**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. 4

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 are (1) Defendants' Motion in Limine No. 2 to Exclude Evidence and Argument Concerning Material Safety Data Sheets (ECF No. 175); (2) Plaintiff's Motion in Limine No. 2 to Exclude Reference to Reason for Addition of Medical Application Statement to Marlex Material Safety Data Sheet (ECF No. 234); (3) Plaintiff's Motion in Limine No. 14 to Exclude Evidence of the ISO Standards/Guidelines to Support Legal Theories or Establish the Product's Safety and Efficacy (ECF No. 230); (4) Plaintiff's Motion in Limine No. 3 to Exclude Evidence relating to the United States Food and Drug Administration (ECF No. 231); (5) Defendants' Motion in Limine No. 8 to Exclude Evidence and Argument Concerning Alleged Fraud on the FDA, Misbranding, or Violation of FDA Regulations (ECF No. 209); and (6) Plaintiff's Motion in Limine No. 16 to Exclude the FDA's Hernia Surgical Mesh Implant's Webpage (ECF No. 233). During the September 3, 2020 conference (ECF Nos. 314, 322) and in Motions in Limine Order No. 2 (ECF No. 331), the Court decided all motions, except for Plaintiff's Motion in Limine No. 2 (ECF No. 234), and stated that this reasoned decision was to follow.

## I. Background[1]

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, 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. Ventralight ST is a prescription medical device used for hernia repairs. (ECF No. 309 at PageID #16717.) 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.*)

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.*) 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

[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 of this case, the reader is directed to the Court's summary judgment opinion and order. (ECF No. 309.)

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

surgery in 2015. The adhesions were diagnosed during a subsequent laparoscopic surgery in October 2016 by Plaintiff's implanting surgeon. (*Id.* at PageID #16740, 16746.)[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 of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. (*Id.* at PageID #16727–65.) Now, various motions in limine and other evidentiary motions are ripe for adjudication.

This opinion addresses the motions in limine regarding the exclusion of Material Safety Data Sheets ("MSDS") for Marlex polypropylene and the Medical Application Caution statement within the Marlex MSDS (ECF Nos. 175, 234), the standards and guidelines from the International Organization for Standardization ("ISO") (ECF No. 230), evidence related to the FDA's § 501(k) process (ECF No. 231), Defendants' allegedly inadequate disclosures to the FDA and violations of FDA regulations (ECF No. 209), and the FDA's webpage about surgical hernia mesh implants (ECF No. 233). A hearing was held on these motions on September 3, 2020. (ECF Nos. 314, 322.) An order memorializing the rulings made during the hearing followed, indicating that a reasoned opinion would be forthcoming. (ECF No. 331.)

## 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

[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. (ECF No. 309 at PageID #16740.)

trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence in advance of trial in order to avoid delay and ensure an evenhanded and expeditious trial." *In re E.I. du Pont De Nemours & Co.*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Ind. Ins. Co.*, 326 F. Supp. 2d at 846; *see also Koch*, 2 F. Supp. 2d at 1388. The denial, in whole or in part, of a motion in limine does not admit all evidence contemplated by the motion; it simply means that the court cannot adjudicate the motion outside of the trial context. *Ind. Ins Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. Evidence that is not relevant is inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403. 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. 2

In Defendants' Motion in Limine No. 2, Defendants argue that any evidence or argument concerning the Marlex MSDS should be excluded because it is not relevant or, in the alternative, it is unduly prejudicial. (ECF No. 175 at PageID #10113–14.) Defendants also argue that the MSDS is comprised of inadmissible hearsay. (*Id.* at Page ID #10120.) Plaintiff contends that the MSDS is relevant to causation and notice. (ECF No. 183 at 10700–06.) The Court denied this motion in part. (ECF No. 331 at PageID #17884.)

Federal regulations require manufacturers to create an MSDS for each hazardous chemical that they use, produce, or import. 29 C.F.R. § 1910.1200(g)(1). The purpose of this section, entitled "[h]azard communication," "is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees." *Id.* at § 1910.1200(a)(1). The purpose of the hazard communication is to protect the occupational safety and health of employees. *See id.* at § 1910.1200(a)(2). Manufacturers are required to "identify and consider the full range of available scientific literature and other evidence concerning the potential hazards" and to "classify" the hazards so that proper protective measures may be taken in the workplace. *Id.* at § 1910.1200(a)(2), (b)(1), (d)(1). The manufacturer here, Phillips Sumika Polypropylene Company, a subsidiary of Chevron Phillips Chemical Company, maintained an MSDS for Marlex Polypropylene that included this "Medical Application Caution" statement:

> Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.
>
> Do not use this Phillips Sumika Polypropylene Company material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Phillips Sumika Polypropylene Company under an agreement which expressly acknowledges the contemplated use.
>
> Phillips Sumika Polypropylene Company makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for use in implantation in the human body or in contact with internal body fluids or tissues.

(ECF No. 175-1 at PageID #10124.) The MSDS also stated that the Marlex polypropylene "[m]ay react with oxygen and strong oxidizing agents, such as chlorates, nitrates, peroxides, etc." (*Id.* at PageID #10129.)

First, relevance. Rule 401 provides a "liberal" "standard of relevance." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993). Courts in "[t]his Circuit appl[y] an 'extremely liberal' standard for relevancy." *United States v.* Collins, 799 F.3d 554, 578 (6th Cir. 2015) (quoting *United States v. Whittington*, 455 F.3d 736, 738 (6th Cir. 2006)); *see also United States v. Pritchard*, 964 F.3d 513, 526 (6th Cir. 2020) ("Federal Rules are extremely permissive as to what evidence is relevant." (quoting *Wood v. Wal-Mart Stores E.*, 576 F. App'x 470, 473 (6th Cir. 2014))). The MSDS clears this bar. Plaintiff argues that his injuries were caused by the ST coating absorbed too quickly, exposing tissue unnecessarily to the polypropylene in the mesh and resulting in adhesions. He also contends that Defendants knew that the Marlex polypropylene had dangerous qualities yet continued to push the mesh into the market. The MSDS tends to make the dangerous character of the mesh and the fact that Defendants were aware of the risks more likely to be true.

Defendants offer no persuasive counterpoints. First, they argue that "Plaintiff is not claiming his injuries were caused by the type of polypropylene resin used in the Ventralight ST"

because Plaintiff claims his injuries were caused by the reabsorption rate of the ST coating. (ECF No. 175 at PageID #10114.) Relatedly, they also argue that Plaintiff has failed to show his adhesions were caused specifically by Marlex polypropylene because all types of polypropylene mesh can cause adhesions. (*Id.* at PageID #10112.) It is well established at this point in the litigation that Plaintiff claims that the ST coating reabsorbed too quickly after implantation which then exposed the bare polypropylene mesh to Plaintiff's organs, rather than simply his fascia, leading to omental adhesions. That all polypropylene mesh can cause adhesions does not mean that the Marlex MSDS is irrelevant to causation, whether Defendants' actions were negligent under the circumstances, or whether Defendants were aware that their device and/or its component parts presented an unreasonable risk to patients, subjecting them to strict liability. Dr. Grischkan's expert testimony supports this theory. As this Court stated in Evidentiary Motions Order No. 5, "Dr. Grischkan's opinion is not that the ST coating itself caused Plaintiff's adhesions. Instead, Dr. Grischkan's opinion is that exposure to the bare polypropylene caused Plaintiff's adhesions." (ECF No. 310 at PageID #16783, 16813.) Defendants cannot ignore the latter links in the chain of causation.

Next, Defendants contend that the MSDS is irrelevant to the finished medical device and is not based on any scientific research. (ECF No. 175 at PageID #10116–18). The allegedly dangerous characteristics of a component of a device are certainly relevant to the question of whether a finished device has dangerous characteristics. And Defendants' argument about a lack of scientific basis for the Medical Application Caution does not render the statement in the MSDS irrelevant. Indeed, Defendants cite no on-point authority for this proposition. Instead, they cite cases dealing with the reliability of scientific expert testimony, which is a different admissibility question than relevance. *See, e.g.*, *Johnson v. Arkema, Inc.*, 685 F.3d 452, 463 (5th Cir. 2012);

*Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 277–78 (5th Cir. 1998) (explaining that "[u]nder the regime of *Daubert* a district judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific" (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996))). Defendants offer "arguments about the weight of the evidence, not its relevance." *United States v. Snyder*, 789 F. App'x 501, 512 (6th Cir. 2019).

Second, hearsay. Hearsay is an out-of-court statement offered for the truth of the matter asserted. Fed. R. Evid. 801(a), (c). Unless a statement falls within an exception or exclusion set forth by the Federal Rules of Evidence, federal statute, or Supreme Court precedent, hearsay is inadmissible. Fed. R. Evid. 802. Plaintiff offers the Marlex MSDS both to show the effect of the statement on Defendants, specifically whether they were on notice of the risks posed by the Ventralight ST, and for the truth of the matter—that the polypropylene resin Marlex should not be implanted in the human body. (ECF No. 183 at PageID #10706). As to the first use, this is a nonhearsay use. *Biegas v. Quickway Carriers, Inc.*, 573 F.3d 365, 379 (6th Cir. 2009) (holding the statement was used "to show that Biegas had been put on notice"); *see also In re C.R. Bard, Inc.*, 810 F.3d 913, 926 (4th Cir. 2016) (concluding that the MSDS Medical Application Caution was admissible nonhearsay demonstrating notice). Defendants do not appear to dispute this that this use of the MSDS is not hearsay or that Defendants' knowledge is relevant to Plaintiff's tort claims.

As to the use of the statement for its truth, no hearsay exception or exclusion applies. Plaintiff argues that the MSDS may be admitted substantively under Federal Rule of Evidence 803(18). Rule 803(18) pertains to Learned Treatises, Periodicals, or Pamphlets. Fed. R. Evid. 803(18). The Rule provides that "[a] statement contained in a treatise, periodical, or pamphlet" is admissible if "the statement is called to the attention of an expert witness on cross-examination or relied on by the expert on direct examination" and "the publication is established as a reliable

authority by the expert's admission or testimony, by another expert's testimony, or by judicial notice." *Id.*

Plaintiff has not established the MSDS as a reliable authority that Marlex polypropylene should not be used in permanent implants in the body, nor can he. *See United States v. Brika*, 416 F.3d 514, 529 (6th Cir. 2005) (noting the burden of evidence's admissibility is on its proponent). The Advisory Committee explains that such statements address by Rule 803(18) are trustworthy and reliable because "a high standard of accuracy [is] engendered by various factors: the treatise is written primarily and impartially for professionals, subject to scrutiny and exposure for inaccuracy, with the reputation of the write at stake." Fed. R. Evid. 803(18) advisory committee's note. There is no indication that this document, written by Phillips Sumika in compliance with federal workplace safety regulations, can satisfy this definition. Rule 803(18) "is not a vehicle for the introduction of any and all reference sources." 30B Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 6938 (2020 ed., West Apr. 2020 update). If an expert relies on the MSDS to demonstrate that the Ventralight ST should not have been used for permanent implantation, Federal Rule of Evidence 703 is more applicable. Fed. R. Evid. 703 ("If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.").

The remaining question is whether the MSDS, when used to demonstrate Defendants' notice, should be excluded under Rule 403. Defendants argue its admission is unduly prejudicial because the jury will consider the MSDS evidence that the Ventralight ST is not suitable for

permanent implantation and that they must put on an expert to explain the regulatory function of MSDS and admit additional evidence to demonstrate the MSDS's lack of scientific basis. (ECF No. 175 at PageID #10119.) None of these arguments is salient to the use of MSDS to show Defendants' notice of the risks accompanying the polypropylene and thus the Ventralight ST. Any risk of prejudice is mitigated with a limiting instruction explaining that the MSDS is only to be considered as evidence of notice and an instruction explaining the regulatory basis for the MSDS. *See* Fed. R. Evid. 105; *see, e.g.*, *United States v. Cordero*, --- F.3d ----, Nos. 19-3540, 3543, 2020 WL 5242412, at *4 (6th Cir. Sept. 3, 2020) (noting that use of a limiting instruction was appropriate to minimize prejudice).

For these reasons, Defendants' Motion in Limine No. 2 is denied in part.

**B. Plaintiff's Motion in Limine No. 2**

Plaintiff argues that evidence of Chevron Phillips's or Phillips Sumika's reason for including the Medical Application Caution in the Marlex MSDS is inadmissible. (ECF. No. 234 at Page ID #12861.) Specifically, Plaintiff asserts that Frank Zakrzewski, a former employee of Chevron Phillips, had no personal knowledge about why the Medical Application Caution was added to the MSDS and that any knowledge is based on hearsay. (*Id.* at PageID #12862–63.) During the September 3, 2020 conference, the Court reserved ruling on this motion and ordered the parties to file supplemental briefing indicating when Defendants learned or believed that the Medical Application Causation was added due to concerns about litigation. (ECF No. 331 at PageID #17884–85.) The briefing is complete. (ECF Nos. 323, 346.)

As a preliminary matter, the intent behind Chevron Phillips's or Phillips Sumika's inclusion of the Medical Application Causation is irrelevant. Because the MSDS is not admissible for the truth of the matter asserted, the actual reason for including the statement has no bearing on

this litigation. Therefore, Zakrzewski's testimony is irrelevant because it is only offered to demonstrate Chevron Phillips's or Phillips Sumika's intent. (ECF No. 258 at PageID #13611–15.) There is thus no need to address Plaintiff's arguments regarding Zakrzewski's lack of personal knowledge or reliance on hearsay as a Federal Rule of Civil Procedure 30(b)(6) designee. However, what Defendants understood to be Chevron Phillips's and Phillips Sumika's intent based on what Defendants knew and observed at the time and whether that belief was reasonable is relevant to whether Defendants' conduct was reasonable under the circumstances or negligent. Thus, it is crucial to determine if there is evidence of when Defendants knew or believed that the MSDS was modified to include that statement as a result of the threat of litigation, rather than bona fide safety concerns about the use of Marlex within the human body.

Roger Darois, the former Vice President of Research and Development at Davol, Inc., provided testimony that does just that. During his deposition, Darois stated that he learned of the Marlex MSDS Medical Application Caution statement in 2007. (ECF No. 234-5 at PageID #12901, p. 184.) Plaintiff's counsel asked whether Phillips Sumika gave permission to Defendants to use Marlex in hernia mesh after the inclusion of the Medical Application Caution statement in 2004. (*Id.* at pp. 219–20.) In response, Darois explained that Davol was never contacted by Phillips Sumika to stop using Marlex in its mesh devices. (*Id.* at p. 221.) However, he attributed Phillips Sumika's lack of communication about the 2004 addition of the statement to a fear of litigation:

> They communicated a fear of litigation because material suppliers were being sued in the late 1990s. That's why they wanted to disassociate the Marlex name with our device. But never once have they ever contacted us directly . . . and say stop using it or we need an agreement [to use Marlex in permanent implementation in the human body].

(*Id.*) Darois clarified further in his declaration that he

> understood [the inclusion of the Medical Application Caution] to be a further attempt to protect [Chevron Phillips] against involvement in meritless personal injury/product liability litigation. This was based not only on my prior

> conversations with CP in 1997, but on general trends taken by raw material suppliers in the medical device industry to reduce risk of involvement in expensive litigation, which were well-known in 2007.

(ECF No. 323-1 at Page ID #17298, ¶ 5.) He also asserted that in 2014 his review of Chevron Phillips's corporate representative's testimony in transvaginal pelvic mesh cases that the Medical Application Caution "was not added due to any scientific testing" confirmed his understanding. (*Id.* at ¶ 6.)

At this time, it appears that Darois lacked personal knowledge of why Chevron Phillips or Phillips Sumika included the Medical Application Caution. Federal Rule of Evidence 602 provides that witnesses may only testify regarding matters of which they have personal knowledge. Fed. R. Evid. 602. This rule extends to Federal Rule of Civil Procedure 30(b)(6) designees, including Darois. *Mays v. LaRose*, 951 F.3d 775, 789–90 (6th Cir. 2020). Although a direct statement to Darois by Chevron Phillips or Phillips Sumika is unnecessary, Darois must still have some basis for his inferred understanding of why the Medical Application Caution was included. Here, Darois points to conversations in 1997 in his declaration, as well as deposition testimony from transvaginal mesh cases in 2014. But it is quite an extrapolation from a 1997 conversation to determine that an alteration to the MSDS in 2007 was related to a decade-old conversation about general litigation trends. And it is pure speculation to infer from the 2014 testimony that the Medical Application Caution was added due to litigation concerns simply. The testimony simply confirms why the statement was *not* added—confirmatory scientific research. Darois even states that neither Chevron Phillips nor Phillips Sumika ever contacted Defendants about the Medical Application Caution or otherwise. Defendants do not identify any other basis from which Darois could infer that the Medical Application Caution was added to address potential litigation. (ECF No. 258 at PageID #13615–16.)

For these reasons, Plaintiff's Motion in Limine No. 2 is granted. If Darois or other witnesses have other bases upon which to base their testimony that Defendants believed the Medical Application Caution was added due to litigation concerns, then at trial the witnesses will be questioned outside of the jury's presence to determine whether the witnesses have personal knowledge as required by Rule 602. Otherwise, such testimony is inadmissible for lack of foundation.

**C. Plaintiff's Motion in Limine No. 14**

In this motion, Plaintiff argues that evidence of the ISO standards and any evidence of Defendants' compliance should be excluded because it is irrelevant and prejudicial. (ECF No. 230 at PageID #12618–19.) Plaintiff explains that the ISO standards used by Defendants do not address safety and efficacy of the Ventralight ST, but instead address Defendants' "quality management systems." (*Id.* at PageID #12618.) The Court denied this motion in part. (ECF No. 331 at PageID #17885.)

FDA regulations require manufacturers of medical devices to "establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part." 21 C.F.R. § 820.5. A "quality system" is "the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management." *Id.* at § 820.3(v). These requirements, known as the "[c]urrent good manufacturing practice," "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." *Id.* at § 820.1(a)(1). The object of these regulations is "to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act." *Id.* The ISO provides quality management systems for companies, and

Defendants rely on ISO standard 10993 (biocompatibility testing requirements), 14951 (risk management), and 14155 (clinical investigation of medical devices for human subjects). (ECF No. 270 at PageID #14244.)

The ISO standards and evidence of Defendants' compliance or noncompliance are relevant. Though federal courts apply the Federal Rules of Evidence when sitting in diversity, *Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6th Cir. 2009) (citing *Legg v. Chopra*, 286 F.3d 286, 289 (6th Cir. 2002)), whether evidence is material, and thus relevant, depends on substantive state law, 19 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 4512 (3d ed., West Apr. 2020 update; *see also Shanklin v. Norfolk S. Ry. Co.*, 369 F.3d 978, 989 (6th Cir. 2004) (applying Rule 401 while considering the requirements of Tennessee tort law). Here, Utah precedent addressing the duty of care in negligence cases is clear—statutory and regulatory standards help define the duty of reasonable care as a matter of law. *Downing v. Hyland Pharmacy*, 194 P.3d 944, 948 (Utah 2008).[4] Thus, the ISO standards that Defendants rely on are relevant to the duty of care Defendants owed Plaintiff.

Plaintiff also argues that this evidence should be excluded under Rule 403. In particular, Plaintiff is concerned that the ISO standards convey a misleading "appearance of certainty and validation" and that the jury may equate compliance with ISO standards with satisfaction of the standard or duty of care. (ECF No. 230 at PageID #12621–24.) Any risk of prejudice or confusion is remedied by an instruction, which this Court shall give, that the ISO standards help define the duty of care, but that compliance with ISO standards is not conclusive evidence that Defendants

[4] Defendants cite *Downing* for the proposition that "relevant statutory and regulatory standards will be relevant to establishing what the duty of care is." (ECF No. 270 at PageID #14246.) The Utah Supreme Court did not address the relevance of statutory and regulatory standards under the Utah Rules of Evidence. Rather, the court in *Downing* considered whether evidence of regulatory and statutory standards demonstrated a factual dispute as to a breach of the duty of care existed at summary judgment. 194 P.3d at 946. The Court assumes the Utah Supreme Court meant "relevant" in the colloquial sense.

satisfied the duty of reasonable care.

Plaintiff's Motion in Limine No. 14 is accordingly denied in part.

**D. Plaintiff's Motion in Limine No. 3**

Plaintiff argues in this motion that all evidence related to the FDA's § 510(k) process should be excluded because the process is not probative of the safety of the Ventralight ST or alternatively, the danger of confusing or misleading the jury is substantial. (ECF No. 231 at PageID #12635.) This motion was denied in part. (ECF No. 331 at PageID #17886.)

The Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act ("FDCA") sets forth three categories of medical devices: Classes I, II, and III, with Class III presenting the most risk of injury or illness. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). Class III devices are subject to the "premarket approval" process ("PMA"), which is a "rigorous" and demanding review process. *Id.* However, Class III devices on the market before 1976 are not subject to the PMA ("grandfathered devices") and any class of device may be marketed if the device is "substantially equivalent," 21 U.S.C. § 360e(b)(1)(A), to a grandfathered device or a device that has undergone PMA review. *Id.* at 477–78; *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317, 322 (2008). The "substantially equivalent" review is "a limited form of review . . . requiring [manufacturers of devices] to submit a 'premarket notification' to the FDA (the process is also known as the '§ 510(k) process,' after the number of the section in the original [FDCA])." *Lohr*, 518 U.S. at 478. The § 510(k) process thus permits the FDA to approve devices for marketing and allows manufacturers to bypass any "further regulatory analysis." *Id.* at 478. Reliance on the § 510(k) process is quite common. *See id.* at 479 ("[T]he § 510(k) premarket notification process became the means by which most new medical devices . . . were approved for the market.").

Crucially, "the § 510(k) process does not comment on safety." *Rodriguez v. Stryker Corp.*,

680 F.3d 568, 574 (6th Cir. 2012). Rather, the § 510(k) process considers "'*equivalence*, not safety,'" which the Supreme Court has determined "provide[s] little protection to the public" because § 510(k) "determinations simply compare" the new device with a device approved through the PMA or with a grandfathered device. *Lohr*, 518 U.S. at 493 (quoting *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1348 (11th Cir. 1995), *aff'd in part and rev'd in part*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996))).

Although the § 510(k) process does not speak to safety, it is nonetheless relevant to this case. The Ventralight ST, a Class II device, was marketed through the § 510(k) process. (ECF No. 231-6 at PageID #12800–01, pp. 14–18.) This is a key piece of the device's history. And as set forth above, federal and state statutes and regulations, among other things, draw the contours of the standard of reasonable care for Defendants in this case. *Downing*, 194 P.3d at 948. The fact that Ventralight ST received a determination of substantial equivalence in the § 510(k) process is part of Defendants' "story." *Old Chief v. United States*, 519 U.S. 172, 189 (1997).

Plaintiff has concerns about "inevitable mini-trials" addressing the meaning of the § 510(k) process and the risk of confusing or misleading the jury. (ECF No. 231 at PageID #12636.) The Court shall instruct the jury on the § 510(k) process and explain that the § 510(k) process does not mean that the FDA vouches for the safety of the device or that the FDA conducts any independent testing on the device. No experts will be permitted to opine on the background or legal meaning of the process. This course sufficiently addresses Plaintiff's Rule 403 concerns. As other courts have noted, exclusion of any evidence about the § 510(k) process also risks confusing the jury because "[m]any of the relevant events in this case occurred in the context of FDA § 510(k) review, and much of the evidence is best understood in that context." *In re Bard IVC Filters Prods. Liab. Litig.*, 289 F. Supp. 3d 1045, 1049 (D. Ariz. 2018). Indeed, jurors "who hear a story . . . may be

puzzled at the missing chapters." *Old Chief*, 519 U.S. at 189 (interpreting the scope of Rule 403). Such is the case here when mention of the FDA is inevitable and a juror may wonder why the Ventralight ST was permitted to be marketed in the first place. On balance, the lesser risk is permitting the jury to hear this evidence, guided by an accurate explanation of the § 510(k) process from the Court.[5]

For these reasons, Plaintiff's Motion in Limine No. 3 is denied in part.

**E. Defendants' Motion in Limine No. 8**

In their Motion in Limine No. 8, Defendants argue that evidence and argument related to alleged fraud on the FDA, misbranding, and violations of FDA regulations should be excluded. (ECF No. 209). This includes Plaintiff's expert testimony from John Quick that Defendants' quality management systems violated FDA regulations, evidence that the Ventralight ST was "misbranded," and other evidence about whether Defendants' FDA submissions were compliant with the FDCA and FDA regulations. (*Id.* at #11784–89.) Defendants argue that this evidence is preempted by *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), whether cast as a fraud-on-the-FDA claim or a claim under state tort law, and is unfairly prejudicial. (*Id.* at 782.) The Court denied this motion in part. (ECF No. 331 at PageID #17886.)

In *Buckman*, the Supreme Court held that claims based on fraud against the FDA brought under state law were impliedly preempted by the FDCA as amended by the Medical Device

[5] The Court is aware that some district courts have concluded that evidence of the § 510(k) process should be excluded under Rule 403 and that Circuit courts have upheld these decisions under an abuse-of-discretion standard. *See, e.g.*, *Eghnayem v. Boston Scientific Corp.*, 873 F.3d 1304, 1317 (11th Cir. 2017); *In re C.R. Bard, Inc.*, 810 F.3d at 922 (noting a consensus of upholding such determinations on appeal). Given the unique evidentiary circumstances of each case, including the inclusion of specific jury instructions, however, these decisions do little to persuade. The fact that such decisions have been upheld on review is more indicative of the standard of review than whether evidence of the § 510(k) process is necessarily excludable under Rule 403. *See, e.g.*, *In re C.R. Bard., Inc.*, 801 F.3d at 920 ("'[E]xcept under the most "extraordinary" of circumstances, where that discretion has been plainly abused,' this Court will not overturn a trial court's Rule 403 decision.").

Amendments of 1976. 531 U.S. at 344. But the Court was careful to exclude state-tort-law claims from the scope of preemption stemming from the 1976 Amendments to the FDCA. First, the Court distinguished a previous case where the claims were based "on traditional state tort law principles." *Id.* at 351–52 (discussing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984)). The Court then "reject[ed] respondent's attempts to characterize both the claims at issue in *Medtronic* (common-law negligence against the manufacturer of an allegedly defective pacemaker lead) and fraud claims here 'as claims arising from violations of [§ 510(k) process application requirements set forth by statute].'" *Id.* at 352. The Court so because those "claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, *not solely from the violation of FDCA requirements*." *Id.* (alterations in original) (emphasis added). Because the claims in *Buckman* "exist[ed] solely by virtue of the FCDA disclosure requirements," the claims were preempted. *Id.* at 353; *see also id.* ("[T]he existence of these federal enactments is a critical element of their case.").

The Sixth Circuit has not interpreted *Buckman* more broadly and has consistently found that only claims premised upon violations of the FDCA or FDA regulations are preempted.[6] In *Fulgenzi v. PLIVA, Inc.*, the court explained that *Buckman* applies only to claims that depend "on a federal-law violation" as "a link in the causal chain or element of the claim." 711 F.3d 578, 588 (6th Cir. 2013). The Sixth Circuit counseled caution "in extending the reasoning of *Buckman* to claims in which the presumption [against preemption] applies, such as the traditional state-tort-

[6] When interpreting federal law, such as the preemptive force of *Buckman*, a transferee federal court applies the circuit precedent of the circuit in which it sits. *See In re U.S. Dep't of Defense and U.S. EPA Final Rule*, 817 F.3d 261, 272 (6th Cir. 2016) (citing *Murphy v. FDIC*, 2038 F.3d 959, 964–65 (11th Cir. 2000)), *rev'd and remanded on other grounds*, *Nat'l Ass'n of Mfrs. v. Dep't of Defense*, 138 S. Ct. 617 (2018); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 911 n.17 (6th Cir. 2003) (noting "that in federal multidistrict litigation there is a preference for applying the law of the transferee district"); *see also In re Porsche Cars N. Am.*, 880 F. Supp. 2d 801, 815 (S.D. Ohio 2012); *In re Nat'l Century Fin. Enterprises, Inc., Inv. Litig.*, 323 F. Supp. 2d 861, 876–77 (S.D. Ohio 2004).

law claims" because such claims do not bear greatly on "'federalism concerns,'" which is the basis of the doctrine of preemption, and instead implicate "'the historic primacy of state regulation of matters of health and safety.'" *Id.* at 586 n.3 (quoting *Buckman*, 531 U.S. at 348). Circuit precedent interpreting *Buckman* has been consistent, explaining that the claims preempted are those that "'require[ ] proof of fraud committed against the FDA' to succeed." *Marsh v. Genentech, Inc.*, 693 F.3d 546, 551 (6th Cir. 2012) (quoting *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965–66 (6th Cir. 2004)).

Undoubtedly, a fraud-on-the-FDA claim could be presented as a state-law-tort claim, and so federal courts must consider the substance of a claim. *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013). But the guiding inquiry is simple—could the claim "exist in the absence of the FDCA?" *Id.* For example, preemption was warranted when a Michigan statute provided tort immunity to drug manufacturers unless they failed to comply with FDA requirements. *Garcia*, 385 F.3d at 966. Such a defense required and was dependent on the defendant's noncompliance with FDA requirements. *Id.* Similarly, when a plaintiff had expressly disclaimed any reliance on state-law failure-to-warn claims and relied exclusively on noncompliance with FDA regulations, the claim was preempted. *McDaniel v. Upsher-Smith Labs., Inc.*, 893 F.3d 941, 944–46 (6th Cir. 2018).

Plaintiff's claims here are state-law-tort claims that do not solely depend on violations of the FDCA or FDA regulations. The crux of Plaintiff's case is that Defendants failed to exercise reasonable care in designing and marketing the Ventralight ST. If the FDCA and all the accompanying FDA regulations were repealed tomorrow, Plaintiff could still rely on state-law negligence and strict-liability principles to bring these claims. And under Utah state law, federal statutes and regulations help define the duty of care, but federal law alone does not set the duty of

care. *See Downing*, 194 P.3d at 948. Thus, Plaintiff's claims are not preempted by *Buckman*.

Defendants attempt to stretch *Buckman* further than precedent permits. They argue that claims may not be premised upon violations of federal law and then assert that evidence referring to noncompliance with federal requirements is tantamount to such a claim. (ECF No. 209 at PageID #11788–89.) There is no support for this assertion. *Buckman* holds that the FDCA preempts claims, not evidence. *Fulgenzi* is clear about this distinction, explaining that even if "the logic of *Buckman* would encourage exclusion of evidence of federal-law violations where possible," evidence of federal-law violations is admissible when "federal law bears on the state duty of care." 711 F.3d at 588. Or, put even more succinctly: "[i]f such evidence is relevant, *Buckman* is no bar to its admission." *Id.* Even negligence per se claims may incorporate violations of the FDCA requirements. *Id.* (collecting cases). Defendants' gloss on what constitutes a *Buckman* claim is exceptionally hard to square with *Fulgenzi* and other Sixth Circuit precedent that emphasizes that *claims* which turn on only federal-law violations are preempted.

Finally, Defendants also encourage exclusion of any evidence that they failed to comply with FDCA or FDA regulatory requirements because that evidence will confuse or mislead a jury, encouraging the jury to conclude that Defendants' purported failure to comply with the federal requirements means Defendants necessarily failed to satisfy their state-law duty of care. (ECF No. 209 at PageID #11789.) Any possibility of juror confusion on this matter is rectified with an instruction. Much like the ISO standards, evidence of federal requirements and whether Defendants complied with them is admissible. An instruction shall be given to the jury, explaining that the federal requirements are evidence of the duty of care and of whether Defendants' actions were reasonable, but not conclusive evidence that Defendants failed to satisfy the duty of reasonable care.

Accordingly, Defendants' Motion in Limine No. 8 is denied in part.

**F. Plaintiff's Motion in Limine No. 16**

In his Motion in Limine No. 16, Plaintiff argues that a printout of the "Hernia Surgical Mesh Implants" webpage from the FDA should be excluded because it is unauthenticated, inadmissible hearsay, and likely to confuse or mislead the jury. (ECF No. 233 at PageID #12844.) The website sets forth general information about hernia surgical mesh, including common "adverse events." (ECF No. 233-1 at PageID #12849–51.) Specifically, the webpage details "the most common adverse events for all surgical repair of hernia—with or without mesh" and "adverse events following hernia repair with surgical mesh" "[b]ased on FDA's analysis of medical device adverse event reports and peer-reviewed, scientific literature." (*Id.* at PageID #12850–51.) The Court denied this motion. (ECF No. 331 at PageID #17886.)

The webpage is authenticated. Federal Rule of Evidence 901 provides a general requirement that a party introducing a piece of evidence "must produce evidence sufficient to support a finding that the item is what the proponent claims it is." Fed. R. Evid. 901(a). The webpage printout contains the domain website and the date indicating when it was accessed. Alternatively, the website is self-authenticating. Fed. R. Evid. 902(5) (stating that a "publication purporting to be issued by a public authority" is self-authenticating); *U.S. EEOC v. E.I. DuPont de Nemours & Co.*, No. Civ. A. 03-1605, 2004 WL 2347559, at *2 (E.D. La. Oct. 18, 2004) (holding that the a United States Census Bureau webpage was self-authenticating).

The webpage is not inadmissible hearsay. Federal Rule of Evidence 803(8) provides an exception for the rule against hearsay for public records if the record sets out one of three types of information, the most relevant here being "factual findings from a legally authorized investigation." Fed. R. Evid. 803(A)(iii). Additionally, it requires that "the opponent does not show

that the source of information or other circumstances indicate a lack of trustworthiness." Fed. R. Evid. 803(8)(B). Because the FDA webpage relies on statements made by those outside of the FDA, as indicated by the webpage's reference scientific literature, the exception provided by Rule 803(A)(iii) is the most applicable." 4 Christopher B. Mueller & Laird C. Kirkpatrick, Federal Evidence § 8:89 (4th ed., West May 2020 Update). "'Opinions, conclusions, and evaluations, as well as facts, fall within the Rule 803(8)[(A)(iii)'] exception[,]' and enjoy a presumption of admissibility." *United States v. Midwest Fireworks Mfg. Co., Inc.*, 248 F.3d 563, 566 (6th Cir. 2001) (citing a previous, differently subdivided version of Rule 803(A)(iii)) (quoting *Bank of Lexington & Trust Co. v. Vining-Sparks Sec., Inc.*, 959 F.2d 606, 616 (6th Cir.1992)). "[L]egally authorized investigation" refers to an agency investigation conducted pursuant to its "official duties" as well as "on matters within its general area of responsibility." *Supra* Mueller & Kirkpatrick at § 8:89. In both types of investigations the agency relies on its "expertise and wherewithal that are necessary to insure [sic] trustworthiness," justifying an exception to the rule against hearsay. *Supra* Mueller & Kirkpatrick at § 8:89.

The FDA webpage at issue here falls within Rule 803(8)(A)(iii). It is the result of a legally authorized investigation. Medical devices are certainly within the purview of the FDA. *See Musgrave v. Breg, Inc.*, No. 2:09-cv-01029, 2011 WL 4502032, at *6 (S.D. Ohio Sept. 28, 2011). It is apparent from the webpage that the FDA reviewed a body of peer-reviewed research and distilled it to a readable summary for "the general public, healthcare professionals, and medical device manufactures." (ECF No. 113-1 at PageID #7737.)[7] Plaintiff also fails to demonstrate a lack of trustworthiness as required by the Rule.

[7] The Court expressly reserves its ruling on Plaintiff's Motion to Exclude the Opinions and Testimony of Defense Expert Donna-Bea Tillman, Ph.D. (ECF No. 113.) To determine the admissibility of evidence, such as the FDA webpage, the Court is permitted to consider otherwise inadmissible evidence. Fed. R. Evid. 104(a).

Plaintiff appears to attempt to rebut the presumption of admissibility by arguing that "[i]t is unclear how the FDA came to issue the statement contained on [an FDA webpage]." (ECF No. 233 at PageID #12845.) Plaintiff relies on *In re Testosterone Replacement Therapy Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 2313201, (N.D. Ill. May 29, 2017), to make this argument. However, the court in *In re Testosterone* did not address Rule 803(A)(iii), but Rule 403, when it explained that "the original source of the data would have much greater probative value. But without the proper context, a jury might give undue weight to an informal statement on the FDA's website." 2017 WL 2313201, at *7. Any concerns that the jury may give improper weight to the FDA webpage is mitigated by the Court's admonition that the parties use the webpage "in a limited fashion," such as during cross-examination. (ECF No. 322 at PageID #17289.)

Accordingly, Plaintiff's Motion in Limine No. 16 is denied. As noted during the September 3, 2020 hearing, Defendants may only rely on the FDA webpage as it existed prior to the surgery. (ECF No. 322 at PageID #17288.) The webpage attached to Plaintiff's motion was accessed on January 23, 2020. (ECF No. 233-1 at PageID #12849.) The webpage from 2020 is not relevant to the issue of what information was available to Dr. Jensen, Plaintiff's implanting surgeon, at the time of surgery. (ECF No. 272 at PageID #14308.)

## IV. Conclusion

For the reasons set forth above and on the record during the September 3, 2020 hearing, Defendants' Motion in Limine No. 2 (ECF No. 175) is **DENIED IN PART**, Plaintiff's Motion in Limine No. 2 (ECF No. 234) is **GRANTED**, Plaintiff's Motion in Limine No. 14 (ECF No. 230) is **DENIED IN PART**, Plaintiff's Motion in Limine No. 3 (ECF No. 231) is **DENIED IN PART**, Defendants' Motion in Limine No. 8 (ECF No. 209) is **DENIED IN PART**, and Plaintiff's Motion

in Limine No. 16 (ECF No. 233) is **DENIED**.

**IT IS SO ORDERED.**

10-20-2020
**DATE**

**EDMUND A. SARGUS, JR.**
**UNITED STATES DISTRICT JUDGE**