IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

CLEMENTINA ROEDER and
RONALD ROEDER, JR.,

Plaintiffs,

v. Case No. 20-1051-JWB

AMERICAN MEDICAL SYSTEMS, INC.,

Defendant.

MEMORANDUM AND ORDER

This matter comes before the court on Defendant's motion for summary judgment (Doc. 85). The motion has been fully briefed and the court is prepared to rule. (Docs. 86, 91, 98.) For the reasons stated herein, Defendant's motion is GRANTED IN PART and DENIED IN PART.

I. Facts and Procedural History

This is a products liability action filed by Plaintiff Clementina Roeder (individually, "Plaintiff") and her husband Ronald Roeder, Jr. (together with Plaintiff, hereinafter referred to as "Plaintiffs") involving injuries allegedly sustained by Plaintiffs due to Defendant's products. On September 2, 2015, Plaintiffs filed a short form complaint against Defendant in an MDL action involving Defendant. *See In re: American Medical Systems, Inc., Pelvic Repair Systems Products Liability Litigation*, Case No. 12-MD-2325 ("MDL"). In that action and as raised in the pretrial order in this case, Plaintiffs seek damages on the basis that Plaintiff suffered significant injuries due to the implantation of Defendant's products.

The following facts are uncontroverted for the purpose of this motion. On January 6, 2011, Plaintiff complained to her physician Dr. Darrell Werth of stress incontinence and discomfort.

Plaintiff had previously suffered from stress urinary incontinence ("SUI") and pelvic organ prolapse ("POP"). Plaintiff was diagnosed with a large cystocele (bladder prolapse) with associated uterine prolapse and urethral hypermobility. Dr. Werth recommended a hysterectomy with anterior mesh cystocele repair and sling suspension of the bladder neck. The proposed treatment involved implanting two vaginal mesh products ("the products"), the MiniArc Precise ("MiniArc") for SUI and the Elevate Anterior Apical System with IntePro Lite ("Elevate") for POP. Defendant American Medical Systems, Inc., manufactured and sold the products. (Docs. 66 at 3-5; 86 at 8-9; 91 at 7.) Dr. Werth testified that he believed that the products were the best options for Plaintiff at the time of treatment. (Doc. 86-2 at 58:23-59:1.)

At the time of treatment, Dr. Werth had implanted over 100 mesh devices for the treatment of POP and over 500 mesh slings. Dr. Werth testified that he was aware at the time of Plaintiff's procedure of risks of infection, chronic pain, vaginal bleeding, dyspareunia (pain with intercourse), and continued incontinence. (Doc. 86-2 at 24:23-27:8, 30:2-24.) Both products have Instructions for Use ("IFUs") that include associated risks with the products. Dr. Werth does not recall relying on the IFUs but he was aware of the risks listed in the IFUs prior to Plaintiff's procedure. Dr. Werth testified that he did not tell Plaintiff about the possibility of painful sex and that she could experience chronic pain after implantation of the products. (Doc. 91-2 at 73:21-74:13.)

Plaintiff told Dr. Werth that she did not want to be implanted with a product that would be "faulty later on." (Doc. 91-1 at 102:22-103:1.) Plaintiff did some internet research on mesh implants and found that some women were having trouble but Plaintiff did not see any evidence of lawsuits regarding the mesh. (*Id.* at 102:11-17.) Dr. Werth allegedly told Plaintiff that he implanted the mesh into his wife, so it was safe. (*Id.* at 103:6-9.) This information resulted in Plaintiff deciding to go ahead with the implant procedure. (*Id.*) Plaintiff signed an informed

consent form stating that she understood that the procedure involved some risks including pain or difficulty with sexual intercourse. (*Id.* at 95:6-96:9.)

The facts surrounding the communication by Dr. Werth of the risks of the mesh to Plaintiff are in dispute here. Although Dr. Werth testified that his routine is to provide a patient with the pamphlet with the risks, which was provided by Defendant, Dr. Werth didn't document this in Plaintiff's case and Plaintiff disputes that she was provided with pamphlets regarding the mesh. (*Id.* at 93:19-21; 86-2 at 19:9-24.) Dr. Werth has also testified that he reviewed the risks of the procedure and the potential for mesh erosion, infection, and bleeding with Plaintiff. (Doc. 86-2 at 18:23-19:8.) Plaintiff has testified, however, that she was not informed of the risks or complications associated with the mesh but that she was only told about the risks associated with surgery. (Doc. 91-1 at 92:21-93:11.) Plaintiff further testified that had she been told that the products would make her more susceptible to urinary tract infections, bleeding, and pain during intercourse, she would not have consented to the procedure. (*Id.* at 132:22-133:10.)

On June 9, 2011, Plaintiff underwent the implant procedure in which the Elevate and MiniArc mesh products were implanted by Dr. Werth to treat Plaintiff's conditions. Immediately after, Plaintiff complained of pain, vaginal bleeding, and worsening incontinence. (Docs. 86 at 4; 91 at 5.) Plaintiff also noticed dyspareunia upon resuming intercourse. Plaintiff also experienced four to five urinary tract infections per year following the implant procedure. (Docs. 86 at 10; 91 at 9-10.)

On August 15, 2011, Plaintiff had a follow-up appointment with Dr. Werth. Plaintiff's medical records show that she reported that she had good bladder control and no discomfort. (Doc. 91-4 at 2.) Her pelvic examination on that date showed good suspension of her cystocele and bladder neck and no sign of mesh erosion. (*Id.*)

On November 1, 2012, Plaintiff had a follow-up appointment with Dr. Werth. The medical records note that Plaintiff had seen advertisements on television regarding mesh repairs. (Doc. 91-5 at 2.) Plaintiff testified that at the time she believed something was wrong with her mesh. (Doc. 91-1 at 125:6-9.) She also testified that she didn't know if there was a problem at that time. (*Id.* at 100:25-101:6.) Plaintiff wanted Dr. Werth to check out the mesh to make sure it was healing okay because she didn't think it was. (*Id.*) Dr. Werth testified that he told Plaintiff that her mesh was doing fine and healing properly. He noted in her records that she had "good support" and no "signs of erosion." (Docs. 91-2 at 49:21-50:2; 91-5 at 2.) The medical records note that Dr. Werth "explained to [Plaintiff] that the mesh itself is not an issue, that it is not toxic. The lawsuits are revolving [sic] some complications that occurred with some of the earlier mesh kits and some apparent complications that developed with poorly trained surgeons but in itself this repair should continue to give her good support and not pose any health problems. She seems comfortable with this." (Doc. 91-5 at 2.) After November 2012, Plaintiff did not see Dr. Werth as a provider.

On July 1, 2015, Plaintiff saw Dr. Brian Flynn and complained of constant vaginal pain and burning, painful sexual intercourse, bleeding, infections, and frequent/urgent urination. Dr. Flynn diagnosed Plaintiff with SUI, cystocele, urinary tract infections, dyspareunia, and complication of genitourinary device. (Doc. 91-6 at 3.) Dr. Flynn believed that Plaintiff's mesh exposure was the cause of her pain and dyspareunia and advised Plaintiff to undergo a near total mesh explant due to her chronic exposure to the mesh and his concern that the mesh was contaminated because bacteria was growing on the mesh. (Doc. 91-7 at 76:23-78:16.) Plaintiff testified that it was at this appointment when she first attributed her pain and other symptoms to the mesh. (Doc. 91-1 at 133:24-134:3.)

The material used in the products, polypropylene mesh, was recommended by its manufacturer for use in carpet backing, ropes, and cordage products. Plaintiff has offered evidence from the manufacturer, Total Petrochemicals, and Dr. Rosenzweig, her expert, that this material is unsuitable for permanent human implantation. Defendant disputes this and has offered its own expert who has opined that the mesh is a safe treatment option. (Docs. 91 at 13; 98 at 7.) Dr. Werth testified that he did not know that Total Petrochemicals wrote a letter dated June 29, 2010, stating that its product is not suitable for human implants. (Doc. 91 at 13; 98 at 7.) He further testified that he does not know whether polypropylene would have a different effect in the abdomen compared to the vagina and would want to know if there were detrimental effects to implanting mesh in the vagina. If there were detrimental effects in implanting polypropylene in the vagina, Dr. Werth would not use those products. (Doc. 91-2 at 81:2-82:1.) Further, Dr. Werth testified that he would want to know if polypropylene mesh was not inert and, as a result, could have detrimental effects on a body. His concern would be toxicity. (*Id.* at 83:6-9.)

Dr. Rosenzweig has opined that the mesh is not inert in that it will degrade over time and that this leads to long term complications. (Doc. 91-10 at 17-22.) Defendants dispute Dr. Rosenzweig's opinions and assert that the mesh is safe for implantation and that all risks were communicated to implanting physicians. (Doc. 98 at 8.) Although this fact is disputed, Plaintiffs contend that the IFUs do not adequately communicate to the user the frequency and severity of the risks disclosed and the safety and effectiveness of the products.

Defendant now moves for summary judgment on the basis that Plaintiffs' claims are barred by the statute of limitations and, alternatively, that her claim under the Kansas Product Liability Act ("KPLA") fails as a matter of law.

II. Standard

Summary judgment is appropriate if the moving party demonstrates that there is no genuine dispute as to any material fact. Fed. R. Civ. P. 56(a). A fact is "material" when it is essential to the claim, and the issues of fact are "genuine" if the proffered evidence permits a reasonable jury to decide the issue in either party's favor. *Haynes v. Level 3 Commc'ns*, 456 F.3d 1215, 1219 (10th Cir. 2006). The court views all evidence and reasonable inferences in the light most favorable to the nonmoving party. *LifeWise Master Funding v. Telebank*, 374 F.3d 917, 927 (10th Cir. 2004).

III. Analysis

This action is brought under the Kansas Product Liability Act ("KPLA"), K.S.A. 60–3301. There are three primary theories of recovery in a product liability case: "(1) negligence; (2) breach of express or implied warranty; and (3) strict liability." *Jones v. Tanks Plus, L.L.C.*, 2013 WL 678368, *3 (Kan. Ct. App. Feb. 22, 2013). The KPLA applies to all legal theories of product liability and merges them into a single product liability claim. *Pedro v. Armour Swift-Eckrich*, 118 F. Supp. 2d 1155, 1158–59 (D. Kan. 2000) (citing *Fennesy v. LBI Mgmt., Inc.*, 18 Kan. App. 2d 61, 65–66, 847 P.2d 1350, 1355 (1993)); *see also* K.S.A. 60-3302(c). "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." *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)). There are three ways in which a product may be defective under Kansas law: "(1) a manufacturing defect, i.e. a flaw in the manufacturing of the product; (2) a warning defect, i.e. a failure to adequately warn of a risk or hazard related to the product design; or (3) a design defect, *i.e.* a product which although perfectly manufactured contains a defect that makes it

unsafe." *Baughn v. Eli Lilly & Co*., 356 F. Supp. 2d 1177, 1183 (D. Kan. 2005) (citing *Savina v. Sterling Drug. Inc*., 247 Kan. 105, 114, 795 P.2d 915, 923 (1990)). Although all theories of recovery merge into one legal theory, a plaintiff may allege multiple defects in a single product. *Id.* Regardless of the theory, a plaintiff must prove that the product defect caused the injury and the condition that caused the injury existed at the time the product left the control of the defendant. *Davison v. C.R. Bard, Inc*., No. 19-2760-EFM-KGG, 2020 WL 2513069, at *3 (D. Kan. May 15, 2020) (citing *Messer*, 210 F. Supp. 2d at 1227).

In this case, Plaintiffs seek to recover damages against Defendant under the following theories: (Count I)[1] Negligence—design, manufacture, testing, inspection, processing, advertising, marketing, labeling, assembling, packaging, distribution, detailing, warnings, instruction, promotion and selling; (Count II) Strict Liability—design defect; (Count III) Strict Liability—manufacturing defect; (Count IV) Strict Liability—failure to warn; (Count V) Strict Liability—defective product; (Count VI and VII) Breach of express warranty; (Count XII) Negligent Infliction of Emotional Distress; (Count XVI) Loss of Consortium; and (Count XVII) Punitive Damages. (Doc. 66 at 5-6.) Plaintiffs identified several claims that were initially present in the short form complaint but have been withdrawn. (*Id.* at 5.)

Defendant argues that Plaintiffs' claims are subsumed into one product liability claim under the KPLA and seeks summary judgment of the following duplicative claims: strict liability defective product, breach of warranty, negligence, and negligent infliction of emotional distress. (Doc. 86 at 12-13.) Plaintiffs do not dispute Defendant's interpretation of Kansas law although Plaintiffs contend that their claims of negligence, failure to warn, and design defect are viable under the KPLA. (Doc. 91 at 6, 15.) Plaintiffs offer no argument in opposition to Defendant's

[1] The references are to the counts in the master complaint in the MDL action.

motion for summary judgment on Plaintiff's breach of warranty claim, strict liability defective product, or the claim of negligent infliction of emotional distress. Therefore, the motion is granted as to those claims. Plaintiffs also do not contest Defendant's motion for summary judgment with respect to Plaintiffs' claim of manufacturing defect. (*Id.* at 27, n. 5.)

Under Kansas law, Plaintiffs' duplicative claims are merged into one product liability claim under the KPLA. *Mattos v. Eli Lilly & Co*., No. 12-1014-JWL, 2012 WL 1893551, at *3 (D. Kan. May 23, 2012). Although the duplicative claims are merged, Plaintiffs' product liability claim can be based on both theories of negligence and strict liability. *See Myrick v. Husqvarna Prof. Prod., Inc.*, 508 F. Supp. 3d 846, 864 (D. Kan. 2020); *Jones*, 2013 WL 678368, *3; *see also* PIK-Civil 4th 128.01 - 128.22. Therefore, although Plaintiff may not recover on each theory of recovery, the court declines to grant summary judgment on Plaintiffs' negligence claim. The court will instruct the jury as to Kansas law which provides a remedy based on both a negligence theory and strict liability.

Based on the pretrial order, Plaintiffs' KPLA claims are based on defects present in both products at issue: warning defects and design defects. Under that background, the court will proceed to the merits of Defendant's arguments.

A. Statute of Limitations

Defendant initially argues that Plaintiffs' product liability claim is barred by the statute of limitations. Under Kansas law, the statute of limitations for a product liability claim is two years. K.S.A. 60-513; *Pedro*, 118 F. Supp. 2d at 1158–59. The two-year statute of limitations begins to run as soon as "the act giving rise to the cause of action first causes substantial injury, or, if the fact of injury is not reasonably ascertainable until some time after the initial act, then the period of limitation shall not commence until the fact of injury becomes reasonably ascertainable to the

injured party...." K.S.A. 60-513(b). A "substantial injury" is one that "justif[ies] an action for recovery of the damages," and does not require a plaintiff to have full knowledge of the extent of her injuries. *Roe v. Diefendorf*, 236 Kan. 218, 222, 689 P.2d 855, 859 (1984) (construing "substantial injury" in § 60-513(b) to mean "actionable injury"); *Brock v. Gatz*, 237 F. App'x 321, 325 (10th Cir. 2007). The trier of fact must decide the issue when the parties present conflicting evidence. *Jones v. Neuroscience Assocs., Inc., P.A.*, 250 Kan. 477, 489, 827 P.2d 51, 59 (1992).

Based on the evidence presented, the court finds that there is conflicting evidence as to when Plaintiffs' claims accrued. Here, Defendant argues that Plaintiffs' claims are barred by the statute of limitations because Plaintiff herself testified that she was concerned about a faulty product and she believed that her mesh was the cause of her symptoms "no later than November 12, 2012." (Doc. 86 at 15.) Although she testified in her deposition that she believed that her mesh was the cause of her problems at the time of her November 2012 visit, she further testified that she "didn't know" if there was a problem at that time. (Doc. 91-1 at 100:25-101:6, 125:2-9.) Also, the medical records show that she wanted Dr. Werth to check her mesh due to her concerns after seeing advertisements on television regarding mesh repairs. Dr. Werth examined Plaintiff, told her that her mesh was doing fine and healing properly, and he documented that she had "good support" and no "signs of erosion." (Docs. 91-2 at 49:21-50:2; 91-5 at 2.) Dr. Rosenzweig also testified that he did not believe that there were any signs of mesh erosion in January 2012. It was not until July 2015 that Plaintiff was treated by Dr. Flynn who believed that Plaintiff's symptoms of chronic pain and other symptoms were due to mesh exposure. (Doc. 91-7 at 76:23-78:16.) Plaintiff also testified that it was at this appointment that she first attributed her pain and other symptoms to the mesh. (Doc. 91-1 at 133:24-134:17.) Plaintiffs filed this action within six months of Plaintiff's appointment with Dr. Flynn.

Viewing this evidence in a light most favorable to Plaintiffs, there is a dispute as to when the cause of action accrued. Defendant's motion for summary judgment on the basis that the claims are barred by the statute of limitations is denied.

B. KPLA Claim

As discussed above, Plaintiffs' claims of product liability are based on both a failure to warn and a design defect. Defendant argues that Plaintiffs cannot succeed in showing either defect.

1. Failure to Warn

The parties do not dispute that the learned intermediary doctrine applies in this case. Although a manufacturer has a duty to warn of dangerous side effects and risks associated with the use of prescription products, a manufacturer fulfills its "legal duty to warn a patient of the risks associated with using a prescription drug if it adequately warns the patient's prescribing physician of the risks." *Kernke v. The Menninger Clinic, Inc*., 173 F. Supp. 2d 1117, 1121–22 (D. Kan. 2001) (citing *Wright v. Abbott Labs., Inc*., 259 F.3d 1226, 1233 (10th Cir.2001) (applying Kansas law). "The learned intermediary rule allows a drug manufacturer to assume a patient places reliance on the physician's judgment and relieves the manufacturer of a duty to assist the physician in communicating with patients." *Humes v. Clinton*, 246 Kan. 590, 600-01, 792 P.2d 1032 (1990). Plaintiffs claim that both products were defective in that they failed to provide an adequate warning regarding certain risks, the frequency and severity of the risks, and the products' safety and effectiveness. Plaintiffs will offer the testimony of Dr. Rosenzweig to opine that the products' warnings were inadequate. In support of its motion for judgment on this claim, Defendant argues that the warnings provided with the products were adequate as a matter of law.

Defendant first asserts that the warnings are presumed "not defective" because Defendant complied with federal regulations, citing to K.S.A. 60-3304(a). That statute states as follows:

> (a) When the injury-causing aspect of the product was, at the time of manufacture, in compliance with legislative regulatory standards or administrative regulatory safety standards relating to design or performance, the product shall be deemed not defective by reason of design or performance, or, if the standard addressed warnings or instructions, the product shall be deemed not defective by reason of warnings or instructions, unless the claimant proves by a preponderance of the evidence that a reasonably prudent product seller could and would have taken additional precautions.

Id.

In response, Plaintiffs argue that FDA's 501(k) process, which was utilized in obtaining authorization for the sale of the products, does not provide safety standards and, therefore, the statute is not applicable. (Doc. 91 at 28-29.) The court agrees. Here, Defendant has not attempted to establish any facts regarding the 501(k) process for the products nor does it identify compliance with "legislative regulatory standards or administrative regulatory safety standards...address[ing] warnings or instructions." K.S.A. 60-3304(a). Defendant argues that compliance with this process deems the products' warnings not defective but wholly fails to identify any regulation that it complied with in crafting the warnings. A regulatory compliance presumption requires evidence of compliance with governmental standards that relate to the alleged defect at issue. *See Schoen By & Through Schoen v. Spotlight Co*., 979 F. Supp. 1379, 1383–84 (D. Kan. 1997) (finding that there was no presumption because the regulation identified did not address warnings); *see also Am. Fam. Mut. Ins. Co. v. Techtronic Indus. N. Am., Inc*., No. CIV.A. 12-2609-KHV, 2014 WL 2040158, at *10, n. 19 (D. Kan. May 16, 2014) (finding statute inapplicable because Defendants failed to point to "applicable regulatory standards which addressed product warnings or instructions.") Therefore, Defendant is not entitled to a presumption that the product is not defective due to adequate warnings.

Defendant also argues that the warnings were adequate as a matter of law because the IFUs "explicitly stated the inherent risks." (Doc. 86 at 19.) "An adequate warning is one that is

reasonable under the circumstances." *Graham by Graham v. Wyeth Lab'ys, a Div. of Am. Home Prod. Corp*., 666 F. Supp. 1483, 1498 (D. Kan. 1987) (citing *Wooderson v. Ortho Pharmaceutical Corp*., 235 Kan. 387, 400, 681 P.2d 1038 (1984)). "A warning may be inadequate in factual content, the expression of facts, or in the method by which it is conveyed." *Id.* Defendant has identified the IFUs' stated inherent risks in its memorandum but failed to set forth any facts addressing the adequacy of the IFUs in its statement of facts. (Doc. 86 at 18-19.) In response, Plaintiffs have asserted that the warnings were inadequate and also cited to expert testimony in support of their arguments. (*See* Doc. 91 at 12-14, 28-30.) Specifically, Dr. Rosenzweig has opined that Defendant failed to warn patients and providers of a significant number of risks pertaining to the products and the "frequency, severity and duration of risks and complications." (Doc. 91-10 at 65-66; 91-11 at 63-64.) Here, the court has not been presented with a sufficient factual basis to rule in favor of Defendant on the adequacy of the warnings and Plaintiff has cited to expert testimony in support of her claim that the warnings were deficient. In Kansas, expert testimony is utilized to determine whether a warning is adequate and "it is well established" that this question is one for the trier of fact. *Graham*, 666 F. Supp. at 1498. Viewing the evidence in a light most favorable to Plaintiffs, the court finds that there is a genuine dispute as to whether the warnings were inadequate.

Finally, Defendant argues that even if the warnings were inadequate Plaintiffs cannot prove that the failure to warn proximately caused Plaintiff's injuries. (Doc. 86 at 19-20.) After showing evidence of a defect through an inadequate warning, Plaintiffs must also provide evidence that the failure to warn proximately caused Plaintiff's injury. *Miller v. Pfizer Inc. (Roerig Div.)*, 196 F. Supp. 2d 1095, 1126 (D. Kan. 2002), *aff'd sub nom. Miller v. Pfizer, Inc*., 356 F.3d 1326 (10th Cir. 2004) (citing *Wooderson v. Ortho Pharm. Corp*., 235 Kan. 387, 409, 681 P.2d 1038, 1057 (1984)).

Kansas law does allow a "rebuttable presumption of causation once plaintiffs have established that a warning is inadequate." *Id.* In a case involving a medical device with a learned intermediary, "the law presumes that but for the inadequate warning, the patient would not have been harmed, since the doctor would have given the patient an adequate warning if she or he had ever received it, and the inadequate warning is therefore the cause of the patient's injury." *Id.* (citing *Wooderson*, 235 Kan. at 409). *See also Davison*, at *8. Defendant may rebut this presumption by establishing that the prescribing physician would not have changed his course of treatment after reading and heeding the additional information in the warning. *Id.* at 1127. If Defendant meets this burden, the presumption disappears and the burden will then shift back to Plaintiffs to prove causation. *Id.*

In its motion, Defendant argues that Plaintiffs have to show that Dr. Werth would have changed his decision to prescribe the products. (Doc. 86 at 19-20.) Defendant, however, has the burden here due to the presumption. After reviewing the testimony of Dr. Werth, the court finds that this is a fact question for the jury. Although Dr. Werth testified that he believed that the products were the best options for Plaintiff at the time of treatment, he also testified that he did not know that Total Petrochemicals wrote a letter stating that its products are not suitable for human implants. (Doc. 91 at 13; 98 at 7.) He further testified that he would want to know if there were detrimental effects to implanting mesh in the vagina and, if there was, he would not use those products. (Doc. 91-2 at 81:2-82:1.) Based on this testimony, Defendant has not established that Dr. Werth would not have changed his course of treatment if he had been provided an adequate warning as opined by Dr. Rosenzweig. *See Davison*, 2020 WL 2513069, at *9 (finding that the defendant had not rebutted the presumption when the prescribing doctor's testimony did not affirmatively state that he would have prescribed the medical device had there been an adequate warning).

Therefore, Defendant's motion for summary judgment on Plaintiffs' product liability claim based on a failure to warn is denied.

2. Design Defect

To succeed on Plaintiffs' product liability claim, Plaintiffs must show that the injury resulted from the condition of the product(s), that condition was unreasonably dangerous, and it existed at the time it left Defendant's control. *Lapham v. Watts Regul. Co*., No. 14-CV-02084-JAR, 2016 WL 248471, at *6 (D. Kan. Jan. 21, 2016). With respect to the design defect theory, Plaintiffs must show that although the product(s) was perfectly manufactured, it contained a defect that made it unsafe. *Id.*

Defendant moves for summary judgment on Plaintiffs' design defect claim on the basis that it is barred by Comment k to Restatement (Second) of Torts § 402A. 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 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.

Id. See also Davison, 2020 WL 2513069, at *6.

Under Kansas law, a seller is protected from liability under this 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." *Davison*, 2020 WL 2513069, at *6 (citing *Savina*, 247 Kan. at 924-26). In arguing that the Comment k exception applies, Defendant cites authority that this exception is available to medical devices but makes no attempt to argue the elements under Kansas law. (Doc. 86 at 21.) Nevertheless, because the court has determined that there is a fact issue as to whether Defendant provided adequate warnings, this defense is not a basis for granting summary judgment. The court further notes that this exception is only applicable to design defect claims based on strict liability. *Davison*, 2020 WL 2513069, *6. Plaintiffs' allegations in the pretrial order assert both theories of negligence and strict liability. Therefore, it would not apply to Plaintiffs' claim based on the theory of negligent design even if Defendant had sufficiently established the exception. *Id.*

Defendant's motion for summary judgment on Plaintiffs' product liability claim based on the Comment k exception is denied.

Defendant also moves for summary judgment on this claim based on the argument that Plaintiffs are required to provide evidence of a safer alternative design -- because they "adopted" the burden of proving evidence of a safer alternative design -- and Plaintiffs cannot do so. (Doc. 86 at 21.) In response, Plaintiffs argue that they have not adopted a burden of proving a safer alternative design. (Doc. 91 at 39.) In Kansas, a plaintiff is not required to propose a feasible alternative design in order to recover on a product liability claim. *Messer*, 210 F. Supp. 2d at 1233. "Evidence of a safer alternative design is only relevant when a defendant produces evidence that a safer design is not feasible." *Id.* Defendant has not taken the position or cited to evidence that

a safer design is not feasible; therefore, Plaintiffs are not required to propose a feasible alternative design.

Defendant's motion for summary judgment on Plaintiffs' product liability claim is therefore denied.

3. Derivative Claims

Defendant also sought summary judgment on Plaintiffs' derivate claims of punitive damages and loss of consortium on the basis that Plaintiffs' product liability claims are subject to dismissal. Because the court has denied Defendant's motion for summary judgment on the product liability claims based on a failure to warn and product defect, the derivative claims are not subject to dismissal.

IV. Conclusion

Defendant's motion for summary judgment is GRANTED IN PART and DENIED IN PART. Defendant's motion is GRANTED with respect to Plaintiffs' product liability claim based on a manufacturing defect, strict liability defective product, breach of warranty, and negligent infliction of emotional distress. Defendant's motion is DENIED as to Plaintiffs' product liability claims under the KPLA, negligence, and Plaintiffs' derivative claims of punitive damages and loss of consortium.

IT IS SO ORDERED. Dated this 15th day of October, 2021.

s/ John W. Broomes
JOHN W. BROOMES
UNITED STATES DISTRICT JUDGE