

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS**

BARBARA JEAN DAVISON

Plaintiff,

vs.

Case No. 2:19-cv-02760-EFM-KGG

C.R. BARD, INC.,

Defendant.

MEMORANDUM AND ORDER

Plaintiff Barbara Davison filed a products liability suit against C.R. Bard, Inc. (“Bard”) arising from the implantation of a medical device designed and manufactured by Bard. This matter comes before the Court on two Motions filed by Bard: a Motion for Summary Judgment (Doc. 19) and a Motion to Exclude Davison’s expert witness, Dr. Konstantin Walmsley (Doc. 21). For the reasons explained below, the Court grants in part and denies in part Bard’s Motion for Summary Judgment. Additionally, the Court orders that it will hold a *Daubert* hearing on Bard’s Motion to Exclude.

I. Factual and Procedural Background

Barbara Davison sued Bard over complications arising from the implantation of an Ajust Adjustable Single Sling System (“Ajust sling”). In April 2010, Davison’s primary care physician referred Davison to Dr. Chu-Chi Chen, a board-certified urologist, after Davison complained of

an ongoing history with urinary tract infections (“UTI”) and stress urinary incontinence (“SUI”). After considering a range of treatment options, Dr. Chen and Davison agreed to treat Davison’s SUI through surgery. On June 29, 2010, Dr. Chen performed a cystoscopy, polypectomy and biopsy, and implanted an Ajust sling in Davison.

A week after the surgery, Davison attended a postoperative appointment with Dr. Chen, during which Davison stated that her SUI symptoms had improved but, also, that she was experiencing some low pelvic pressure. More than two years after the surgery, Davison began to experience pelvic pain, vaginal pain, and dyspareunia (pain during sexual intercourse) that increasingly worsened. Davison’s pain continued for several years until Davison was treated by Dr. Dionysius Veronikis in December 2015. Dr. Veronikis concluded that Davison’s pain was related to the Ajust sling. Dr. Veronikis removed Davison’s Ajust sling, after which Davison’s pain symptoms dramatically improved.

On January 17, 2017, Davison filed a Short Form Complaint directly into *In re: C.R. Bard, Inc. Pelvic Repair System Products Liability Litigation*, MDL Number 2187, in the U.S. District Court for the Southern District of West Virginia. The MDL’s Master Complaint raised eight Counts: (Count I) Negligence—designing, manufacturing, marketing, labeling, packaging and selling (Count II) Strict Liability—Design Defect; (Count III) Strict Liability—Manufacturing Defect; (Count IV) Strict Liability—Failure to Warn; (Count V) Breach of Express Warranty; (Count VI) Breach of Implied Warranty; (Count VII) Loss of Consortium; and (Count VIII) Punitive Damages. Davison, in her Short Form Complaint, opted to bring a claim under every Count except Count VII (Loss of Consortium).

Dr. Konstantin Walmsley provided an expert report on Davison’s behalf. In this report, Dr. Walmsley opines that Bard’s Ajust sling contained various avoidable design defects that made

the product unsafe for use. He also opines that Bard failed to adequately warn physicians that certain characteristics of the Ajust sling—including pore size, mesh weight, degradation, cytotoxicity, and incompatibility with strong oxidizers—increased the likelihood that patients would suffer adverse outcomes.

While this case was still in the Southern District of West Virginia, Bard filed a Motion for Summary Judgment and a Motion to Exclude the Opinions and Testimony of Dr. Walmsley. Shortly after the motions were fully briefed, the case was transferred to the United States District Court for the District of Kansas for final resolution. This Court has reviewed the pleadings and exhibits on both motions, and now rules as follows.

II. Legal Standard

A. Motion to Exclude

The Court is obligated to act as a gatekeeper with respect to the admission of expert testimony.¹ Rule 702 of the Federal Rules of Evidence governs the admissibility of opinions based on scientific, technical, or specialized knowledge. Rule 702 provides that:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.²

¹ *Esparza v. Regent Ins. Co.*, 2019 WL 3020898, at *2 (D. Kan. 2019).

² Fed. R. Evid. 702(a)–(d).

The burden is on the proponent of expert testimony to show “ ‘a grounding in the methods and procedures of science’ which must be based on actual knowledge and not ‘subjective belief or unaccepted speculation.’ ”³ To determine whether an expert opinion is admissible, the Court performs a two-step analysis. First, the Court must determine “if the expert’s proffered testimony . . . has ‘a reliable basis in the knowledge and experience of his or her discipline.’ ”⁴ The Court must then inquire into whether the proposed testimony is sufficiently “relevant to the task at hand.”⁵ An expert opinion “must be based on facts which enable [him] to express a reasonably accurate conclusion as opposed to conjecture or speculation, . . . [but] absolute certainty is not required.”⁶

In *Daubert*, the Supreme Court provided a non-exhaustive list of four factors that the trial court may consider when conducting its inquiry under Rule 702: (1) whether the theory used can be and has been tested; (2) whether it has been subjected to peer review and publication; (3) the known or potential rate of error; and (4) general acceptance in the scientific community.⁷ Each factor may or may not be pertinent, depending on the nature of a particular issue, the expert’s particular expertise, and the subject of the expert’s testimony.⁸ “The court has ‘considerable

³ *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 780 (10th Cir. 1999) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993)).

⁴ *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1232–33 (10th Cir. 2005) (quoting *Daubert*, 509 U.S. at 592) (alterations omitted); see also *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 883–84 (10th Cir. 2005).

⁵ *Norris*, 397 F.3d at 884.

⁶ *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1222 (10th Cir. 2003) (quotation omitted).

⁷ *Daubert*, 509 U.S. at 593–94.

⁸ *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 153 (1999).

leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.’ ”⁹

B. Summary Judgment

Summary judgment is appropriate if the moving party demonstrates that there is no genuine issue as to any material fact, and the movant is entitled to judgment as a matter of law.¹⁰ A fact is “material” when it is essential to the claim, and issues of fact are “genuine” if the proffered evidence permits a reasonable jury to decide the issue in either party’s favor.¹¹ The movant bears the initial burden of proof and must show the lack of evidence on an essential element of the claim.¹² If the movant carries its initial burden, the nonmovant may not simply rest on its pleading but must instead “set forth specific facts” that would be admissible in evidence in the event of trial from which a rational trier of fact could find for the nonmovant.¹³ These facts must be clearly identified through affidavits, deposition transcripts, or incorporated exhibits—conclusory allegations alone cannot survive a motion for summary judgment.¹⁴ The Court views all evidence and reasonable inferences in the light most favorable to the party opposing summary judgment.¹⁵

⁹ *Esparza*, 2019 WL 3020898, at *2 (quoting *Kumho Tire*, 526 U.S. at 152).

¹⁰ Fed. R. Civ. P. 56(a).

¹¹ *Haynes v. Level 3 Commc’ns, LLC*, 456 F.3d 1215, 1219 (10th Cir. 2006).

¹² *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 851 (10th Cir. 2003) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23, 325 (1986)).

¹³ *Id.* (citing Fed. R. Civ. P. 56(e)).

¹⁴ *Mitchell v. City of Moore*, 218 F.3d 1190, 1197 (10th Cir. 2000) (citing *Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 671 (10th Cir. 1998)).

¹⁵ *LifeWise Master Funding v. Telebank*, 374 F.3d 917, 927 (10th Cir. 2004).

III. Analysis

A. Bard's Motion to Exclude (Doc. 21)

Bard seeks to exclude the opinions and testimony of Davison's expert witness, Dr. Konstantin Walmsley, under Federal Rule of Evidence 702 and *Daubert*. The Court has broad discretion in determining how to perform its gatekeeping function under *Daubert*—the “most common method for fulfilling this function is a *Daubert* hearing, although such a process is not specifically mandated.”¹⁶ Here, although neither party has requested that a *Daubert* hearing be held, the Court determines, after a careful review of the pleadings, that it would be prudent to hold a *Daubert* hearing before the Court renders a decision on Bard's Motion to Exclude.

Furthermore, after the Court's review of the pleadings on Bard's Motion for Summary Judgment, it is evident that the merits of Bard's Motion for Summary Judgment hinge, at least in part, on whether Dr. Walmsley's expert opinions are admissible. Therefore, to the extent that the Court can rule on Bard's Motion for Summary Judgment independent of whether Dr. Walmsley's opinions pass *Daubert* scrutiny, the Court rules as follows. But to the extent such a ruling is contingent on deciding Bard's Motion to Exclude, the Court holds its ruling on those claims in abeyance until a *Daubert* hearing is conducted and a ruling is issued on Bard's Motion to Exclude.

B. Bard's Motion for Summary Judgment (Doc. 19)

The Kansas Product Liability Act (“KPLA”) governs “all product liability claims regardless of the substantive theory of recovery.”¹⁷ This includes:

[A]ny claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly,

¹⁶ *Energy Intelligence Grp., Inc. v. CHS McPherson Refinery, Inc.*, 300 F. Supp. 3d 1356, 1381–82 (D. Kan. 2018) (citations omitted).

¹⁷ *Savina v. Sterling Drug, Inc.*, 247 Kan. 105, 795 P.2d 915, 931 (1990).

installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product. It includes, but is not limited to, any action based on, strict liability in tort, negligence, breach of express or implied warranty, breach of, or failure to, discharge a duty to warn or instruct, whether negligent or innocent, misrepresentation, concealment or nondisclosure, whether negligent or innocent, or under any other substantive legal theory.

“To establish a prima facie case based on negligence or strict liability in a products liability case, a plaintiff must produce evidence to establish three elements: (1) the injury resulted from a condition of the product; (2) the condition was an unreasonably dangerous one; and (3) the condition existed at the time it left defendant’s control.”¹⁸ “Kansas law recognizes three ways in which a product may be defective: (1) a manufacturing defect; (2) a warning defect; and (3) a design defect.”¹⁹ “[R]egardless of the theory upon which recovery is sought for injury, proof that a product defect caused the injury is a prerequisite to recovery, and the condition which caused the injury—be it a manufacturing defect, a warning defect or a design defect—must have existed at the time the product left defendant’s control.”²⁰

Here, Davison seeks to recover damages from Bard under the following legal theories: (Count I) Negligence—designing, manufacturing, marketing, labeling, packaging and selling (Count II) Strict Liability—Design Defect; (Count III) Strict Liability—Manufacturing Defect; (Count IV) Strict Liability—Failure to Warn; (Count V) Breach of Express Warranty; (Count VI) Breach of Implied Warranty; (Count VIII) Punitive Damages. The Master Complaint included a potential claim for Loss of Consortium (Count VII), but Davison opted not to bring this claim.

¹⁸ *Messer v. Amway Corp.*, 210 F. Supp. 2d 1217, 1227 (D. Kan. 2002), *aff’d*, 106 F. App’x 678 (10th Cir. 2004) (citing *Jenkins v. Amchem Prods., Inc.*, 256 Kan. 602, 886 P.2d 869, 886 (1994)).

¹⁹ *Delaney v. Deere & Co.*, 268 Kan. 769, 999 P.2d 930, 936 (2000)

²⁰ *Messer*, 210 F. Supp. 2d at 1227 (citations omitted).

Bard filed a Motion for Summary Judgment on all of Davison’s claims. Davison, in her Response, only addressed Bard’s arguments with respect to her claims for manufacturing defect, design defect, and failure to warn. So, the Court will begin its analysis with those claims.

1. Manufacturing Defect

A manufacturing defect claim under Kansas law requires proof “that a flaw was present in the product at the time it was sold and that the defective condition caused the claimed injury.”²¹ Unlike a design defect, which applies to every unit of a product, a manufacturing defect occurs when the plaintiff’s specific unit does not conform to the product’s design specifications.²²

Here, Bard argues that Davison’s manufacturing defect claims fail for lack of any evidentiary support. In response, Davison argues that her expert—Dr. Konstantin Walmsley—opines that various defects exist in both the design and manufacture of the Ajust sling. Although Davison cites generally to Dr. Walmsley’s Expert Report without highlighting any specific portion of that report, Davison does list a series of alleged defects with the Ajust sling, including fraying, oxidation, roping, degradation, pore size, and the use polypropylene mesh. Bard, in reply, argues that Davison is erroneously relying on testimony that the Ajust sling was defectively designed to assert that the Ajust sling contained a manufacturing defect. The Court agrees.

Setting aside the question raised by Bard regarding Dr. Walmsley’s qualifications to opine on the adequacy of Bard’s manufacturing process, a review of Dr. Walmsley’s Expert Report reveals no opinions that the Ajust sling implanted in Davison differed from other Ajust slings or did not conform with Bard’s design specifications. Rather, Dr. Walmsley opines that each of the

²¹ *Lapham v. Watts Regulator Co.*, 2016 WL 248471, at *7 (D. Kan. 2016) (citations omitted).

²² See *Jenkins*, 886 P.2d at 887 (finding no viable manufacturing defect claim because the plaintiff did not assert that the product contained a flaw not present in other product units).

alleged defects mentioned by Davison—fraying, oxidation, roping, degradation, pore size, and the type of polypropylene—are design defects in all of Bard’s Ajust slings. A manufacturing defect claim requires proof that the plaintiff’s specific product does not conform with the product’s design specifications, and Davison presents no evidence that her Ajust sling contained such a flaw. Accordingly, the Court grants summary judgment in Bard’s favor on Davison’s manufacturing defect claims in Counts I and III.

2. *Design Defect*

Bard seeks summary judgment on Davison’s defective design claims brought under theories of negligence (Count I) and strict liability (Count II). Bard argues it is entitled to summary judgment for two reasons. First, Bard asserts that Davison has presented insufficient evidence to show that a design defect caused her injuries. Second, Bard argues that Davison’s design defect claims are barred by Comment k to the Restatement (Second) of Torts § 402A. The Court considers each in turn.

i. Causation

To prevail on a defective design claim, Davison must show that her injuries were caused by a defect in the design of her Ajust sling.²³ To show causation, Davison primarily relies on the opinions of her designated expert, Dr. Walmsley. In addition, Davison relies on her own testimony in which she recalls that her gynecologist, Dr. Kresie, attributed her injuries to the Ajust sling. Finally, Davison relies on the testimony of Dr. Veronikis, who surgically removed Davison’s Ajust sling.

²³ *Wilcheck v. Doonan Truck & Equip., Inc.*, 220 Kan. 230, 552 P.2d 938, 942 (1976) (stating that “proof that a defect in the product caused the injury is a prerequisite to recovery”).

As an initial matter, the Court concludes that Davison's reliance on her own testimony and Dr. Veronikis' testimony is misplaced. Regarding Davison's testimony, Davison stated that Dr. Kresie told her that "what [she] had gone through was related to the mesh." The Court discerns, at a minimum, three problems with Davison's reliance on Dr. Kresie's opinion. First, it is hearsay.²⁴ Second, even if Dr. Kresie's statement were admissible, Dr. Kresie's does not provide any facts supporting her opinion that Davison's pain is related to the Ajust sling.²⁵ Third, even if Dr. Kresie held the opinion that Davison's injuries are "related to the mesh," Dr. Kresie does not opine that the injuries were caused by a *design defect* in the product. Based on these shortcomings, Dr. Kresie's purported statement cannot defeat Bard's Motion for Summary Judgment.

Davison's reliance on Dr. Veronikis' deposition testimony is likewise unavailing because Dr. Veronikis never connected Davison's injuries with a design defect in the Ajust sling. Granted, Dr. Veronikis did attribute Davison's pain with her Ajust sling. But Dr. Veronikis opined that the problem with Davison's mesh was related to the implantation method, not the product itself. Indeed, contrary to Davison's position that polypropylene mesh is unsuitable for implantation in humans, Dr. Veronikis stated: "Do I think that a piece of polypropylene mesh implanted as the engineer designed it is safe, as long as the surgeon implants it in the right spot, yes."²⁶ Davison points to no statement by Dr. Veronikis linking Davison's injuries with any of the alleged design defects in Bard's Ajust slings.

²⁴ See *Samarah v. Danek Med., Inc.*, 70 F. Supp. 2d 1196, 1206 (D. Kan. 1999).

²⁵ *Id.* ("Even if this statement were [not hearsay], however, the court finds it insufficient to prevent summary judgment because it is unsupported by specific facts to support the conclusion for which it stands.").

²⁶ Doc. 19, Exhibit 5, at 8; *id.* at 13 ("[T]he implantation technique, although [] not part of the litigation, is what forces the mesh to do this.").

Davison also argues that causation can be inferred from her own testimony and Dr. Veronikis' testimony which shows that Davison and her treating physicians pursued several theories to remedy Davison's pain, but Davison drastically improved only after Dr. Veronikis removed the Ajust sling. The Court agrees that this evidence has some relevance, as it shows at least a correlation between Davison's injuries and the Ajust sling. But correlation is not causation, and the Court agrees with Bard that this matter is sufficiently complex that to prove causation requires expert testimony.²⁷ Circumstantial evidence alone is not enough to survive summary judgment.

The only expert opinion evidence Davison puts forth on the issue of causation comes from Dr. Walmsley, who, as the Court discussed above, is the subject of Bard's Motion to Exclude. Simply put, if Dr. Walmsley's expert opinions on causation pass *Daubert* scrutiny, Davison has sufficient evidence on the issue of causation to survive summary judgment. Conversely, if Dr. Walmsley's expert opinions on causation are deemed unreliable, Bard is entitled to summary judgment as Dr. Walmsley is Davison's only expert who can speak to causation.

ii. Comment k defense

Bard also argues that Davison's design defect claims are barred by Comment k to the Restatement of Torts (Second) § 402A. Comment k protects a product seller from liability when a product is unavoidably unsafe.²⁸ Comment k states:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads

²⁷ See *Savina*, 795 P.2d at 936.

²⁸ *Id.* at 924.

to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

In Kansas, a product seller is protected from liability under the Comment k exception if: (1) the product was properly manufactured and provided adequate warnings, (2) the product's benefits justify its risks, and (3) the product was incapable of being made safer.²⁹

Bard appears to argue that both of Davison's design defect claims are barred by Comment k. However, Comment k applies to design defect claims based only on strict liability—it does not apply to negligent design claims.³⁰ So, the Court's analysis of Bard's Comment k defense applies only to Davison's strict liability design defect claim (Count II). The Court denies Bard's Motion for Summary Judgment on Davison's negligent design claim (Count I) based on a Comment k defense.

Regarding Count II, Bard argues that each element of a Comment k defense is met here. Under the first element, Bard must show that Davison's Ajust sling was properly manufactured

²⁹ *See id.* at 924–26.

³⁰ *Id.* at 924 (“Comment k establishes an exception to the test for *strict product liability* as set forth in § 402A.”) (emphasis added).

and accompanied by appropriate warnings. As discussed above, the Court grants summary judgment on Davison’s manufacturing defect claim because Davison presented no evidence that her Ajust sling did not comply with Bard’s design specifications. For that same reason, the Court agrees with Bard that it has satisfied that element of a Comment k defense.

Bard also argues that the Ajust sling contained adequate warnings because the product’s Instructions for Use (“IFU”) stated that pain and dyspareunia were possible adverse outcomes following the implantation of an Ajust sling. “The test to determine adequacy of a warning is whether the warning is ‘reasonable under the circumstances.’”³¹ Davison asserts that the Ajust sling contained inadequate warnings because the Ajust sling IFU did not warn that certain characteristics of the Ajust sling—including pore size, mesh weight, degradation, cytotoxicity, and incompatibility with strong oxidizers—increased the likelihood for adverse outcomes.

Davison’s argument that the IFU’s warning was inadequate relies on Dr. Walmsley’s expert opinions. But Bard argues that Dr. Walmsley is not qualified to opine on the adequacy of the Ajust sling IFU. The Court is reserving its ruling on Dr. Walmsley’s qualifications pending a *Daubert* hearing. Therefore, the Court will likewise hold in abeyance ruling on the merits of Bard’s Comment k defense until the Court holds a *Daubert* hearing and rules on whether to admit or exclude Dr. Walmsley’s opinions on the adequacy of the warnings.

In sum, both of Bard’s arguments for granting summary judgment on Davison’s design defect claims—no evidence of causation and a Comment k defense—hinge on the admissibility of Dr. Walmsley’s expert opinions. Thus, the Court will hold in abeyance ruling on Bard’s Motion

³¹ *Humes v. Clinton*, 246 Kan. 590, 792 P.2d 1032, 1043 (1990).

for Summary Judgment on Davison’s defective design claims pending a ruling on Bard’s Motion to Exclude.

3. *Failure to Warn*

Davison asserts claims for negligent failure to warn (Count I) and strict liability failure to warn (Count IV). “Under Kansas law, [a] product, though perfectly designed and manufactured, may be defective if not accompanied by adequate warnings of its dangerous characteristics.”³² A failure to warn claim, whether based on negligence or strict liability, “is measured by whether the warning was reasonable under the circumstances.”³³ To hold a product seller liable for a defective warning, the seller must have “actually or constructively known of the risk that triggers the warning.”³⁴ Indeed, in this way, the Kansas Supreme Court has indicated that there is little difference in bringing a defective warning claim under a negligence or strict liability theory.³⁵ In cases involving medical devices, Kansas courts apply the learned intermediary doctrine, which states that a manufacturer or seller satisfies its duty to warn when it warns the prescribing doctor of the product’s inherent risks.³⁶

Before discussing the issues raised in Bard’s Motion, the Court first addresses Davison’s argument regarding the KPLA’s exceptions to the duty to warn, codified in K.S.A. § 60-3305. Candidly, Davison’s argument on this issue is difficult to follow. Davison first declares that the KPLA does not preempt her failure to warn claim. To support this argument, Davison cites K.S.A.

³² *Messer*, 106 F. App’x at 684 (citation and quotations omitted).

³³ *Messer*, 210 F. Supp. 2d at 1229.

³⁴ *Savina*, 795 P.2d at 928.

³⁵ *Id.*

³⁶ *See Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1121 (D. Kan. 2002).

§ 60-3305, which states that the KPLA does not impose a duty to warn in the following circumstances:

(b) to situations where the safeguards, precautions and actions would or should have been taken by a reasonable user or consumer of the product similarly situated exercising reasonable care, caution and procedure; or

(c) to warnings, protecting against or instructing with regard to dangers, hazards or risks which are patent, open or obvious and which should have been realized by a reasonable user or consumer of the product.³⁷

Simply put, under § 60-3305, the KPLA carves out exceptions to the general duty to warn, including when the product's danger is open and obvious.³⁸ In defending against a failure to warn claim, a seller or manufacturer may rely on § 60-3305's exceptions to argue that it had no duty to warn a product user of certain dangers.³⁹

Here, Davison argues that summary judgment is inappropriate because factual questions exist about whether § 60-3305's exceptions apply in this case. The problem with this line of argument, however, is that Bard has not invoked any of § 60-3305 exceptions to argue that the company had no duty to provide adequate warnings. Instead, Bard takes the position that it did provide adequate warnings. For this reason, the Court cannot discern how § 60-3305 has any relevance to this case.⁴⁰ Indeed, it appears that Davison is attempting to refute a defense to liability that Bard never raised. Thus, the Court determines that Davison's discussion of § 60-3305 does not provide a reason to deny Bard's Motion for Summary Judgment.

³⁷ K.S.A. § 60-3305(b)-(c).

³⁸ See *Hiner v. Deere & Co.*, 340 F.3d 1190, 1193-94 (10th Cir. 2003).

³⁹ See *id.*

⁴⁰ Furthermore, even if Bard had argued that one of § 60-3305's exceptions applies in this case, it is unclear to the Court how § 60-3305 relates to Davison's argument that the KPLA does not "preempt" or "supersede" her failure to warn claim.

Next, Bard argues that summary judgment on Davison's failure to warn claims is appropriate for two reasons. First, Bard argues that Davison cannot prove that Bard's warnings were inadequate. Second, Bard argues that even if Davison had evidence that Bard's warnings were inadequate, Davison cannot prove that the defective warning was the proximate cause of Davison's injuries.

As the Court previously discussed, Davison's sole evidence that Bard's warnings were inadequate comes from Dr. Walmsley. Dr. Walmsley opines that Bard failed to adequately inform physicians about all the possible dangers associated with the Ajust sling in the products IFU. Bard, in turn, challenges Dr. Walmsley's qualification to opine on the adequacy of the Ajust sling IFU. Whether summary judgment should be granted on Davison's failure to warn claim is, ultimately, contingent on the admissibility of Dr. Walmsley's expert opinions regarding the contents of the IFU. Thus, it is currently unclear whether a genuine factual dispute exists regarding the adequacy of Bard's warnings. The Court will reserve its ruling on this issue pending the *Daubert* hearing and its ruling on Bard's Motion to Exclude.

Bard's second argument, however, is not connected to the admissibility of Dr. Walmsley's testimony. Here, Bard argues that even if the warnings accompanying the Ajust sling were inadequate, Davison cannot show that those defective warnings caused her injuries. Both parties agree that in this type of case—one involving a medical device with a learned intermediary—Davison is entitled to a presumption of causation.⁴¹ Bard can rebut that presumption by showing

⁴¹ See *Vanderwerf v. SmithKlineBeecham Corp.*, 529 F. Supp. 2d 1294, 1309 (D. Kan. 2008).

that Davison's implanting physician, Dr. Chen, would have prescribed the Ajust sling even with the additional warnings.

Bard argues that it has rebutted the presumption of causation because Dr. Chen testified that, even if additional or different warnings were included in the Ajust sling IFU, Dr. Chen would still have recommended the Ajust sling to Davison. The Court, however, does not have the same reading of Dr. Chen's deposition testimony as Bard. Bard cites the following excerpt from Dr. Chen's deposition testimony:

Q. If there was a different warning in the precautions or the adverse events section of the instructions for use for the AJUST sling, would that have changed your decision to implant the AJUST in Ms. Davison?

...

A. If there [was] more information to know if AJUST have a difference, then I would learn I may change mind, but at that time I thought it, I learned AJUST was good for her. So, no, no change.

Although Dr. Chen's answer is not entirely clear—and a review of Dr. Chen's testimony immediately preceding this line of inquiry shows that he was having difficulty understanding Bard's attorney's question on this matter—it appears to the Court that Dr. Chen is indicating that additional warning *may* have changed his prescribing decision. At the very least, the Court concludes that Dr. Chen's position on this matter is inconclusive. Because the onus is on Bard to establish that the prescribing physician would not have changed his course of treatment, the Court holds that Bard has failed to rebut the presumption of causation. So, the Court denies the motion for summary judgment on Davison's failure to warn claims based on Bard's proximate causation argument.

4. *Davison's remaining claims*

With respect to Davison's claims for breach of implied warranty, breach of express warranty, and negligent inspection, marketing, packaging, and selling, Bard contends that summary judgment is appropriate because Davison either brings no evidence in support of these claims or lacks a legal basis for recovery.⁴² Davison, in her Response, failed to address these claims in any way. As a result, the Court concludes that Davison has abandoned these claims. Therefore, the Court grants summary judgment on these claims based on Davison's failure to oppose summary judgment or address the concerns raised by Bard in its memorandum in support of its Motion.⁴³

Finally, Bard seeks summary judgment on Davison's claim for punitive damages (Count VIII). Bard argues that a claim for punitive damages is derivative, meaning Davison must first be entitled to actual or compensatory damages before punitive damages can be awarded. Thus, Bard argues that if all of Davison's other claims are dismissed, her claim for punitive damages necessarily fails. The Court agrees with Bard's position. However, although it is possible that each of Davison's claims will be dismissed following a ruling on Bard's Motion to Exclude, currently the Court is delaying ruling on Davison's design defect and failure to warn claims.

⁴² Bard also argues that Count VII—loss of consortium—should be dismissed. But Davison's Short Form Complaint stated that she was not raising a loss of consortium claim, so the Court need not make a ruling on this matter.

⁴³ *Scotwood Indus., Inc. v. Frank Miller & Sons, Inc.*, 435 F. Supp. 2d 1160, 1171 (D. Kan. 2006) (citing *Hinsdale v. City of Liberal*, 19 F. App'x 749, 768–69 (10th Cir. 2001)) (holding that party who failed to respond to arguments raised in motion for summary judgment abandoned those claims making summary judgment appropriate); see also *Freebird Commc'ns, Inc. Profit Sharing Plan v. Roberts*, 2019 WL 5964583, at *7 (D. Kan. 2019) (“Because Plaintiffs do not address Defendants’ arguments with respect to their aiding and abetting tortious interference, aiding and abetting conversion, and aiding and abetting misappropriation of trade secrets claims, they have abandoned them, and summary judgment on those claims is warranted on that basis.”).

Accordingly, it would be premature for the Court to rule on Bard's request for summary judgment on Davison's claim for punitive damages.

IT IS THEREFORE ORDERED that C. R. Bard, Inc.'s Motion for Summary Judgment (Doc. 19) is **GRANTED IN PART AND DENIED IN PART**. Specifically, summary judgment is **GRANTED** in Bard's favor on Davison's Negligent Manufacturing, Marketing, Inspection, Packaging, and Selling claims (Count I), Strict Liability Manufacturing defect claim (Count III), Breach of Express Warranty claim (Count V), and Breach of Implied Warranty claim (Count VI). The Court will **HOLD IN ABEYANCE** ruling on Bard's Motion for Summary Judgment on Davison's Negligent Design and Failure to Warn claims (Count I), Strict Liability Design Defect claim (Count II), Strict Liability Failure to Warn claim (Count IV), and Punitive Damages claim (Count VIII).

IT IS FURTHER ORDERED that the Court will hold a *Daubert* hearing on Bard's Motion to Exclude the Opinions and Testimony of Dr. Konstantin Walmsley (Doc. 21).

IT IS SO ORDERED.

Dated this 15th day of May, 2020.



ERIC F. MELGREN
UNITED STATES DISTRICT JUDGE