IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

LORI HOFFMAN,

Plaintiff,

v. **Civil Action No. 2:12-cv-04433**

BOSTON SCIENTIFIC CORP.,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Defendant's Motion for Summary Judgment*)

Pending before the court is defendant Boston Scientific Corporation's ("BSC") Motion for Summary Judgment against Plaintiff Lori Hoffman [Docket 56]. As set forth below, BSC's Motion for Summary Judgment is **GRANTED IN PART** with respect to Ms. Hoffman's claims for manufacturing defect, under theories of strict liability and negligence; and failure to warn, under theories of strict liability and negligence. BSC's Motion for Summary Judgment is **DENIED IN PART** with respect to Ms. Hoffman's claims for strict liability for design defect, negligence, breach of express warranty, and breach of implied warranty.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are nearly 70,000 cases currently pending, approximately 19,000 of which are in the BSC MDL, MDL 2326. In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial

discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a "wave" of cases to be prepared for trial and, if necessary, remanded. (*See* Pretrial Order # 65, *In re: Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-002326, entered Dec. 19, 2013, *available at* http://www.wvsd.uscourts.gov/MDL/boston/orders.html). This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. Ms. Hoffman's case was selected as a Wave 2 case by the plaintiffs.

Ms. Hoffman was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System (the "Obtryx") on February 23, 2009. (Am. Short Form Compl. [Docket 7], at 3–4). She received the surgery at a hospital in Provo, Utah. (*Id.* at 4). As a result of implantation of the Obtryx, she has allegedly experienced various injuries. She brings the following claims against BSC: strict liability for design defect, manufacturing defect, and failure to warn; negligence; breaches of express and implied warranties; and punitive damages. (*Id.* at 4–5). In the instant motion, BSC moves for summary judgment on the grounds that Ms. Hoffman's "legal theories are without evidentiary or legal support." (BSC's Mot. for Summ. J. & Mem. in Supp. ("Mem. in Supp.") [Docket 56], at 1).

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the

evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor." *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105 F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law. "When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation." *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on

diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

Here, Ms. Hoffman filed her case in Utah. Thus, the choice-of-law principles of Utah guide this court's choice-of-law analysis. The parties agree, as does this court, that these principles compel application of Utah law. Utah follows the Restatement (Second) of Conflict of Laws. Thus, "[i]n an action for a personal injury, the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship . . . ." Restatement (Second) of Conflict of Laws § 146 (1971). Here, the alleged wrong occurred in Utah, and Utah has the most significant relationship to the claims. Thus, I apply Utah's substantive law to the claims in this case.

III. Analysis

BSC argues that it is entitled to summary judgment in this case because Ms. Hoffman's claims lack either evidentiary or legal support. Ms. Hoffman has agreed not to pursue claims for: (1) strict liability for manufacturing defect; and (2) negligent manufacturing. (Pls.' Resp. in Opp'n to BSC's Mot. for Summ. J. ("Resp.") [Docket 79], at 16). Accordingly, BSC's Motion for Summary Judgment on Ms. Hoffman's claims for strict liability for manufacturing defect and negligent manufacturing is **GRANTED**. Below, I apply the summary judgment standard to each remaining claim.

A. Strict Liability for Design Defect

Under Utah law, strict products liability is governed by section 402A of the Restatement (Second) of Torts. *Ernest W. Hahn, Inc. v. Armco Steel Co.*, 601 P.2d 152, 156 (Utah 1979). Accordingly, a manufacturer who sells a product "in a defective condition unreasonably dangerous to the user or consumer" is strictly liable "for physical harm thereby caused to the ultimate user or consumer." Restatement (Second) of Torts § 402A (1965). To recover, a plaintiff must establish: "(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." *Lamb v. B & B Amusements Corp.*, 869 P.2d 926, 929 (Utah 1993).

For a product to be "unreasonably dangerous," it must be "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. Nonetheless, a product is presumed to be not defective

> where the alleged defect in the plans or designs for the product or the methods and techniques of manufacturing, inspecting and testing the product were in conformity with government standards established for that industry which were in existence at the time the plans or designs for the product or the methods and techniques of manufacturing, inspecting and testing the product were adopted.

Id. § 78B-6-703.

Here, BSC argues that Ms. Hoffman's claim for strict liability for design defect fails because BSC complied with FDA regulations and requirements in bringing the Obtryx to the market. Critical to Ms. Hoffman's case, however, when assessing the application of a government standards rebuttal, "parties may not present evidence regarding the 510(k) clearance process or

subsequent FDA enforcement actions" because "[t]he 510(k) process is not a safety statute or administrative regulation." *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755–56 (S.D. W. Va. 2014); *see also Tingey v. Radionics*, 193 F. App'x 747 (10th Cir. 2006) (applying Utah law) (holding that 510(k) clearance did not qualify for the government standards rebuttal). Accordingly, the rebuttable presumption afforded by section 78B-6-703 is not applicable to Ms. Hoffman's case.

BSC next argues that Ms. Hoffman's claim for strict liability for design defect fails under the "unavoidably unsafe" doctrine. Comment k of section 402A of the Restatement describes certain products as "unavoidably unsafe products." Under Utah law, "the seller of such products, when the products are properly prepared and marketed and distributed with appropriate warnings, should not be held strictly liable for the 'unfortunate consequences' attending their use." *Grundberg v. Upjohn Co.*, 813 P.2d 89, 92 (Utah 1991). "Thus, under Utah law, comment k shields manufacturers and sellers of [unavoidably unsafe products] from strict liability based on allegations of a design defect." *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003).

Courts have varied in the application of comment k. Some courts have found that comment k categorically bars design defect claims for certain medical products. *See, e.g.*, *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) (leading case adopting categorical approach). Thus, in these states, comment k is an absolute bar to claims of design defect for particular classes of products. Other courts have adopted a case-by-case approach. *See, e.g.*, *Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 308 (Idaho 1987) (leading extant case adopting case-by-case approach). In the case-by-case states, whether comment k bars a design defect claims depends on the particular product at hand.

The Supreme Court of Utah has categorically barred claims for strict liability for design defect arising out of the use of prescription drugs. *See Grundberg*, 813 P.2d at 95. The court, however, has not extended the application of comment k's preclusive effect to bar claims arising out of the use of medical devices. Importantly, in deciding to categorically label prescription drugs as "unavoidably unsafe," the *Grundberg* court relied heavily on society's need for a complex scheme to regulate the manufacture of prescription drugs, including a risk/benefit analysis employed by the FDA. 813 P.2d at 96–99. The Supreme Court of Utah explained:

> To determine whether a drug's benefit outweighs its risk is inherently complex because of the manufacturer's conscious design choices regarding the numerous chemical properties of the product and their relationship to the vast physiologic idiosyncracies of each consumer for whom the drug is designed. Society has recognized this complexity and in response has reposed regulatory authority in the FDA. Relying on the FDA's screening and surveillance standards enables courts to find liability under circumstances of inadequate warning, mismanufacture, improper marketing, or misinforming the FDA—avenues for which courts are better suited. Although this approach denies plaintiffs one potential theory on which to rely in a drug products liability action, the benefits to society in promoting the development, availability, and reasonable price of drugs justifies this conclusion.

Id. at 99. Differing from a defective prescription drug, the defective design of a medical device approved via the 510(k) clearance process is not smoked out under the screening and surveillance standards of the FDA. *See Lewis*, 991 F. Supp. 2d at 761–62 ("[T]he 510(k) process relates to a medical device's equivalence to a pre-existing device; it does not require 'full consideration of the product's risks and benefits[.]'"). In light of this reasoning, I predict that the Supreme Court of Utah would not apply comment k as a categorical bar to claims for strict liability for design defect arising out of the use of medical devices such as the Obtryx.

Accordingly, the application of comment k to this case is a mixed question of law and fact, *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 463 (Ct. App. 1985), *disapproved of on other grounds by Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988), and "require[s] a full evidentiary hearing."

Toner, 732 P.2d at 308. In turn, I find that the issue of whether the Obtryx and the Pinnacle are unavoidably unsafe cannot be resolved at the summary judgment stage. To the extent that BSC otherwise contends that summary judgment is warranted, I find that genuine disputes of material fact exist with regard to whether the Obtryx is unreasonably dangerous. Furthermore, the plaintiff has offered concrete evidence from which a reasonable juror could return a verdict in her favor. Therefore, BSC's Motion for Summary Judgment on Ms. Hoffman's strict liability for design defect claim is **DENIED**.

B. Strict Liability for Failure to Warn

Under Utah law, "in order for a warning to be adequate, 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). Specifically, "[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.* (quoting *Pavlides v. Galveston Yacht Basin, Inc.*, 727 F.2d 330, 338 (5th Cir. 1984)). Importantly, "[i]n 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 v. Armour of Am., Inc.*, 929 P.2d 340, 346 (Utah 1996).

Relevant to my analysis here, Utah courts adhere to the learned intermediary doctrine. As stated by the Supreme Court of Utah, under the learned intermediary doctrine, "manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient." *Schaerrer*, 79 P.3d at 928. The United States Court of Appeals for the Tenth Circuit,

applying Utah law, has predicted that Utah courts would likewise apply the learned intermediary doctrine to failure to warn claims arising out of the use of medical devices. *Tingey v. Radionics*, 193 F. App'x 747, 757 (10th Cir. 2006) ("Courts have applied this doctrine to claims involving medical devices, . . . and we assume Utah would do so as well."). Accordingly, I do the same.

Here, Ms. Hoffman has failed to present evidence demonstrating that the alleged inadequate warnings proximately caused her injuries. Indeed, the record does not show that Dr. Oldroyd, the implanting physician, would have altered his decision to prescribe the product had he known of additional warnings. *See House*, 929 P.2d at 346. Instead, to establish causation, Ms. Hoffman relies on Dr. Oldroyd's testimony that the warning provided on the Material Safety Data Sheet would "be cause for concern." (Oldroyd Dep. [Docket 79-2], at 88:2–3). Ms. Hoffman's evidence is insufficient. Indeed, such evidence requires a reasonable juror to speculate, based only on mere *possibility*, that Dr. Crouch would have altered his decision to prescribe the product simply because of "cause for concern." *See House*, 929 P.2d at 346. Accordingly, a reasonable juror cannot infer that allegedly inadequate warnings proximately caused Ms. Hoffman's injuries. Therefore, BSC's Motion for Summary Judgment on Ms. Hoffman's claims for failure to warn is **GRANTED**.

C. Negligence

Under Utah law, "[i]n a products liability case, the plaintiff must . . . prove that there was a duty owed by the defendant to the plaintiff, that the duty was breached and that the conduct complained of was the cause in fact of the injury." *Barson ex rel. Barson v. E.R. Squibb & Sons, Inc.*, 682 P.2d 832, 835 (Utah 1984). To determine "whether a duty of reasonable care exists, a court should consider 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.'" *Niemela v.*

Imperial Mfg., Inc., 263 P.3d 1191, 1198 (Utah Ct. App. 2011) (quoting *Slisze v. Stanley-Bostitch*, 979 P.2d 317, 320 (Utah 1999)).

Here, Ms. Hoffman's negligence claims fall into the same three categories as her strict liability claims: (1) negligent manufacturing, (2) negligent failure to warn, and (3) negligent design. (*See* Master Long Form Compl. & Jury Demand, MDL No. 2326, ¶¶ 55–59; Am. Short Form Compl. [Docket 7] ¶ 13). BSC has moved for summary judgment on each category. As noted above, Ms. Hoffman does not contest summary judgment on her negligent manufacturing claim.

1. Design Defect

As discussed above, *see supra* Section III.A, genuine disputes of material fact exist with regard to whether the Obtryx is unreasonably dangerous. Therefore, BSC's Motion for Summary Judgment on Ms. Hoffman's negligent design claim is **DENIED**.

2. Failure to Warn

As discussed above, *see supra* Section III.B, Ms. Hoffman has failed to present evidence demonstrating that the alleged inadequate warnings proximately caused her injuries. Therefore, BSC's Motion for Summary Judgment on Ms. Hoffman's negligent failure to warn claim is **GRANTED**.

D. Breach of Express Warranty

Under Utah law, an express warranty is "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part 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." Utah Code Ann. § 70A-2-313(1). Generally, "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). Critically, however, "a consumer can recover for breach of an express warranty despite a lack of privity." *State of Utah v.*

GAF Corp., 760 P.2d 310, 315 (Utah 1988). Thus, even if Ms. Hoffman merely relied on the medical judgment of Dr. Oldroyd in deciding to have the Obtryx implanted, a reasonable juror could find that Ms. Hoffman, naturally, relied on the express warranties of BSC as were allegedly provided to Dr. Oldroyd, which formed the basis for Dr. Oldroyd's medical judgment.[1]

Here, genuine disputes of material fact exist with regard to: (1) whether an express warranty was made; and (2) whether Dr. Oldroyd relied on the express warranty as the "basis of the bargain." *See* Utah Code Ann. § 70A-2-313(1). Therefore, BSC's Motion for Summary Judgment on Ms. Hoffman's breach of express warranty claim is **DENIED**.

E. Breach of Implied Warranty

BSC argues that Ms. Hoffman's breach of implied warranty claim fails because "[t]he term 'warranty' as used in tort law is synonymous with strict liability." *Salt Lake City Corp. v. Kasler Corp.*, 855 F. Supp. 1560, 1572 (D. Utah 1994). Because a reasonable juror could determine that BSC defectively designed the Obtryx, *see supra* Section III.A, 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). Therefore, BSC's Motion for Summary Judgment on Ms. Hoffman's breach of implied warranty claim is **DENIED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that BSC's Motion for Summary Judgment [Docket 56] is **GRANTED IN PART** with respect to Ms. Hoffman's claims for

[1] *Cf. Michael v. Wyeth, LLC*, No. CIV.A. 2:04-0435, 2011 WL 2150112, at *9 (S.D. W. Va. May 25, 2011) (denying summary judgment on breach of express warranty because even though "plaintiff testified that she did not rely on any statements made by defendants . . . she did rely upon her doctors' recommendations," and as a result, "a presumption arises that [manufacturer's] affirmations were at least part of the 'basis of the bargain' that led plaintiff to ingest [the] drugs"); *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 [defendant'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."); *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 602, 625 (E.D. Pa. 2008) (same).

manufacturing defect, under theories of strict liability and negligence; and failure to warn, under theories of strict liability and negligence. BSC's Motion for Summary Judgment is **DENIED IN PART** with respect to Ms. Hoffman's claims for strict liability for design defect, negligence, breach of implied warranty, and breach of express warranty.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: October 6, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE