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 AND ORDER NO. 5

Plaintiff Steven Johns and defendants C.R. Bard, Inc. and Davol Inc. filed various motions in limine to exclude evidence and motions to seal exhibits in this case. Now before the Court are (1) Plaintiff's Motion in Limine No. 9 to Exclude Any Evidence or Argument that Ventralight ST or Other "ST" Products are Still on the Market (ECF No. 245); (2) Defendants' and the Americas Hernia Society Quality Collaborative Foundation's ("AHSQCF") Motions to Seal Exhibit 2 to Plaintiff's Motion in Limine No. 7 and Exhibit A to Plaintiff's Motion in Limine No. 9 (ECF Nos. 250, 255); (3) Defendants' Motion in Limine No. 5 to Preclude Records, Testimony, Reference, or Argument Concerning FDA Inspections and Third-Party Audits (ECF No. 178); (4) Defendants' Motion to Seal Exhibits P and K to Plaintiff's Opposition Brief to Defendants' Motion in Limine No. 5 (ECF No. 194); and (5) Defendants' Motion in Limine No. 6 to Exclude Any Evidence or Argument Concerning Foreign Regulatory Actions (ECF No. 179).

On September 3, 2020, the Court held a hearing on outstanding motions in limine, including Plaintiff's Motion in Limine No. 9 and Defendants' Motion in Limine No. 5. (ECF No. 322 at PageID #17285–86.) The Court reserved judgment on these motions. (ECF No. 331 at PageID #17886.) Another motions-in-limine hearing was held on September 10, 2020, and the

Court considered additional outstanding motions in limine, such as Defendants' Motion in Limine No. 6. (ECF No. 345 at PageID #18587–90.) Again, the Court reserved judgment on the motion. (ECF No. 332 at PageID #17887–88.)

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

[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.

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. (*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 motions in limine regarding evidence that the Ventralight ST or other ST products are still on the market (ECF No. 245), evidence pertaining to FDA inspections or third-party audits obtained in response to FDA inspections related to the Composix Kugel Hernia Patch (ECF No. 5), and evidence concerning foreign regulatory actions, specifically the British Standards Institution ("BSI") (ECF No. 179). This decision also addresses three related motions to seal. (ECF Nos. 194, 250, 255.)

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*, 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 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. 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 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. Plaintiff's Motion in Limine No. 9

Plaintiff argues in this motion that the Court should exclude evidence that the Ventralight ST or other ST products are still on the market. (ECF No. 245 at PageID #13118.) According to Plaintiff, this evidence is irrelevant under Rule 401 and unfairly prejudicial and misleading under Rule 403 because the Ventralight ST was allowed to go to market as a result of the § 510(k) approach, which does not address safety. (*Id.* at PageID #13121). Moreover, the FDA did not possess all pertinent evidence of adverse events because Defendants did not report all adverse event reports known to them, including trend analysis from the AHSQCF. (*Id.* at PageID #13122–23.) Therefore, the FDA lacked complete information that would have enabled it to decide whether to recall the devices. (*Id.*) Defendants respond that the § 510(k) process does address safety and efficacy, that Plaintiff relies on an impermissible "fraud-on-the-FDA" theory, and that excluding evidence showing the ST products are still on the market unduly prejudices Defendants. (ECF No. 265 at PageID #14107–13.)

First, relevance. The fact that the ST products are still on the market is relevant to this case. Plaintiff's Utah design defect claims, based on both strict liability and negligence, require evidence of whether the product was "unreasonably dangerous to the user or consumer or to his property," *Brown v. Sears, Roebuck & Co.*, 328 F.3d 1274, 1279 (10th Cir. 2003) (citing *Ernest W. Hahn, Inc. v. Armco Steel Co.*, 601 P.2d 152, 158 (Utah 1979)) (strict liability), or evidence of what Defendants knew or should have known under the circumstances, *see, e.g. 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). That the ST products remained on the market is probative of safety because it indicates that the FDA has not had any basis for a recall, such as recurrent death or serious injury. *See* 21 C.F.R. § 803.50(a)(1).

Plaintiff asserts that the § 510(k) process is not indicative of safety and that this process is pertinent to the fact that the ST products are still on the market. (ECF No. 245 at PageID #13121.) The Court agrees that the § 510(k) process does not address safety (ECF No. 355 at PageID #18767–68), but Plaintiff misses the mark. The recall process is more relevant to whether a product is *still* permitted to be on the market, rather than the process that allowed the product to enter the market in the first place. Regardless, evidence of the § 510(k) process is admissible because it speaks to the history of the Ventralight ST. (*Id.* at PageID #18768–69.)

Plaintiff then counters that the fact that the ST products remain on the market is less an indication of safety than it is the result of Defendants' deficient mandatory reports to the FDA of device malfunctions likely to cause serious injury or death, upon which the FDA would base a decision to recall the device. (ECF No. 245 at PageID #13122 (citing §803.50(a)(1).) This may be the case, but this is an argument about the appropriate weight of the evidence, not its relevance. *United States v. Snyder*, 789 F. App'x 501, 512 (6th Cir. 2019). If Defendants offer evidence that the Ventralight ST is still on the market, then the Plaintiff is free to attack this evidence any number of ways, including that any absence of a recall is due to Defendants' incomplete mandatory reports. Defendants' response that evidence related to its disclosures to the FDA is prohibited under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), finds little traction. As the Court concluded in Motions in Limine Order No. 4, *Buckman* prohibits fraud-on-the-FDA *claims*,

not mere evidence, because such claims are preempted by the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act ("FDCA"). (ECF No. 355 at PageID #18769–73.) Plaintiff's claims are not preempted, and mere evidence of the adequacy of Defendants' disclosures to the FDA is insufficient under Sixth Circuit precedent to trigger preemption under *Buckman*. (*Id.*)

Finally, Plaintiff contends that the probative value of evidence that the Ventralight ST and other ST products remain on the market is substantially outweighed by the risk of unfair prejudice, as well as confusing and misleading the jury. (ECF No. 245 at PageID #13123.) The Court is unpersuaded. If Defendants introduce evidence that the ST products are still on the market, then Plaintiff will rebut it as noted above. As this Court has noted before, jurors "who hear a story . . . may be puzzled at the missing chapters." *Old Chief v. United States*, 519 U.S. 172, 189 (1997) (interpreting the scope of Rule 403). A jury will naturally wonder what the current status of the Ventralight ST is. Thus, whether the device at issue or devices similar to it are still in use is part of this story, and Defendants shall be permitted to tell it. The evidence does not pose undue risk of prejudice or misleading the jury.

For these reasons, Plaintiff's Motion in Limine No. 9 is denied.

B. Motions to Seal Exhibit Attached to Plaintiff's Motions in Limine Nos. 7 & 9

Defendants and the AHSQCF urge the Court to seal a document created by the AHSQCF that details the rate of reoccurrence of hernias after surgical mesh repair surgeries, as reported by surgeons, of the Ventralight ST as compared to devices not manufactured by Defendants. (ECF Nos. 250, 255.) Plaintiff attaches this exhibit to two motions. First, he attaches it to his Motion in Limine No. 9 to demonstrate the type of information that Defendants' disclosures to the FDA lacked. (ECF No. 245 at PageID #13123.) Second, Plaintiff attaches it to his Motion in Limine No.

7, where he argues that AHSQCF reports detailing rates of Defendants' device complications should be excluded. (ECF No. 243 at #13074).[4] Plaintiff does not oppose these motions to seal.

Whether to seal records is a decision left to the sound discretion of the district court. *See Kondash v. Kia Motors Am., Inc.*, 767 F. App'x 635, 637 (6th Cir. 2019) (citing *Meyer v. Goldberg, Inc. v. Fisher Foods, Inc.*, 823 F.2d 159, 161 (6th Cir. 1983)). However, a district "court's discretion to seal its record is bounded by a 'long-established legal tradition' of the 'presumptive right of the public to inspect and copy judicial documents and files.'" *Rudd Equip. Co., Inc. v. John Deere Constr. & Forestry Co.*, 834 F.3d 589, 593 (6th Cir. 2016) (quoting *In re Knoxville News-Sentinel Co., Inc.*, 723 F.2d 470, 747 (6th Cir. 1983)). While a district court may enter a protective order during discovery on a mere showing of "good cause," Fed. R. Civ. P. 26(c)(1), "'very different considerations apply' . . . 'when the parties place material in the court record.'" *Shane Grp., Inc. v. Blue Cross Blue Shield of Mich.*, 825 F.3d 299, 305 (6th Cir. 2016) (citations omitted). "'[T]he public has a strong interest in obtaining the information contained in the court record,'" thus the moving party has a "heavy" burden of overcoming a "'strong presumption in favor of openness' as to court records." *Id.* (citations omitted). The moving party must "analyze in detail, document by document, the propriety of secrecy, providing reasons and legal citations." *Id.* "Ultimately, the movant must show that 'disclosure will work a clearly defined and serious injury . . . . And in delineating the injury to be prevented, specificity is essential.'" *Id.* at 307–08 (citations omitted).

[4] The Court reserves judgment on the merits of Plaintiff's Motion in Limine No. 7 (ECF No. 243) and rules only on the motions to seal in this opinion and order. The Court also reserves judgment on AHSQCF's Motion in Limine Re: Use of Reports Prepared by AHSQCF (ECF No. 180), which also addresses data from the AHSQCF (though none contemplated by these motions to seal). The substantive issue of admissibility of both motions will be addressed in a later opinion.

When the motion to seal goes to "the content of the information to be disclosed to the public," courts in this circuit "consider, among other things, the competing interests of the defendant's right to a fair trial, the privacy rights of participants or third parties, trade secrets, and national security." *Rudd*, 834 F.3d at 593. The existence of a trade secret "is typically enough to overcome the presumption of access" to the records by the public. *Shane Grp.*, 825 F.3d at 308 (quoting *Baxter Int'l, Inc. v. Abbott Lab.*, 297 F.3d 544, 546 (7th Cir. 2002)). "[T]he seal itself must be narrowly tailored" to a "compelling reason why certain documents or portions thereof should be sealed." *Id.* at 305. Similarly, the court "that chooses to seal court records must set forth specific findings and conclusions which justify nondisclosure." *Id.* at 306 (quotation omitted).

Defendants and AHSQCF argue that the AHSQCF document is a trade secret. Under the Utah Trade Secrets Act, they must show that they "possessed a protectable trade secret," meaning that it benefits economically from information not "generally known" or "ascertainable by proper means" by the public. *Surgenez, LLC v. Predicative Therapeutics, LLC*, --- F. Supp. 3d ----, No. 2:19-cv-295-RJS-DAO, 2020 WL 2736120, at *6 (D. Utah May 26, 2020) (quoting Utah Code Ann. § 13-24-2(4)(a)). They must also show that they took reasonable efforts to keep the information secret. *Id.* (citing § 13-24-2(4)(b)).[5]

Defendants and AHSQCF have demonstrated that they both have a protectable trade secret that they have reasonably attempted to protect. AHSQCF collects data regarding hernia repair devices, from Bard, Davol, and its competitors. (ECF No. 250 at PageID #13161.) To access data, industry participants must become a subscriber and pay AHSQCF. (*Id.*) As a subscriber, industry

[5] Defendants rely on Ohio law in their brief. (ECF No. 250 at PageID #13163 n.1 (quoting Ohio Rev. Code § 1333.61(D).) Generally, the "state law suppl[ying] the rule of decision" governs matters undefined or unaddressed by the Federal Rules of Evidence. Fed. R. Evid. 302 (presumptions); *see also* 501 (privileges). Therefore, Utah law would supply the rule for trade secrets here. Conveniently, Utah and Ohio law are identical. *Compare* Utah Code Ann. § 13-24-2(4)(a), (b) *with* Ohio Rev. Code § 1333.61(D).

participants may only access reports related to their own devices. (*Id.*) Thus, from both AHSQCF's and a subscriber's perspective, the comparative data is not generally known or ascertainable to others by proper means. Additionally, both AHSQCF and Defendants benefit economically from this information. Subscribers pay AHSQCF to gain access to its data and reports, while Defendants have the benefit of the reports, enabling them to better compete in the medical device market. Finally, AHSQCF and Defendants have taken reasonable efforts to keep this data secret. AHSQCF strictly limits subscribers' use and disclosure of its data and reports, including the document here. (ECF No. 255 at PageID #13589.) Moreover, Defendants have not disclosed the information in this report. (*See* ECF No. 250 at PageID #13165.)

Defendants and AHSQCF have also indicated specific injuries that they would suffer were this information unsealed. Defendants would suffer an economic and competitive loss if competitors were to have access to information about the Ventralight ST. (ECF No. 250 at PageID #13164.) AHSQCF, a nonprofit engaged in research, would be impacted because it would lose the ability to keep data confidential, disincentivizing manufacturer participation in data collection and other research efforts. (ECF No. 255 at PageID #13590.)

Moreover, the public's interest in this information is not greater than Defendants' and AHSQCF's proprietary interests. The general public would generally never have access to this information because subscriber-unique data is only available to industry participants who are subscribers. Additionally, the exhibit only shows how the Ventralight ST fares in preventing hernia reoccurrences compared to competitor devices en mass, so the report alone provides little in the way of specific information to the public or consumers. Therefore, the public's interest in this particular report is slight. Defendants' and AHSQCF's interests in sealing the exhibits which contain trade secrets outweigh the public's interest in disclosure of the records.

For these reasons, the motions to seal are granted.

C. Defendants' Motion in Limine No. 5

In their fifth motion in limine, Defendants argue that evidence related to FDA inspections and third-party audits regarding the Composix Kugel Hernia Patch should be excluded. (ECF No. 178 at PageID #10261; ECF No. 195 at PageID #11594.) Specifically, Defendants contend that the FDA-related evidence is irrelevant, unfairly prejudicial, and inadmissible hearsay and that the third-party-audit evidence is irrelevant and inadmissible hearsay. (ECF No. 178 at PageID #10265–70; ECF No. 195 at PageID #11595–99.) Plaintiff responds that this evidence demonstrates "systematic failures within both Bard and Davol to engage in proper quality control, to support their product specifications with scientific evidence, and numerous other failures" that impact all Defendants' hernia mesh products. (ECF No. 190 at PageID #10772.)

The FDA regularly inspects manufacturing facilities such as Defendants' to determine whether the facility is compliant with the FDCA and other related acts, as well as FDA regulations. (ECF No. 178-1 at PageID #10278.) These findings are recorded on a form FDA 483 – Inspectional Observations. (*Id.* at PageID #10277.) The inspector reports her findings in an Establishment Inspection Report ("EIR"). (*Id.* at PageID #10285.) A Warning Letter may then be sent to a facility, which notifies the facility of "violations of regulatory significance." (ECF No. 178-2 at PageID #10292.) The object of these letters it to achieve "prompt voluntary compliance" with federal law. (*Id.*)

In 2006, Defendants issued a voluntary recall of the Composix Kugel due to broken "recoil ring[s]," a component of the device. (ECF No. 178 at PageID #10266.) Prior to the recall, the FDA inspected Defendants' Rhode Island facility in 2006, which led to 483 observations and an EIR. (*Id.* at PageID #10264.) The FDA conducted a second investigation in 2007, which led to a warning

letter. (*Id.*) In 2008, the FDA investigated Defendants' Puerto Rico facility, leading to 483 observations and a warning letter. (*Id.*)

Defendants retained various third-party auditors. They retained two after the voluntary recall. (*Id.* at PageID #10265.) Then in 2008, Defendants hired two different auditors. (*Id.*) All audits were conducted "to evaluate internal process and make recommendations to improve policies relative to corrective and preventative action." (*Id.*) Plaintiff seeks to introduce into evidence these FDA inspection materials related to Composix Kugel, as well as evidence from the third-party audits. (ECF No. 190 at PageID #10772.)

Based on Plaintiff's response to this motion in limine, it appears that Plaintiff intends to offer evidence of the Composix Kugel FDA inspection materials in large part to support his manufacturing defect claim. (ECF No. 190 at PageID #10776–78.) Summary judgment was granted on Plaintiff's manufacturing defect claim, however. (ECF No. 309 at PageID #16744.) Therefore, any evidence related to this claim is irrelevant and inadmissible.

As for whether the FDA-inspections and third-party audit evidence is admissible to support Plaintiff's design defect, failure to warn, and other negligence claims, Defendants are largely correct that it is not. The Composix Kugel is not a predicate device to the Ventralight ST, and the Composix Kugel has key differences from the Ventralight ST, such as the recoil ring. (ECF No. 178 at PageID #10266.) Thus, evidence from the FDA inspections and third-party audits that are device-specific are irrelevant to this case. True, Plaintiff identifies one area of overlap between the Composix Kugel and the Ventralight ST, contending that the FDA inspections addressed Sepramesh and Sepra Technology (the "ST" in "Ventralight ST"). (ECF No. 190 at PageID #10778 & n.15.) He points to a 2008 summary of an FDA audit prepared by Virginia Garcia, Senior Regulatory Affairs Associate at Davol, Inc. (ECF NO. 190-17.) But Garcia's report simply notes

that the FDA inspector asked about Sepramesh technology, which was mentioned in an "RGL complaint." (*Id.* at PageID #11419.) Standing alone, this is too vague to constitute probative evidence.

The clear implication from Plaintiff's briefing is that because the Composix Kugel device was recalled for being defective, as evidenced by the FDA inspections and third-party audits, it is more likely that Defendants' Ventralight ST device is defective as well. But this is overt character evidence, or "the classic propensity argument that [Federal] Rule [of Evidence] 404(b) prohibits." *United States v. Blakely*, 375 F. App'x 565, 573 (6th Cir. 2010). In other words, Plaintiff "generaliz[es] a defendants' earlier bad act to bad character and taking that as raising the odds that he did the later bad act now charged[.]" *Old Chief*, 519 U.S. at 180–81.

Nevertheless, the Court can discern one narrow admissible purpose for this evidence. Evidence that would otherwise be properly considered inadmissible character or propensity evidence may be admitted for other purposes, including to show knowledge. Fed. R. Evid. 404(b). Therefore, Plaintiff may introduce evidence from the Composix Kugel FDA investigations and third-party audits that tend to prove that Defendants were aware of breaches of the FDCA and FDA regulations *if* he can show that Defendants committed the same or substantially similar violations in relation to the Ventralight ST prior to implantation in Plaintiff. Such evidence is relevant to whether Defendants knew or should have known that the Ventralight device was "unreasonably dangerous to the user or consumer or to his property" for a strict liability design defect claim, *Brown*, 328 F.3d at 1279, and whether Defendants' conduct was reasonable and Plaintiff's harm foreseeable as a result of these FDCA and FDA regulation violations for his negligence claims, *see Fortune*, 107 F. Supp. 3d at 1204; *House*, 929 P.2d at 343.

Plaintiff points to at least one such instance. He argues that the third-party auditors

considered whether Defendants satisfied International Organization for Standardization ("ISO") 13485 for the Composix Kugel device (ECF No. 190 at PageID #10784)—a standard that both parties recognized Defendants follow in relation to the Ventralight ST to satisfy the FDA requirement under 21 C.F.R. § 820 for a quality system. (ECF No. 230 at PageID #12618; ECF No. 270 at PageID #14242–43.) And as this Court recently explained, evidence pertaining to violations of FDA regulations, including 21 C.F.R. § 820, which standards from the ISO may satisfy, help define the duty of care under Utah tort law. (ECF No. 355 at PageID #18765.) Given the breadth and volume of the evidence attached to this briefing, it is unclear if Plaintiff has other evidence that will pass through the eye of this needle.[6]

In relation to the third-party audits, Defendants contend that the audits are "[r]etrospective self-analyses" and are thus irrelevant. (ECF No. 179 at PageID #10269.) It is unclear to the Court why the fact that a party has taken steps to review itself renders the audits irrelevant. Moreover, Defendants provide no support for this assertion. They cite *Reichold Chemicals, Inc. v. Textron, Inc.*, 157 F.R.D. 522 (N.D. Fla. 1994), and *Segura v. City of Reno*, 116 F.R.D. 42 (D. Nev. 1987), but these cases do not consider relevance; they address discovery privileges—the self-critical analysis privilege and the executive privilege. *Reichold*, 157 F.R.D. at 527 (self-critical analysis privilege); *Segura*, 116 F.R.D. at 45 (executive privilege). Defendants have not asserted these privileges.[7] A self-prompted audit in response to the Composix Kugel FDA inspections is relevant

[6] Because this evidence may only be admitted to demonstrate notice or knowledge, it is unnecessary to address whether the FDA materials and third-party audits are hearsay evidence. *See Biegas v. Quickway Carriers, Inc.*, 573 F.3d 365, 379 (6th Cir. 2009) (explaining that out-of-court statements introduced to show notice are not hearsay).

[7] In any case, Utah does not recognize the self-critical analysis privilege. *See* Fed. R. Evid. 501 (stating in civil cases the state law supplying the rule of decision governs privileges). And the executive privilege is a privilege against discovery. *Madsen v. United Television, Inc.*, 801 P.2d 912, 915 (Utah 1990). Thus, by producing the third-party audit evidence during discovery, Defendants have waived this privilege. *Cf. Terry v. Bacon*, 269 P.3d 188, 192 (Utah Ct. App. 2011) (explaining that the attorney-client privilege, a discovery privilege, was waived when the evidence at issue was produced).

to the extent that it demonstrates that Defendants were aware of FDCA and FDA regulatory violations that were also present while designing the Ventralight ST.

Defendants also argue that admission of evidence of FDA investigations and third-party audits regarding Composix Kugel will unduly confuse, prejudice, and mislead the jury, and the Court is inclined to agree generally based on the nature and volume of exhibits attached to this briefing. This case will demand much of jurors, introducing them to scientific, medical, regulatory, and statutory information. The introduction of all the evidence about another device attached to this briefing would risk overloading the jury.

Yet the narrowness of this opinion will require Plaintiff to make sweeping cuts and redactions in its FDA and third-party audit evidence regarding Composix Kugel such that any risk of prejudice is drastically limited. For example, no details of the Composix Kugel's design, its recall, or its nonconformity is relevant to prove notice. Moreover, it will be made clear to the jury that Composix Kugel is not a predicate device or substantially similar to the Ventralight ST. The only relevant features from the FDA inspections and third-party audits related to Composix Kugel are FDCA and FDA regulatory violations that Defendants also allegedly committed when making the Ventralight ST.

Finally, Defendants argue that the jury will be misled by evidence of the FDA inspections, mistaking the inspections and related documents, such as the EIR and the warning letters, as formal agency findings. (ECF No. 178 at Page ID #10267.) This is remedied by a simple explanation that the jury is more than capable of understanding—that an EIR or a warning letter is antecedent to a formal finding. In the unlikely event that Defendants do not challenge this evidence, the Court will instruct the jury that the FDA inspection materials and warning letter do not represent an official finding.

Accordingly, Defendants' motion is granted in part and denied in part.

D. Motions to Seal Exhibits Attached to Plaintiff's Opposition Brief to Defendants' Motion in Limine No. 5

Defendants move to seal Exhibits K and P to Plaintiff's Opposition Brief to Defendants' Motion in Limine No. 5. (ECF No. 194.) Defendants argue that these exhibits contain proprietary information and should be sealed, as well as that these exhibits are irrelevant and unnecessary to the Court's determination of the motion in limine. (*Id.* at PageID #11585–86.) In response to this latter argument, the Court reviewed exhibits attached to several of Plaintiff's briefs in this case. It then ordered Plaintiff to show that the exhibits attached were necessary to decide the motions as required by Local Civil Rule 7.2(e). (ECF No. 319 (referring to this motion to seal, as well as two other motions to seal not addressed in this opinion).) In response, Plaintiff withdrew Exhibit K, as well as most pages of Exhibit P. (ECF No. 347 at PageID #18675.) Therefore, this motion only addresses whether the remaining pages of Exhibit P (ECF No. 190-20) should remain sealed.

Exhibit P is a Microsoft Word document from Defendants regarding an ongoing, unpublished clinical study involving Phasix ST, a different hernia mesh device manufactured by Defendants. (ECF No. 194 at PageID #11586; ECF No. 190-20 at PageID #11482.) The document even has Track Changes and redline edits. (ECF No. 190-20 at PageID #11482.) Plaintiff explains that the passage referencing a determination made by the BSI shows Defendants were in contact with BSI, and that this passage makes the document relevant. (ECF No. 347 at PageID #11483.) Plaintiff states that BSI conducted a third-party audit for Defendants, (ECF No. 190 at PageID #10784), though Defendants dispute this, (ECF No. 194 at PageID #11590). Plaintiff uses this evidence to support his contention that Defendants' employees who created the audit documents had personal knowledge, as required by the business record exception to hearsay, Federal Rule of Evidence 803(6)(A). (ECF No. 190 at PageID #10786.)

As set forth above, Defendants carry a heavy burden to overcome the "strong presumption in favor of openness' as to court records" because of the public's "strong interest in obtaining the information contained in the court record." *Shane Grp.*, 825 F.3d at 305 (citations omitted). And courts in this circuit consider the competing interests of the public's right to record information and the parties' privacy rights. *Rudd*, 834 F.3d at 593; *see also supra* Section III.B.

At least one district court has specifically concluded that unpublished clinical studies should remain sealed, and its reasoning is persuasive. In *Bracco Diagnostics, Inc. v. Amersham Health Inc.*, the district court concluded that the defendant had a "legitimate private interest in maintaining . . . confidential internal studies and analyses under seal." No. 03–6025 (FLW), 2007 WL 2085350, at *9 (D.N.J. July 18, 2007). The court emphasized that the unpublished clinical studies, as well as documents related to these studies, are highly confidential and would not be available to the public were it not for civil discovery. *Id.* And, as is also required in this circuit, the court concluded that the defendant had shown a specific injury that would result from unsealing the documents. *Id.* The court determined "that the information contained in the subject materials could be manipulated or distorted by competitors for a business advantage." *Id.* (citing *In re Cendant Corp.*, 260 F.3d 183, 194 (3d Cir. 2001)). Additionally, the chance to publish the study in a scientific journal could be lost because journals are unlikely to publish studies when the information has already been released to the public in some manner. *Id.*

Defendants' interest in keeping this document under seal outweighs the public's interest in this record document. Defendants contend that this study is highly confidential. And, absent the discovery in this case, the public would not have access to this information. However, it is important to note that the public will presumably have access to this study when it is published, which means the information contained within is verified and final. Thus, the reliable information

in this document will not always be inaccessible to the public. And importantly, Defendants have shown a specific injury. Because the clinical study is ongoing, the document's statements are neither final nor complete. Thus, the information is more susceptible to alteration and distortion than finalized, published information, as in *Bracco*. Finally, Defendants also contend that the chance to publish the study in a journal could be impacted by unsealing Exhibit P. Defendants have met their burden justifying that the seal remain on Exhibit P.

Defendant's motion to seal is granted.

E. Defendants' Motion in Limine No. 6

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.*)[8] 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

[8] 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.").

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, and standardization for quality management systems.[9] And it describes itself as a developer of quality control standards.[10] 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."[11] A "conformity assessment" of a device performed by a notified body is a prerequisite for placing a product on the EU market.[12] Importantly, a notified body is not the equivalent of the FDA—the European Medicines Agency ("EMA") is.[13] 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.[14] 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

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[9] 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)

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

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

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

[13] 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).").

[14] 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).

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 (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.[15] 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 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,

[15] 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.

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 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.)[16]

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

[16] 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.

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.

IV. Conclusion

For the reason set forth above, Plaintiff's Motion in Limine No. 9 (ECF No. 245) is **DENIED**, Defendants' Motion in Limine No. 5 (ECF No. 178) is **GRANTED IN PART AND DENIED IN PART**, and Defendants' Motion in Limine No. 6 (ECF No. 179) is **DENIED**. Additionally, Defendants' and AHSQCF's motions to seal the AHSQCF report (ECF Nos. 250, 255) are **GRANTED**. The clerk is directed to maintain the seal on ECF Nos. 243-2 and 245-1. Finally, Defendants' motion to seal its internal document related to the BSI audit (ECF No. 194) is **GRANTED**. The clerk is directed to maintain the seal on ECF No. 190-20, specifically from PageID #11480–83; Plaintiff has withdrawn the remaining pages (ECF NO. 347 at PageID #18675).

IT IS SO ORDERED.

11/3/2020
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE