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-01509

MOTIONS IN LIMINE OPINION & ORDER No. 11

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 Defendants' Motion in Limine No. 14 to Exclude Evidence and Argument Concerning Defendants' Conduct Postdating Plaintiff's Implant Surgery (ECF No. 215), Plaintiff's Motion in Limine No. 22 to Exclude Any Evidence or Argument Concerning Alleged Negligence or Fault of His Treating Surgeon Dr. Jensen (ECF No. 246), Defendants' Motion in Limine No. 11 to Exclude Evidence and Argument Related to Pelvic or Transvaginal Mesh Devices (ECF No. 212), and Defendants' Motion in Limine No. 13 to Limit Evidence and Argument of Other Litigation (ECF No. 214.)

I. Background¹

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation ("MDL"), alleging "that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs,

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. *In re Davol, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1-6 (S. D. Ohio Sept. 1, 2020).

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. 2020 WL 5223363, at *1. The Food and Drug Administration ("FDA") cleared it for use through the premarket notification § 510(k) process in 2010 and later cleared it for use with the Echo 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.* at *1–2.

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.* at *4. 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, Dr. Jensen. *Id.* at *5.3 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

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

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. 2020 WL 5223363, at *14.

of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. *Id.* at *6–25. Now, various motions in limine and other evidentiary motions are ripe for adjudication.

This opinion addresses Defendants' Motion in Limine No. 14 (ECF No. 215), Plaintiff's Motion in Limine No. 22 (ECF No. 246), Defendants' Motion in Limine No. 11 (ECF No. 212), and Defendants' Motion in Limine No. 13 (ECF No. 214).

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 the moving 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. Defendants' Motion in Limine No. 14

In Defendants' motion, they argue that any conduct occurring after Plaintiff's implantation surgeries should be excluded as irrelevant, prejudicial, or as a subsequent remedial measure under Federal Rule of Evidence 407. (ECF No. 215 at PageID #11959–62.) Defendants specified during the hearing on the motion that any of their conduct after Plaintiff's first surgery is inadmissible in light of the Court's summary judgment opinion. (ECF No. 360 at PageID #18823.)⁴

⁴ Plaintiff raises arguments related to Defendants' conduct after August 2015, such as the implantation of his second Ventralight ST, that allegedly caused other injuries. (ECF No. 295 at PageID #1625-57.) The summary

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"). Thus, the Court considers only the evidence that Defendants specify in their motion: Defendants' responses to the FDA's 2017 483 audit and the DVL-020 study initiated in response to new European regulations. (ECF No. 360 at PageID #18823.)

First, Defendants' responses to the FDA's 2017 483 audit. What Defendants mean by "responses" is ambiguous, so the Court considers both Defendants' communications regarding the audit and subsequent actions in response to the audit. Defendants' communications may be relevant to their knowledge and the reasonableness of their conduct in relation to the Ventralight ST and its implantation in Plaintiff in 2015. The audit summary states that the last inspection was in 2012 and examines Defendants' actions between 2012 and 2017. (ECF No. 295-2 at PageID #16269-70.) It even describes complaints prior to Plaintiff's surgery. (*Id.* at PageID #17275 (addressing a complaint dated April 30, 2015).) The audit also examines Defendants' manufacturing and design operations, as well as a variety of company procedures and policies. (*E.g.*, *id.* at PageID #16270-74.) To the extent that the audit and Defendants' communications address Defendants' conduct, knowledge, and status of affairs leading up to Plaintiff's surgery,

judgment opinion holding that Plaintiff's only viable injury is omental adhesions from the implantation of his first Ventralight ST forecloses these arguments. 2020 WL 5223363, at *13-14.

they are relevant. See, e.g., Musgrave v. Berg, Inc., No. 2:09-cv-01029, 2011 WL 4502032, at *4 (S.D. Ohio Sept. 28, 2011).⁵

Next, the actions Defendants took in response to the 2017 FDA audit and in response to impending European Regulations, the DVL-020 study. Rule 407 provides that "[w]hen measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove: negligence; culpable conduct; a defect in a product or its design; or a need for a warning or instruction." Fed. R. Evid. 407. This is simple enough.

But the scope of Rule 407 is unclear. In the typical Rule 407 case, an event causes harm to the plaintiff and the defendant acts in response to this event to remediate future harm. For example, a store owner starting to salt their parking lot during snowstorms after a patron slips and falls in the parking lot is an example of a subsequent remedial measure. In this case, however, it is clear that it was not Plaintiff's injury or a complaint about his injury that triggered Defendants' responses to the FDA audit in 2017 or the commencement of the DVL-020 study; it was the FDA audit and impending European regulations, respectively.

At the same time, these actions appear to satisfy the definition of a subsequent remedial measure, "[w]hen measures are taken that would have made an earlier injury or harm less likely to occur. Fed. R. Evid. 407. To illustrate, any actions taken in response to the FDA audit would have had the effect of bringing Defendants into compliance with federal regulations. Federal regulations help define the standard of care under Utah law. *Downing v. Hyland Pharmacy*, 194 P.3d 944, 948 (Utah 2008). Therefore, it is axiomatic that had Defendants been in compliance with FDA regulations before or at the time of Plaintiff's surgery, Plaintiff's injuries would have been less likely to occur because Defendants would have at least been closer to satisfying their duty of care.

⁵ Plaintiff argues that Defendants urge the exclusion of the 2017 FDA audit (ECF No. 295 at PageID #16259), but the Court does not interpret Defendants' motion as encompassing the audit itself.

A number of courts have considered and are split on "whether Rule 407 applies where a measure has the effect of making an injury or harm less likely to occur even if the motivation for the measure is unconnected to that injury or harm or even to improving safety" or when there is no causal connection between the measure and the injury or harm. Kenneth W. Graham, Jr., 23 Fed. Prac. & Proc. Evid. § 5283 (2d ed.) West law (updated October 2020) (footnote omitted). Some courts literally interpret the rule, concluding that neither a motivation to remediate nor a causal connection to the plaintiff's injury is required. In Martin v. Norfolk Southern Railyard Co., the court held that the rule applied even when two years had elapsed between the injury and the remedial measure and when the measure was taken pursuant to an existing corporate policy. 271 S.W. 3d 76, 88 (Tenn. 2008) (interpreting Tennessee Rule of Evidence 407, which is identical to the earlier version of Federal Rule of Evidence 407 prior to the stylistic amendments in 2011); see also Cholpek v. Fed. Ins. Co., 499 F.3d 692, 700 (7th Cir. 2007) (concluding that the intent or motive behind a measure is irrelevant); Johnson v. State, 233 P.3d 1133, 1136 (Az. 2010) (holding that no causal connection between the injury and measure is required) (interpreting Arizona Rule of Evidence 407 which is identical to Tennessee Rule of Evidence 407). On the other hand, some have concluded that Rule 407 is inapplicable when there is no causal connection, i.e. when the measure was not taken in response to the injury-causing event in the case. Brazos River Auth. v. GE Ionics, Inc., 469 F.3d 416, 431-32 (5th Cir. 2006); In re Aircrash in Bali, Indonesia, 871 F.2d 812, 816 (9th Cir. 1989). In these cases, some courts have concluded that applying the Rule to measures not taken to improve safety, but to improve, for example, performance, does not satisfy the purpose of the Rule. In re Aircrash in Bali, 871 F.2d at 816 ("The purpose of Rule 407 is to ensure that prospective defendants will not forego safety improvements because they fear that these improvements will be used against them as evidence of their liability."). To the Court's knowledge, the Sixth Circuit has not expressly addressed this issue.

The better interpretation of Rule 407 is that there must be some sort of causal connection or nexus between the injury-causing event and the subsequent measure. Under the literal interpretation of the rule, there is no logical limit to the Rule's application; a measure taken ten years after the injury-causing event could be considered a subsequent remedial measure because it is actually subsequent and may have reduced the likelihood that the harm would have occurred had the measure been in place earlier. This is nonsensical. See Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 587 (1993) ("We interpret the legislatively enacted Federal Rules of Evidence as we would any statute"); Green v. Bock Laundry Mach. Co., 490 U.S. 504, 510–11 (1989) (applying the canon against absurdity to the Federal Rules of Evidence). Accordingly, it is necessary to evaluate the history and the policies of Rule 407. Green, 490 U.S at 510–11 (declining to follow the plain text of Rule 609(a)(1) when the result would be "unfathomable" and turning to the history of Rule 609 to interpret the text).

The statutory history of the Rule demonstrates that the event causing the injury must be the trigger for the subsequent remedial measure. The original version of Rule 407 provided that "after an event, measures are taken which, if taken previously, would have made the event less likely to occur, evidence of the subsequent measures is not admissible to prove negligence or culpable conduct in connection with the event." Act of Jan. 2, 1974, Pub. L. No. 93-595 1975, 88 Stat 1928.

⁶ The difference between the intent or motive and the cause underlying a remedial measure may be semantic in some cases. Here, however, it appears to be undisputed that the Defendants' responses to the 2017 FDA audit and the European regulations were not triggered by Plaintiff's injury. Accordingly, the Court declines to address whether a party's motive matters when applying Rule 407. A much more difficult case would be when a causal connection exists but a defendant's motivation is disputed, such as when a defendant takes action shortly after an injury-causing event, suggesting a causal connection between the event and the measure and claims that the response was not in reaction to the injury-causing event, but to improve performance or pursuant to company policy. Fortunately, this is not that case.

The text "in connection with the event" supplies such a causal connection. Subsequent amendments did not purport to change this meaning. In 1997, the Advisory Committee deleted this phrase, but it did not list this deletion as one of the substantive changes to the Rule, and the 2011 amendments were expressly limited to stylistic changes. Fed. R. Evid. 407 advisory committee notes to 1997 amendment; *see also* Graham, *supra*, at. § 5281 (reaching the same interpretation of the Rule's statutory history).

The two policies or purposes behind Rule 407 also show that the Rule requires more than mere subsequence. The first policy is that subsequent remedial measures are "equally consistent with injury by mere accident [and] through contributory negligence," meaning evidence of such measures is poor proof of fault. Fed. R. Evid. 407, advisory committee notes to 1972 proposed rules (noting that "the rule rejects the notion that 'because the world gets wiser as it gets older, therefore it was foolish before." (quoting *Hart v. Lancashire & Yorkshire Ry. Co.*, 21 L.T.R. N.S. 261, 263 (1869))); *Bryan v. Emerson Elec. Co., Inc.*, 856 F.2d 192, at *2 (6th Cir. 1988) (unpublished table decision). The first policy makes little sense applied to a measure that occurs years after an event that caused harm. Certainly, the measure may be still equally probative (or not probative) of an accident or negligence—but after enough time, the risk of admitting the evidence is less that the jury will conflate evidence of an innocent accident with evidence of negligence, but that the evidence of the later measure is simply irrelevant to proving any earlier negligence and is likely to distract the jury from the timeframe at issue. This is the province of Rules 401, 402, and 403—not Rule 407.

The second policy is that people should be encouraged to take steps to improve safety, which they would be deterred from doing if such acts would be counted against them in court. Fed. R. Evid., advisory committee notes to 1972 proposed rules; *Fry v. CSC Trans., Inc.*, 933 F.3d 591,

604 (6th Cir. 2019). When a supposed remedial measure has no connection to the harm at issue in the case, it is difficult to imagine why any deterrence would result. If defendants do not view the measures taken as connected to a harm-causing event, then it is unlikely that they would be disincentivized from taking these actions and in anticipation of litigation of the injury-causing event.⁷

Neither Defendants' responses to the 2017 FDA audit nor the DVL-020 study are subsequent remedial measures because Plaintiff's injury did not trigger these actions. It is undisputed that Defendants took these steps in response to the FDA audit and in response to changes in European regulations. Defendants themselves even state that these events "lack[] a logical connection to the facts in this case." (ECF No. 215 at PageID #1196.) The timing of Defendants' responses further supports this conclusion. Their responses to the audit would have occurred after 2017, and the DVL-020 study began in 2018—both at least two years after Plaintiff's surgery. (ECF No. 181 at PageID #10668.) Thus, Defendants identify no subsequent remedial measures excludable under Rule 407.8

Defendants cite a litany of Rule 407 cases, including Yates v. Ortho-McNeil-Janssen Pharms., Inc., 808 F.3d 281 (6th Cir. 2015). (ECF No. 215 at PageID #11960.) None address a

⁷ A third historical policy supports this interpretation as well. Prior to the modernization of the definition of hearsay, conduct in response to an event was considered an admission through conduct. Graham, Jr., supra, at § 5282. For example, a defendant storeowner's act of salting an icy parking lot, supra Page 6, would have been hearsay if offered to demonstrate fault or negligence. Without some sort of causal connection to the event, it is difficult to conclude that the hearsay declarant intended their act as an assertion. Fed. R. Evid. 801(a).

⁸ Plaintiff argues that government-mandated, nonvoluntary acts fall outside of the definition of subsequent remedial measures. (ECF No. 295 at PageID #16260.) Whether government-mandated acts may be subsequent remedial measures is unclear in this circuit. Recently, the Sixth Circuit in *Frye* expressed doubt that such measures are barred by Rule 407. 933 F.3d at 604. But in *Bauman v. Volkswagenwerk Aktiengesellschft*, the court reversed the district court's admission of evidence of a change in design to a car door latch, concluding that the design change was a subsequent remedial measure under Rule 407—despite Volkswagen's contention that the design was changed to comply with government regulations. 621 F.2d 230, 233 (6th Cir. 1980). The Court need not address this issue because it has already determined Rule 407 does not apply.

disconnectedness between the injury-causing event and the subsequent measure. Therefore, these authorities provide no assistance.

Nevertheless, Rules 401 and Rules 403 still apply. Regarding DVL-020, the Court's prior conclusion remains unaltered, that the DVL-020 is relevant and not prejudicial evidence when offered to demonstrate that Defendants could have conducted long-term clinical testing prior to Plaintiff's first surgery. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ----, Nos. 2:18-md-2846, No. 2:18-cv-01509, 2020 WL 6440261, at *11(S.D. Ohio Nov. 3, 2020). Defendants provide no countervailing authorities. Most relevantly, they point to *Christ v. Sears, Roebuck & Co.*, 149 F.3d 1182 (6th Cir. 1998) (unpublished table decision). In *Christ*, the court held that evidence of the 1993 design of a product was irrelevant to the issue of whether the technology for the design existed in 1979 and that the 1993 design would prejudice the jury while examining the 1979 design. 149 F.3d at *2–3. The DVL-020 study, however, is relevant because it shows that Defendants had the capability to perform long-term clinical testing earlier, which poses no threat of *undue* prejudice. 2020 WL 6440261, at *11

However, Defendants' acts in response to the 2017 FDA audits are irrelevant and their admission would be unduly prejudicial. The focus of Plaintiff's claims is Defendants' conduct in relation to the Ventralight ST leading up to and during 2015. The FDA audit itself provides information about this timeframe, as does any evidence of Defendants' violations of FDA regulations in 2015, 2020 WL 6603657, at *9–10, but Defendants' actions in response to the 2017 audit do not. Whether Defendants took steps to bring themselves into compliance with FDA regulations in 2017 is irrelevant to the nature of Defendants' actions and knowledge in 2015. Moreover, this evidence would likely confuse the jury and would prolong trial, as Rule 403 forbids.

Plaintiff's sole response is that the audit and Defendants' responses show that Defendants remained in noncompliance even after 2015, demonstrating a "pattern of conduct." (ECF No. 295 at PageID #16258.) Evidence showing that the Defendants were later in noncompliance is not only irrelevant and prejudicial for the reasons set forth above, but it is also propensity reasoning prohibited by Federal Rule of Evidence 404(a). In other words, it is designed to entice the jury to conclude that because the Defendants were regularly in noncompliance, they were in noncompliance in 2015. Plaintiff relies on *Dykes v. Raymark Industries, Inc.*, 801 F.2d 810 (6th Cir. 1986), to argue that this evidence is admissible to "demonstrate[] an attitude on the part of the defendant 'consistent' with the culpable conduct the plaintiff claimed existed prior to the injury." (ECF No. 295 at PageID #16256.) Plaintiff misreads *Dykes*. There, the Sixth Circuit was referring to post-injury documents that reflected the defendants' knowledge and mindset *at the time of the injury. Dykes*, 801 F.3d at 818. This is not a loophole permitting the admission of character evidence.

For these reasons, Defendants' motion is denied with regard to a blanket order requesting that any evidence of post-2015 conduct be excluded, to any communications Defendants had in response to the 2017 FDA audit, and to the DVL-020 study. It is granted as to Defendants' actions in response to the 2017 FDA audit. This ruling is subject to the following. No party shall introduce evidence of Defendants' communications or responses to the 2017 FDA audit without prior Court approval. Any evidence must address Defendants' conduct or knowledge during or before Plaintiff's first surgery.

B. Plaintiff's Motion in Limine No. 22

In his motion in limine, Plaintiff argues that any evidence or argument concerning Dr. Jensen's alleged negligence or fault should be excluded as irrelevant and unduly prejudicial under

Rule 403. (ECF No. 246 at PageID #13129, 13131–33.) Defendants contend that they should be permitted to present evidence that Dr. Jensen caused Plaintiff's injuries, *i.e.* present a theory of alternative causation. (ECF No. 278 at PageID #14565.) A hearing was held on October 28, 2020, and the Court reserved judgment, stating that a reasoned decision would follow. (ECF No. 366 at PageID #18929.)

First, relevance and the impact of this Court's summary judgment decision, which limited Plaintiff's injuries in this case to his omental adhesions resulting from his first surgical hernia repair in 2015. During the hearing, Plaintiff argued that any evidence of Dr. Jensen's alleged fault or negligence related to Plaintiff's recurrent hernia, diastasis, and pain was irrelevant based on this summary judgment decision. (ECF No. 360 at PageID #18813.) Defendants responded that this kind of evidence is relevant to the overall story of the case and to the causation of the omental adhesions from the first surgery. (*Id.*)

Both sides are correct to some extent. Defendants are correct in that the fact that Plaintiff's first hernia was located within a diastasis that was repaired at the same time as his hernia during the 2015 surgery may be relevant to causation of his adhesions. (*Id.* at PageID #18814.) For example, Defendants' expert Dr. Novitsky opined that given the existence of the diastasis and the location of the hernia within it, Dr. Jensen should have counseled Plaintiff to lose weight first and questioned the need for the 2015 surgery at all. (ECF No. 278-1 at PageID #14586.) This evidence tends to suggest that any product-related defect by Defendants was not the cause of Plaintiff's injury—his implanting surgeon's approach was. Moreover, causation is certainly material in this case. And Rule 403 does not prevent parties from telling a complete story, which here includes the

⁹ It is important to note that the connection to adhesions is unclear at this point. Dr. Novitsky discussed "failures," but what comprises those failures is not apparent. (See ECF No. 278-1 at PageID #14586.) To be admissible as alternative causation at trial, Defendants must show that Dr. Jensen's conduct caused the adhesions.

circumstances surrounding Plaintiff's first hernia repair. *Old Chief v. United States*, 519 U.S. 172, 188–90 (1997).

But Defendants will not be permitted to introduce evidence that Dr. Jensen caused Plaintiff's recurrent hernia, diastasis, or pain. Defendants prevailed at summary judgment, showing that Plaintiff had not created a genuine factual dispute regarding causation for these injuries. Defendants cannot now claim that these injuries are relevant to this case. This evidence is irrelevant and would confuse the jury by discussing injuries and surgeries no longer at issue in this case. This evidence also has qualities of character evidence, encouraging the jury to conclude that because Dr. Jensen has a track record of causing injuries to Plaintiff, he must have caused Plaintiff's injuries in 2015. See Fed. R. Evid. 404.

Plaintiff's primary argument against admitting evidence of Dr. Jensen's conduct in relation to the 2015 surgery is that under Utah law, specifically *Field v. Boyer Co.*, 952 P.2d 1078 (Utah 1998), a party cannot allocate fault to a non-party. (ECF No. 246 at PageID #13131.) In *Field*, the Utah Supreme Court considered whether the Utah Liability Reform Act ("LRA"), Utah Code Ann. § 78-27-38, "allows a comparison of fault between a party defendant and a nonparty, unknown assailant." *Field*, 952 P.2d at 1080. There, the court concluded that fault could only be allocated to parties. *Id.* at 1081. Thus, Plaintiff argues, evidence of Dr. Jensen's fault cannot be introduced. (ECF No. 246 at PageID #13131.)

Plaintiff misreads *Field*. In *Field*, the Utah Supreme Court did not treat fault and causation interchangeably. The court recognized that "fault" as defined in the statute included an "actionable breach of duty" and proximate cause. *Id.* (quoting Utah Code Ann. § 78-28-37(2)). Later decisions would emphasize "responsibility" as an alternate definition for "fault." *Graves v. N.E. Servs., Inc.*, 345 P.3d 619, 633 (Utah 2014) (quoting *Mulherin v. Ingersoll-Rand Co.*, 628 P.2d 1301, 1304

(Utah 1998)). Although fault under the Utah statute includes an element of causation, precedent demonstrates it is not synonymous with causation. A person may have engaged in conduct causing the plaintiff's injury, but not be at fault because he failed to breach a legal duty, and vice versa. *Field* confirms that the purpose behind the LRA is to prevent the assignment of fault, *i.e.* liability for damages, to nonparties. *Jedrziewski v. Smith*, 128 P.3d 1146, 1150 (Utah 2005) (summarizing the holdings in *Field*). ¹⁰ It certainly does not stand for the proposition that a party may not present evidence of intervening or alternative causation.

Plaintiff argues that if Defendants wanted to point fingers at Dr. Jensen, then they should have joined him in this action. (ECF No. 246 at PageID #13131.) It is true that the LRA requires defendants to join any person "who may have caused or contributed to the injury or damage," but only to "determine[] their respective portions of fault," not causation. *Field*, 952 P.2d at 1082 (quoting Utah Code. Ann. § 78-27-41(1). In other words, a plaintiff suing under tort law in Utah must join any parties he seeks to hold liable or else he cannot later seek contribution. *Metro Aviation, Inc. v. United States*, No. 2:10-CV-445-TC, 2014 WL 2708630, at *4 (D. Utah June 16, 2014).

This is consistent with the example given by the Utah Supreme Court in *Field*. The court noted that it was appropriate to consider a nonparty's conduct in apportioning fault, which alludes to intervening or alternative causation. In this example, the court described an unknown, "erratic driver who might *cause* a defendant who was negligently following too closely to swerve and hit another car whose driver was negligently driving too fast." *Field*, 952 P.3d at 1081 (emphasis added). But it explained that fault, if any, could only be allocated such that the "allocation of fault

¹⁰ Indeed, this part of the holding in *Field* is quite straightforward compared to the other issue in *Field*, whether the LRA apportions fault between intentional and negligent tortfeasors—a "riddle" which took almost twenty years to solve. The LRA applies to intentional and negligent torts, *Graves*, 345 P.3d at 628, as well as to strict liability claims, *Bylsma v. R.C. Willey*, 416 P.3d 595, 601 (Utah 2017).

to the plaintiff and defendant would have to equal 100%." *Id.* What this means is that under Utah law, a plaintiff cannot argue in one action that a defendant is 80% responsible and a nonparty is 20% responsible, nor may a defendant argue the same in a subsequent contribution action against the nonparty. But this does not exclude the obvious—in the event that the plaintiff fails to demonstrate causation entirely, potentially because another actor caused the injury, the percentage of fault attributable to the defendant is 0%. This is where Defendants seek to introduce evidence of Dr. Jensen's conduct, and this is appropriate under the Federal Rules of Evidence and Utah state law.¹¹

This leads to an important caveat: Defendants may introduce evidence that Dr. Jensen's decisions as Plaintiff's implanting surgeon caused his injuries, but they may not argue that Dr. Jensen was negligent. An argument that Dr. Jensen was negligent is tantamount to an argument that Dr. Jensen was at fault, which is clearly forbidden by *Field. See also* § 78-27-37(1) (listing negligence as an example of fault). Defendants could offer testimony, for example, that Dr. Jensen's decision to perform a surgery on Plaintiff was the cause of Plaintiff's adhesions, but they cannot characterize his decision as negligent. Thus, Plaintiff is incorrect that Defendants need to introduce evidence of the standard of care for Dr. Jensen (ECF No. 246 at PageID #13133); expert causation testimony is sufficient because the issue is causation—not Dr. Jensen's negligence.

For these reasons, Plaintiff's motion is granted to the extent that Defendants seek to introduce evidence of Dr. Jensen's conduct related to his hernia and diastasis reoccurrences and

¹¹ That Defendants may have been unable to join Dr. Jensen or else risk destroying diversity does not give Plaintiff an unfair advantage. In the instant case, it is all or nothing—Plaintiff will demonstrate that Defendants are 100% or 0% at fault under the LRA. If Plaintiff succeeds here, issue preclusion appears to prevent him from bringing a medical malpractice suit against Dr. Jensen later. See Buckner v. Kennard, 99 P.3d 842, 847 (Utah 2004) (setting forth Utah's issue preclusion or collateral estoppel test); see also Hall v. Sinn, Inc., 102 F. App'x 846, 848 (5th Cir. 2004) (concluding that plaintiff was precluded from bringing a subsequent products liability lawsuit when 100% of the fault for plaintiff's injuries was decided in an earlier case, which included medical malpractice claims, under a similar Louisiana statute requiring a plaintiff to bring a cause against all parties potentially at fault in one action).

pain, as well as evidence of his negligence or fault. However, Plaintiff's motion is denied to the extent that Defendants seek to admit evidence that Dr. Jensen's conduct caused Plaintiff's adhesions, though without commentary on the nature of his conduct.

C. Defendants' Motion in Limine No. 11

In this motion in limine, Defendants argue that any evidence or argument related to transvaginal or pelvic mesh devices, including lawsuits and regulatory actions, as well as subsequent decisions by Defendants not to continue marketing these devices, should be excluded as irrelevant, unduly prejudicial, and as hearsay. (ECF No. 212 at PageID #11883–92.) Plaintiff responds that such evidence is relevant, is not unduly prejudicial or otherwise excludable under Rule 403, and is not hearsay because he seeks to introduce this evidence to demonstrate Defendants' notice of issues with polypropylene mesh implants. (ECF No. 283 at PageID #15661–70.) An initial hearing was held on this motion on September 10, 2020, and the Court reserved judgment. (ECF No. 332 at PageID #17888.) A second hearing with expert testimony was held on November 10, 2020 and continued to December 8, 2020 to aid the Court in understanding the similarities and differences between the hernia and the transvaginal pelvic mesh devices. (ECF Nos. 371 & 377.) The parties were directed to file post-hearing briefs that succinctly and explicitly identified the similarities or differences between the Ventralight ST and the transvaginal pelvic mesh devices, which the parties have done. (ECF Nos. 384, 385, 387, 388.)

1. Hearsay

First, this evidence is not inadmissible hearsay because Plaintiff seeks to introduce this evidence to demonstrate Defendants' notice. *Beigas v. Quickway Carriers, Inc.*, 573 F.3d 365, 379 (6th Cir. 2009).

2. Relevance

Second, the transvaginal pelvic mesh lawsuits and regulatory actions are relevant to Defendants' notice of the risks posed by implanting Marlex polypropylene resin in the human body. Notice is critical to Plaintiff's design defect claims based on negligence and strict liability. Fortune v. Techtronic Indus. N. Am., 107 F. Supp. 3d 1199, 1204 (D. Utah 2015) (quoting Slisze v. Stanley-Bostitch, 979 P.2d 317, 320 (Utah 1999)) (negligence); House v. Armour of Am., Inc., 929 P.2d 340, 343 (Utah 1996) (strict liability); see also supra, Part II. Rule 401 defines relevance as evidence that "has any tendency to make a fact more or less probable without the evidence" and "the fact is of consequence in determining the action." Fed. R. Evid. 401. The Sixth Circuit has interpreted relevancy under Rule 401 generously, describing the "relevance threshold" as "very low," United States v. Sumlin, 956 F.3d 879, 889 (6th Cir. 2020) (quoting United States v. Whittington, 455 F.3d 736, 739 (6th Cir. 2006)), and "extremely permissive," United States v. Pritchard, 964 F.3d 513, 526 (6th Cir. 2020) (quoting Wood v. Wal-Mart Stores, E., LP, 576 F. App'x 470, 472 (6th Cir. 2014)). Evidence must simply have "the slightest probative worth." United States v. Inzuna-Arenas, --- F. App'x ----, No. 19-3830, 2020 WL 6821688, at *3 (6th Cir. Nov. 20, 2020) (quoting Whittington, 455 F.3d at 738–39)).

Plaintiff identifies several similarities between the mesh devices that indicate the devices are similar enough to be relevant to Defendants' notice. The Ventralight ST was made of Marlex polypropylene, which then oxidized within the human body, degraded, and resulted in adhesions. (ECF No. 283 at PageID #115661; ECF No. 384 at PageID #20441–43). It is undisputed that the transvaginal pelvic meshes were made from Marlex polypropylene resin or that the transvaginal

¹² Plaintiff also points to the inadequate pore sizes and use of animal studies in both types of mesh, but he does not link these commonalities to adhesions. (ECF No. 384 at PageID #20443.) If these characteristics are unrelated to Defendants' notice of adhesion formation, the only injury left in this case, the pore-size and animal-study evidence is irrelevant.

pelvic mesh devices saw degradation within the human body due to oxidation of the Marlex polypropylene. At the hearing, Dr. El-Ghannam explained that in the transvaginal pelvic mesh devices, the Marlex polypropylene degraded from oxidation, causing cracking, roughening, and stiffening of the mesh. (ECF No. 371 at PageID #20132–33.) This resulted in adhesions. (*Id.*) Dr. El-Ghannam went on to explain that because the transvaginal, pelvic, and Ventralight ST devices were all made out of Marlex polypropylene (and accompanied by the Marlex Material Safety Data Sheet, which specifically warned about oxidation in implantation uses in the Medical Application Caution statement), designed to support soft tissue, and implanted in "highly vascularized" regions of the body, Defendants should have anticipated similar problems in the Ventralight ST. (*Id.* at 20138–41.) Therefore, evidence of the transvaginal pelvic mesh litigation and regulatory actions is relevant to whether Defendants knew or should have known the Ventralight ST was unreasonably dangerous because the Marlex polypropylene caused adhesions, as well as whether Defendants' subsequent actions were reasonable in light of this knowledge.¹³

Defendants raise various counterarguments, but all go to the weight, not relevance, of the transvaginal pelvic mesh evidence. In the most recent briefing, Defendants argue that there are many differences between the Ventralight ST hernia mesh device and the transvaginal pelvic mesh device. (ECF No. 385 at PageID #20691–96.) But none of these arguments shows transvaginal pelvic mesh device evidence has no probative value to proving that Defendants knew or should have known that the exposure of Marlex polypropylene to internal organs and tissues would oxidize and cause adhesions. Defendants assert that Plaintiff "offers no argument why Dr. El-

¹³ Defendants argue that any evidence that they decided to discontinue marketing the transvaginal pelvic mesh devices is irrelevant. (ECF No. 212 at PageID #11891.) If Plaintiff can show the decision to discontinue marketing the transvaginal pelvic mesh devices put Defendants on notice of the risks presented by Marlex polypropylene, then the discontinuation of the transvaginal pelvic mesh devices is relevant. Defendants' arguments that this decision was based on business motivations and not safety motivations (*id.*) goes to the weight, not relevance, of this evidence, *United States v. Snyder*, 789 F. App'x 501, 512 (6th Cir. 2019).

Ghannam (or Plaintiff) *needs* to introduce transvaginal pelvic mesh devices," (ECF No. 388 at PageID #20879) (emphasis added), but one piece of circumstantial evidence need not be conclusive on its own to be relevant. *Inzuna-Arenas*, 2020 WL 6821688, at *3 (explaining that "[e]vdence may not be excluded merely because it is insufficient to prove the ultimate point for which it is offered"). Certainly, Defendants' arguments are ones that a jury should hear in weighing the transvaginal pelvic mesh evidence. But none of these arguments warrant exclusion of the evidence as irrelevant.

Next, Defendants argue that the transvaginal pelvic mesh evidence fails to address the cause of Plaintiff's injury—the too-quick absorption of the ST layer. (ECF No. 212 at PageID #11884; ECF No. 385 at PageID #20691–92; ECF No. 388 at PageID #20881–82.) Defendants mischaracterize Plaintiff's theory of injury. The Court has rejected this interpretation of Plaintiff's theory of injury, clarifying that Plaintiff's theory is two-fold: first, that the resorption of the ST layer led to the exposure of polypropylene and second, that this led the premature exposure of the polypropylene to tissues in the body, causing oxidization and resulting in adhesions. 2020 WL 6603657, at *3. The transvaginal pelvic mesh evidence concerns the second link in the chain of causation—oxidation of the polypropylene in the body.

Defendants then argue that the transvaginal pelvic mesh evidence is irrelevant to Defendants' notice or knowledge of risks associated with Marlex polypropylene because hernia devices existed before the transvaginal pelvic mesh devices and thus the transvaginal pelvic mesh devices did not inform the design of the Ventralight ST. (ECF No. 388 at PageID #20881.) This may be true, but Plaintiff's point is that the later legal and regulatory activity surrounding the transvaginal pelvic mesh devices *should have* informed subsequent hernia mesh device designs given the failures of the transvaginal pelvic mesh devices related to the Marlex polypropylene.

This evidence is relevant to Defendants' knowledge, as well as the reasonableness of their conduct in light of that knowledge.

Relatedly, the parties dispute the degree in organizational overlap between the divisions in Bard that developed the pelvic and hernia mesh devices. (ECF No. 283 at PageID #15663; ECF No. 371 at PageID #20172–79). Overlap between the division responsible for hernia mesh and the division responsible for transvaginal pelvic mesh research and development would be more convincing evidence that Defendants knew or should have known about the dangers presented by Marlex polypropylene based on the transvaginal mesh litigation. But an overlap of divisions is not required to show this evidence is relevant to whether the Defendants knew or should have known about the risks of using Marlex polypropylene in the Ventralight ST.

Defendants also argue that courts regularly exclude evidence of other lawsuits against defendants as irrelevant. (ECF No. 212 at PageID #11885.) Those cases are distinguishable because they did not consider notice. *McLeod v. Parson Corp.*, 73 F. App'x 846, 853–54 (6th Cir. 2003) (evidence of a plan); *Cannon v. Licking Cty.*, No. 2:17-cv-0004, 2019 WL 5543032, at *3 (S.D. Ohio Oct. 25, 2019) (evidence of causation); *Skibniewski v. Am. Home Prods. Corp.*, No. 99–0842–CV–W–FJG, 2004 WL 5628157, at *4 (W.D. Mo. Apr. 1, 2004).

Finally, Defendants contend that the devices are not "substantially similar." (ECF No. 212 at PageID #11886.) 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). It is unclear what form of evidence Plaintiff seeks to admit in relation to the transvaginal pelvic mesh litigation. If it is a summary of transvaginal pelvic mesh MDLs, traits of the entire MDL, or other evidence related to the MDL broadly, it would be illogical to apply the substantial-similarity test. The focus of this test is on discrete incidents, which explains the

requirement "that the accidents must have occurred under similar circumstances or share the same cause." *Id.*; *Palataka v. Savage Arms, Inc.*, 535 F. App'x 448, 459 (6th Cir. 2003) (applying the substantial-similarity test to individual lawsuits the party sought to admit). But if Plaintiff is not introducing specific cases, then there is no reason why the substantial-similarity test should apply to each of the thousands of cases in the transvaginal pelvic MDL. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F.Supp.3d ----, 2020 WL7065764, at *10 (S.D. Ohio Dec. 3, 2020) (declining to require the application of the substantial-similarity test to general figures and statistics).

In any event, Plaintiff satisfies the substantial-similarity test. 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 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); cf. 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."). The transvaginal pelvic mesh devices were made of Marlex polypropylene, which was accompanied by the warning in the Marlex Material Safety Data Sheet ("MSDS")—a fact Defendants do not dispute. The fact that the devices were implanted in different areas of the human body, were shaped differently, and that the pelvic mesh lacked an ST coating (ECF No. 212 at PageID #11887), are differences, to be sure. But these differences do not indicate that the evidence has no probative value regarding Defendants' knowledge that polypropylene oxidized, degraded, and then encouraged formation of adhesions. Thus, the transvaginal and pelvic mesh litigation was similar enough to raise Defendants' awareness of these risks. *See* 2020 WL 7065764, at *8–9 (discussing the substantial-similarity test in the notice context).

3. Rule 403

Defendants argue that evidence of transvaginal pelvic mesh litigation should be excluded under Rule 403, contending that evidence of other trials would inevitably lead to mini-trials, delays, and jury confusion. (ECF No. 212 at PageID #11888; ECF No. 385 at PageID #20696; ECF No. 388 at PageID #20882.) Defendants' notice and knowledge of risks presented by the Ventralight ST and/or its components are critical to Plaintiff's design defect claims based on negligence and strict liability. *Fortune*, 107 F. Supp. 3d at 1204 (quoting *Slisze*, 979 P.2d at 320 (negligence); *House*, 929 P.2d at 343 (strict liability). The presentation of relevant evidence will not unduly lengthen trial or prejudice Defendants. Defendants will surely challenge this evidence by pointing out the differences between the devices, the method of implantation, etc. The jury then must decide what weight to accord the evidence stemming from the transvaginal and pelvic mesh litigation.

Moreover, any risk of confusion or prejudice is remedied by a limiting instruction. Notice is a discrete issue and the jury will be given a limiting instruction that evidence from the transvaginal pelvic device litigation may only be considered in relation to Defendants' notice. Fed. R. Evid 105. Were Plaintiff offering evidence of other device litigation to prove causation, it might be the case that mini-trials would result. Defendants would have to introduce evidence to refute causation for the Ventralight ST *and* refute causation for the transvaginal pelvic mesh devices.

This would have the effect of relitigating the transvaginal pelvic mesh cases. But here, Plaintiff is offering this evidence to demonstrate Defendants' knowledge and notice, which does not require the level of detail that refuting causation would.

But Defendants' point is well-taken in light of recent proceedings. A relatively discrete issue—whether the Ventralight ST and transvaginal pelvic mesh devices are similar enough to demonstrate that Defendants knew or should have known of the risks posed by the polypropylene, a preliminary question of admissibility—has spanned two expert witness hearings (ECF Nos. 371, 380) and a set of supplemental briefs (ECF Nos. 384, 385, 388). And at times, both parties have taken the Court rather far afield from this issue, particularly with regard to the organizational structure of Defendants' divisions responsible for hernia mesh and transvaginal pelvic mesh devices and the individuals involved in each division.

Although this type of evidence was ancillary to the admissibility of the evidence under Federal Rule of Evidence 104, the Court at this time declines to decide whether this evidence is inadmissible due to Rule 403 concerns. This will depend on the exact evidence offered, the questions asked during examination of witnesses, etc. For these reasons, Defendants' motion in limine is denied.

D. Defendants' Motion in Limine No. 13

Next, Defendants argue that evidence and argument of other litigation involving similar Bard products should be excluded as irrelevant under Rule 401, as character evidence under Federal Rule of Evidence 404, and as inadmissible hearsay. (ECF No. 214 at PageID #11946–50, 11955.) Plaintiff counters that Defendants fail to point to specific evidence, that this kind of evidence is relevant, and that it is admissible despite Federal Rule of Evidence 404(b)(2) as evidence of motive, intent, knowledge, absence of mistake, and lack of accident. (ECF No. 294 at

PageID #16239.) The Court reserved judgment on this part of Defendants' motion. (ECF No. 332 at PageID #17888.)

In general, Defendants' motion and Plaintiff's opposition brief lack specificity, so neither may gain the benefit of a specific ruling here. *See Sperberg*, 519 at F.2d at 712 ("Orders in limine which exclude broad categories of evidence should rarely be employed. A better practice is to deal with questions of admissibility of evidence as they arise."). Defendants do not point to any device-specific litigation apart from the transvaginal pelvic mesh litigation discussed *supra*. Therefore, the Court declines to grant this motion. However, the reasoning above would be instructive for any other prior litigation Plaintiff may seek to introduce to show knowledge or notice, *supra* Part III.C, and knowledge is an express exception under Rule 404(b)(2), Fed. R. Evid. 404(b)(2). 14

In the same vein, the Court declines to green-light Plaintiff's assertions that evidence of prior litigation would be admissible not only to prove notice but also intent and other Rule 404(b)(2) exceptions. (ECF No. 294 at PageID #16239.) Without more, it would be inappropriate to speculate whether any evidence Plaintiff may present would be admissible on these grounds.

Accordingly, the remaining part of Defendants' motion is denied.

IV. Conclusion

For the reasons set forth above, Defendants' Motion in Limine No. 14 (ECF No. 215) is **GRANTED IN PART AND DENIED IN PART**; Plaintiff's Motion in Limine No. 22 (ECF No. 246) is **GRANTED IN PART AND DENIED IN PART**; Defendants' Motion in Limine No. 11 (ECF No. 212) is **DENIED**; and Defendants' Motion in Limine No. 13 (ECF No. 214) is **DENIED**.

¹⁴ Defendants did not argue that evidence of transvaginal pelvic mesh litigation was inadmissible under Rule 404 as character evidence. (See ECF No. 323.)

IT IS SO ORDERED.

<u>2/10/2021</u>	s/Edmund A. Sargus, Jr.
DATE	EDMUND A. SARGUS, JR.
	UNITED STATES DISTRICT JUDGE