UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT LOUISVILLE

CIVIL ACTION NO. 3:09-CV-354-H

RONNA DALTON and
JOHN DALTON,

PLAINTIFFS

V.

ANIMAS CORPORATION, DEFENDANT

MEMORANDUM OPINION AND ORDER

Plaintiffs, Ronna and John Dalton (collectively "the Daltons"), brought this diversity action against Animas Corporation, alleging various tort and contract claims, as well as Kentucky statutory violations. This action arises from injuries Mrs. Dalton suffered when the Animas infusion pump she used somehow dispensed an overdose of insulin. The circumstances of the injurious overdose are disputed. Nevertheless, Defendant has moved for summary judgment on all claims. For the reasons that follow, the motion is sustained in part and denied in part.

I.

Animas Corporation is a Delaware corporation that manufactures external insulin infusion pumps, including the Animas Model 2020 infusion pump (the "2020 Pump"). The 2020 Pump automatically injects precise doses of insulin for the treatment of diabetes. Insulin leaves the pump's cartridge and is delivered to the user via tubing and a needle attached to the body. The pump software controls the timing and dosage of the infusions. After an insulin cartridge is empty, the user must replace the cartridge, which typically occurs once every three days. When doing so, the user is required to perform a "Rewind/Align/Prime" operation (the "Prime Operation"). The

purpose of the Prime Operation is to remove any air from the system that may result from replacing the insulin cartridge. To perform the Prime Operation, the user must press and physically hold down the pump's "OK" button until insulin is seen dripping from the tube. During this process, the user is warned to always remove the tubing from her body.

Mrs. Dalton used the 2020 Pump without incident for nearly one year. On April 21, 2008, Mrs. Dalton received a low cartridge warning. Although she does not have a specific memory of doing so, Mrs. Dalton believes that she would have replaced the insulin cartridge and performed the Prime Operation. The software confirms this, showing that Mrs. Dalton changed the cartridge and performed the Prime Operation at 10:00 p.m. that evening.

Mrs. Dalton went to bed that night in her bedroom, which is separate from her husband's. During the night, Mr. Dalton woke his wife to inform her the Replace Battery Alarm on her 2020 Pump was sounding. The software indicates that the alarm sounded at 4:42 a.m. Mrs. Dalton testified that she got out of bed, went to the kitchen and changed the pump's battery. At 5:05 a.m., the software reflects that the battery was changed. Mrs. Dalton testified that she did not do anything else at that time, because she would be waking up in a few hours to take a shower, which would require her to disconnect. At 5:08 a.m., the 2020 Pump sounded an alarm because a Prime Operation was not performed following the battery replacement. The software registered that Mrs. Dalton began the process at 5:09 a.m. At 5:10 a.m., an Empty Cartridge Alarm sounded; approximately 125.5 units of insulin was dispensed into Mrs. Dalton's body.

Plaintiffs filed this action against Defendant, claiming that a defect in Mrs. Dalton's 2020 Pump caused an over-infusion, resulting in personal injuries to Mrs. Dalton. Plaintiffs have asserted claims based on strict liability, negligence, breach of express and implied warranty, violations of the

Kentucky Consumer Protection Act, loss of consortium, and punitive damages.

II.

Summary judgement is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Summary judgment is appropriate "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In assessing a summary judgment motion, the court must examine any pleadings, depositions, answers to interrogatories, admissions, and affidavits in the light most favorable to the non-moving party. Fed. R. Civ. P. 56(c).

Plaintiffs brought the following claims: Count I (Strict Liability), Count II (Negligence), Count III (Breach of Express and Implied Warranty), Count IV (Violation of the Kentucky Consumer Protection Act, KRS § 367.170) ("KCPA"), Count V (Damages), Count VI (Loss of Consortium) and Count VII (Punitive Damage). Several claims alleged in the Complaint warrant dismissal. The Court will address each count individually.

III.

In Kentucky, a plaintiff may prevail on a strict products liability claim when he or she meets the requirements of Restatement (Second) of Torts §402A, which "imposes strict liability on one who sells any product in a defective condition unreasonably dangerous to the user or consumer." *Leslie v. Cincinnati Sub-Zero Products, Inc.*, 961 S.W.2d 799, 803 (Ky. Ct. App. 1998)(internal citation omitted). Accordingly, a plaintiff has the burden of showing an identifiable, unreasonably

dangerous defect. *See Gray v. General Motors Corp.*, 133 F.Supp. 2d 530, 533 (E.D. Ky. 2011), *aff'd*, 312 F.3d 240 (6th Cir. 2002). Kentucky law is clear that evidence that merely surmises or speculates as to a defect is not sufficient. *Midwestern V.W. Corp. v. Ringley*, 503 S.W.2d 745, 747 (Ky. 1973).

Additionally, the plaintiff must establish causation, that the product was a "substantial factor" in bringing about the alleged harm. *See Bailey v. N. Am. Refractories Co.*, 95 S.W.3d 868, 873 (Ky. Ct. App. 2001). Circumstantial evidence may be used to establish legal causation if such evidence is "sufficient to tilt the balance from possibility to probability." *Morales v. Am. Honda Motor Co., Inc.*, 151 F.3d 500, 507 (6th Cir. 1998).

A recent Sixth Circuit case further distilled the plaintiff's burden in a product liability action. *See Siegel v. Dynamic Cooking Systems, Inc.*, 2012 WL 4459915 (6th Cir. Sept. 26, 2012). In that case, experts could not determine whether a defective oven design or from a manufacturing defect caused the gas leak leading to the explosion. After trial, the District Court granted a directed verdict in favor of the manufacturer. The court held that the plaintiff did not meet her burden of establishing a manufacturing defect through circumstantial evidence because she failed to eliminate other probable causes of the injury. She undermined her manufacturing defect claim by introducing evidence of a design defect.[1] The Sixth Circuit reversed, holding that "a Plaintiff like Siegel can prove a product liability claim using the fact of the malfunction if she eliminates those causes for which the manufacturer would not be liable." *Id*. at *11 (citing *Perkins v. Trailco Mfg. & Sales Co.*, 613 S.W.2d 855, 857-58 (Ky. 1981)).

[1] The law distinguishes between two types of defects: (1) a manufacturing defect, which is a deviation from a product's design that creates an unreasonable risk of harm, *Wright v. General Elec. Co.*, 242 S.W.3d 674, 682 (Ky. Ct. App. 2007); and (2) a design defect, which is a defect that "exists when a product is built in accordance with its intended specifications, but the design itself is inherently defective or poses unreasonable dangers to consumers." 63A AM. JUR. 2d *Products Liability* § 869 (2012).

Since the manufacturing and design defects were both attributed to the defendant, the plaintiff could proceed with two theories of liability against that defendant. The Court reasoned that "[a] plaintiff is not required to show precisely *how* a product is defective, but simply must show *whether* it was defective." *Id.* A plaintiff can accomplish this by "ruling out other theories of causation: '[W]here an injury may as reasonably be attributed to a cause that will excuse the defendant as to a cause that will subject it to no liability, no recovery can be had.'" *In re Beverly Hills Fire Lit.*, 695 F.2d 207, 218 (6th Cir. 1982)(quoting *Sutton's Adm'r v. Louisville & N.R. Co.*, 181 S.W. 938, 940 (1916)). In sum, a plaintiff may present two or more potential theories explaining the defect in a products liability action, so long as each theory is attributable to the defendant.[2]

Plaintiffs bring their strict liability claim under three theories: a manufacturing defect (the "stuck button theory") and two design defects (the "prime limit theory," and the "change of battery theory"). The Court will address each individually.

A.

Plaintiffs' experts maintain that a manufacturing defect is one possible cause of the over-infusion of insulin. Specifically, according to the "stuck button theory," the pump's "OK" button stuck during the Prime Operation, causing the device to dispense the entire cartridge of insulin. Plaintiffs have failed, however, to offer any evidence of this beyond speculation. *See Siegel v. Ky. Farm Bureau Mut. Ins. Co.*, 2010 WL 3000746, at *4 (W.D. Ky July 26, 2010)("Kentucky common

[2]Citing the recent *Siegel* case, Defendant argues that Plaintiffs may not use an expert's opinion to infer causation unless Plaintiffs eliminate all other reasonable explanations for the accident. However, this opinion is consistent with the recent *Siegel* case. There are no proffered alternative explanations for the over-infusion that would absolve Defendant of its liability. Defendant maintains that an alternative cause for Mrs. Dalton's injury is that she did not follow known warnings by failing to disconnect from the pump during the Prime Operation. However, in that circumstance, a prime limit would have prevented the over-infusion. As will be discussed, a reasonable jury could find the 2020 Pump to be unreasonably dangerous despite the directives to disconnect the pump during the Prime Operation because it lacked a prime limit feature.

law and applicable Sixth Circuit case law are clear: the finder of fact cannot be asked to speculate, suppose, or surmise that there was a manufacturing defect."); *see also* 63 AM. JUR. 2d *Products Liability* § 6 (2012)("When the plaintiff relies upon circumstantial evidence, however, he or she has the burden of establishing circumstances from which the facts necessary to prove the claim may be inferred without resort to conjecture and speculation, and the circumstances proved must point reasonably to the desired conclusion.")

Plaintiffs' experts have had ample opportunity to examine Mrs. Dalton's pump and have not proffered any evidence of a stuck key. Mr. Michael Klimowicz, Plaintiffs' electrical engineer expert, manipulated the pump and was unable to recreate the "stuck key theory." He testified that he pressed the button over thirty times and it never did stick. Absent actual evidence, or circumstantial evidence that rises about mere speculation, that the pump had a defective, stuck button, Plaintiffs cannot pursue their products liability claim under the "stuck button theory."

B.

Plaintiffs also assert that the 2020 Pump was defectively designed. A product may be defective if it was designed "according to an unreasonably dangerous design." *Jones v. Hutchinson Mfg., Inc.*, 502 S.W.2d 66, 69 (Ky. 1973). "The maker is not required to design the best possible product or one as good as others make or a better product than the one he has, so long as it is reasonably safe." *Sturm, Rudger & Co. v. Bloyd*, 586 S.W.2d 19, 21-22 (Ky. 1979). Thus the inquiry in a design defect case is "whether the product creates such a risk of an accident of the general nature of the one in question that an ordinarily prudent company engaged in the manufacture of such a product would not have put it on the market." *Montgomery Elevator Co. v. McCullough*, 676 S.W.2d 776, 780 (Ky. 1980)(internal quotation omitted). "[I]n Kentucky, in order to prove a

product is 'unreasonably dangerous' as designed, a plaintiff is required to produce competent evidence 'of a feasible alternative design' that would have prevented the injury.'" *Cummins v. BIC USA, Inc.*, 835 F.Supp.2d 322, 326 (W.D. Ky. 2011)(quoting *Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35, 42 (Ky. 2004)).

1.

Plaintiffs argue under the "prime limit theory," that the 2020 Pump was defectively designed because it did not include a prime limit, a feature that limits the amount of insulin dispensed during a Prime Operation. Thus, theoretically, the prime limit feature prevents an over-infusion. Plaintiffs' experts assert that the prime limit feature would have prevented Mrs. Dalton's injuries.

Defendant argues that Plaintiffs have failed to prove that the absence of a prime limit caused this incident or that another design would have prevented Mrs. Dalton's injuries.[3] Defendant contends that Plaintiffs have offered nothing beyond a theoretical possibility that an unspecified prime limit would have avoided Mrs. Dalton's injuries. Plaintiffs counter that the 2020 Pump was unreasonably dangerous because a mere warning to disconnect while priming did not eliminate the possibility of impaired users improperly using the device. Diabetics are prone to experience bouts of hypoglycemia that can impair cognitive ability. Plaintiff proffers other insulin pumps on the market featuring a prime limit and notes that the 2020 Pump had the capacity to install such technology. Because the 2020 Pump lacked such a feature, Plaintiffs argue that it is defective.

[3] Defendant argues that the Plaintiffs' experts' inability to determine what the prime limit should have been renders this theory irrelevant. Plaintiffs' experts do not agree or disagree on what the prime limit should be, each suggesting a limit somewhere between 5 and 30 units of insulin. Defendant contends that a 30-unit prime limit would likely have resulted in injuries to Mrs. Dalton; thus a prime limit feature would not have prevented the incident. However, the Court finds the Plaintiffs argument is not so specific. Plaintiffs simply argue that the 2020 Pump is defectively designed because it altogether lacked a prime limit. The experts merely approximated a prime limit amount. Therefore the "prime limit theory" suggests that the maximum delivery of insulin that can be expelled during a Prime Operation can be set according to the pump's length of tubing and/or the specific needs of the user. The Court will focus on whether *a* prime limit, rather than a *5 unit* prime limit or a *30 unit* prime limit, would have prevented Mrs. Dalton's injuries.

The Court finds that Plaintiffs' prime limit theory establishes that a different design both was feasible and might have prevented Mrs. Dalton's injuries. As Defendant has argued, users are cautioned to disconnect during the Prime Operation in the 2020 Pump user guide, during user training and in warnings displayed on the pump itself. Mrs. Dalton underwent three hours of training on the use of the 2020 Pump and stated that she knew to disconnect the pump from her body during the Prime Operation.[4] Notwithstanding this evidence, a reasonable jury might still find the 2020 Pump to be defective because Defendant failed to anticipate users who may mistakenly stay attached during the Prime Operation.

It is reasonably foreseeable that a user may be in a hypoglycemic state during the Prime Operation and not be cognizant of the risk associated with staying connected to the pump. *See Ostendorf v. Clark Equipment Co.*, 122 S.W.3d 530, 535 (Ky. 2003)(stating "it is the legal duty of a manufacturer to use reasonable care to protect against foreseeable dangers"). Diabetics are prone to experience hypoglycemic episodes. A jury could conclude that Defendant's warnings and training were insufficient to make the 2020 Pump safe for its intended users. Therefore, Defendant should have anticipated misuse of their product given that such a user's memory and cognitive ability may, at times, be impaired. A prime limit would prevent an impaired or incoherent user from over-infusing oneself when inadvertently attached during the Prime Operation. A reasonable jury could find, therefore, that Defendant should have anticipated such misuse and designed the device with a prime limit feature, and that the 2020 Pump was unreasonably dangerous for lacking such a feature.

[4] The Court notes that Mrs. Dalton has received previous training on a different insulin pump manufactured by Medtronic, but these three hours focused primarily on features in Animas' 2020 Pump.

2.

Plaintiffs additionally argue that the 2020 Pump is defective because it requires a Prime Operation following a battery change, thus exposing users to a medically unnecessary Prime Operation. Defendant counters that a Prime Operation is necessary following a battery change to reinitiate the force sensor and cartridge position and ensure no conditions have changed that may have introduced air into the system.

The "change of battery theory" is related to the "prime limit theory," in that a prime limit would have prevented an over-infusion during a Prime Operation initiated by a change of battery. However, this theory is also independent from the "prime limit theory." Plaintiffs have proffered evidence of other pumps on the market that did not require a prime after a battery change. The prime that resulted in Mrs. Dalton's over-infusion would not have occurred had the 2020 Pump not required a Prime Operation following a battery change. Defendant argues that requiring a Prime Operation in this instance protected against a greater risk, the chance that the device misaligns during a change of battery and introduces air into the system. Whether the Prime Operation is necessary and, correspondingly, whether the device is unreasonably dangerous by requiring this process following a battery change, is sufficiently disputed for a jury to decide.

Accordingly, the Court finds summary judgment on Plaintiffs' design defect claim is inappropriate at this juncture.

IV.

"A plaintiff in Kentucky can bring a defective design claim under either a theory of negligence or strict liability." *Ostendorf*, 122 S.W.3d at 535. Both Plaintiffs' strict liability and negligence claims are premised on their argument that the product is unreasonably dangerous, *i.e.*,

that the product created an unreasonable risk of foreseeable injury. However, negligence focuses on the conduct of the manufacturer, and specifically whether the manufacturer used reasonable care to protect against foreseeable dangers, while strict products liability focuses on the defective product itself. *Id*. Courts employ a risk-utility balancing test that assesses the manufacturer's decision to design a product in a certain manner and whether the manufacturer exercised reasonable care in making the design choices it made. *Id*.

Because the Court finds that a reasonable jury could find that the 2020 Pump had a design defect, a reasonable jury could also find that Animas was negligent in its design of the 2020 Pump. *See Ostendorf*, 122 S.W.3d at 535 (holding that a plaintiff may bring a defective design claim under a theory of negligence or strict liability and both theories are premised on the argument the product is unreasonably dangerous); *see also Nichols v. Union Underwater Co., Inc.*, 602 S.W.2d 429, 433 (Ky. 1980)(stating the distinction between negligence and strict liability "is of no practical significance so far as the standard of conduct required of the defendant . . . is reasonable care"). Accordingly, the negligence cause of action remains. However, as noted above, a defective design claim proceeds under a theory of negligence *or* strict liability. At a recent conference in chambers, counsel for Plaintiffs advised the Court that they planned to primarily pursue the strict liability claim. Though it may be possible for Plaintiffs to pursue different theories for recovery in a design defect case, the Court cautions a negligence claim duplicating the recovery available under strict liability generally does not add anything to the case and risks jury confusion.

V.

Plaintiffs' claims for both breach of warranty and for violation of the KCPA seem likely to fail and do not add substantial value to their case.

If a product is proven to be defective, a Defendant may be contractually liable for a breach of warranty. *McCoy v. General Motors, Corp.*, 47 F.Supp.2d 838, 839 (E.D. Ky. 1998). Because the Court has not dismissed Plaintiffs' claims for design defects, Plaintiffs may pursue their breach of warranty claim. It should be noted that damages for this claim may be restrained given the 2020 Pump's limited warranty. If Plaintiffs are able to prove the 2020 Pump was in fact defective, Defendant argues that the limited warranty expressly limits their remedy to repair or replacement of the pump.

Plaintiffs' claim for breach of an implied warranty of fitness for a particular purpose fails because Mrs. Dalton's use of the 2020 Pump was not peculiar. *See* KRS § 355.2-315 ("Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required . . . there is . . . an implied warranty that the goods shall be fit for such purpose."). Mrs. Dalton used the 2020 Pump for its ordinary purpose – as an insulin delivery product. Absent an allegation that Mrs. Dalton used the device for a particular purpose of which Defendant would have reason to know, this claim must be dismissed.

The Plaintiffs' claim based on alleged violations of the KCPA must also be dismissed. The KCPA prohibits "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce," where "unfair shall be construed to mean unconscionable." KRS § 367.170. Plaintiffs have not identified any conduct of Defendant that constituted a KCPA violation. Rather, their Complaint generally states, "Animas misrepresented the efficacy and safety of the Animas 2020 insulin infusion pump." The Plaintiffs' Response to Defendant's Motion for Summary Judgment does not defend their KCPA claim.

The Court's review of the record has not revealed a viable claim. Plaintiffs have not alleged facts upon which a reasonable jury could find Defendant intentionally, knowingly, or in bad faith took malign actions affecting Plaintiffs. Therefore, Plaintiffs' KCPA claim fails as a matter of law.

VI.

In Kentucky, a claim for "loss of consortium is derivative of an injured plaintiff's claim." *Norton v. Canadian Am. Tank Lines*, 2009 WL 931137, at *2 (W.D. Ky. Apr. 3, 2009)(citing *Daley v. Reed*, 87 S.W.3d 247 (Ky. 2002)). As such, Mr. Dalton's claim is entirely dependent upon the success of his wife's product liability claim. Given that Plaintiffs do have remaining claims against Defendant, summary judgment on Mr. Dalton's loss of consortium claim is inappropriate at this time.

During a pre-trial conference with both parties, it was clear to the Court that the Plaintiffs' main objective in trial is to pursue the products liability claim based on a design defect in the 2020 Pump. The negligence, breach of warranty, and loss of consortium claims appear to be secondary. Most likely, they will be accounted for if and when the jury is charged with assessing liability and damages.

VII.

Count V of the Complaint, entitled "Damages," asserts a nebulous cause of action for various types of damages. This count is dismissed as a matter of law, because damages are a prayer for relief, not a cause of action.

Defendant has also moved for summary judgment as to Plaintiffs' claim for punitive damages, which is set forth as a separate cause of action in Count VII. However, a claim for punitive damages is not a separate cause of action, but a remedy potentially available for another

cause of action. *Toon v. City of Hopkinsville*, 2011 WL 1560590, at *3 (W.D. Ky. April 14, 2011)(citing *Salisbury v. Purdue Pharm., L.P.*, 166 F. Supp. 2d 546, 548, n. 1 (E.D. Ky. 2001)). Plaintiffs' strongest claim is a design defect under strict liability. The claim here is that Defendant should have done more than warn users about the dangers of over-infusion and should have known that no amount of training could adequately prepare users to follow safety procedures.

To proceed on a claim for punitive damages Plaintiffs must have some evidence from which a reasonable jury could find malice or reckless disregard for a product user's safety. *Kinney v. Butcher*, 131 S.W.3d 357, 359 (Ky. Ct. App. 2004). Here, the evidence is that Defendant took many actions to ensure user safety. The question is whether those actions were reasonably sufficient. Thus, while the evidence may raise issues of negligence, it does not suggest any questions as to malice or malicious disregard. The evidence does not submit to such an inference. Consequently, Plaintiffs' claim for punitive damages must be dismissed.

Being otherwise sufficiently advised,

IT IS HEREBY ORDERED that Defendant's Motion for Summary Judgment is GRANTED in part and Plaintiffs' claims for a manufacturing defect (the "stuck button theory"), under the KCPA and for punitive damages are DISMISSED WITH PREJUDICE.

The remaining claims are Count I (Strict Liability with respect to the defective design theories), Count II (Negligence), Count III (Breach of Express Warranty) and Count VI (Loss of Consortium).

December 20, 2012

John G. Heyburn II, Judge
United States District Court

cc: Counsel of Record