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 et. al v. C.R. Bard*,**
Case No. 2:18-cv-01320

MOTIONS IN LIMINE OPINION AND ORDER NO. 36

Defendants' Motion *in Limine* ("MIL") No. 3

This matter comes before the Court on C.R. Bard, Inc. ("Bard") and Davol Inc.'s ("Davol") (collectively, "Defendants") MIL No. 3 to Exclude Evidence and Argument Concerning Irrelevant Bard Devices, (ECF No. 175), which Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi ("Plaintiffs" or "the Milanesi's") oppose. (ECF No. 257.)

For the reasons stated herein, the Court **DENIES WITHOUT PREJUDICE** Defendants' MIL No. 3. (ECF No. 175.)

I.[1]

The Milanesi's 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.)

The relevant facts here are as follows: The Ventralex hernia patch is a prescription medical device used for umbilical and small ventral hernia repairs. One side of the device contains polypropylene mesh, while the other contains a layer of polytetrafluoroethylene ("ePTFE"). The ePTFE side is meant to face and protect the bowel as the device's polypropylene mesh incorporates into the tissue on the opposite side. Inside the device is a "ring" or "memory coil" that is meant to "spring open" so the patch lies flat against the abdominal wall once it is implanted. If that ring were to unintentionally fold inward (*i.e.*, "buckle"), it would risk exposing the bowel to bare polypropylene. This has been known to cause various physical injuries, such as fistulae and adhesions.

The Ventralex comes in three sizes: small, medium, and large. The small and medium patches were released in July 2002, four years before the large patch. To market the small and medium patch, Bard needed to satisfy the Food and Drug Administration's ("FDA") section 510(k) premarket clearance process. This required Bard to demonstrate that the Ventralex's design was "substantially equivalent" to a device that the FDA had already fully approved (*i.e.*, a "predicate" device). In this case, that predicate device was Bard's Composix Kugel—which, like the Ventralex, contained a memory coil and ePTFE layer.

Between 2005 and 2006, Bard voluntarily recalled certain product codes of the Composix Kugel due to concerns that its memory coil could break. Around this time, Bard was subject to various FDA inspections and third-party audits.

In 2006, Defendants released the large version of the Ventralex patch. Because the patch was based on it small and medium versions—which, in turn, were based on the Composix Kugel—it was considered part of Bard's "family" of Kugel products.

On July 11, 2007, 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. Dr. Karanbir Gill, Mr. Milanesi's surgeon, used a large Ventralex hernia patch to repair Mr. Milanesi's injury. Ten years later, on May 25, 2017, Mr. Milanesi was diagnosed with a recurrent entrapped or obstructed ventral incisional hernia. He received emergency surgery the next day. On June 1, 2017, Mr. Milanesi returned for another emergency surgery to remove a high-grade post-operative bowel obstruction caused by "adhesions in the right lower quadrant." Afterwards, Mr. Milanesi developed a recurrent abdominal wall hernia near his previous surgery sites.

Plaintiffs allege that the Mr. Milanesi's injuries resulted from the implantation of the large Ventralex patch. Specifically, they allege that Mr. Milenesi's Ventralex patch "buckled," causing its polypropylene side to adhere to his bowels, leading, in turn, to a high-bowel blockage and, subsequently, multiple hospitalizations. Plaintiffs make three principal allegations to support their claim: (i) that "polypropylene resin oxidatively degrades in vivo," (ii) that the ePTFE layer of the large Ventralex device contracts more than the polypropylene side, which in combination with the too-weak memory coil ring, causes the device to "buckle," and (iii) that the Ventralex's ePTFE layer was prone to infection because of its small pore size, which, they assert, is big enough for bacteria to grow in, but too small for white blood cells to enter to intercept the bacteria.

In addition to the Kugel product "family," Bard markets the Ventralight ST—the hernia mesh device at issue in the first bellwether case of this MDL, *Johns*. It also maintains a variety of

pelvic mesh products, which, like the Ventralex, contain polypropylene. Those devices have also been the subject of various products liability litigation in other jurisdictions. Defendants anticipate that Plaintiffs "will attempt to introduce evidence and argument concerning issues" related to these pelvic mesh products, as well as the Composix Kugel and the Ventralight ST. Defendants now move to either limit and/or preclude this evidence at trial under Federal Rules of Evidence 402, 403, 404, and 802.

II.

"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 in advance of trial in order to avoid delay and ensure an evenhanded and expeditious trial." *In re E.I. du Pont De Nemours & Co.*, 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. The denial, in whole or in part, of a motion *in limine* does not

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. Evidence that is not relevant is inadmissible. Fed. R. Evid. 402. Additionally, under Federal Rule of Evidence 802, a court must exclude hearsay statements, unless provided otherwise by (i) a federal statute, (ii) the Federal Rules of Civil Procedure, and (iii) other rules prescribed by the Supreme Court of the United States. Fed. R. Evid. 802. A court may also exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403. Likewise, under Federal Rule of Evidence 404(b), a court must dismiss evidence of a party's past "wrong, crime, or act" that is introduced for the purpose of proving that, on some *other* occasion, the party acted accordingly. This bar on "character" evidence, however, does not extend to evidence that is introduced for "another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident." Fed R. Evid. 404(b).

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.

It is important to first recognize the evidence that is *not* at issue. Specifically, "Bard

recognizes that evidence regarding the development, design, and material used in the Ventralex small and medium and "limited" evidence on the Composix Kugel "may be relevant to the reasonableness of the design of the Ventralex and its Instructions for Use." (ECF No. 175 at PageID #13697.) Thus, Defendants do not challenge Plaintiffs' ability to introduce such evidence at trial.

Defendants do, however, contest Plaintiffs' ability to introduce evidence of the Composix Kugel's "ring breaks, recalls, FDA inspections, and third-party audits," which, they argue, is both irrelevant and unduly prejudicial to their case. (*Id.* at PageID #13697, 13700-01.) They also seek to prevent Plaintiffs from admitting evidence related to its other, non-predicate hernia mesh products—such as the Ventralight ST—as well as evidence pertaining to the lawsuits Bard has faced for its pelvic mesh products. (*Id.* at PageID #13699-704.)

A. Composix Kugel Ring Breaks, Recalls, Inspections, and Audits

Defendants acknowledge that they have already requested the Court in their first and fifth motions *in limine* to preclude Plaintiffs from introducing "evidence related to the Composix Kugel ring breaks, recalls, FDA inspections, and third-party audits." (ECF No. 175 at PageID #13700.) Here, they appear to reiterate their overall contention in those motions that such evidence is both irrelevant and unduly prejudicial to Plaintiffs' case. (ECF No. 175 at PageID #13700.) This argument is much more fleshed out in the motions that Defendants reference, which the Court intends to address in a separate order. (*See* Def's Mot. *in Limine* No. 1 to Exclude Evidence and Argument Concerning Composix Kugel Ring Breaks and Recall, ECF No. 172; Def's Mot. *in Limine* No. 5 to Exclude Evidence and Argument Concerning FDA Inspections and Third-Party Audits, ECF No. 190.) Thus, they will not be addressed here.

B. Bard's Other Hernia and Pelvic Mesh Products

Defendants primarily seek to prevent Plaintiffs from admitting evidence relating to any "non-predicate hernia or pelvic mesh device" sold by Bard. (ECF No. 175 at PageID #13697.) This includes, but is apparently not limited to, evidence relating to "certain devices with absorbable components, the ST hydrogel coating (as in *Johns*), inguinal hernia repair devices, fixation systems, and pelvic mesh devices." (*Id.* at PageID #13697.) They argue that this evidence should be excluded because it is both irrelevant, unfairly prejudicial, impermissible "character" evidence, and inadmissible hearsay.

To support their argument, Defendants note various decisions by this Court in *Johns* to preclude Plaintiffs from admitting "other-device" evidence that (i) was merely offered for propensity purposes or (ii) did not concern the "adhesions" the *Johns* plaintiff allegedly suffered. (*Id.*.) The Court's approach to those matters has not changed. That is, to the extent Plaintiffs intend to introduce evidence of other Bard products that is *solely* meant to show that Bard "was a bad corporation," it is inadmissible under Rule 404. (ECF No. 322 at 22.) Likewise, any other-device evidence that Plaintiffs intend to use to demonstrate that Defendants knew of the health risks associated with the use of polypropylene in a medical implant must be connected to the injuries that Mr. Milanesi allegedly suffered—which, unlike in *Johns*, include bowel erosion, fistulae, an "infection in an abscess cavity," adhesions, and a recurrent hernia. (*See Johns*, ECF No. 395 at PageID #20961; Disp. Mot. Order No. 3, ECF No. 167 at PageID #13612.)

Notably, Defendants seek to have the Court do more than just reiterate the holdings above. Rather, they request a blanket order that prevents Plaintiffs from presenting *all* evidence related to "non-predicate" hernia mesh or pelvic mesh devices. They do so largely without specifying the specific documents or testimony they want to keep out, nor *which devices* this evidence relates to. (*See* ECF No. 283) (arguing that "*[M]any of these other devices*" are irrelevant because they "came

to market ***after*** Mr. Milanesi's July 11, 2007 implant"). Instead, they assert that all of Bard's non-predicate hernia mesh or pelvic mesh devices are so materially different from the Ventralex that any evidence related to them is irrelevant to Plaintiffs' injuries, theory of causation, or notice.[2]

The Court has declined to entertain such sweeping requests both in *Johns* and this case. (*See Johns*, ECF No. 415 at PageID #22181) (declining to consider any evidence that Defendants did not specify in their Motion *in Limine* No. 14, which broadly sought to exclude "any evidence" that was related to conduct that occurred "after Plaintiff's first surgery"); (*see also* Mot. in Limine Order No. 28, ECF No. 301) (denying Defendants' motion because it was "not clear" what evidence Defendants asked the Court to exclude). Because it is unclear what specific devices Defendants refer to—and, by extension, what documents or testimony they wish to keep out—the Court does so again here.

IV.

Accordingly, the Court **DENIES WITHOUT PREJUDICE** Defendants' Motion *in limine* No. 3. (ECF No. 175.)

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

[2] In a footnote, Defendants state that, because "these issues were fully briefed in *Johns*, Bard will not provide the full background or arguments again but does incorporate those motions and supplemental briefs here by reference." (ECF No. 175 at PageID #13697.) Of course, those briefs were all tailored to the Ventralight ST—a device that Defendants labored to distinguish from the Ventralex (as well as Bard's other products). (*See*, *e.g.*, *Johns*, ECF No. 176 at PageID #10196.) They do not, however, contemplate how the Ventralex is categorically different from all non-predicate Bard devices, nor why all evidence related to those devices should be precluded in *this* case.