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. 42

Defendants' Motion *in Limine* ("MIL") No. 7

Defendants C.R. Bard, Inc. and Davol, Inc. filed a Motion *in Limine* to Exclude Evidence and Argument Concerning Non-Existent Duties (Defendants' MIL No. 7, ECF No. 179), which is opposed by Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi (ECF No. 265). For the reasons that follow, the Court **GRANTS IN PART** and **DENIES IN PART** Defendants' MIL No. 7.

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. 7, they move to exclude under Federal Rule of Evidence 401 and 403 evidence and argument concerning allegedly non-existent duties. (Defs' MIL No. 7, ECF No. 179.)

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 Defendants' motion to exclude evidence of nonexistent duties. (Case No 2:18-cv-01509, MIL Order No. 3, ECF No. 332 at PageID #17888.) The Court ruled that the plaintiff "may not present evidence or argument regarding [Defendants'] ability to obtain a Premarket Approval ("PMA"), though he may present evidence regarding ISO standards/guidelines" in accordance with the Court's ruling on the plaintiff's MIL to exclude evidence of ISO standards/guidelines. (*Id.*)

A. Duty to Test

Defendants first argue that any evidence and argument that Defendants owed or breached an independent duty to conduct additional testing should be excluded. (Defs' MIL No. 7, ECF No. 179 at PageID #13804.) Defendants claim that Florida law does not require "an independent duty to test, or require [Defendants] to perform specific additional testing or research on the Ventralex, such as a pre-market randomized clinical trial or a long-term animal study." (*Id.*) Defendants argue that there is also no such duty under federal law. (*Id.* at PageID #13804-05.) Defendants also claim that any evidence or argument concerning a duty to test would be confusing, prejudicial, and likely to cause delay. As such, Defendants ask that the Court exclude any argument regarding a duty to test.

As the Court noted at the September 10, 2020 MIL hearing in *Johns*, "[t]here's no duty

to test in the law. We agree with that. But there's a duty not to misrepresent or omit. I think it's subtle but it's important." (Case No 2:18-cv-01509, ECF No. 345 at PageID #18601.) The plaintiff's counsel stated that "[t]here's no duty [to test] in the regulations. There is a duty in the ISO standards which the Court has ruled in as industry standards. In other words, the design process, you have user needs which you design to meet, and the only way you can make sure you meet those user needs is through testing. So the ISO standard, while it won't throw you in jail, it is evidence of the industry standard[.]" (*Id.*) In their response to Defendants' motion in this case, Plaintiffs agree that there is no independent cause of action for a duty to test, but argue that evidence that Defendants could have performed additional testing is highly relevant. (Pls' Mem. in Opp., ECF No. 265 at PageID #16337.) Plaintiffs claim that the lack of an independent cause of action does not preclude Plaintiffs from introducing evidence and argument that "Defendants could have conducted additional testing on the Ventralex patch and that a reasonable manufacturer should have taken steps to conduct additional testing." (*Id.*) As the Court stated in *Johns*, "ISO standards are in; I've already ruled on that [in regards to Plaintiffs' MIL 14]. . . . But if [testing is] recommended by the ISO, then that will come in for the same reasons I let the defendant use that as well." (Case No 2:18-cv-01509, ECF No. 345 at PageID #18604.) The Court adopts its previous ruling in *Johns*. Consistent with the Court's ruling in MIL Order No. 20 (ECF No. 287) on Plaintiffs' MIL No. 14 (ECF No. 209), Plaintiffs may present evidence regarding ISO standards/guidelines.

B. Evidence of Alternative Regulatory Pathway

Defendants next argue that any evidence that Defendants should have filed a PMA, submitted a 510(k) application, or followed another regulatory pathway would be misleading, confusing, and highly prejudicial. (Defs' MIL No. 7, ECF No. 179 at PageID #13806.) In ruling

on Plaintiffs' MIL No. 3, this Court held that "Defendants should not be precluded from presenting evidence that the Ventralex Large Hernia Patch was legally on the market pursuant to FDA guidelines." (MIL Order No. 15, ECF No. 276 at PageID #16829.) The Court agreed that Defendants' decision to use the no-510(k) process in getting the Ventralex Large to market was part of Defendants' "story." (*Id.*; *see also Old Chief v. United States*, 519 U.S. 172, 189 (1997).) In Defendants' MIL No. 25, Defendants asked the Court to prohibit Plaintiffs from discussing Defendants' choice to use the no-510(k) process. (Defs' MIL No. 25, ECF No. 188.) In denying Defendants' MIL 25, the Court reiterated that the no-510(k) process is admissible as part of Defendants' story, and ruled that Plaintiffs cannot be prohibited from responding to that evidence. (MIL Order No. 15, ECF No. 276 at PageID #16835.) As the Court reasoned, "Plaintiffs are not presenting evidence that the Ventralex Large Hernia Patch was illegally on the market. Instead, they are simply disagreeing with Defendants that Bard utilized the appropriate route to market." (*Id.* at PageID #16836.)

As part of Defendants' MIL No. 7, Defendants again argue that "[a]ny evidence that [Defendants] should have filed a PMA, submitted [a] 510(k) application or followed another regulatory pathway would be misleading, confusing, and highly prejudicial." (Defs' MIL No. 7, ECF No. 179 at PageID #13806.) However, for the reasons stated in this Court's MIL Order No. 15 (ECF No. 276), this portion of Defendants' Motion is denied.

C. Evidence of Duty to Train

Defendants next assert that "there is no basis in law or fact to allow Plaintiffs to offer evidence and argument concerning a non-existent duty to train Dr. Gill[,]" the surgeon who implanted the Ventralex in Mr. Milanesi. (Defs' MIL No. 7 at PageID #: 13803.) Defendants specify that:

> Plaintiffs likely will argue that Bard owed a duty to train Mr. Milanesi's implanting physician, Dr. Karinbir Gill. *See* Master Compl., MDL ECF No. 67, at ¶ 41. Under Florida law, however, medical device manufacturers have no duty to train state-licensed physicians on the use of their products. As Dr. Gill could not recall whether he ever attended any hernia repair training courses sponsored by Bard, there is no evidence either way on whether Bard trained or offered to train Dr. Gill.

Id.

Plaintiffs respond that they "do not intend to assert a claim that the Defendants had a "duty to train physicians." (Pls' Mem. in Opp., ECF No. 265 at PAGEID #16339.) Instead, they contend that Defendants provided training to physicians in the form of classes and affirmative representations from sales representatives. To the extent that Defendants affirmatively undertook to provide training to physicians, it is appropriate for Plaintiffs to introduce evidence that the Defendants did so poorly.

Consequently, this portion of Defendants' motion is denied.

D. Evidence of Duty to Warn Plaintiffs or the General Public

Last, Defendants posit that "Plaintiffs are also likely to argue that Bard owed a duty to warn Mr. Milanesi or the general public directly." (Defs' MIL No. 7, ECF No. 179 at PageID #13803) (citing Master Compl., MDL ECF No. 67, at ¶ 134). Defendants maintain that because Florida follows the learned intermediary doctrine, Bard's duty to warn with the Ventralex, a prescription medical device, ran solely to the prescribing and implanting physician, Dr. Gill. Therefore, they conclude that "Plaintiffs should be precluded from offering evidence and argument about a non-existent duty to directly warn." *Id*.

Plaintiffs disagree that the learned intermediary doctrine prohibits testimony as to how a manufacturer's warning affected others, contending that "when there is a failure to adequately warn the physician, the [LID] as a defense simply drops away." (Pls' Mem. in Opp., ECF No. 265 at PageID #16340) (citing *Perez v. Wyeth Labs. Inc.*, 161 N.J. 1, 19 (1999). Additionally, Plaintiffs

posit that irrespective of the learned intermediary doctrine, Defendants have a duty to be truthful and accurate in all labeling for Ventralex as mandated by FDA regulations governing medical devices.

Plaintiffs, however, point to no source of a duty, and therefore may not speak to a "duty to warn" in this context. Yet, Defendants' actions related to its warnings about the Ventralex is relevant and admissible. Therefore, Defendants' request is granted in part and denied in part.

IV. Conclusion

For the reasons set forth above, the Court **GRANTS IN PART** and **DENIES IN PART** Defendants' MIL No. 7 (ECF No. 179).

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