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. 40

Defendants' Motion *in Limine* ("MIL") No. 6

Defendants C.R. Bard, Inc. and Davol, Inc. filed a Motion *in Limine* to Exclude Evidence and Argument Concerning Foreign Regulatory Actions (Defendants' MIL No. 6, ECF No. 178), which is opposed by Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi (ECF No. 257). For the reasons that follow, the Court **DENIES** Defendants' MIL No. 6.

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 allegations that defects in defendants' polypropylene hernia mesh products can lead to

[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.

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. 6, they move to exclude evidence and argument of certain foreign regulatory actions, specifically an audit done after Mr. Milanesi's surgery in preparation for the implementation of new medical device regulations in the European Union (Defs' MIL No. 6, ECF No. 178.)

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 denied Defendants' motion to exclude evidence and argument concerning foreign regulatory actions. (Case No 2:18-cv-01509, MIL Order No. 5, ECF No. 359 at PageID #18796–801.) In ruling on Defendants' motion, the Court stated:

> Defendants argue in this motion that evidence or argument related to foreign regulatory actions should be excluded as prejudicial. Specifically, Defendants reference audits completed by the BSI and aver that Plaintiff plans to rely on these audits to demonstrate a "major nonconformity" in the Ventralight ST, along with some of Defendants' other devices, with European Union ("EU") regulations. (ECF No. 179 at PageID #10630.) Additionally, Defendants point to a clinical study initiated in response to the BSI audits, titled "DVL-020." (*Id.*) Defendants explain that an audit was sought so that they would be able to bring themselves into compliance with new Medical Device Regulations ("MDR") in the EU that were to take effect in 2020. (*Id.*)[2] Plaintiff responds that Defendants "mischaracterize" the BSI evidence. (ECF No. 191 at PageID #11565.) He contends that the BSI is not a foreign regulator and that he will introduce the BSI evidence not to show a lack of compliance with EU regulations, but to show that Defendants could have conducted long-term clinical studies before the Ventralight ST was implanted in Plaintiff and that Defendants were aware of certain adverse effects of the device—all of which was indicated in Defendants' communications with BSI. (*Id.* at PageID #11564–67.)
>
> Whether BSI is a foreign regulator is a difficult question. BSI is a private company that performs a host of services, including consulting, compliance audits,

[2] Defendants do not identify any other foreign regulatory evidence. Accordingly, this opinion only addresses BSI evidence. At this time, the Court declines to exclude all foreign regulatory evidence without the benefit of the evidence in front of it or at least more particularity. *See Yates v. Ford Motor Co.*, No. 5:12-CV-752-FL, 2015 WL 2189774, at *14 (E.D.N.C. May 11, 2015) ("Nevertheless, courts within this circuit have declined to grant motions broadly seeking to exclude evidence of foreign regulatory actions when those motions, as here, lack specificity and context.").

and standardization for quality management systems.[3] And it describes itself as a developer of quality control standards.[4] But BSI is also a notified body, "an organisation designated by an EU country to assess the conformity of certain products before being placed on the market."[5] A "conformity assessment" of a device performed by a notified body is a prerequisite for placing a product on the EU market.[6] Importantly, a notified body is not the equivalent of the FDA—the European Medicines Agency ("EMA") is.[7] It appears that once a device has obtained a conformity assessment from a notified body, the EMA provides some level of review of the assessment and ultimately makes a recommendation to the European Commission, which provides market authorization.[8] The Court need not decide whether BSI is a foreign regulator, however, because even were the Court to conclude that BSI is a foreign regulator, the BSI-related evidence is still admissible.

Some courts have excluded evidence related to foreign regulatory actions taken by foreign regulators as unduly prejudicial, time consuming, and confusing for the jury. *Hurt v. Coyne Cylinder Co.*, 956 F.2d 1319, 1327 (6th Cir. 1992) (concluding that "foreign legal standards have been found excludable by the 11th Circuit, and we now follow that holding" (citation omitted)); *Deviner v. Electrolux Motor, A.B.*, 844 F.2d 769, 773 (11th Cir. 1988) (upholding the district court's ruling that admitting evidence of Swedish law would confuse the jury). Courts have explained that admission of foreign regulatory actions would lead to "'mini-trials' regarding the grounds for those [regulatory] decisions and the regulatory schemes of the countries involved." *Yates v. Ford Motor Co.*, No. 5:12-CV-752-FL, 2015 WL 2189774, at *14 (E.D.N.C. May 11, 2015) (quoting *In re Seroquel Prods. Liab. Litig.*, 601 F. Supp. 2d 1313, 1318 (M.D. Fla. Mar. 11, 2009)). Most courts have reached the decision to exclude evidence under Rule 403 evidence of foreign regulatory actions when the evidence is put forth to demonstrate a product defect or a breach of the duty of care. A few courts, however, have excluded such evidence even when offered to prove facts other than "that Defendants violated foreign law," such as notice. *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007); *see also Katzenmeier v. Blackpowder Prods. Inc.*, 628 F.3d 948, 950 n.4

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[3] BSI, *Our Services*, https://www.bsigroup.com/en-US/our-services/ (last visited October 27, 2020); BSI, Financial Information, https://www.bsigroup.com/en-US/about-bsi/Financial-information (last visited October 27, 2020)

[4] ISO, *BSI, United Kingdom*, https://www.iso.org/member/2064.html (last visited October 27, 2020).

[5] European Commission, *Notified bodies*, https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies_en (last visited October 27, 2020).

[6] European Commission, *Conformity assessment*, https://ec.europa.eu/growth/single-market/goods/building-blocks/conformity-assessment_en (last visited October 27, 2020).

[7] FDA, *A Look at the European Medicines Agency*, https://www.fda.gov/animal-veterinary/animal-health-literacy/look-european-medicines-agency (last visited October 27, 2020) ("EMA has a similar role as FDA in the review and approval of certain drugs for people and animals in the European Union (EU).").

[8] European Commission, *Medial Devices*, https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices (last visited October 27, 2020); European Commission, *Obtaining an EU marketing authorization, step-by-step*, https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/obtaining-eu-marketing -authorisation-step-step (last visited October 27, 2020).

(8th Cir. 2010). Others have declined to do so, concluding that evidence of foreign regulatory actions is not unduly prejudicial or time consuming when used to prove notice and knowledge. *See In re Yasmin & Yaz (Drospireone) Mktg., Sales Pracs. & PMF Prods. Liab. Litig.*, Nos. 3:09-cv-10012-DRH-PMF, 3:09-cv-20021-DRH-PMF, 3:10-cv-10223-DRH-PMF, 2011 WL 6740391, at *2 (S.D. Ill. Dec. 22, 2011); *In re Levaquin Prods. Liab. Litig.*, No. 08-5743 (JRT), 2010 WL 46767973, at *5 (D. Minn. 2010).

The distinction between the two uses of foreign regulatory actions, one for defining the design defect and the standard of care and the other for notice and knowledge, is persuasive. When a foreign regulatory action is offered to demonstrate a design effect or a breach of the standard of care, the defendant manufacturer must contextualize the action and refute any adverse determinations because evidence of foreign regulatory violations is in effect evidence of strict liability or negligence. *See In Re Seroquel*, 601 F. Supp. 2d at 1318 (noting that "negative decisions of three foreign regulators," Japan, Holland, and France, would require extensive contextualization so that the jury could understand the regulatory frameworks, introducing significant mini-trial concerns). This justifies the mini-trial concern. But when the evidence is put forward to demonstrate mere notice, no such contextualization is necessary. This approach is not inconsistent with *Hurt*—the only Sixth Circuit case to address the admissibility of foreign regulatory actions. The court in *Hurt* excluded evidence of "foreign legal standards" when used to demonstrate that an acetylene container was defective, to show the availability of an alternative safety device. 956 F.2d at 1326–27. *Hurt* did not address use of foreign regulatory actions to prove notice or knowledge.

Here, Plaintiff does not purport to offer this evidence to define a design defect or the standard of care.[9] Therefore, determining whether Defendants were on notice that the Ventralight ST had adverse events and had the ability to conduct additional testing does not require a dive into the complexities of European regulatory schemes and its differences from the American regulatory framework.

Additionally, there is no risk that the jury will be tempted to defer to BSI's determination that more clinical testing was necessary because the BSI audit was not a final agency determination. Rather, the BSI audit, which then led to the additional clinical testing of the Ventralight ST and Sepramesh, was prospective; the new MDR was not slated to go into effect until this year. *Compare In re Levaquin*, 2010 WL 4676973, at *5 (emphasizing that the risk of prejudice to the defendant was low because the plaintiff had "not presented a final regulatory action to which a jury might defer out of confusion") *with In re Seroquel*, 601 F. Supp. 2d at 1318 (concluding that a jury might be more inclined to abdicate its

[9] In Plaintiff's Motion in Limine No. 14, Plaintiff sought to exclude evidence of ISO standards that Defendants relied upon to satisfy FDA regulations. (ECF No. 230.) However, the ISO standards satisfied FDA regulatory requirements, and thus helped define the standard of care under Utah law holding that state and federal regulations and statutes define the standard of care. (ECF No. 355 at PageID #18766.) Because Plaintiff does not offer this evidence to define the standard of care, this Court need not consider whether the Supreme Court of Utah would permit foreign regulations to define the standard of care.

responsibilities and defer to the negative decision of three foreign regulators").

> Defendants argue that Plaintiff's theory that they should have conducted a clinical study sooner because it would have better protected Plaintiff and other consumers would leave the jury to "second-guess FDA decisions." (ECF No 179 at PageID #16035.) That Plaintiff will argue at trial that Defendants should have conducted more clinical studies is beyond a doubt, but this is a relevant point as to Plaintiff's design defect and failure to warn claims. Plaintiff offers this evidence not to demonstrate that Defendants violated foreign regulations even while they satisfied the FDCA and FDA regulations, but to show that Defendants had notice of certain issues and that they could have feasibly conducted long-term clinical studies on the Ventralight ST. With this use of the evidence in mind, it is unclear how the jury may be tempted to second guess the FDA. Even so, evidence of federal law violations is admissible to prove the standard of care and violations thereof under Utah tort law, so long as the claims do not depend solely on FDCA or FDA regulatory violations. (ECF No. 355 at PageID #18771.)[10]
>
> For these reasons, Defendants' motion is denied. Plaintiff will be permitted to introduce evidence regarding the BSI audit and the subsequent long-term clinical testing to show notice of possible dangers and ability to conduct the studies of the Ventralight ST device. The parties may explain why Defendants obtained a BSI audit, that Defendants were not yet in noncompliance with the forthcoming MDR, and that the BSI is an organization that provides assessments, which are perquisites to placing devices on the market in the EU. This is a relatively narrow point, which should not lead the trial or the jury far afield.

(*Id.*) In this case, Defendants In its MIL No. 11, the Court specifically addressed Defendants' arguments that the foreign regulatory evidence should be inadmissible because it occurred after the plaintiff's surgery:

> 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 . . . the

[10] For this reason, Defendants' concerns that the BSI-related evidence implicates *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), (ECF No. 179 at PageID #10632), are misplaced.

commencement of the DVL-020 study; it was the . . . impending European regulations[.]

. . .

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.[11] 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

[11] 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.

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. 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.[12]

> [T]he DVL-020 study [is not a] subsequent remedial measure[ ] because Plaintiff's injury did not trigger these actions. It is undisputed that Defendants took these steps in response to the . . . 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. [T]he DVL-020 study began in 2018—. . . 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.[13]
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> 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 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.

(Case No 2:18-cv-01509, MIL Order No. 11, ECF No. 415 at PageID #22182–87.) The same

[12] 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).

[13] 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.

reasoning applies here, and the Court adopts its prior ruling in *Johns*. "[T]he 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." (*Id.* at PageID #22187.)

IV. Conclusion

For the reasons set forth above, the Court **DENIES** Defendants' MIL No. 6 (ECF No. 178).

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