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 AND ORDER NO. 44

Defendants' Motion *in Limine* ("MIL") No. 14

Defendants C.R. Bard, Inc. and Davol, Inc. filed a Motion *in Limine* to Exclude Evidence and Argument Concerning Defendants' Conduct Postdating Plaintiff Antonio Milanesi's Implant Surgery (Defendants' MIL No. 14, ECF No. 184), which is opposed by Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi (ECF No. 230). For the reasons that follow, the Court **GRANTS IN PART** Defendants' MIL No. 14.

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.

In Defendants' MIL No. 14, they move to exclude under Federal Rules of Evidence 401 and 403 evidence and argument concerning any of their conduct after Mr. Milanesi's July 11, 2007 surgery (Defs' MIL No. 14, ECF No. 184.)

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

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 granted in part and denied in part Defendants' motion to exclude evidence concerning Defendants' conduct that postdated the plaintiff's surgery. (Case No 2:18-cv-01509, MIL Order No. 11, ECF No. 415 at PageID #22180–88.) In ruling on Defendants' motion, the Court noted that:

> Defendants' argument that any evidence of Defendants' conduct after Plaintiff's first surgery is per se irrelevant is a bludgeon when the Federal Rules of Evidence call for a scalpel. Federal courts decline to grant broad motions in limine seeking exclusion of categories of evidence, requiring parties to identify evidence and its uses with specificity. *See Sperberg*, 519 F.2d at 712. For this reason, the Sixth Circuit has rejected a bright-line, cut-off-date approach to post-injury evidence. *Dykes v. Raymark Indus., Inc.*, 801 F.2d 810, 818 (6th Cir. 1986) (adopting a "case-by-case approach" to determining the admissibility of "post-injury evidence").

(*Id.* at PageID #22181.) In *Johns*, this Court declined to issue a broad ruling excluding any post-surgery evidence, and instead limited its ruling to the specific evidence that Defendants noted in their Motion.

The Court will do the same in this case. In their motion, Defendants specifically mention: FDA inspections related to the Composix Kugel or otherwise; third-party audits related to the Composix Kugel recall; the Composix Kugel discontinuation; the Sepramesh IP due diligence; the switch from a Polyethylene Terephthalate ("PET") recoil ring in the Ventralex to a fully-absorbable polydioxanone ("PDO") ring; material safety data sheets; and the clinical study

being conducted because of European regulatory changes (also known as DVL-20). (Defs' MIL No. 14, ECF No. 184 at PageID #13964.)

The majority of these issues have been addressed in relation to Defendants' other MILs. The Court denied in part Defendants' MIL No. 5 regarding FDA inspections and third-party audits. (MIL Order No. 38, ECF No. 314.) The Court will address the issue regarding the switch from a PET ring to a PDO ring in a separate order. The Court denied in part and reserved judgment in part on Defendants' MIL No. 2 regarding material safety data sheets. (MIL Order No. 32, ECF No. 308.) And the Court denied Defendants' MIL No. 6 regarding foreign regulatory actions, including the DVL-20 study. (MIL Order No. 40, ECF No. 316.)

In addition to Defendants' MIL No. 14, many of the parties' MILs and responses include arguments regarding events that occurred after Mr. Milanesi's July 11, 2007 surgery, and whether Defendants had a continuing duty to warn under Florida law. The parties submitted supplemental briefing on the continuing duty to warn issue. (ECF Nos. 291, 292, 306, & 307.)

Defendants claim that "any conduct of [Defendants] *after* July 11, 2007, is irrelevant to the warning, design and fraud claims Plaintiffs assert in this case. Moreover, any possible probative value the evidence may have is outweighed by the unfair prejudice. Indeed, any actions [Defendants] took after Mr. Milanesi's implant surgery neither logically nor legally can lead to notice, let alone liability." (Defs. MIL No. 14, ECF No. 184 at PageID #13965.)

In response, Plaintiffs argue that, under Florida law, manufacturers have a continuing duty to warn, so Defendants' post-surgery conduct is relevant pursuant to that continuing duty. (Pls. Mem. in Opp., ECF No. 266 at PageID #16377–80.) Plaintiffs point to *Johns-Manville Sales Corp. v. Janssens*, 463 So. 2d 242 (Fla. Dist. Ct. App. 1984), in which the plaintiff introduced liability evidence of the defendant's knowledge of asbestos hazards beyond the date of the plaintiff's

exposure to the defendant's product. The District Court of Appeal held that "[e]vidence of repetition and concealment of offensive conduct after it initially occurred is indicative of malice or evil intent sufficient to support punitive damages." *Id.* at 256.

In the Court's order for supplemental briefing, the Court asked the parties to specifically address the issue of "whether, under Florida law, the conduct of a medical device manufacturer or its upstream suppliers is relevant to the issue of notice when that conduct occurs after the manufacturer's device is implanted in a specific patient." (ECF No. 283.) It is clear that under Florida law, manufacturers of certain products have a continuing duty to warn. *See High v. Westinghouse Elec. Corp.*, 610 So. 2d 1259, 1263 (Fla. 1992) (finding that the defendant "had a duty to timely notify the entity to whom it sold the electrical transformers . . . once it was advised of the PCB contamination"); *Sta-Rite Indus., Inc. v. Levey*, 909 So. 2d 901, 905 (Fla. Dist. Ct. App. 2004) (jury question existed on failure to warn claim "in the light of similar severe accidents which occurred both before and after the sale of the [pool] pump in question"); *Johns-Manville*, 463 So. 2d at 256 (finding evidence admissible in asbestosis case as "relevant to [the defendant's] continuing duty to warn and its breach thereof," and that a "continuing duty to warn was properly at issue in the trial court under the plaintiffs' general allegations of negligent failure to warn"). However, it is unclear whether, under Florida law, that duty applies to a medical device that has already been implanted in a patient.

In their supplemental briefing (ECF No. 291), in addition to *Johns-Manville*, Plaintiffs cite to *Sta-Rite Indus., Inc. v. Levey*, 909 So. 2d 901, which applied the continuing duty to warn in the context of a pool pump, and Florida civil jury instructions regarding a continuing duty to warn. *In re Standard Jury Instructions in Civil Cases – Report No. 13-01 (Prod. Liab.)*, 160 So.3d 869, 876–77 ("Under certain circumstances, a manufacturer has a duty to warn about particular risks of

a product even after the product has left the manufacturer's possession, and has been sold or transferred to a consumer or end-user."). Plaintiffs conclude that, because *Johns-Manville* is binding and there is no binding authority that says the duty does not apply to permanently implanted medical devices, Defendants had a continuing duty to warn regarding the Ventralex and post-surgery evidence is admissible to show Defendants' liability for Plaintiffs' injuries. (ECF No. 291.) Plaintiffs also argue that "even if this Court were to exclude certain evidence under the 'causation' approach urged by Defendants, it should admit the evidence insofar as it relates to pre-implant issues and subsequent concealment and fashion an appropriate jury instruction." (ECF No. 306 at PageID #17344.)

In their supplemental briefing, Defendants note that "there are no records suggesting [Mr. Milanesi] ever went back to, or sought further treatment from, [his implanting physician] Dr. Gill, and it was not until 10 years later in May 2017 that Mr. Milanesi went to see any physician for any symptoms related to his hernia surgery." (ECF No. 292 at PageID #16938.) Defendants allege that "no Florida state court has held that a post-sale duty to warn exists for an implantable medical device after a person has been implanted with said product." (*Id.* at PageID #16936.) Defendants point to a case in which the United States District Court for the Middle District of Georgia applied Florida law regarding a continuing duty to warn in a case concerning a suburethral sling device. *In re Mentor Corp.*, No. 4:08-MD-2004, 2015 WL 5722799 (M.D. Ga. Sept. 29, 2015). In the *Mentor* case, the court contrasted the *Sta-Rite* case and *Munoz ex rel. Munoz v. S. Miami Hosp., Inc.*, 764 So. 2d 854 (Fla. Dist. Ct. App. 2000), *approved sub nom. Saunders v. Dickens*, 151 So. 3d 434 (Fla. 2014), a medical malpractice case in which a doctor was not warned about a patient's potential kidney problems, noting that "[those] cases do not, however, permit the Court to speculate as to what [the implanting surgeon] would have done with those warnings," and noted

that the case "involve[d] a complex decision regarding a medical device that had already been implanted in [the patient's] body." *Id.* at *3–4. The court concluded that there was "absolutely no evidence in the present record suggesting that additional warnings about the ObTape infection rate should have caused [the implanting surgeon] to contact his otherwise healthy patients and suggest that they undergo additional medical treatment for symptoms they did not have." *Id.* at *4.

Defendants also point to the language in the Florida civil jury instructions regarding the continuing duty to warn. Defendants claim that the language "under certain circumstances" shows an intent to limit the application of a post-sale duty to warn, and that the duty should not apply in every situation. (ECF No. 292 at PageID #16940.) Defendants state that "[n]o Florida state case has concluded that a 'certain circumstance' includes a situation in which a medical device has been implanted in a patient." (*Id.*) As such, Defendants argue that their actions or knowledge after July 11, 2007 should be excluded.

The Court agrees with Defendants' reasoning as it relates to using evidence of a continuing duty to warn to show causation and liability for Plaintiffs' injuries. Nonetheless, the same evidence of Defendants' alleged concealment may be admissible and relevant to show malice or reckless disregard. Because such evidence is admissible only for that purpose, the Court will give a limiting instruction to the jury. *Johns-Manville*, 463 So. 2d at 256 ("Evidence of repetition and concealment of offensive conduct after it initially occurs is indicative of malice or evil intent sufficient to support punitive damages.").

IV. Conclusion

For the reasons set forth above, the Court **GRANTS IN PART** Defendants' MIL No. 14 (ECF No. 184).

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