. 2011) ("[C]ourts typically impose the yard stick of 'substantial similarity' to ferret out those [prior incidents or accidents] that could not be expected to raise the manufacturer's awareness."); *cf. Rye*, 889 F.2d at 102 (applying the substantial-similarity test when plaintiff sought to introduce prior incidents as evidence of notice and causation). It is clear that neither "great specificity," *Surles*, 474 F.3d at 297, nor perfectly identical circumstances, *Rye*, 889 at 102, are required to show substantial similarity.

Defendants argue for a standard that is too exacting. Defendants urge the Court to admit only MDRs, AERs, or other complaints where the patient has an identical medical background. (ECF No. 213 at PageID #11930.) For example, they point to Plaintiff's obesity, diabetes, age, location of the mesh placement, type of repair procedure, and the existence of a device with ST coating. (*Id.* at PageID #11930–31.) For the purpose of knowledge, mindset, and notice, this is much more than substantial similarity. . . . [T]his level of granular medical history is unnecessary to show that Defendants were aware of risk presented by the Ventralight ST.

Accordingly, this portion of Defendants' motion is denied; the Court will not broadly exclude MDRs for a lack of substantial similarity at this moment. That being said, Plaintiff's proffer contains mostly MDRs that were made after the implantation of a Ventralight ST. Thus, these MDRs are irrelevant to notice. *Surles*, 474 F.3d at 298 ("The relevance of similar incidents depends in part on their proximity in time to the incident at issue in the case before the court.") (considering whether other incidents were evidence of notice). But at trial, Plaintiff may offer MDRs, AERs, and other complaints that are substantially similar to Plaintiff's experience. Based on the information before it, the Court preliminarily concludes that substantial similarity will be met if an MDR, AER, or complaint indicates that (1) the patient had the same injury as Plaintiff—adhesions, (2) the Ventralight ST or another ST device was implanted, (3) the repair was made to a hernia or other similar, abdominal soft-tissue injury; and (4) the repair method was laparoscopic, unless Plaintiff can show that open surgeries pose the same risk of adhesions as laparoscopic surgeries. Of course, Defendants are free to attack these prior incidents on the basis that the circumstances are not adequately similar to give notice. *Coolidge v.*, 2018 WL 5919088, at *3. But any details beyond what is required of the substantial-test similarity test for notice go to the weight, not admissibility, of the prior-incident evidence. *Id.*

(MIL Order No. 7, Case No 2:18-cv-01509, ECF No. 375 at PageID #20345–47.) The Court also addressed Defendants' Rule 403 argument that evidence of other incidents will unfairly prejudice them at trial, confuse the jury, and delay the trial:

> At this time, it is uncertain how Plaintiff plans to present evidence of the MDRs, AERs, and other complaints, and in what volume. If Plaintiff plans to rely on the number of MDRs, AERs, etc. or summaries of them and admits the reports only to show the underlying support, Defendants will not be *unfairly* prejudiced because the evidence is probative of their state of mind. However, if Plaintiff intends to produce dozens of MDRs and to walk through them, the mini-trial concern looms. For this reason, the Court will deny this portion of Defendants' motion at this time.

(*Id.* at PageID #20347–48.) The Court also ruled on Defendants' argument that MDRs submitted by healthcare providers are inadmissible by law in civil actions pursuant to 21 U.S.C. § 360i(b) (*Id.* at PageID #20342–45), but Defendants make no such argument in this case.

Defendants here argue that the Court should exclude all evidence or argument regarding MDRs and complaints related to patients other than Mr. Milanesi because such evidence lacks substantial similarity to Plaintiffs' case, will cause "unfair prejudice, jury confusion, and unnecessary delay," and is inadmissible hearsay to which no exception applies. (Defs' MIL No. 12, ECF No. 192 at PageID #14422–25.)

A. Rule 403

As to Defendants' Rule 403 argument, the Court adopts its ruling on the similar motion in *Johns*. Plaintiffs may introduce evidence "on the number of MDRs, [complaints related to patients other than Mr. Milanesi], etc. or summaries of them and admit[ ] the reports only to show the underlying support," which will not unfairly prejudice Defendants "because the evidence is probative of their state of mind." (MIL Order No. 7, Case No 2:18-cv-01509, ECF No. 375 at PageID #20347–48.) Plaintiffs may only use evidence of MDRs and complaints relating to other patients to show knowledge or notice and may not use the evidence to show that the Ventralex

caused Plaintiffs' injuries.

B. Substantial Similarity

As to Defendants' argument that incidents involving other patients lack substantial similarity to Plaintiffs' case, the Court again adopts the reasoning from its ruling in *Johns*. The Court will not broadly exclude complaints about any other patients whose circumstances are not identical to Mr. Milanesi's. Based on the information before it, the Court preliminarily concludes that substantial similarity will be met if an MDR or complaint indicates that (1) the patient had the same injury as Mr. Milanesi; (2) the device at issue contained ePTFE and/or a memory coil ring; (3) the repair was made to a hernia or other similar, abdominal soft-tissue injury; and (4) the device was placed in an intraperitoneal position.

C. Hearsay

Defendants argue that evidence of MDRs and complaints related to other patients are inadmissible hearsay to which no exceptions apply. However, in accordance with the Court's Rule 403 analysis, *see supra* Part III.A, any MDRs and complaints that are introduced may only be used to show notice or knowledge. Because the MDRs and complaints may not be used to show that the Defendants' product caused Plaintiffs' injuries, the evidence is not being offered for the truth of the matter asserted and therefore is not hearsay.

Defendants also argue that "any MDR or complaint dated after Mr. Milanesi's implant cannot possibly go to notice." (Defs' MIL No. 12, ECF No. 192 at PageID #14425.) The issue of post-surgery evidence as it relates to notice and the Plaintiffs' claim of a continuing duty to warn will be addressed in a later MIL Order.

IV. Conclusion

For the reasons set forth above, the Court **DENIES** Defendants' MIL No. 12 (ECF No. 192). The Court will allow evidence of MDRs or complaints which indicate that (1) the patient had the same injury as Mr. Milanesi; (2) the device at issue contained ePTFE and/or a memory coil ring; (3) the repair was made to a hernia or other similar, abdominal soft-tissue injury; and (4) the device was placed in an intraperitoneal position. The evidence may only be used to show the Defendants' knowledge or state of mind and may not be used to show that the Ventralex caused Plaintiffs' injuries.

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.

12/13/2021
DATE

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