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

DISPOSITIVE MOTIONS ORDER NO. 1

Bard's Motion for Summary Judgment

This matter is before the Court on Defendants Davol Inc. and C.R. Bard, Inc.'s (collectively "Bard") Motion for Summary Judgment (ECF No. 29), Plaintiff's Opposition (ECF Nos. 69 and 165)[1] and Bard's Reply (ECF No. 90). For the reasons set forth below, the Court **GRANTS IN PART AND DENIES IN PART** Bard's Motion.

I.

Plaintiff Steven Johns' case is the first bellwether trial of the thousands of cases brought against Bard in this multidistrict litigation ("MDL"). The Judicial Panel on Multidistrict Litigation described the cases in this MDL as follows:

> All of the actions share common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections.

(Transfer Order, MDL 2846 ECF No. 1.)

[1] With the Court's leave, Plaintiff filed a corrected opposition brief on May 26, 2020.

A. Ventralight ST Product

Ventralight ST is a prescription medical device used for hernia repair and is one of Bard's products at issue in this MDL. The FDA cleared it for use through the 510k process on July 15, 2010, and later cleared it for use with the Echo positioning system on April 1, 2011. (*See* FDA website, 510k Premarket Notification Database, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN3/pmn.cfm (last visited March 25, 2020); *see also* Instructions for Use ("IFU") ECF No. 29-4.) It is a multicomponent device made of a mesh of polypropylene, polyglycolic acid (PGA) fibers, and a bioresorbable coating called Sepra Technology ("ST"). (*Id.*)[2] The bioresorbable coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed to maximize tissue attachment to support the hernia repair. (*Id.*)

Plaintiff contends that Bard knew the component parts of the mesh were dangerous and unsafe for use in medical devices. (Pl's Opp. to Mot. for Summary Judgment at 1, ECF No. 165.) According to Plaintiff, Bard knew that polypropylene is not suitable for permanent implantation in the human body, that the ST coating resorbs too quickly, and that the PGA fibers created an increased inflammatory response. (*Id.*)

1. Polypropylene

Plaintiff contends Bard ignored warnings about the safety of the polypropylene materials Bard used to make their hernia mesh devices. (*Id.* at 2.) For example, the polypropylene material from which the Ventralight ST mesh was manufactured came with a Material Safety Data Sheet ("MSDS") containing a "MEDICAL APPLICATION CAUTION" stating "Do not use this [ ] material in medical applications involving permanent implantation in the human body or

[2] The ST coating is chemically known as HA/CMC/PEG. (*See* Babensee Rep. at 21, ECF No. 112-1.)

permanent contact with internal body fluids and tissues," as well as a statement of the "Incompatibility With Other Materials," stating the material "may react with oxygen and strong oxidizing agents . . ." (*See* Babansee Rep. at 15-16.) Additionally, the manufacturer of the Marlex polypropylene resin used in the Ventralight ST device, Phillips Sumika, sent its customers a written "Technical Service Memorandum" warning that strong oxidizing agents "can chemically attack Marlex polypropylene causing degradation of the resin" and "eventual embrittlement of the resin." (*Id*. at 16.) According to Plaintiff, Bard nonetheless continued to source polypropylene for its mesh devices, and was actively trying to hide its use from various manufacturers as early as 1997. (*See* Darois Dep. 174, ECF No. 165-5.)

2. ST Coating

Plaintiff further contends that Bard knew the ST coating on its Ventralight ST devices absorbs quicker than it claimed, and too quickly to provide benefit. (Pl.'s Opp. at 4.) According to Bard's surgeon training materials, "in an intra-abdominal repair, placing polypropylene is dangerous because aggressive in-growth into visceral tissues like bowel[sic] can result in obstruction and fistulae." (*See* ECF No. 165-10; *see also* LaFever Dep. 377-381, ECF No. 165-6.) Davol's former Vice President of Research & Development testified that bare polypropylene should not be place intaperitoneally without a barrier. (*See* Darois Dep. 102:6-22, ECF No. 165-5.)

Instead, according to Plaintiff, either a permanent non-polypropylene layer (such as "ePTFE") or a resorbable layer (such as the ST coating) is necessary to ensure that the peritoneum heals over and covers the mesh patch. As of the 2000s, Bard had multiple products with ePTFE barriers, but sought to develop a resorbable barrier device for its hernia franchise. Instead of creating a resorbable barrier from scratch, Bard acquired the rights in December 2007

to Genzyme's Sepramesh IP product and its Sepra Technology, which Genzyme used in the Seprafilm coating of its Sepramesh products. (LaFever Dep. 385-387.) Bard used the Sepra Technology to develop its own line of resorbable barrier products with ST coating including the Ventralight ST. (*See* Reitman Rep. at 21, ECF No. 29-5.)

Plaintiff contends that Bard's internal documents show Bard knew prior to the license acquisition that the ST coating on Genzyme's devices "was flawed and would resorb too quickly to provide the claimed benefits in preventing adhesions and promoting proper incorporation." (Pl.'s Opp. at 6.) Bard's internal documents criticized the Sepramesh devices because the hydrogel barriers resorbed within 7 or 14 days. For example, a 2006 memorandum listed the following as weaknesses of the Genzyme Sepramesh IP: "[h]ydrated gel resorbs in 14 days. Not enough time for reperitonealization . . . Mesh is exposed after adhesion barrier resorbs." (*See* MPPE-01496875, ECF No. 165-9.) Additionally, Davol received an animal study from Genzyme in October 2006 observing adhesions in the animals and that "the hydrogel was 95% resorbed at 2 wks." (MPPE- 09154074-075, ECF No. 165-11.) During the due diligence period for the acquisition, however, Bard noted that Genzyme did not have data supporting its claim that the ST hydrogel coating lasted even 14 days. (*See* MPPE-03745210, ECF No. 165-12; MPPE-00555916, ECF No. 165-13.)

According to Plaintiff, concerns regarding the early resorption of the hydrogel coating carried over into Bard's resorbable barrier ST products. On July 14, 2015, Bard sent its sales force an open letter signed by Davol's Vice President of Regulatory Affairs addressing concerns about the safety of the ST coatings, in light of a petition by a non-profit consumer advocacy group, Public Citizen, to the FDA to withdraw approval of Seprafilm in the United States. The letter explained the history of Genzyme's Seprafilm and Bard's ST product family and stated that

"the petition does not question any hernia mesh products containing the Sepra® Technology (ST)" and "there are a number of factors that separate the use of Seprafilm alone from the use of Sepra technology in a hernia mesh material." (MPPE-12417607-608, ECF No. 165-14.) The letter also stated "please note that the Sepra hydrogel is broken down by the body and resorbed very quickly. It is essentially gone in 7 days and excreted in the urine within 28 days." (*Id.*) That same day, a sales manager replied to the letter voicing the following concerns:

> Not to hit the panic button or anything - but this letter says the barrier 'Is essentially gone in 7 days'.. But in the family brochure it says 'the hydrogel barrier resorbs within 30 days providing visceral protection during the critical healing period'.
>
> I know we've always said it lasts for up to 30 days, if we start saying 7 days, it may compromise surgeons' opinions of how effective the barrier is.

(*Id.*) On July 17, 2015, the sales and global marketing teams were emailed the following:

> We made a slight clarification to the "Sepra" resorption profile statement on page 2 of the original letter. Please note that per the Seprafilm IFU, it is broken down by the body and resorbs within 7 days. Davol's Sepra Technology coating becomes a hydrated gel that resorbs within 30 days.

(MPPE-06255412-416, ECF No. 165-15.) In August 2015, the sales teams was notified that Davol decided to cease the use of the Davol ST customer letter, and that if customers asked about the citizen petition, the sales team should respond that the petition did not involve Davol products and to not comment further. (*Id.*) A revised FAQ sent to the team in September 2015 stated that "Seprafilm and the Sepra Technology (ST) used on Davol meshes are not the same formulations" and again stated that the citizen petition was specific to Seprafilm and not Davol's ST line of hernia mesh. (*Id.*) There was no mention of the resorption rate for the Sepra coating.

When asked about the "Dear Valued Customer" letter and the reference to the 7-day absorption period, former Davol President Dan LaFever testified:

> Q: My question to you is simply this: Have you ever seen claim data that shows that the ST resorption window is, in fact, 14 days?
>
> A: I have never seen that data. I don't even know if it's clinically relevant. But I have not seen that data.
>
> Q: And certainly not 30 days; is that true?
>
> A: I have never seen data on seven, 14, 30. That's for Roger Darois and Robin Drago to deal with, now Tom Hutchinson, who went from quality to regulatory later on. But he's making a claim that can be substantiated with data, and that's the - - that's the only option that he has, because those are the only substantiated, tested claims.
>
> Q: Is the seven days?
>
> A: Yes.

(LaFever Dep. 441:17-442:13.) The Instructions for Use ("IFU") for the Ventralight ST product state:

> The visceral side of the mesh is bioresorbable coating that separates the mesh from underlying issue and visceral organ surfaces to minimize tissue attachment to the mesh. Shortly after hydration, the biopolymer coating becomes a hydrated gel that is resorbed from the site in less than 30 days.

(*See* Instructions for Use, ECF No. 29-4 at PAGEID#567.) Bard disputes Plaintiffs' theory about the early resorption of its ST coating, and stands by the safety and labeling of its ST line of devices, which indicate that the coating has up to a 30-day resorption rate. Bard has argued in this litigation that the documents upon which Plaintiff relies were created before Bard acquired the ST technology, "well before the Ventralight ST was developed and cleared by FDA," and that Bard conducted studies and performed further due diligence to validate the resorption period. (*See* Mot. to Strike Jensen Decl. at 13, ECF No. 75.) Bard contends its animal studies support its claim that the ST coating has a resorption period of up to 30 days, and that Plaintiff fails to address the lack of clinical data suggesting the resorption period has lead to any complications in implanted patients. (*Id.* at 12.)

B. Plaintiff Steven Johns

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Bard's allegedly defective Ventralight ST. In 2014, Plaintiff began experiencing an abdominal bulge that eventually became painful whenever he stood up. (Johns Dep. 41:23-43:5, ECF No. 29-1.) Plaintiff was diagnosed with a symptomatic ventral hernia within a diastasis recti (a separation of the two rectus abdominal muscles) in July 2015. (Jensen Dep. 38:15-41:2, 47:11-48:9, ECF No. 29-2.) Plaintiff underwent laparoscopic surgery to repair the hernia and diastasis in August 2015, and Plaintiff's treating physician, Joseph Weldon Jensen, D.O., implanted Plaintiff with Ventralight ST Mesh. (*Id*. at 41:3-7, 47:11-48:18, 49:20-50:3.)

Plaintiff's symptoms returned several months later—specifically, the abdominal bulge and pain. (Johns Dep. 59:1-12.) Plaintiff was diagnosed with a recurrent ventral hernia in September 2016, and underwent a second laparoscopic surgery in October 2016. (Grischkan Supp. Rep. at 9, ECF No. 48-1; Jensen Dep. 61:22-63:2, 65:2-68:10, 71:6-10; Johns Dep. 39:10-16.) During the October 2016 surgery, Dr. Jensen "found significant omental adhesions to the entire Ventralight ST mesh" and performed "lengthy arthroscopic [sic] lysis of the dense omental adhesions from the prior mesh implant, then the old surgical mesh was excised with blunt, sharp, and electrocautery dissections." (Grischkan Supp. Rep. at 9; Jensen Dep. 65:2-25, 69:2-9; Grischkan Dep. 455:19-456:6, 457:15-25, ECF No. 29-3.). Dr. Jensen removed the Ventralight ST device, and, according to Dr. Grischkan, Dr. Jensen "performed a primary repair of the previous hernia defect." (Grischkan Supp. Rep. at 9.) Bard maintains that while Dr. Jensen had diagnosed a recurrent hernia before surgery based on Plaintiff's complaints, he only found a recurrent diastasis, rather than a recurrent hernia, when he operated. (*See* Bard's Mot. for Summary Judgment at n.1 (citing Jensen Dep. 69:23-70:2).) The parties agree, however, that

after removing the Ventralight ST device, Dr. Jensen then implanted another Ventralight ST device. (*See* Grischkan Supp. Rep. at 9.)

Plaintiff's symptoms again returned in December 2016, and in April 2019 he was diagnosed with another hernia within the diastasis recti. (Grischkan Supp. Rep. at 9; Johns Depo. at 68:16-70:23, 76:12-15; Jensen Dep. 73:25-74:12.) In April 2019, Dr. Jensen and another surgeon performed an open recurrent ventral repair and implanted a different type of mesh device. (Grischkan Supp. Rep. at 9; Johns Dep. 77:7-10; Jensen Dep. 73:25-76:1, 78:20-81:18.) Dr. Jensen did not enter the intra-abdominal space, and testified that he did not see the prior Ventralight ST mesh, did not remove that device, and did not know what the condition of that mesh was. (Grischkan Supp. Rep. at 9; Jensen Dep. 78:5-11.) The Ventralight ST used during Plaintiff's October 2016 remains implanted today.

In May 2019, Plaintiff testified that he was still recovering from his April 15, 2019 surgery and experiencing pain, and that it was a much more painful recovery because it was an open—rather than laparoscopic—surgery. (Johns Dep. 81:9-82:11; 107:23-108:12) He also stated that "[o]ther than having to have the surgery again," he was not having any physical issues that he believed were due to the Ventralight ST device. (*Id*. at 84:3-7.) Plaintiff testified he began to experience anxiety beginning in 2016 when he realized he would need a third surgery, "especially when [he] knew [he] was going to have an open surgery," though the anxiety ceased after the 2019 surgery was completed. (*Id*. at 106:21-107:22.) In November 2019, however, Plaintiff reported that he was experiencing some left-side abdominal pain near the location of the second Ventralight ST mesh implant. (Grischkan Supp. Report at 10.)

Plaintiff contends the omental adhesions discovered in his October 2016 surgery were a result of the failure of the ST coating on the Ventralight ST, that the second hernia originated

from complications to Plaintiff's abdominal wall caused by those adhesions, and that the continued presence of the second Ventralight ST currently inside his body continues to threaten his health and well-being and cause pain. (Pl.'s Opp. at 10-11.) He alleges it is probable he will need additional surgery for either chronic pain or to address these possible complications. (*Id*.)

Bard maintains that neither of the Ventralight ST devices implanted in Plaintiff were defective, relying on the testimony of Plaintiff's treating physician Dr. Jensen that he did not believe either Ventralight ST device caused Plaintiff's injuries or is defective. (Mot. at 6. (citing Jensen Dep. 82:12-83:17).) Bard contends that Plaintiff's recurrent hernia claim is not supported by any medical evidence, and that Plaintiff's claim that he has current pain as a result of his second Ventralight ST is entirely speculative and unsupported. (*Id*. at n. 1& 2.) According to Bard, Plaintiff's injuries "are limited to alleged asymptomatic omental adhesions detected during his second surgery." (Mot. at 1.)

II.

Plaintiff initiated this action against Bard on October 3, 2018 in the United States District Court for the District of Utah. (*See* ECF No. 3.) Pursuant to Conditional Transfer Order 14, the Judicial Panel on Multidistrict Litigation transferred this action to this Court as part of this MDL on November 20, 2018. (*See* ECF No. 8.) This case was approved as one of the twelve Bellwether Discovery Pool cases proposed by the parties, (*see* MDL 2846 ECF No. 125), and then as one of the six Bellwether Trial Pool cases. Both parties urged this Court to select this case as the first bellwether case to be tried in his MDL. (*See* MDL 2846 ECF No. 318.) And both parties agreed that this case, arising in Utah, could be tried in Ohio. (*See* Tr. of Mar. 6, 2019 Conf. at 7-8, MDL 2846 ECF No.113); *see Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998); 28 U.S.C. § 1407(a) (cases transferred to MDL courts "shall be remanded by the [MDL Panel] at or before the conclusion of such pretrial proceedings to the

district from which it was transferred unless it shall have been previously terminated"); *but see In re Carbon Dioxide Indus. Antitrust Litig.*, 229 F.3d 1321, 1326 (11th Cir. 2000) (finding parties could stipulate to case to be tried in transferee court because "[i]t is clear from the Court's opinion in *Lexecon* that section 1407 is not a jurisdictional limitation, but rather 'a venue statute that . . . categorically limits the authority of courts (and special panels) to override a plaintiff's choice [of forum].'"); *Mann v. Lincoln Elec. Co.*, No. 1:06-CV-17288, 2011 WL 3205549, at *2 (N.D. Ohio July 28, 2011) ("Thus, a plaintiff may decide not to raise an otherwise-valid objection to venue and 'consent to remain in the transferee district for trial.'") (quoting Manual for Complex Litig. Fourth § 21.132 at 224).

In federal diversity actions, state law governs substantive issues and federal law governs procedural issues. *Legg v. Chopra*, 286 F.3d 286, 289 (6th Cir. 2002) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938)). And in an MDL, "the choice-of-law principles that the transferor court will apply are those of the State were the transferor court sits, and not, for example, the choice-of-law principles . . . where the MDL court sits." *In re Welding Fume Prod. Liab. Litig.*, No. 1:03-CV-17000, 2010 WL 7699456, at *12 (N.D. Ohio June 4, 2010). "This is because: (1) '[i]n diversity cases we apply the choice-of-law rules…of the forum state;' and (2) '[i]n MDL cases, the forum state is typically the state in which the action was initially filed before being transferred to the MDL court.'" *Id.* (citing *CenTra, Inc. v. Estrin*, 538 F.3d 402, 409 (6th Cir. 2008); *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941); *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 454 (E.D. La. 2006)). "Given that a case remanded by [an] MDL Court to a transferor court was originally filed in either that transferor court, or in a State court within that federal district before removal, it is the choice-of-law principles of the State where the transferor court sits that will apply." *Id.*

Because Plaintiff filed his original complaint in the United States District Court for the District of Utah before this case was transferred to this Court, the parties and this Court agree that Utah choice-of-law principles determine the substantive law applicable to Plaintiff's claims. "Utah uses the 'significant relationship' standard for choice of law issues in tort claims." *Bulletproof Techs., Inc., v. Navitaire, Inc.*, No. 2:03-CV-00428 PGC, 2005 WL 2265701, at *7 (D. Utah Aug. 29, 2005). Plaintiff is a Utah resident. He sought treatment in Utah, and was implanted with his mesh devices in Utah. The Court will therefore apply Utah substantive law to Plaintiff's claims.

III.

Plaintiff's June 2019 amended complaint asserts the following claims under Utah law: 1) negligence; 2) strict products liability: design defect; 3) strict products liability: manufacturing defect; 4) strict products liability: failure to warn; 5) breach of express warranty; 6) breach of implied warranty; 7) breach of implied warranty of merchantability; 8) violation of consumer protection laws; 9) negligent misrepresentation and/or fraud; and 10) punitive damages. (ECF No. 17.) Bard has moved for summary judgment on all of Plaintiff's claims. (*See* ECF No. 29.)

Pursuant to Federal Rule of Civil Procedure 56(a), summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The Court may therefore grant summary judgment if the nonmoving party who has the burden of proof at trial fails to make a showing sufficient to establish the existence of an element that is essential to that party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The moving party "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions" of the record which demonstrate "the absence of a genuine issue of material fact." *Id.* at 323. The burden shifts to the nonmoving party who "'must set forth specific facts showing that there is a genuine issue for trial.'" *Anderson v.*

Liberty Lobby, Inc., 477 U.S. 242, 250 (1986) (quoting Fed.R.Civ.P. 56(e)). "The evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255 (citing *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158-59 (1970)). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion for judgment or for a directed verdict." *Id*.

A genuine issue of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id*. at 248; *see also Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (the requirement that a dispute be "genuine" means that there must be more than "some metaphysical doubt as to the material facts"). Consequently, the central issue is "'whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.'" *Hamad v. Woodcrest Condo. Ass'n*, 328 F.3d 224, 234-35 (6th Cir. 2003) (quoting *Anderson*, 477 U.S. at 251-52).

IV.

Bard contends summary judgment is warranted on all of Plaintiffs claims. Bard does not however, separately address Plaintiff's negligence claim. (*See* Count I of Amend. Compl., ECF No 17.) Bard instead addresses Plaintiff's negligence claim in the context of his products liability claims as an alternative theory to strict liability, arguing Plaintiff's claims for the same reasons under either theory. Specifically, Bard argues both of Plaintiff's design defect claims fail for lack of causation (and that his strict liability design defect claim fails because Plaintiff cannot show any safer, feasible, alternative design), that both manufacturing defect claims fail because there is no evidence that Plaintiff's devices deviated from their design specifications, and that both

failure to warn claims fail because he cannot establish proximate causation under the learned intermediary doctrine. Bard does not, however, argue that Plaintiff has failed to show Bard was negligent or breached any duty owed to him for any of his negligence claims. The Court will only address the grounds on which Bard has moved for summary judgment.

Bard also argues Plaintiff's implied warranty claims fail for the same reasons his product liability claims fail, and that Plaintiff's negligent misrepresentation and express warranties claim cannot survive because there is no evidence either Plaintiff or his treating physician relied on any representations or warranties by Bard. Finally, Bard contends Plaintiff's Consumer Sales Practices Act and punitive damages claims fail as a matter of law.

A. Products Liability Claims

Under Utah law, both negligence and strict liability theories are available in products liability cases. *See Bishop v. GenTec Inc*., 48 P.3d 218, 225-26 (Utah 2002) (citing Restatement (Third) of Torts: Products Liability § 2 cmt. n (1997)). Utah law recognizes "three types of product defects: manufacturing flaws, design defects, and inadequate warnings regarding use." *Grundberg v. Upjohn Co.*, 813 P.2d 89, 92 (Utah 1991); *see also* Restatement (Third) of Torts: Prod. Liab. § 2. Plaintiff has alleged claims for manufacturing defect, design defect, and inadequate warning under both strict liability and negligence theories. (Pl.'s Opp. at 13, 18, 22.) The Court will address each in turn.

1. <u>Design Defect – Strict Liability and Negligence</u>

The Utah Supreme Court has adopted the doctrine of strict products liability as defined by Section 402A of the Restatement (Second) of Torts, which states, a manufacturer "who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer,

or to his property," even if "the seller has exercised all possible care in the preparation and sale of his product." *See 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); Restatement (Second) Restatement (Second) of Torts § 402A (1965)).

"Utah has since applied a 'three-part test' that a plaintiff must satisfy to sustain a cause of action for strict products liability." *Brown*, 438 F.3d at 1279 (citing *Burns v. Cannondale Bicycle Co.*, 876 P.2d 415, 418 (Utah Ct.App. 1994)). In an action alleging design defect, the plaintiff must show "'(1) that the product was unreasonably dangerous due to a defect or defective condition, (2) that the defect existed at the time the product was sold, and (3) that the defective condition was a cause of the plaintiff's injuries.'" *Fortune v. Techtronic Indus. N. Am.*, 107 F. Supp. 3d 1199, 1202 (D. Utah 2015) (quoting *Brown*, 328 F.3d at 1279).

"A design defect or a defective condition exists if the defect 'made the product unreasonably dangerous to the user or consumer.'" *Id*. (quoting Utah Code Ann. § 78B-6-703). The Utah Products Liability Act defines "unreasonably dangerous" as:

> [T]he product was dangerous to an extent beyond which would be contemplated by the ordinary and prudent buyer, consumer or user of that product in that community considering the product's characteristics, propensities, risks, dangers and uses together with any actual knowledge, training, or experience possessed by that particular buyer, user, or consumer.

Utah Code Ann. § 78B-6-702. Courts have interpreted this language as encompassing "an objective consumer expectations test supplemented with a subjective test based on "'individual knowledge, training, and experience of the particular buyer.'" *Fortune*, 107 F.Supp.3d at 1202 (quoting *Brown*, 328 F.3d at 1282). The Utah Supreme Court has "held that 'it is . . . possible to simultaneously bring a negligence and a strict liability claim' involving a product." *Brown*, 328 F.3d at 1283 (quoting *Slisze v. Stanley-Bostitch*, 979 P.2d 317, 319 (Utah 1999)). The District of

Utah has explained:

> To establish a claim of negligence, there must be a duty of reasonable care owed by the defendant to the plaintiff and a breach of that duty. Under Utah law, ascertaining whether a duty of reasonable care exists requires considering the following factors: "(1) the extent that the manufacturer could foresee that its actions would cause harm; (2) the likelihood of injury; (3) the magnitude of the burden of guarding against it; and (4) the consequences of placing the burden on the defendant." Utah courts have refused to recognize a duty "to refrain from marketing a non-defective product when a safer model is available." "In so holding, the court[s] clearly [use] the same meaning of 'defective' as in strict liability claims." Thus, the disposition of a strict product liability claim under design defect leads to the disposition of the negligence claim.

Fortune, 107 F. Supp. 3d at 1204 (internal citations omitted).

Bard has moved for summary judgment on Plaintiff's design defect claims only on the grounds that Plaintiff's strict liability design defect claim fails because Plaintiff has not offered any admissible evidence of an alternative design, and that both design defect claims fail because Plaintiff cannot shown any design defect caused Plaintiff' injuries.

i. Alternative, Safer Design

While Plaintiff contends Utah law does not require him to prove a safer alternative design, federal courts applying Utah law have held that plaintiffs in strict liability design defect cases have the burden of showing "'an alternative, safer design, practicable under the circumstances, was available at the time the [products] were sold.'" *Wankier v. Crown Equip. Corp.*, 353 F.3d 862, 867 (10th Cir. 2003) (quoting *Allen v. Minnstar, Inc.*, 8 F.3d 1470, 1479 (10th Cir.1993)).[3] This Court adopts the reasoning of these courts and finds that Plaintiff bears

[3] *See also Allen*, 8 F.3d at 1480 n.9 (10th Cir. 1993) (rejecting design defect claim because "[t]here was no showing of an alternative which was technically feasible and practicable in terms of cost and the overall design and operation of the product."); *see also Brown*, 328 F.3d at 1279; *see also Fortune*, 107 F.Supp.3d at 1202 ("In interpreting Utah law, the Tenth Circuit has required the evidence show both that an ordinary consumer would not have appreciated the danger posed by the product and that an 'alternative, safer design, practicable under the circumstances' was available at the time the product was sold.") (quoting *Allen*, 8 F.3d at 1479).

the burden of making such a showing here.

Bard argues Plaintiff has failed to show "any feasible alternative design would have prevented the injuries alleged by Plaintiff in this case—omental adhesions—as required by Utah law." (Mot. at 14.) Plaintiff contends he "need only demonstrate the practicability of safer designs" and that he has met his burden here by showing "that at the time the Ventralight ST hernia mesh patch was implanted in Plaintiff, there were safer alternative designs for hernia mesh products[.]" (Pl.'s Opp. at 21.) Plaintiff offers the opinions of Dr. Julia Babensee as to safer alternative designs, who opines that "'that a safer, feasible alternative product to the Bard products would be a mesh product that had larger pores (to get effective porosity of at least 1 mm), more elasticity to the polymer, used a more appropriate resorbable polymer, and/or was biologic in primary composition.' (Ex. A 28–31.)." (Pl.'s Opp. at 21-22.)

In response, Bard contends "[t]he alternatives offered by Plaintiff [see Opp., ECF No. 69, at 20-21] show that the best he can do is to propose devices of a different class, or devices that were not available at the time of Plaintiff's surgery….[n]one of these proposals actually identifies any safer alternative device." (Reply at 13, ECF No. 90.) According to Bard, there is "widespread consensus among courts" that "the existence of an altogether different product or a different surgical technique does not satisfy the burden to identify a feasible alternative design." (Mot. at 13.) Bard further contends Plaintiff's claim fails because "[a]ll of Plaintiff's proposed alternatives either do not actually identify any other device, constitute different procedures, or identify mesh that would not be indicated for Plaintiff in this case, let alone have been shown to be available to Dr. Jensen at his hospital." (Reply at 15.)

But Bard cites no case applying Utah law for the proposition that Plaintiff's alternative designs must be a single, specific product already on the market embodying all of the qualities

Plaintiff's expert has offered as safer alternatives. The Tenth Circuit has instead used language that Plaintiff must show alternative designs are "practicable under the circumstances" and "technically feasible." *Allen*, 8 F.3d at 1479 (internal citations omitted)[4]; *see also Brown*, 328 F.3d at 1279 ("This circuit, however, has interpreted Utah law to require that the plaintiff prove the practicability of a safer design.") (citing *Allen*, F.3d at 1472); *see also Wankier*, 353 F.3d at 866 (10th Cir. 2003) ("In *Allen*, this Court examined the then-current state of Utah products liability tort law, and concluded the plaintiff, in a design defect case, 'bear[s] the burden of showing that an alternative, safer design, practicable under the circumstances, was available at the time the [products] were sold.'") (citing *Allen*, 8 F.3d at 1479).

Utah courts have also not addressed this "different product" distinction on which Bard relies here. Instead, Utah courts have described the alternative design requirement as "in essence a risk-utility balancing test, weighing the costs of an alternative design against its benefits." *Brown*, 328 F.3d at 1279 (citing Restatement Third § 2 cmt. d). For example, in *Tingey v. Radionics*, the Tenth Circuit held that in order to satisfy Utah's "'risk-utility balancing test'" for her design defect claim, the plaintiff was required to present evidence "'there was an alternative, safer ... design [for the device], practicable under the circumstances, [that] was [technically] feasible" and that would have prevented the accident that allegedly caused the injury to her bladder nerves." 193 Fed.Appx. 747, 756 (10th Cir. 2006) (quoting *Allen*, 8 F.3d at 1479). The plaintiff made a sufficient showing of the "practicability of a safer design" to survive summary

[4] The *Allen* court held "in making our best effort to ascertain and apply Utah law, we conclude that the district judge did not err in holding that the plaintiff did bear the burden of showing that an alternative, safer design, practicable under the circumstances, was available at the time the boat and engine were sold." 8 F.3d at 1479. The court explained that the "crucial issue" was whether at the time the products were sold, "there was an alternative, safer engine design, practicable under the circumstances, and whether the alternative design was feasible. Necessary proof would include evidence that alternatives are 'technically feasible' for manufacturing a pleasure planing boat with a propeller guard." *Id.* (citing *See Wilson v. Piper Aircraft Corp.*, 282 Or. 61, 577 P.2d 1322, 1327 (1978)).

judgment on her design defect claim under Utah law by presenting evidence that the allegedly defective medical device "could still perform its essential functions," even if a component of the device was eliminated. *Id*. at 756. The device at issue was a radiofrequency lesion generator that allegedly injured the plaintiff when the nurse operating the device flipped a voltage "toggle switch" on, without first turning the device's voltage control to zero or activating a "frequency switch" that had a fail-safe mechanism, resulting in a sudden ten-fold spike in electrical current into the plaintiff. Unlike the frequency switch, the toggle switch did not have a fail-safe mechanism that would automatically shut off the device if it was not set to zero. *Id*. at 750-752. An engineer deposed in the case had opined that the entire device would need to be re-designed to develop a fail-safe mechanism for the toggle switch—if such a re-design was even feasible. *Id*. at 756. The plaintiff, however, presented evidence that the toggle switch was added primarily for convenience, and that there was no medical reason why the toggle switch could not be eliminated, even if the device would lose some of its other functions. *Id*. at 757. The Tenth Circuit held that if the "the additional measure of safety afforded by the microprocessor failsafe design could not in fact be achieved in the case of the toggle switch, a jury could find that a safer alternative would be to eliminate the switch altogether." *Id*. at 757.

Other courts applying a "risk-utility" test like Utah's analyze whether the proposed alternative design is "fundamentally" or "substantially" a different product. *See, e.g. In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 766 (5th Cir. 2018) (citing *Brockert v. Wyeth Pharm., Inc.*, 287 S.W.3d 760, 770 (Tex. App. 2009); *Caterpillar Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995)); *see also Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 900 (E.D. Va. 2010) ("Important in this regard is that an alternative design must not be an altogether essentially different product . . . Put another way, an alternative design is not

reasonable if it alters a fundamental and necessary characteristic of the product."). To be sure, whether a proposed alternative is a different product can be obvious. For example, "a proposal to add two additional wheels to a motorcycle or to 'fully enclose the cab' of a convertible" are not alternative designs. *In re DePuy*, 888 F.3d at 766 (citing *Caterpillar*, 911 S.W.2d at 385).

But these cases disagree that "a slight difference in degree—that is, that the alternative does all of the things for which the allegedly defective product was designed, but does not do one of them quite as well—automatically renders the plaintiff's proposed alternative an entirely different product." *Id*. at 767.[5] Moreover, these cases seemingly reject Bard's contention that Plaintiff's proposed alternatives are insufficient because "none of the devices offered by Plaintiff have a[sic] resorbable barrier that can be implanted laparoscopically with a robot that would eliminate the adhesions." (Reply at 13.)[6] The Fifth Circuit in *In re DePuy* held that a jury could reasonably conclude that a hip implant with a plastic component was a viable alternative design to a hip implant with a metal component, rejecting the defendant manufacturer's contention that

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[5] *In In re DePuy*, the Fifth Circuit explained:

> Texas's risk-utility test plainly contemplates that a proposed alternative design might reduce a product's utility—that is, its capacity to perform a function for which it was designed—without rendering the alternative an entirely different product. If any distinction in degree rendered the proposed alternative a different product as a matter of law, that would effectively moot the substantive balancing test for liability. Where the distinction is one of degree only, the risk-utility framework provides the proper mode of analysis.

888 F.3d at 767.

[6] Moreover, these cases seemingly reject Bard's very specific characterization of the relevant product: "a hernia mesh patch with a resorbable ST coating that can be implanted laparoscopically with robotic assistance[.]" (Reply at n.7.) As in this case, the parties in *In re DePuy* disputed how to characterize the product: "Is it a 'high-stability, low-wear' implant, of which MoP and MoM are merely two alternative iterations? Or is it the discrete MoM design, in which case MoP is a completely different beast?" 888 F.3d at 766. The Fifth Circuit recognized that its interpretation of Texas case law could not "dispel the underlying problem of characterization," for "parties could merely dispute the level of generality at which the product's function could be described." *Id*. at 766, n.9. But the court concluded that this "kind/degree" distinction had support in case law and cohered with Texas' design defect law. *Id.* at 767.

they were "entirely different product[s]." 888 F.3d at 766-67. Similarly, the Tenth Circuit in *Tingey* concluded that eliminating a specific component—the toggle switch—could be a feasible alternative design. 193 Fed.Appx. at 756. And in *Michael v. Wyeth, LLC*, the district court held the plaintiff's proposed alternative design of "natural" progestin instead of "synthetic" progestin was "within the same class of [hormone replacement therapy] drugs that allegedly injured" the plaintiff and denied summary judgment. No. 2:04-0435, 2011 WL 2150112, at *12 (S.D.W.V. 2011).

In any event, whether a proposed alternative design is a different product is "typically a question of fact, not law." *Torkie-Tork*, 739 F. Supp. 2d at 900 (holding whether plaintiff's proposed alternative designs—lowering dosage or substituting natural for synthetic progestin—would "fundamentally alter" the drug as to render it an entirely different product was an issue of fact properly submitted to a jury.); *see also Michael*, 2011 WL 2150112, at *12 (same).

Here, Plaintiff has a made a sufficient showing of proposed alternative designs to survive summary judgment. Plaintiff has proposed alternative designs for the Ventralight ST device, contending:

> Dr. Babensee also offers an opinion as to safer alternative designs. Dr. Babensee notes in her report, "I believe that a safer, feasible alternative product to the Bard products would be a mesh product that had larger pores (to get effective porosity of at least 1 mm), more elasticity to the polymer, used a more appropriate resorbable polymer, and/or was biologic in primary composition." (Ex. A 28–31.) Dr. Babensee further opines as follows:
>
> > An example of a product that approaches these criteria is Bard Soft, a non-absorbable, low density monofilament polypropylene mesh with an estimated weight of 44-52 g/m² with macropores of approximately 2.7 mm.182 Additional considerations for a safer, feasible alternative product would be to use medical grade polypropylene and anti-oxidant addition to polypropylene or coating with an oxygen free radical scavenger. Another approach undertaken by Dr. S. Badylak and colleagues has been to add a coating of the polypropylene mesh with a extracellular matrix (ECM) such as porcine dermal or urinary bladder ECMs to attenuate the extent of the

> foreign body reaction, with constructive remodeling (e.g. fewer FBGCs and more blood vessels) through an effect on the macrophage phenotype from pro-inflammatory M1 to alternatively activated M2.[.] One such device is produced by Cook Biotech, named Zenapro®[.]

(Pl.'s Opp. at 20-21.) Dr. Babensee further opines:

> Another approach has been the coating of the polypropylene mesh with an angiogenic co-polymer containing methacrylic acid (MAA) which improved the tissue reaction to the mesh with more vascular structures and less fibrosis.
>
> Bard also designed, developed and marketed a product that was fully biologic, XenMatrix®AB,187 comprised solely of noncrosslinked porcine acellular dermal matrix bioprosthetic. It is expected that as with other noncrosslinked extracellular matrix-derived devices, the host would constructively remodel this matrix to achieve more physiologic tissue which is vascularized and not fibrotic.
>
> Alternate devices include coating of a lightweight polypropylene mesh (28 g/m2) with a large pore size (3.8 mm) with a different resorbable polymer that would not result in an acidic environment from its degradation products, such as poliglecaprone, in the UltraPro device by Ethicon (weight after coating is 55 g/m2).
>
> In the Phasix mesh, Bard took the approach of a fully degradable device for hernia repair in the preparation of a poly-4-hydroxybutyrate (P4HB) polymeric mesh which would provide immediate short-term support, similar to a traditional nonresorbable mesh, but provide an absorbable scaffold that enables the abdominal wall to remodel to host tissue over a resorption time of 12-18 months post implantation.

(Babensee Rep. at 29-30.) These alternative designs clearly contemplate the use of mesh and even the use of polypropylene mesh, as well as different formulations of the resorbable coating that is alleged to be defective here. Plaintiff has made a sufficient showing of the practicability of a safer alternative design to survive summary judgment on this element of his design defect claim. *See Tingey*, 193 F. App'x at 756-57. Similarly, whether Plaintiff's proposed alternative designs would have prevented Plaintiff's injury is a question for the jury. *Michael*, 2011 WL 2150112, at *11 (citing *Torkie-Tork*, 739 F. Supp. 2d at 901).

The cases relied on by Bard where courts held as a matter of law that proposed alternatives were different products are distinguishable. While Bard is correct that courts have recognized that different products cannot constitute alternative designs, none of the cases Bard cites in support applied Utah law. Moreover, these cases involved products that courts found were clearly different products or treatment methods, or that challenged an entire category of products. *See Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999) (holding "other products that do not use pedicle screws" are not alternative designs to pedicle screws under Texas law even though they treat the same ailment because "[u]nderlying this argument is the assumption that all pedicle screws are defective and there can be no system using pedicle screws that would be an acceptable product."); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at *2 (D. Nev. Jul. 22, 2013) ("The fact that an alternative method of surgical hernia repair was potentially available does not support[] Plaintiff[s'] design defect claim. . . [N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support this particular claim" under Nevada law); *see Barnes v. Medtronic, PLC*, No. 2:17-cv-14194, 2019 WL 1353880, at *2 (E.D. Mich. Mar. 26, 2019) (rejecting Plaintiff's theory that "all polyester hernia meshes are unacceptable" and holding proposed alternatives were "alternative treatment methods or alternative types of mesh, not alternative production practices or designs for polyester hernia mesh" under Michigan law).

These cases involved proposed alternatives that were "obviously of a different categorical and structural ilk." *See In re DePuy*, 888 F.3d at 769 (citing *Theriot*, 168 F.3d at 255). Here, Plaintiff is not contending that mesh should not have been used at all or categorically challenging all hernia mesh products. Accordingly, this Court cannot conclude the Plaintiff's proposed alternative designs are different products as a matter of law.

ii. Causation

Bard next contends that Plaintiff's strict liability and negligent design defect claims fail because Plaintiff has failed to prove "that any purported defect caused Plaintiff's injuries." (Mot. at 15.) Under Utah law, the plaintiff in a design defect action must show that the "'defective condition was a cause of the plaintiff's injuries.'" *See Fortune*, 107 F. Supp. 3d at 1202 (D. Utah 2015) (quoting *Brown*, 328 F.3d at 1279). "Accordingly, it is not enough to simply show that the product failed." *Burns v. Cannondale Bicycle Co.*, 876 P.2d 415, 418 (Utah Ct. App. 1994) ("In sum, in order to defeat defendants' motion for summary judgment, Burns must provide some *evidence* that a defect existed at the time he bought the bicycle and that the defect caused his injury. It is not enough to merely contend that a defect existed, show that an accident occurred, and assume the two are necessarily related.") (emphasis in original).

Despite Bard's arguments to the contrary, Plaintiff has shown evidence of a tangible injury through the testimony of Dr. Grischkan who opines the adhesions required "lengthy arthrosopic [sic] lysis of the dense omental adhesions from the prior mesh implant" and the surgical excision of the mesh "with blunt, sharp, and electrocautery dissections," making the surgery more complex and resulted in "longer anesthesia, longer operative time and exposure to increased risks" which also "increases the cost of the procedure[.]" (Grischkan Supp. Rep. at 9; Grischkan Dep. 886:18-888:11.)

Bard contends that neither of the Ventralight ST devices implanted in Plaintiff were defective or responsible for Plaintiff's claimed injuries, relying on Plaintiff's treating physician's testimony that he did not believe either Ventralight ST device he implanted failed or was defective, or caused Plaintiff's injuries. (Jensen Dep. 82:12-83:17.)

Plaintiff has offered sufficient evidence, however, to create an issue of fact as to whether

design defects in the Ventralight ST caused Plaintiff's omental adhesions through the expert testimony of Dr. Babensee and Dr. Grischkan. As Plaintiff explains, Dr. Babensee's testimony establishes how defects in the design of the Ventralight ST can cause injuries in general:

> Dr. Babensee notes that the mechanical properties of the polypropylene, especially its lack of flexibility and elasticity, can create friction around the implant, which can prevent proper integration into the tissue. (Ex. A at 11-12.) Furthermore, smaller pore size of the mesh can negatively affect the ability of the mesh to integrate with the surrounding tissue, a problem that is especially acute in the Ventralight ST due to the fact that the polypropylene is co-knitted with the PGA fibers. (*Id.* at 14-15.) In addition to mechanical properties of polypropylene, the chemical properties of the Ventralight ST components create problems for proper tissue integration. Polypropylene is well-known to be associated with a strong foreign body response *in vivo*, which can inhibit effective tissue ingrowth. (*Id.* at 9-11.) The Ventralight ST components exacerbate the foreign body response due to the presence of the PGA fibers, which degrade into glycolic acid, creating an acid dump at the implant site which leads to inflammation and tissue destruction and prevent proper reperitonealization. (*Id.* at 23-24.) Furthermore, the Ventralight ST is prone to wrinkling, which can also prevent proper tissue integration. (*Id.* 24.) Dr. Babensee also is in agreement with Dr. Grischkan that the ST barrier degrades before reperitonealization can complete, exposing the polypropylene to the viscera and the risk of adhesions. (*Id.* at 24-26.)

(Pl.'s Opp. at 19.) Dr. Grischkan's differential diagnosis regarding the cause of Plaintiff's omental adhesions, in conjunction with Dr. Babensee's testimony, establishes a genuine issue of material fact as to whether a defect in the Ventralight ST caused Plaintiff's injuries. (*See* Grishkan Supp. Rep. at 10-12.) The Tenth Circuit has explained the evidence required to establish causation under Utah law under *Alder v. Bayer Corp.*, 61 P.3d 1068, 1085-90 (Utah 2002) "does not require a plaintiff to provide direct proof through medical studies of the mechanism of the illness or to quantify the harmful exposure necessary to have produced the harm alleged by the plaintiff. Instead, a plaintiff may establish causation circumstantially through the use of differential diagnosis." *Tingey*, 193 Fed.Appx. at 764.

However, as set forth in this Court's opinion on Bard's motion to exclude Dr. Grischkan's expert testimony, Dr. Grischkan's opinions regarding the cause of Plaintiff's alleged

recurrent hernia from 2016, the cause of Plaintiff's alleged current pain, and Plaintiff's need for future surgery are unreliable and inadmissible. Plaintiff therefore has not established a genuine issue of material fact with respect to the cause of any alleged injuries other than his omental adhesions. *See Tingey*, 193 Fed.Appx. at 764 ("Where causation would not be obvious to an unaided finder of fact, however, plaintiff must also present some documented proof or expert medical testimony that exposure to the harmful substance could have been a cause of the type of injury that plaintiff received."); *see also Fitz v. Synthes (USA)*, 990 P.2d 391, 393 (Utah 1999) ("This court has held that medical expert testimony is required to prove proximate cause in a medical injury case.") (citing *Frederickson v. Maw*, 227 P.2d 772, 773 (Utah 1951)).

Accordingly, Bard's motion for summary judgment on Plaintiff's strict liability and negligent design defect claims is **DENIED** with respect to Plaintiff's claims relating to his omental adhesions as found in the surgery in October of 2016, and **GRANTED** with respect to Plaintiff's claims relating to his alleged subsequent 2016 recurrent hernia, current pain, and future surgeries.

2. Manufacturing Defect – Strict Liability and Negligence

Plaintiff asserts claims for manufacturing defect under both strict liability and negligence theories. As with design defect claims, a plaintiff asserting a strict liability manufacturing defect claim "must prove that (1) the manufacturing defect made the product unreasonably dangerous, (2) the defect was present at the time of the product's sale, and (3) the defect caused the plaintiff's injury." *Kirkbride v. Terex USA, LLC*, 798 F.3d 1343, 1351 (10th Cir. 2015) (citing *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003). "[P]roof of a defect under a negligent manufacture theory will necessitate proof that the defective condition of the product was the result of negligence in the manufacturing process, or proof that the manufacturer knew or should have known of the defective condition[.]" *Bishop*, 48 P.3d at 225-26.

Under either theory, "[a] manufacturing defect claim, by its nature, involves a deviation from the product's design specifications, to the injury or potential injury of a user. The gravamen of the tort is not defective design but defective execution of the design." *Wankier*, 353 F.3d at 867; *Cerveny v. Aventis, Inc.*, No. 2:14-CV-00545, 2015 WL 13640496, at *1 (D. Utah July 14, 2015) ("In order to plead and prove a manufacturing flaw, Plaintiffs must show that the [the product] was defective as a result of a mistake in the manufacturing process.") (citing *Wankier*, 353 F.3d at 867).

Bard argues summary judgment is warranted under either theory because Plaintiff cannot establish that either device implanted in him deviated from the product's specifications, and that Bard has affirmative evidence Plaintiff's devices were manufactured in accordance with their specifications and without defects. Plaintiff contends he has presented evidence of "multiple manufacturing issues that caused defects in the Ventralight ST mesh," and that these defects include "roughening and smaller poor[sic] size, caused Plaintiff's injuries." (Pl.'s Opp. at 23.)

Specifically, Plaintiff points to the following as evidence of a manufacturing defect:

> Ahmed El-Ghannam, Ph.D. opined, "[t]he damage to the surface of Bard's polypropylene meshes, in my expert opinion, are more likely than not created by Bard's storage and/or manufacturing processes. For instance, the temperature for thermoforming was high enough to cause partial melting during cyclic mechanical stresses against the surface." (El-Ghannam Report at 50, attached as Exhibit S) Dr. El-Ghannam further found that the "deformation and degradation of multiple layers of the polypropylene mesh lead to damage areas in which the fibers were piled and loosely bound together on the surface allowing entrapment of pores between them," which caused the poores to be too small. ." (*Id.*)
>
> Dr. El-Ghannam conducted imaging scans of Ventralight ST exemplars. Imaging of Ventralight ST revealed "[s]evere surface defects were observed on the polypropylene fibers, along with debris. A peak at about 1440 cm 1 in FTIR indicates that oxidative degradation has already started to occur even in the pristine device." (*Id.* at 69.) Put simply, the polypropylene in Ventralight ST degrades so quickly that it becomes roughened well before it is put into the body.

(Pl.'s Opp. at 23.) Bard contends this evidence is insufficient to prove a manufacturing defect claim. First, Bard contends Plaintiff does not contest or challenge Dr. Reitman's opinion that "Plaintiff's two Ventralight ST devices did not different from manufacturing specifications." (Reply at 5.) Second, Bard argues "Plaintiff confuses the evidence necessary to support a design defect claim versus a manufacturing defect claim, relying on the opinions of their *design* expert, Dr. El-Ghannam." (*Id*.) According to Bard, Dr. El-Ghannam "does not provide an opinion that Plaintiff's Ventralight ST device(s) differed from manufacturing specifications," and he was not given "the specific lot history records for Plaintiff's Ventralight ST devices to offer any case-specific opinion." (*Id*. at 5-6.) Instead, Dr. El-Ghannam's opinions "relate to the claim that Bard's general—and not unit-specific—manufacturing processes result in hernia mesh devices, including the Ventralight ST device, that show signs of polypropylene degradation prior to being implanted in the human body." (*Id*. at 5-6.)

This Court agrees. Plaintiff does not allege the defects he identifies—degradation and

roughening of the surface and smaller pore size—were caused by any deviation from the product's design specification. Instead, Dr. El-Ghannam opines that "damage to the surface of Bard's polypropylene meshes, in my expert opinion, are more likely than not created by Bard's storage and/or manufacturing processes," such as high temperatures for thermoforming. (Pl.'s Opp. at 23.) In another MDL involving Bard's mesh products, the plaintiffs presented similar evidence in support of their manufacturing defect claim, alleging Bard's process subjected materials to extreme temperatures "as well as mechanical forces during that heating process that significantly exceed the mesh's reported tensile strength." *In re C.R. Bard, Inc.*, No. 2:10-CV-01224, 2013 WL 2431975, at *4 (S.D.W. Va. June 4, 2013). Judge Joseph R. Goodwin opined:

> Although this process is part of the manufacturing process of the Avaulta products, it would fall within the category of a *design* defect and not a *manufacturing* defect if the process, albeit faulty, were the same for all of these products. In contrast, if the expert had testified—for example—that the particular Avaulta product implanted in Ms. Rizzo went through thermal and mechanical processes that caused the product to degrade and which deviated from Bard's processes for the same Avaulta products generally, then he may have provided evidence of a manufacturing defect.
>
> Similarly, the alleged inadequate pore size and use of improper polypropylene material in the Avaulta products is a design issue—the plaintiffs do not allege that the Avaulta products implanted in Ms. Rizzo had a different average pore size or were made out of different polypropylene material than Avaulta products generally.

Id. at *4-5 (emphasis in original).

Likewise here, Plaintiff does not contend that his particular Ventralight ST devices went through a heating or storage process that deviated from Bard's specifications generally, or differed from any other Ventralight ST products. Plaintiff's proffered evidence relates to Bard's manufacturing process applicable to all of its products, not just Plaintiff's, and is therefore an issue of design rather than manufacturing. Plaintiff has therefore presented no evidence that either Ventralight ST device implanted in him "deviat[ed] from the product's design

specifications" as required for both his negligent and strict liability claims. *See Wankier*, 353 F.3d at 867.[7] Accordingly, Bard's motion for summary judgment on both Plaintiff's negligent and strict liability manufacturing defects claims is **GRANTED**.

[7] At oral argument, Plaintiff's counsel offered the 2012 Product Performance Specification (Rev. 6) for the Ventralight ST in support of Plaintiff's manufacturing defect claim, arguing the document indicates the product must meet certain functional requirements at six months and pass biocompatibility but that the Ventralight ST never had any biocompatibility testing. (*See* Tr. at 40-42, ECF No. 298.) But as with Dr. El-Ghannam's testimony, this evidence goes to Bard's design of the entire Ventralight ST product line. Plaintiff has offered no evidence his particular devices deviated from these specifications as required by Utah law.

3. Failure to Warn – Strict Liability and Negligence

Plaintiff alleges both negligent failure to warn and strict liability failure to warn claims. Plaintiff contends Bard "failed to adequately warn of (1) risks associated with PGA acids that impair wound healing; (2) the risks associated with the short absorption timeframe for the ST coating; (3) the presence of carcinogenic antioxidants in the Ventralight ST; and (4) of the risks associated with the non-medical grade polypropylene used to manufacture the Ventralight ST." (Pl.'s Opp. at 13.)

"[U]nder Utah law, a manufacturer may be held strictly liable for any physical harm caused by its failure to provide adequate warnings regarding the use of its product." *House v. Armour of Am., Inc.*, 929 P.2d 340, 343 (Utah 1996) ("*House II*"). "Where a manufacturer knows or should know of a risk associated with its product, the absence or inadequacy of warnings renders that product unreasonably dangerous, subjecting the manufacturer to strict liability." *Id.* (internal quotations omitted). To establish a strict liability failure to adequately warn claim, a plaintiff must show: "(1) that Defendants had a duty to warn, (2) that the warning was inadequate, (3) that the inadequate warning made the product unreasonably dangerous, and (4) that the lack of an adequate warning caused the injury." *Feasel v. Tracker Marine LLC*, 460 P.3d 145, 152 (Utah Ct. App.), *cert. granted sub nom. Feasel v. Tracker Marine*, 466 P.3d 1072 (Utah 2020) (citing *House II*, 929 P.2d at 343, 346). Similarly, to establish a negligent failure to warn claim, a plaintiff must show: "(1) defendant's failure to exercise reasonable care because he did not provide an adequate warning; (2) the lack of an adequate warning made the product defective and unreasonably dangerous; and (3) the lack of an adequate warning was a cause of plaintiff's injuries." *Christison v. Biogen Idec Inc.*, No. 2:11-CV-01140-DN-DBP, 2014 WL 7261300, at *8 (D. Utah Dec. 18, 2014) (citing Model Utah Jury Instructions CV1018 (2d ed. Aug.15, 2014),

http://www.utcourts.gov/resources/muji/; *House II*, 929 P.2d at 344).

"In any failure to warn claim, a plaintiff must show that the failure to give an adequate warning in fact caused the injury; i.e., that had warnings been provided, the injured party would have altered his use of the product or taken added precautions to avoid the injury." *House II*, 929 at 346 (citing *Barson*, 682 P.2d at 836-37). "But if the event which produced the injury would have occurred regardless of the defendant's conduct, then the failure to provide a warning is not the proximate cause of the harm and the plaintiff's claim must fail." *Id*. (internal quotations omitted).

Bard argues Plaintiff's failure to warn claims both fail because Plaintiff cannot establish proximate causation under the learned intermediary doctrine.

i. Learned Intermediary Doctrine

Under Utah's learned intermediary doctrine, "it is the manufacturer's duty to warn the doctor of the dangers associated with a dangerous drug, rather than the patient." *Tingey*, 193 Fed.Appx. at 757 n.4 (citing *Barson*, 682 P.2d 832). Though the Utah Supreme Court has not expressly addressed whether the learned intermediary doctrine applies to medical device claims, the Tenth Circuit has suggested that is does. *Id*. ("Courts have applied this doctrine to claims involving medical devices . . . and we assume Utah would do so as well.") Accordingly, this Court will apply the learned intermediary doctrine to Plaintiff's failure to warn claims. *See Flandro v. Bos. Sci. Corp.*, No. 2:13-CV-17027, 2015 WL 5842823, at *4-5 (S.D.W. Va. Oct. 6, 2015) (applying learned intermediary doctrine to plaintiff's mesh claims under Utah law).

Bard contends Plaintiff's failure to warn claims fail for lack of causation because, pursuant to the learned intermediary doctrine, Bard's duty to warn runs only to Plaintiff's implanting physician, Dr. Jensen, who testified that he did not recall reading or relying on the

Instructions for Use ("IFU") for the Ventralight ST and that he would not have changed his treating decisions even if he received additional warnings. (Mot. at 7-10.) According to Bard, "[a] claim based on allegedly inadequate instructions or warnings fails when there is no evidence that the user read or relied on the instructions." (*Id*. at 8-9); *see Lewis v. Johnson & Johnson*, 601 F. App'x 205, 208-09 (4th Cir. 2015) ("When a physician relies on her own experience and examination of a patient in deciding to prescribe a device, and not on the device's warning, the warning is not the cause of the patient's injury."); *see also In re Wright Med. Tech., Inc., Conserve Hip Implant Prods. Liab. Litig.*, 127 F. Supp. 3d 1306, 1359 (N.D. Ga. 2015) (applying Utah law) ("[W]here a warning is provided, but a physician does not read it or rely on it, a person cannot assert a failure to warn claim, even if the warning is defective.").

Utah courts have not expressly addressed a learned physician's failure to read a product warning,[8] but other courts have interpreted Utah law as requiring a plaintiff to show the treating physician would have altered his decision to prescribe the product had he known of additional warnings in order to establish proximate causation under the learned intermediary doctrine. *See Stewart v. Bos. Sci. Corp.*, No. 2:12-CV-03686, 2015 WL 5842762, at *6 (S.D.W. Va. Oct. 6, 2015) (citing *House II*, 929 P.2d at 346); *Hoffman v. Bos. Sci. Corp.*, No. 2:12-CV-04433, 2015 WL 5842785, at *5 (S.D.W. Va. Oct. 6, 2015) (same). For example, summary judgment was

[8] At least one federal district court has concluded that Utah courts would "likely following the reasoning and decisions of many other jurisdictions and find that where a learned intermediary fails to read a warning, a plaintiff is foreclosed from asserting a failure to warn claim." *In re Wright Med. Tech., Inc., Conserve Hip Implant Prods. Liab. Litig.*, 127 F. Supp. 3d at 1359, n.56 (citing *Okuda v. Pfizer Inc.*, No. 1:04–CV–00080, 2012 WL 2685053, at *1-2 (D. Utah July 6, 2012) (finding prescribing doctor's testimony that he "generally did not read any information received from sales representatives, and that he would not rely upon any such information" precluded a plaintiff's claim for breach of warranty, negligent misrepresentation, and fraud, because the plaintiff could not show any evidence that the plaintiff's prescribing physicians relied on any specific representations made by the defendant.")).

warranted when a physician testified that he would have still used the product even if he had been provided additional warnings. *Jeffries v. C. R. Bard, Inc.*, No. 2:16-CV-11798, 2018 WL 700799, at *4 (S.D.W. Va. Feb. 2, 2018) (applying Utah law). Similarly, a doctor's testimony that he would have passed any additional warnings to his patient did not establish that the doctor would have altered his decision to prescribe the product had he known of additional warnings. *See Stewart*, 2015 WL 5842762, at *6 (citing *House II*, 929 P.2d at 346). The learned intermediary doctrine applies in cases like this "because '[i]t is the physician who is best situated to weigh the potential risks associated with a [product] against the possible benefits of the [product] and the unique needs and susceptibilities of each patient." *Id*. (quoting *Schaerrer*, 79 P.3d at 928).

Here, Plaintiff has presented sufficient evidence to create an issue of fact as to whether Dr. Jensen read and relied on the Ventralight ST's warnings, and whether he would have altered his decision to prescribe the Ventralight ST product for Plaintiff had he known of additional warnings. The deposition testimony of Dr. Jensen, taken alone, is somewhat equivocal. At his deposition, Dr. Jensen testified that he was sure he had seen technique guides and product brochures from Bard. (Jensen Dep. 25:22-26:10.) He also testified he might read Instructions for Use ("IFU") sometimes prior to using a product, and that he was sure he had seen the Ventralight ST IFU before, but could not specifically recall reading it. (*Id*. at 33:20-34:3.) Dr. Jensen also could not recall at his deposition whether he had attended a Bard conference, but he testified that he had attended several manufacturers' training sessions, and that he had "maybe" attended one hosted by Bard. (*Id*. at 22-25:7.) Dr. Jensen testified that he educates himself about different products that are available by, among other things, attending mini conferences. (*Id*. at 24:14-17.)

In his February 19, 2020 declaration, however, Dr. Jensen explained that since his

deposition, Dr. Jensen has reviewed documents that he did not have an opportunity to review before his deposition and that were not made available to him during his deposition. (Jensen Decl. at ¶ 5.) The declaration states:

> 6. A key part of my decision to use Ventralight ST in Mr. Johns (as well as many of my other patients) was the surgeon training I received from Bard/Davol. I have seen Bard/Davol internal records indicating that I received surgeon training about Ventralight ST (and other Bard/Davol hernia products) in Portland, Oregon, on May 16, 2011, and that the materials for the training I attended included a "Sell Sheet" for Ventralight ST.
>
> 7. The Ventralight ST Sell Sheet (or brochure) from 2011 that I reviewed indicates that the resorption period for the ST hydrogel in Ventralight ST is up to thirty days. I have reviewed the Ventralight ST IFU from that time period which likewise references that the resorption period for the ST hydrogel in Ventralight ST is up to thirty days. While I do not have an independent memory of reviewing the Ventralight ST IFU back when I first began using it almost nine years ago in 2011, it is my pattern and practice to review product IFUs before my first use of the product and I am confident that I would not have departed from that pattern and practice with respect to Ventralight ST.

(Jensen Decl. ¶¶ 6-7.) As the declaration explains, Dr. Jensen's recollection was refreshed after his deposition by Bard's internal documents showing Dr. Jensen did in fact attend at least one Bard training session at a conference in May 2011 and that product materials were provided at that session. And while Dr. Jensen testified at his deposition that he always makes "an independent decision" whether or not a product is safe and effective to use, (Jensen Dep. 26:11-27:6), he did not testify that he *never* relies on manufacturers' trainings, product brochures, or technique guides. In fact, Dr. Jensen testified that he relies on hernia mesh manufacturers to provide him with accurate information about the risks and benefits of their devices, including the Ventralight ST mesh, (*id*. at 105:20-24), and to share with him information regarding adverse events associated with a hernia mesh. (*Id*. at 106:10-14.) Dr. Jensen also testified that he expects Bard to provide accurate information about the device and instructions for use, (*id*. at 106:4-8.) He testified that it is important that Bard publish truthful, up-to-date, and accurate information

about the Ventralight ST that does not understate the risks or overstate the benefits. (*Id.* at 106:16-107:13.)

These facts are distinguishable from cases relied on by Bard. In *In re Wright Medical Technology*, the district court concluded that the learned intermediary doctrine precluded the plaintiff's failure to warn claims under Utah law because the "the undisputed evidence is that [the treating physician] did not and would not have read the insert warnings that were provided with the device implanted to replace Plaintiff's right hip." 127 F. Supp. 3d at 1361. There was no evidence in the record that the treating physician ever read the warnings for the allegedly defective product, or any other hip implant device, before or after the plaintiff's surgery. *Id.* The physician testified that he preferred to "educate himself" on products and review studies and what went into a design. *Id.*

Similarly, in *Lewis v. Johnson & Johnson*, the Fourth Circuit affirmed the district court's award of summary judgment to the defendant manufacturer on the plaintiff's failure to warn claim because the plaintiff did not establish that "'*but for* the inadequate warning,' [the physician] 'would not have used or prescribed'" the product. 601 F. App'x at 208 (quoting *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008)) (emphasis in original). There, the treating physician had definitively testified that she did *not* rely on the device's instructions for use in prescribing the device for the plaintiff. *Id.* Instead, the physician relied on the plaintiff's "bladder diary, urodynamics, physical exam, and discussions regarding her desired outcomes[.]" *Id.* While the treating physician testified she had read the product's instructions at one point in time, the court found that the plaintiff had offered "no evidence to rebut [the physician]'s own testimony that she did not rely on the document in deciding to prescribe the TVT." *Id.* at 209.

Dr. Jensen's deposition testimony together with his declaration demonstrates that an issue of fact exists on Plaintiff's failure to warn claims, precluding summary judgment. The evidence here is much more analogous to cases where an issue of fact is found. For example, in *Sanchez*, Judge Goodwin found there was a dispute of fact under California law as to whether the treating physician read or relied on the defendants' product warnings based on very similar testimony to what Dr. Jensen provided here. 38 F.Supp.3d at 735 ("Although Dr. Wiltchik could not pinpoint exactly when she read the DFUs, she clearly testified that she had read them at some point[.]"). Judge Goodwin further held:

> [T]here is at least a dispute of fact whether Dr. Wiltchik relied on the DFUs accompanying the Pinnacle device. Dr. Wiltchik testified that she would not have used the Pinnacle device had the Pinnacle DFU characterized dyspareunia as a "warning/potential complication" rather than as an "adverse event." Dr. Wiltchik also stated that the Pinnacle DFU did not warn about the rates of certain complications, including pain, infection, erosion and exposure of the mesh, failure of the implantation procedure, and recurrence of prolapse and incontinence. She then testified that she wanted to know this information because it would affect her "risk/benefit analysis" in prescribing the Pinnacle device. Accordingly, I **FIND** that there is a genuine dispute of fact whether inadequate warnings on the Pinnacle DFU caused the plaintiffs' injuries.

Id. at 735-36 (internal citations omitted).

Still, Bard claims that Plaintiff cannot establish Dr. Jensen would have altered his decision to use the Ventralight ST even if additional warnings had been provided. (Mot. at 9.) According to Bard, Dr. Jensen testified that he was aware of the potential risks and complications associated with the Ventralight ST, including adhesions and recurrence, and that he felt the Ventralight ST was the "best option" for Plaintiff. (*Id*.)

Dr. Jensen's declaration explains that since his deposition, he has reviewed Bard's internal documents that discuss the resorption rate of the hydrogel coating acquired by Bard and for Ventralight ST and whether it sufficient to allow for reperitonealization. He now states:

> 14. No one from Bard or Davol ever informed me that the ST hydrogel barrier could be resorbed within seven days. I did not know that fact from any source independent of Bard or Davol. Had I known that the ST hydrogel barrier could be resorbed within seven days or anything substantially less than thirty days, I would not have used the Ventralight ST in Steven Johns.

(Jensen Decl. at ¶ 14.)

Although Dr. Jensen did not have the benefit of reviewing these documents prior to or during his deposition, he still testified that he would want to know and it "would be significant" if the ST coating resorbed before reperitonealization. While Dr. Jensen initially responded "not necessarily" when asked if learning the hydrogel coating would absorb within seven days would have impacted his decision to use with Ventralight ST in Plaintiff, the very next thing he said was that "[i]t depends on the time frame." (Jensen Dep. 121:4-10.) Though Dr. Jensen could not remember the exact timing of reperitonealization, he explained that he would need to know "if there was a big gap or something" between when the ST coating resorbed and reperitonealization. (*Id*. at 121:13-24) Dr. Jensen also testified it would be important information for him to know if the hydrogel coating resorbed within seven days. (*Id*. at 120:21-121:3.) Now having reviewed those documents, Dr. Jensen's statements in the declaration clarifies that he would not have used the Ventalight ST in Plaintiff had he known that the coating could resorb within seven days. (Jensen Decl. ¶ 14.)

This Court has rejected Bard's arguments that Dr. Jensen's declaration was an improper "sham affidavit" (*see* EMO 4, ECF No. 168), while also granting Bard leave to redepose Dr. Jensen regarding his declaration. (*See* PTO 16, MDL 2846 ECF No. 390.) Bard's remaining arguments regarding perceived inconsistencies in Dr. Jensen's testimony and the circumstances giving rise to the declaration may cast doubt on the credibility of the statements therein. But a district court considering a motion for summary judgment may not weigh evidence or make

credibility determinations. *See Daugherty v. Sajar Plastics, Inc.*, 544 F.3d 696, 702 (6th Cir. 2008); *Anderson*, 477 U.S. at 255 ("Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion for summary judgment or for a directed verdict."); *Bard v. Brown Cty., Ohio*, No. 19-3468, 2020 WL 4783746, at *14 (6th Cir. Aug. 18, 2020) ("[P]roof that a party . . . has made prior inconsistent statements is not a rare event in our courts. Juries are regularly called upon to consider evidence of that sort, and we all know that prior inconsistency does not inexorably lead to defeat.") (quoting *Hanson v. Madison Cty. Det. Ctr.*, 736 F. App'x 521, 537 (6th Cir. 2018)).

ii. Adequacy of Warning and Heeding Presumption

Plaintiff contends that even without Dr. Jensen's declaration, he has sufficient evidence to support his failure to warn claims based on Utah's "heeding presumption." (Pl.'s Opp. at 16-17.) This doctrine provides that "'in cases in which it cannot be demonstrated what the plaintiff would have done had he or she been adequately warned, the plaintiff should be afforded a rebuttable presumption that he or she would have followed an adequate warning had one been provided." *Kirkbride*, 798 F.3d at 1351 (quoting *House II*, 929 P.2d at 347). "Under Utah law this presumption must be rebutted by a preponderance of the evidence." *Id*. (citing Utah R. Evid. 301; *Barron v. Labor Comm'n*, 274 P.3d 1016, 1020 n. 3 (Utah Ct.App.2012)).

Bard contends the heeding presumption does not apply to Plaintiff's claims because Bard provided an adequate warning. (Mot. at 10-11.) In order for a warning to be adequate under Utah law, "it must completely disclose all the risks involved, as well as the extent of those risks." *House v. Armour of Am., Inc.*, 886 P.2d 542, 551 (Utah Ct. App. 1994) *aff'd*, 929 P.2d 340 (Utah 1996) ("*House I*"). "'A warning must (1) be designed so it can reasonably be expected to

catch the attention of the consumer; (2) be comprehensible and give a fair indication of the specific risks involved with the product; and (3) be of an intensity justified by the magnitude of the risk." *Id*. (citing *Pavlides*, 727 F.2d at 338). "[A] warning's overall adequacy 'must be judged in light of the ordinary knowledge common to members of the [relevant] community' at the time of sale." *Groesbeck v. Bumbo Int'l Tr.*, 718 F. App'x 604, 617 (10th Cir. 2017) (citing *House I*, 866 P.2d at 551; *see also* Utah Code Ann. § 78B–6–703(1) (explaining that the claimed defect—inadequate warnings—must exist at the time of sale); *Dimick v. OHC Liquidation Trust*, 157 P.3d 347, 350 (Utah Ct. App. 2007) (same)). "The adequacy of a warning ordinarily 'presents a question of fact, to be resolved by the trier of fact.'" *Feasel*, 460 P.3d at 152 (quoting *House I*).

Bard contends its warning was adequate as a matter of law because the Ventralight ST IFU properly advised of the risk of adhesions, and that Dr. Jensen was independently aware of that risk. (*See* Reply at 9 (citing IFU, ECF No. 29-4; Jensen Dep. 32:2-20).) Here, the relevant Ventralight ST IFU states:

> The visceral side of the mesh is bioresorbable coating that separates the mesh from underlying tissue and visceral organ surfaces to minimize tissue attachment to the mesh. Shortly after hydration, the biopolymer coating becomes a hydrated gel that is resorbed from the site in less than 30 days.

(MPPE-05899309; *see also* ECF No. 29-4.)[9] The IFU further states under "Contraindications" that "[l]iterature reports there is a possibility for adhesion formation when the polypropylene is

[9] The Court notes that the IFU filed by Plaintiff is for the "Ventralight ST Mesh with Echo 2 Positioning System," a different device which was not cleared by the FDA until May 1, 2017, https://www.accessdata.fda.gov/cdrh_docs/pdf17/K170294.pdf, and thus appears irrelevant to Plaintiff's claims regarding the Ventralight ST devices implanted in 2015 and 2016. (ECF No. 165-20.) Notably, this IFU states "the biopolymer coating becomes a hydrated gel that is resorbed from the site in less than 30 days, as observed in a preclinical model, which may not correlate to performance in humans." This is a difference from the IFU for the Ventralight ST implanted in Plaintiff, but there is no evidence or argument before this Court why this warning would be relevant to Plaintiff's claims.

placed in direct contact with the bowel or viscera." (*Id*.) The IFU lists the following possible complications: "seroma, adhesions, hematomas, inflammation, extrusion, fistula formation, infection, allergic reaction, and recurrence of the hernia or soft tissue defect." (*Id*.)[10] Under "Warnings," the IFU states:

> Ensure proper orientation; the coated side of VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There is a possibility for adhesion formation when the polypropylene side is placed in direct contact with the bowel or viscera (reference Surface Orientation section below).

(*Id*.) But Plaintiff's claim is that Bard failed to warn of, *inter alia*, "the risk associated with the short absorption timeframe of the ST coating," not that Bard failed to warn of the risks of adhesions at all. Specifically, Plaintiff alleges that the early resorption of the ST coating exposes the omentum and internal organs to bare polypropylene that can lead to adhesions and other complications.

None of the warnings provided "explicitly link" the timing of the resorption of the ST coating with the risk of adhesions. *See Feasel*, 460 P.3d at 153. Moreover, the statement that the ST coating "becomes a hydrated gel that is resorbed from the site in less than 30 days" does not specifically warn the user that the coating could resorb in as few as seven days as Plaintiff asserts. Because Bard's warnings do not specifically warn that early resorption of the ST coating could cause adhesions as Plaintiff has alleged, Bard has not shown the warning is adequate as a matter of law. "A jury may well conclude that the warnings, read together, were adequate, but without more explicit warnings" this issue cannot be resolved as a matter of law. *See id*. at 154.

Finally, Bard contends the record show that additional warnings would not have avoided

[10] The Ventralight ST product brochure likewise states "[u]nique hydrogel barrier swells to minimize tissue attachment to the visceral side of the mesh" and that "[t]he hydrogel barrier resorbs within 30 days." (*See* MPPE-06623661.)

Plaintiff's injury—adhesions. (*See* Reply at 10.) This Court disagrees. As set forth above, Dr. Jensen's declaration states that had he known the ST coating could be resorbed "within seven days or anything substantially less than thirty days," he "would not have used the Ventralight ST in Steven Johns." (Jensen Decl. ¶ 14.) But even without Dr. Jensen's declaration, there is an issue of fact as to whether "the event which produced the injury would have occurred" regardless of Bard's conduct, and thus whether Bard's failure to warn was the proximate cause of Plaintiff's injuries. Dr. Jensen testified it "would be significant" and he would want to known if the ST coating resorbed before reperitonealization or within seven days. Bard has not presented evidence rebutting this heeding presumption.

The Court therefore finds Plaintiff has offered sufficient evidence to create an issue of fact as to whether Bard's failure to warn proximately caused Plaintiff's injuries. Accordingly, Bard's motion for summary judgment on Plaintiff's strict liability and negligent failure to warn claims is **DENIED**.

B. Breach of Implied Warranty and Breach of Implied Warranty of Merchantability

The parties agree that "[u]nder Utah law, the elements of breach of an implied warranty and products liability are essentially the same." *Creech v. Stryker Corp.*, No. 2:07-cv-22-DAK, 2012 WL 33360, at *1 (D. Utah Jan. 6, 2012); (*see* Pl.'s Opp. at 26; *see* Bard's Reply at 16.) "Thus, Plaintiffs' 'implied warranty claims are controlled by, and indistinguishable from, the products liability claim.'" *Creech*, 2012 WL 33360, at n.2 (quoting *Salt Lake City Corp. v. Kasler Corp.*, 855 F.Supp. 1560, 1567 (D.Utah 1994) (holding plaintiff's breach of warranty tort claim was "subsumed by the court's analysis and decision with respect to the strict liability claims.")); *see also Straub v. Fisher and Paykel Health Care*, 990 P.2d 384, 389 n. 1 (Utah 1999) ("[T]he elements of strict liability and breach of warranty are essentially the same.").

The Tenth Circuit has likewise held that for tort claims for "breach of the implied warranty of merchantability, Utah law provides that the warranty is breached only if the plaintiff establishes the elements of a strict-products-liability claim for defective manufacture, defective design, or failure to warn." *Kirkbride*, 798 F.3d at 1354 (citing *Grundberg*, 813 P.2d at 92).

Because a reasonable juror could find that Bard defectively designed the Ventralight ST and/or failed to provide an adequate warning, a reasonable juror could also find that Bard breached an implied warranty. *See Flandro v. Bos. Sci. Corp.*, No. 2:13-CV-17027, 2015 WL 5842823, at *6 (S.D.W. Va. Oct. 6, 2015) ("Because a reasonable juror could determine that BSC defectively designed the Advantage . . . a reasonable juror could likewise find that BSC breached an implied warranty. *See, e.g.*, Utah Code Ann. § 70A-2-314(1) (Utah's statutory provision for the implied warranty of merchantability.")).

Accordingly, Bard's motion for summary judgment on Plaintiff's breach of implied warranty and breach of implied warranty of merchantability claims is **DENIED.**

C. Negligent Misrepresentation

Utah law recognizes the tort of negligent misrepresentation, "'which provides that a party injured by reasonable reliance upon a second party's careless or negligent misrepresentation of a material fact may recover damages resulting from that injury when the second party had a pecuniary interest in the transaction, was in a superior position to know the material facts, and should have reasonably foreseen that the injured party was likely to rely upon the fact.'" *Christison*, 199 F. Supp. 3d at 1320 (quoting *Price-Orem Inv. Co. v. Rollins, Brown & Gunnell, Inc.*, 713 P.2d 55, 59 (Utah 1986)); *Mitchell v. Smith*, No. 1:08-CV-103 TS, 2010 WL 5172906, at *8 (D. Utah Dec. 14, 2010) ("Under Utah law, to prove negligent misrepresentation several elements must be shown: (1) the plaintiffs reasonably relied on the defendant's representation, (2) the representation constitutes a "careless or negligent misrepresentation of a material fact," (3) the defendant "had a pecuniary interest in the transaction," (4) the defendant "was in a superior position to know the material facts," and (5) the defendant "should have reasonably foreseen that the injured party was likely to rely upon the" misrepresentation.") (quoting *Price-Orem Inv. Co.*713 P.2d at 59).

Bard contends Plaintiff's negligent misrepresentation claim fails because "Plaintiff has no evidence of a misrepresentation made by Bard to Plaintiff or Dr. Jensen, nor evidence of any reliance by Plaintiff or Dr. Jensen." (Mot. at 17; *see also* Reply at 16.) In fact, Plaintiff testified he had never heard of Bard before filing this action, he had never communicated with anyone from Bard, and did not rely on any written material from Bard. (*See* Johns Dep. 98:10-99:11.)

Privity of contract is not required, however, to establish a negligent misrepresentation claim. *Christison*, 199 F. Supp. at 1320 (quoting *Price-Orem*, 713 P.2d at 59). Thus, it may be sufficient that Dr. Jensen relied on a representation by Bard, and that Plaintiff in turn relied on

Dr. Jensen's' medical judgment. *See Okuda v. Pfizer Inc.*, No. 1:04-CV-00080, 2012 WL 2685053, at *1 (D. Utah July 6, 2012) (granting summary judgment on negligent misrepresentation claim because "Plaintiff offers no evidence that would support a determination that any of Plaintiff's prescribing physicians relied on any specific representation of fact attributable to defendants.").

As set forth above with Plaintiff's failure to warn claims, genuine issues of material fact exist with regarding whether Bard made a misrepresentation to Dr. Jensen and whether Dr. Jensen relied on that misrepresentation. Therefore, Bard's motion for summary judgment on Plaintiff's negligent misrepresentation claim is **DENIED**.

D. Breach of Express Warranty

Plaintiff alleges a claim for breach of express warranty. Under Utah law, "[t]o prove that there was an express warranty, Plaintiff[] must show that (1) Defendant[] made affirmations or promises, including product descriptions, that (2) became a basis of the bargain." *Marcovecchio v. Wright Med. Grp., Inc.*, No. 2:18-CV-00274, 2019 WL 1406606, at *7 (D. Utah Mar. 28, 2019) (quotations omitted); *see also* Utah Code Ann. § 70A-2-313(1)(a) ("Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.")

"It is generally true that reliance is necessary to establish a cause of action for express warranty." *Mgmt. Comm. of Graystone Pines Homeowners Ass'n on Behalf of Owners of Condominiums v. Graystone Pines, Inc.*, 652 P.2d 896, 900 (Utah 1982); *see also Marcovecchio*, 2019 WL 1406606, at *8 ("To state a claim, Plaintiff must allege that the product descriptions were communicated to him or his doctor and became the basis of the bargain."). "It is also true that the existence of reliance, as well as the express warranty itself, is a factual issue to be determined by the fact-finder." *Graystone Pines, Inc.*, 652 P.2d at 900.

Plaintiff argues that a genuine issue of material fact exists on his express warranty claim because "Defendants made misrepresentations in the IFUs" as set forth in support of his negligent misrepresentation claim. (Pl.'s Opp. at 25.) Bard contends it is entitled to summary judgment on Plaintiff's breach of express warranty claim because Plaintiff has not shown that either he or Dr. Jensen relied on any warranties by Bard. (*See* Reply at 16.) With respect to Plaintiff, Bard again argues there is no evidence Plaintiff ever received any representations directly from Bard, let alone relied on those materials. (Reply at 17).

But similar to negligent misrepresentation claims, privity is not required to establish a claim for breach of express warranty. *See State of Utah v. GAF Corp.*, 760 P.2d 310, 315 (Utah 1988). Plaintiff need not establish that Bard made any affirmations directly to him. Instead, he could show that he relied on Dr. Jensen's medical judgment, and that Dr. Jensen in turn relied on the affirmations made by Bard in forming that judgment relied upon by Plaintiff. *See Flandro*, 2015 WL 5842823, at *5 (applying Utah law) ("Thus, even if Ms. Flandro merely relied on the medical judgment of Dr. Macy, the implanting physician, in deciding to have the Advantage implanted, a reasonable juror could find that Ms. Flandro, naturally, relied on the express warranties of BSC as were allegedly provided to Dr. Macy, which formed the basis for Dr. Macy's medical judgment."); *Michael*, 2011 WL 2150112, at *9 (denying summary judgment on breach of express warranty because even though the plaintiff did not rely on any statements by defendant, she did rely on her doctors' recommendation who received the statements, giving rise to a presumption that the manufacturer's warranties were part of the "basis of the bargain" leading to plaintiff's use of medication); *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 972 (E.D. Wis. 2009) (denying summary judgment on express warranty claim where plaintiff did not read drug manufacturer's labeling but relied upon doctor's recommendations, and holding that "a reasonable jury could find that GSK's representations to Dr. Todd, which were then communicated to the [plaintiffs], constitute an affirmation forming a 'basis of the bargain' for [plaintiff's] use of Paxil.").

As set forth above with Plaintiff's failure to warn and negligent misrepresentation claims, genuine issues of material fact exist with regarding whether an express warranty was made by Bard and whether Dr. Jensen relied on the warranties as the basis of the bargain. Bard's motion for summary judgment on Plaintiff's breach of express warranty claim is **DENIED**.

E. Consumer Sales Practices Act

Although Plaintiff had alleged a claim for violation of Utah's Consumer Sales Practices Act, Utah Code Ann. § 13-11-22, Plaintiff's Liaison Counsel informed the Court during oral argument that Plaintiff was withdrawing that claim and presented no opposition to that part of his case being dismissed. (*See* Tr. at 42:17-20, ECF No. 298.) Accordingly, Bard's motion for summary judgment on Plaintiff's Consumer Sales Practices Act claim is **GRANTED.**

F. Punitive Damages

Finally, Plaintiff seeks an award of punitive damages. Under Utah law, punitive damages may only be awarded if compensatory of general damages are awarded and if it is established by clear and convincing evidence that Bard's acts or omissions "are the result of willful and malicious or intentionally fraudulent conduct, or conduct that manifests a knowing and reckless indifference toward, and a disregard of, the rights of others." Utah Code Ann. § 78B-8-201; *see also Daniels v. Gamma West Brachytherapy, LLC*, 221 P.3d 256, 269 (Utah 2009) ("As stated in the plain language of the statute, two types of conduct justify an award of punitive damages: (1) 'willful and malicious or intentionally fraudulent conduct' or (2) 'a knowing and reckless indifference toward, and a disregard of, the rights of others.'"). To establish that a "tortfeasor's actions were knowing and reckless, a party must prove that the tortfeasor knew of a substantial risk and proceeded to act or failed to act while consciously ignoring that risk." *Daniels v. Gamma W. Brachytherapy, LLC*, 221 P.3d 256, 269 (Utah 2009); *see also Diversified Holdings, L.C. v. Turner*, 63 P.3d 686, 699 (Utah 2002) ("While simple negligence will not support punitive damages, negligence manifesting a knowing and reckless indifference toward the rights of others will.").

Bard contends Plaintiff has failed to identify evidence of Bard's conduct that rises to this level, and that "because it complied with all FDA requirements and regulations, punitive damages are not warranted." (Reply at 19-20.)

This Court disagrees. First, the Utah punitive damages statute contains an exception for drug manufacturers where the drug received premarket approval by the FDA and is generally recognized as safe and effective by conditions established by the FDA and applicable regulations, including packaging and labeling regulations. *See* Utah Code Ann. § 78B-8-203.

This exception does not apply if it shown the drug manufacturer withheld or misrepresented information required to be submitted to the FDA. *Id*. Moreover, this exception does not apply to medical device manufacturers. In fact, the Utah Supreme Court has recently "join[ed] the many courts that have observed the 510(k) process is concerned primarily with equivalence, not safety" and declined to hold that, as a matter of law, medical devices that have entered the market through the 510(k) process are exempt from strict products liability claims "because of the differences between the FDA's rigorous oversight of prescription drugs and the 510(k) process for medical devices[.]" *Burningham v. Wright Med. Tech., Inc.*, 448 P.3d 1283, 1290 (Utah 2019). The court explained:

> [I]f a medical device is subjected to FDA scrutiny for safety, and the FDA deems the device to be either unsafe or capable of being made safer, the FDA will deny the manufacturer's application to market the device. *See* 21 U.S.C. § 360e(d)(2). Whereas, if a device enters the market through the 510(k) process, the FDA has not evaluated the device for safety, and the device has no approval from the FDA in that regard. Accordingly, we cannot know whether the device is safe, incapable of being made safe, or unreasonably dangerous

Id. The Court therefore disagrees that Bard's compliance with FDA regulations precludes punitive damages as a matter of law.

Second, at this juncture, Plaintiff has presented sufficient evidence to establish genuine issues of fact exist as to whether Bard's "intentionally fraudulent conduct" or displayed "knowing and reckless indifference." Specifically, there are genuine issues of fact as to whether Bard misrepresented or concealed information regarding the timing of the resorption of the ST and the substantial risks associated with such early resorption—such as the exposure of bare polypropylene to the visceral organs—that could lead a jury to conclude they acted willfully or recklessly. Accordingly, Bard's motion for summary judgment on Plaintiff's claim for punitive damages is **DENIED**, subject to renewal, if appropriate, after evidence is presented at trial.

V.

For the reasons set forth above, the Court **GRANTS IN PART AND DENIES IN PART** Bard's Motion.

IT IS SO ORDERED.

9/1/2020
DATE

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