UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT LOUISVILLE

CIVIL ACTION NO. 3:09-CV-00573-H

KRIS PRATHER, PLAINTIFF

V.

ABBOTT LABORATORIES, ET AL., DEFENDANTS

MEMORANDUM OPINION AND ORDER

This is a products liability and negligence case in which Plaintiff, Kris Prather, alleges that a medical device, the Pain Control Infusion Pump ("PCIP"), manufactured by Defendant, B. Braun Medical, Inc., caused severe and permanent damage to her shoulder.[1] The PCIP is a medical device prescribed to alleviate the pain of a post-operative patient by delivering a continuous infusion of a local anesthetic into the post-operative site. Prather alleges several tort claims related to the PCIP after she developed chondrolysis in her shoulder, including strict products liability, negligence, breach of express and implied warranties, fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraud. She seeks compensatory and punitive damages.

This case is now before the Court on a motion for summary judgment filed by Defendant. For the following reasons, the Court will grant the motion, and this case will be dismissed.[2]

I.

[1] Initially, Prather named fifteen defendants in her Complaint. Later, she voluntarily dismissed thirteen defendants. Sgarlato Laboratories, Inc. ("Sgarlato"), for whom B. Braun manufactured the device at issue, has failed to participate due to its dissolution in 2009. Presently, B. Braun is the only remaining defendant.

[2] In addition, Defendant filed a motion to exclude the testimony of Plaintiff's expert Dr. Suzanne Parisian, which is now fully briefed. It is unnecessary for the Court to resolve that motion in order to resolve the instant motion for summary judgment. The Court did review the briefs and appreciates the effort put forth by the parties, as it did illuminate the Court's understanding of the medical complexities associated with this case.

On June 18, 2001, Prather underwent arthroscopic surgery on her left shoulder to treat a posterior labral tear. Her orthopedic surgeon, Dr. Felix Savoie, performed the surgery. At the end of the procedure, Dr. Savoie implanted the PCIP in the intra-articular space of Prather's shoulder to help alleviate any post-surgery pain. Essentially, the PCIP is a medical device designed to administer the continuous injection of pain medication, in this case bupivacaine, directly into certain areas of the body. Defendant manufactured the PCIP for Sgarlato pursuant to a distribution agreement. Sgarlato marketed the PCIP and sold it to hospitals, including River Oaks Hospital, the location of Prather's surgery. Dr. Savoie testified that he was not involved in the hospital's decision to buy a particular pain pump brand.

Initially, Prather's post-surgery recovery looked promising. However, two years later, Prather complained of shoulder pain. Several appointments and surgeries later, doctors formally diagnosed Prather as having glenohumeral chondrolysis, a painful condition involving the rapid and permanent breakdown of the cartilage in the shoulder joint.[3]

Next, the Court will summarize the regulatory history of the PCIP's, which provides a necessary backdrop to this case. The Federal Food and Drug Administration ("FDA") regulates medical devices such as the PCIP, a Class II device. 21 C.F.R. § 880.5725(b). Prior to marketing a Class II medical device, the manufacturers must satisfy the FDA premarket approval process. 21 U.S.C . § 360e. A device manufacturer can do this in one of two ways: (1) by obtaining Premarket

[3] Prather's claims are potentially time barred. Kentucky imposes a one-year statute of limitations for personal injury actions. KRS § 413.140. Prather met with a handful of doctors and underwent several reconstructive surgeries in the years following her June 2001 surgery. Defendant maintains that as early at 2004, Prather understood that she had lost a substantial amount of cartilage in her shoulder. At that time, Defendant argues that Prather had to conduct a reasonable investigation into the cause of her injury. She failed to do so, and as such, Defendant contends that Prather's Complaint, which was filed on June 27, 2008, is untimely and her claims should be barred by the statute of limitations. Prather counters that her cause of action did not accrue until November 2007 when she learned of both her injury and its cause. Since this matter is resolved on the merits, the Court declines to rule on this argument.

Approval ("PMA") following a rigorous application process in which the applicant must establish that a new or modified device is both safe and effective, or (2) by obtaining Premarket Notification, which a manufacturer can procure under section 510(k) of the Federal Food, Drug and Cosmetic Act (a "510(k) clearance"). *See id.* This second avenue is available to manufacturers who can demonstrate to the FDA that the device to be marketed is at least as safe and effective, that is "substantially equivalent," to an existing FDA-approved device (known as a "predicate device"). 21 U.S.C. § 360(k); 21 C.F.R. §807. If the FDA determines that the applicant's device is "substantially equivalent" to a "predicate device," it can obtain 510(k) clearance. 21 U.S.C. § 355(b)(1)(F); *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996)("If the FDA concludes on the bases of the § 510(k) notification that the device is 'substantially equivalent' to a preexisting device, it can be marketed without further regulatory analysis.").

On March 19, 1999, the FDA approved Sgarlato's 510(k) clearance for the PCIP. In the application, Sgarlato claimed substantial equivalence to the Ambulatory Drug Delivery System, an infusion device designed to deliver medicine intravenously through a catheter during surgery. The FDA cleared the PCIP for the following use, as set out in Sgarlato's Statement of Indications for Use:

> The Pain Control Infusion Pump is a single use device intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative management of pain following surgery. Medication is intended to be delivered percutaneously through a catheter.

ECF No. 266-10. The label for the PCIP stated that it was "for continuous delivery of medication for control of pain." ECF No. 266-8.

Prather's main allegation is that Defendant failed to consider scientific and medical literature, published prior to the June 2001 surgery, which put Defendant on notice that the use of pain pumps to deliver anesthetic medications directly into the shoulder joint could cause severe harm. According to Prather, Defendant failed to perform any tests concerning the safety of the intra-articular infusion of anesthetics, and that Defendant manufactured the device for such a use under a flawed regulatory submission. Because of this failure, inadequate warnings and instructions for use accompanied the PCIP.

II.

Defendant has moved for summary judgment on all claims. Summary judgment is appropriate where "there is no genuine dispute as to any material fact." FED. R. CIV. P. 56(c). Initially, the moving party bears the burden of proving that no genuine issues of material fact exists and that it is entitled to judgment as a matter of law. *Celotex Corp v. Catrett*, 477 U.S. 317, 323 (1986). The nonmoving party opposing a properly supported motion for summary judgment may not rest on mere denials or allegations to defeat such a motion, but must set forth "specific facts showing that there is a genuine issue for trial." *Id*. at 324. In deciding a motion for summary judgment, the Court will view the facts in a light most favorable to the nonmoving party. *Matsushita Electric Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986). This Court has diversity jurisdiction and as such, will apply Kentucky substantive law. *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938).

Prather's main claim in this dispute is for products liability. Specifically, Prather alleges that Defendant should be liable for manufacturing the PCIP for Sgarlato, as Defendant failed to consider scientific literature, available prior to the June 2001 surgery, which alerted Defendant of the risk of

harm created by the continuous infusion of a local anesthetic into the shoulder's intra-articular space.

In Kentucky, product liability actions are governed by the Kentucky Product Liability Act ("KPLA"). *See* KRS § 411.300-.350.[4] A plaintiff may advance three different causes of actions against a manufacturer: (1) strict liability, (2) negligence, and (3) breach of warranty. *Williams v. Fulmer*, 695 S.W.2d 411, 413 (Ky. 1985). Additionally, Kentucky law recognizes three theories of product liability: (1) defective design, (2) defective manufacture, and (3) failure to warn. *Clark v. Hauck Mfg. Co.*, 910 S.W.2d 247, 251 (Ky. 1995), *overruled on other grounds by Martin v. Ohio Cnty. Hosp. Corp.*, 295 S.W.3d 104 (Ky. 2009). To recover under any product liability claim, the plaintiff must prove the existence of a "defect," *McCoy v. Gen. Motors Corp.*, 47 F. Supp. 2d 838, 839 (E.D. Ky. 1998), and legal causation. *Morales v. Am. Honda Motor Co., Inc.*, 71 F.3d 531, 537 (6th Cir. 1995)(citing *Huffman v. SS. Mary & Elizabeth Hosp.*, 475 S.W.2d 631, 633 (Ky. 1972)). Prather's product liability claim is premised on strict liability, negligence and breach of express and implied warranties. Though the claims are closely related, the Court will address each individually.

III.

Prather's strict liability claim is based on the theory that the PCIP was defective, either in its design or because Defendant failed to warn of irreversible cartilage damage caused by the PCIP. Kentucky follows the Restatement (Second) of Torts. *Dealers Transp. Co. v. Battery Distrib. Co.*, 402 S.W.2d 441, 446-47 (Ky. 1966). Section 402A of the Restatement imposes strict liability on

[4] The KPLA defines a product liability action as "any action brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, testing, listing, certifying, warning, instructing, marketing, advertising, packaging or labeling of any product." KRS § 411.300.

a product manufacturer "who sells any product in a defective condition unreasonably dangerous to the user." RESTATEMENT (SECOND) OF TORTS § 402A(1).

A.

Comment k to the Restatement (Second) of Torts § 402A provides an exception to the general rule of strict liability for "apparently useful and desirable product[s], attended with a known but apparently reasonable risk." *Id.* at cmt. k.[5] *See McMichael v. Am. Red Cross*, 532 S.W.2d 7, 9-11 (Ky. 1975)(ruling that comment k is applicable under Kentucky law).

Comment k acknowledges that "some products, such as certain drugs, are so beneficial and necessary that the manufacturer of these products should not, in all instances, be held strictly liable for unforeseeable harm." *Graham by Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1496 (D. Kan. 1987). "When applying Comment k to Kentucky law, the manufacturer's liability is limited to . . . warning defects, where a manufacturer's failure to market a drug or vaccine without adequate warnings of its dangers renders the product defective." *Foister v. Purdue Pharma, L.P.*, 295 F. Supp.

[5] Comment k provides in full:

> *Unavoidably unsafe products.* 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.

2d 693, 705 (E.D. Ky. 2003)(internal quotation omitted). Thus, if comment k applies to the instant action, Defendant can only be liable under a theory of strict liability for failure to warn of the risk of cartilage damage associated with the PCIP.[6]

At issue is whether the PCIP, a prescription medical device, is within comment k's purview. As stated in the comment, unavoidably unsafe products "are especially common in the field of drugs." RESTATEMENT (SECOND) OF TORTS § 402A cmt. k; *see also Hill v. Searle Labs.*, 884 F.2d 1064, 1069 (8th Cir. 1989)(noting that "exceptional products are more likely to be found in the field of prescription drug products"). Though that may be the case, comment k certainly does not foreclose the possibility of extending its reach to medical devices. *See Clark v. Danek Med., Inc.*, 1999 WL 613316, *4 (W.D. Ky. Mar. 29, 1999)(stating that a spinal fixation device implant "is the sort of desirable but unavoidably unsafe product described by the Restatement (Second) of Torts, § 402A, comment k"); *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 357-58 (Cal. Ct. App. 1992)(applying comment k to a prescription implanted medical device, reasoning that it was more analogous to a pharmaceutical than other medical devices, such as a wheelchair); *Breen v. Synthes-Stratec, Inc.*, 947 A.2d 383, 388 (Conn. Ct. App. 2008)(holding that "comment (k) is not limited to prescription drugs but also is applicable to medical devices such as the plates implanted in the plaintiff's body"). Rather, comment k operates when the product at issue is unavoidably unsafe - that is, it is both useful and desirable, but marked by a known, reasonable risk.

In Kentucky, the scope of comment k is determined on a case-by-case basis. *Weiss v. Fujisawa Pharm. Co.*, 2006 WL 3533072, *3 (E.D. Ky. Dec. 7, 2006). "The most common

[6] "[C]omment k immunizes certain products from strict liability claims based on alleged defective design, though not from strict liability claims based on alleged defective manufacture or inadequate warning." *Toner v. Lederle Labs.*, 732 P.2d 297, 308 (Idaho 1987). Prather has not advanced a manufacturing defect claim.

approach is to extend comment k protection when the apparent benefits of the drug exceed the apparent risks, given the scientific knowledge available when the drug was marketed." *Id*.[7]

The PCIP is a prescription implantable medical device that provides a stream of anesthesia directly into a patient's operative site via a catheter. The Court does not discern a meaningful difference between this device and a prescription drug, and does not believe the framers of comment k would exclude such a product. The PCIP is highly useful and desirable product used for post-operative pain management. As will be discussed, to the extent scientifically knowable at the time, the risk of injury posed by the PCIP was marginal. *See Toner*, 732 P.2d at 306 (stating that the weighing of the product's benefit versus its risk must be done at the time the product is distributed to the plaintiff).[8] Therefore, the Court finds that the PCIP is within the ambit of comment k.

B.

[7] The *Weiss* Court goes on to provide an analytical framework in determining whether comment k properly applies to the product at issue:

> Helpful factors include (1) the drug's overall usefulness and benefit; (2) the likelihood and seriousness of injury; (3) the availability of a substitute product at the time of sale and distribution; (4) the manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness; and (5) the expense involved in eliminating the unsafe character of the product. This Court may also consider (1) whether the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the risk posed by the product was substantial and unavoidable; and (3) whether the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review.

Weiss, 2006 WL 3533072, at *3 (internal citations omitted).

[8] This finding is consistent with other cases, including cases involving a pain pump similar to the PCIP, in which courts have applied comment k to implantable medical devices. *See Rodriguez v. Stryker Corp.*, 2011 WL 31462, *6 (M.D. Tenn. Jan. 5, 2011), *aff'd* 680 F.3d 568 (6th Cir. 2012)("There is no dispute that the plaintiff's strict liability claims are governed by Comment K to Section 402A of the Restatement (Second) of Torts. That is, while strict liability usually attaches to manufacturers of defective or unreasonably dangerous products for the injuries caused thereby, Comment K imposes a well-recognized exception for 'unavoidably unsafe products,' such as prescription medical devices."); *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 575 (6th Cir. 2012) (applying comment k as the plaintiff did not argue that the district court erred in applying comment k to his claim); *Kee v. Zimmer*, 871 F. Supp. 2d 405, 409 (E.D. Pa. 2012)(extending comment k to prescription medical devices). *But see Senn v. Merrell-Dow Pharm., Inc.*,751 P.2d 215, 218 (Or. 1998)(declining to rule on the applicability of comment k because the analysis is highly fact-dependent and should be considered by the court only after a full evidentiary hearing).

Having found that comment k applies, the "crucial question raised by any unavoidably unsafe product is whether the manufacturer provided an adequate warning. If accompanied by an adequate warning, a desirable but unsafe product is not unreasonably dangerous." *Clark*, 1999 WL 613316, at *4; *see Graham*, 666 F. Supp. at 1498 ("The comment thus recognizes that while some products are inherently dangerous, the user has a right to know of these inherent risks so that he can make an informed decision; in the absence of such warning, the product is deemed to be defective."). Generally, a manufacturer has a duty to warn of dangers that it either knew or should have known. *Tipton v. Michelin Tire Co.*, 101 F.3d 1145, 1149-50 (6th Cir. 1996); *CertainTeed Corp. v. Dexter*, 330 S.W.3d 64, 79 (Ky. 2010)(quoting *Post v. Am. Cleaning Equip. Corp.*, 437 S.W.2d 516, 520 (Ky. 1968)(holding that "liability for a manufacturer follows only if it knew or should have known of the inherent dangerousness of the product and failed to 'accompany [] it with the quantum of warning which would be calculated to adequately guard against the inherent danger'")).

In 2004, Kentucky formally adopted the learned intermediary doctrine from the Restatement (Third) of Torts. *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 770 (Ky. 2004). The doctrine, "which is an exception to the general rule that a manufacturer's duty to warn of any risks or dangers inherent in the product runs to the ultimate consumer, relieves the prescription drug manufacturer from liability to the ultimate consumer if it provides an adequate warning about the drug to the prescribing physician." *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93, 109 (Ky. 2008); *Larkin*, 153 S.W.3d at 764 ("Providing an adequate warning to the prescribing physician relieves the manufacturer of its duty to warn the patient regardless of how or if the physician warns the

patient.").[9] Although the duty to warn may only run to the learned intermediary, it must nevertheless be adequate. *Larkin*, 153 S.W.3d at 764.[10]

In sum, a manufacturer's duty to warn is discharged if it warns a learned intermediary of risks that were either known or knowable considering the state of medical knowledge available at the time of manufacture and distribution. Here, the question of liability turns on whether Defendant, at the time of Prather's 2001 surgery, knew or should have known that the PCIP posed a danger of chondrolysis, sufficient to prompt a duty to warn. Defendant argues that no medical authority suggested a link between the intra-articular use of the PCIP and chondrolysis at the time of Prather's surgery. Accordingly, Defendant maintains it cannot be held liable for a failure to warn of such a risk.

The record unequivocally establishes that at the time of Prather's surgery, there existed no published literature specifically correlating chondrolysis to intra-articular pain pump use, and as such Defendant did not have *actual* knowledge of such as association. However, Prather argues that medical literature published before 2001 put Defendant on notice of the potential negative effects

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[9] The rationale underlying the doctrine is that

> only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy.

Larkin, 153 S.W.3d at 763 (quoting RESTATEMENT (THIRD) OF TORTS § 6 cmt. b).

[10] The Kentucky Supreme Court in *Larkin* defined an adequate warning as "sufficient to apprise the general practioner as well as the unusually sophisticated medical man of the dangerous propensities of the drug." *Id*. at 764 (internal quotation omitted). Importantly, the manufacturer's duty to adequately warn is confined to *foreseeable dangers*. *Low v. Lowe's Home Ctrs., Inc.*, 771 F. Supp. 2d 739, 742 (E.D. Ky. 2001). *See also Hackett v. Breg, Inc.*, 2011 WL 4550186, *1 (D. Colo. 2011)("A product is not defective or unreasonably dangerous if a particular risk was not known or knowable by the manufacturer in light of the generally recognized and prevailing scientific and technical knowledge available at the time of manufacture and distribution."); *Montgomery Elevator Co. v. McCullough*, 676 S.W 2d 776 (Ky. 1984)(stating that a "manufacturer is presumed to know the qualities and characteristics, and the action condition, of his product at the time he sells it").

that local anesthetics have on cartilage cells. Had Defendant performed a review of the medical and scientific literature available to it at that time, Prather urges that Defendant would have foreseen that the intra-articular use of the PCIP would result in severe cartilage damage. As such, Defendant had a duty to warn or investigate further into that risk of harm. Prather, primarily through the expert report of Dr. Suzanna Parisian, presents several articles in support of this argument.

Defendant principally relies on a recent Sixth Circuit case to argue that Prather's proffered articles do not create a triable issue of fact of whether Defendant should have known that the PCIP could cause chondrolysis. *See Rodriguez v. Stryker Corp.*, 680 F.3d 568, 575 (6th Cir. 2012). In *Rodriguez*, a case that is remarkably similar to the case at bar, the plaintiff brought a products liability action against the manufacturer of an anesthetic infusion pain pump alleging that the pump implanted in plaintiff's shoulder following orthopedic surgery caused severe cartilage destruction. The plaintiff premised the manufacturer's liability on a duty to warn theory, arguing that the medical literature available at the time of surgery put the manufacturer on notice that its pain pump could cause chondrolysis, and as such, the manufacturer had a duty to warn of that risk. *Id.* at 570-71. The Sixth Circuit affirmed the lower court's decision, wherein it dismissed the case at the summary judgment stage based on the court's finding that the risk of chondrolysis was not knowable at the time of plaintiff's surgery. *Id.* at 577. After analyzing the medical literature plaintiff presented, the Sixth Circuit held:

> When all is said and done, not one of Rodriguez's thirteen articles shows that medical experts understood in 2004 that infusing a joint with bupivacaine for two days could cause irreversible cartilage damage. [The manufacturer] had no duty to understand what the relevant medical literature did not.

Id. at 572[11]; *see also*, *Mack v. Stryker*, 2012 WL 3599458, *10 (D. Minn. Aug. 14, 2012)(holding that the medical community did not draw a connection between pain pumps and chondrolysis, or any similar injury suffered, until 2005). In sum, the Sixth Circuit concluded that none of the articles presented supported "the conclusion that [the manufacturer] reasonably should have known about the risk that its pumps could cause chondrolysis." *Rodriguez*, 680 F.3d. at 572. Guided by Sixth Circuit precedent, to the extent Prather submits articles that were reviewed and rejected in the Sixth Circuit's *Rodriguez* decision, those articles are insufficient to charge Defendant with a duty a warn of the risk of chondrolysis from use of the PCIP.[12]

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[11] The Sixth Circuit cites a passage from the lower court decision that this Court finds worth reiterating:

> While the pre–2004 medical articles raise the general notion that health of (usually animal) cartilage could be weakened by prolonged exposure to certain "foreign elements," it is a bridge way too far to say that Stryker—in the context in which infusion pumps were broadly used and medically accepted without reservation—should have, prior to marketing the pain pump, culled through seven decades of literature, found the sporadic articles raising this concern, ignored all the authority/evidence to the contrary, and then independently concluded that its pain pump could cause chondrolysis, particularly where no one in the medical community connected the destruction of cartilage to the use of pain pumps until after the plaintiff's surgery.

Id. at 573 (quoting *Rodriguez*, 2011 WL 31462, at *7).

[12] It is worth mentioning a seemingly contradictory Sixth Circuit case that came out less than three months after *Rodriguez*. In *Krumpelbeck v. Breg*, 491 F. App'x. 713 (6th Cir. 2012), the Sixth Circuit reversed the district court's decision to grant summary judgment for the manufacturer as to plaintiff's statutory claims for defective design and inadequate warning or instruction. Like the case at bar and *Rodriguez*, the plaintiff in *Krumpelbeck* brought a product liability action against the manufacturer of an infusion pump alleging that the pump implanted in plaintiff's shoulder caused her to develop chondrolysis. *Rodriguez* applied Tennessee substantive law and *Krumpelbeck* applied Ohio substantive law. The different outcomes in these cases can be attributed to how the courts cast the defendant manufacturer's duty to warn. In *Krumpelbeck*, the Sixth Circuit ruled that the district court framed the duty owed

> too narrowly. While the medical literature as of March 2005 was insufficient to put [the manufacturer] on notice of the risk of chondrolysis specifically, Krumpelbeck pointed to numerous articles and published studies prior to that time that found a link between infusion of chemicals into the joint space and harm of the same general nature as that Krumpelbeck suffered – damage and destruction of the cartilage . . . [And accordingly, a] reasonably jury could conclude . . . that it was sufficient to put [the manufacturer] on notice of the risk of chondrolysis prior to her surgery.

Krumpelbeck, 491 F. App'x at 719. This more general duty to warn is proscribed by the Ohio Product Liability Act, which requires courts to consider several statutory factors in determining whether a risk of harm is foreseeable. Specifically, courts applying Ohio law must consider whether the risk is foreseeable under the lens of a "consumer expectations" test. OHIO REV. CODE ANN. § 2307.75(B)(5). This test provides that a product may be defectively designed if "[i]t is more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." OHIO REV. CODE ANN. § 2307.75(A)(2). As the *Krumpelbeck* Court noted, "[t]he focus of the consumer-expectation test . . . is not the risks known to the manufacturer, but rather, the consumer's understanding and appreciation of the dangers associated with use of the product." *Krumpelbeck*, 491 F. App'x at 719.

Dr. Parisian identifies two articles, published before the June 2001 surgery, that the *Rodriguez* Court did not address. The Court will briefly summarize the articles as follows:

> 1. In 1998, the *Hospital for Joint Diseases* published an article documenting a case of glenohumeral osteoarthritis in the shoulder following exposure to gentian violet during a rotator cuff surgery. ECF No. 266-20. Gentian violet is an antiseptic dye found in markers that are used to mark a patient's skin prior to surgery.
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> 2. In 2000, the *International Skeletal Society* published an article describing a case of "rapid and severe chondrolysis appearing after the intra-articular leakage of cement during injection of a benign acetabular subchondral cyst, leading to hip replacement." ECF No. 266-21. The substance leaked was acrylic cement.

The Court concludes that these articles do not support the conclusion that in 2001, Defendant should have known of the risk of cartilage damage due to the intra-articular infusion of an anesthetic. Prather argues that since these two additional articles were not before the *Rodriguez* Court, the factual findings of that case are inapplicable. The Court is not persuaded. The additional articles suffer from the same deficiencies as the articles rejected by the *Rodriguez* Court.[13] Specifically, these articles document the effects of exposure to solutions that are fundamentally different than the anesthetic medication used in the PCIP.

The Court finds that the entirety of the articles presented by Prather are insufficient to create a factual issue of whether Defendant should have known of the risk of cartilage damage caused by

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Such a statutory mandate is not found in the KPLA. In fact, the Kentucky Supreme Court renounced the consumer expectations test in favor of the prudent manufacturer test for strict liability, which requires an examination into what the manufacturer knew or should have known at the time its product was sold. *Nichols v. Union Underwear Co. Inc.*, 602 S.W.2d 429, 432 (Ky. 1980). This Court is inclined to follow the *Rodriguez* decision given that the KPLA tracks Tennessee product liability law with respect to a manufacturer's duty of care. *Compare* KRS § 411.310 *with* TENN. CODE ANN. § 29-28-105(b). It is worth noting that the court in *Mack v. Stryker Corporation* cited the *Krumpelbeck* district court opinion as an example of a court dismissing the case based on the its finding that the risk of cartilage damage were not knowable at the time of plaintiff's surgery, and that the Sixth Circuit reversed that decision based on "state *statutory* grounds." 2012 WL 3599458, at *6 (emphasis added).

[13] For instance, the 1998 article documenting the adverse effects of gential violet is substantially the same as an article that was plainly rejected by the *Rodridguez* Court. *See Rodriguez*, 680 F.3d at 571 (noting that several articles presented by the plaintiff wrongly tied the risk of chondrolysis to "gentian violet (a dye)").

the prolonged exposure of an anesthetic via the intra-articular use of a pain pump. A manufacturer will not be charged with constructive knowledge of a risk that was unknown in the medical community. *See Mack*, 2012 WL 359948, at *10 (reasoning that the plaintiff's position averred that the manufacturer "should have been the first one in the medical community to perform the right tests, connect all of the dots, and ultimately determine that intra-articular use of the pain pump could be harmful to cartilage. The law does not obligate [the manufacturer] to be a pioneer, particularly when existing literature did not objectively forewarn of injury"); *Toner*, 732 P.2d at 307 (stating that "sellers need not be clairvoyant").

As medical experts in the relevant field had yet to fully appreciate the risks allegedly presented by a pain pump such as PCIP at the time of Prather's surgery, Defendant had no duty to warn. Absent such a duty, Defendant cannot be held strictly liable on a failure to warn theory.

IV.

Having dismissed Prather's strict liability claim, the Court now turns to Prather's product liability claim based on negligence. Prather's negligence action alleges that Defendant (1) defectively designed the PCIP; (2) failed to warn of the knowable risk of danger posed by the PCIP according to research medical literature available at the time of Prather's surgery; (3) failed to conduct sufficient safety tests; and (4) manufactured the PCIP for an unapproved use. These theories of negligence somewhat overlap, but the Court will address each one at a time.

A.

First, Prather alleges that Defendant's product was negligently and defectively designed. In Kentucky, a plaintiff can bring a defective design claim under a theory of strict liability or negligence, the foundation of both theories being that the product is "unreasonably dangerous."

Ulrich v. Kasco Abrasives Co., Ky., 352 S.W.2d 197, 200 (Ky. 1976). Strict liability typically focuses on the condition of the product while a negligence inquiry examines whether the manufacturer exercised the proper degree of care to protect against foreseeable dangers when manufacturing the product for the consumer. *Ostendorf v. Clark Equip. Co.*, 122 S.W.3d 530, 535 (Ky. 2003). In a design defect case, Kentucky courts employ a risk-utility test to "assess decisions made by manufacturers with respect to the design of their products. *Id*. Importantly, "the risk-utility test examines what the manufacturer knew or should have known *at the time the product was sold*." *Id*.[14]

Prather premises her negligent design defect claim on the theory that the PCIP was unreasonably dangerous because it bore the risk of chondrolysis. However, Prather cannot maintain this claim given that this Court, as a matter of law, finds that the medical knowledge in existence at the time Defendant manufactured the PCIP did not indicate a risk of chondrolysis from an anesthetic infusion pump. Without more, it appears that Defendant conformed to the state of the art when it manufactured the PCIP. As such, Prather's negligent design defect claim fails.

B.

Next, Prather contends that Defendant was negligent for failing to warn doctors of the risks associated with pain pumps and cartilage degradation. "A supplier of a product may . . . have a duty to warn arising out of general negligence principles." *C & S Fuel, Inc. v. Clark Equip. Co.*, 552 F. Supp. 340, 347 (E.D. Ky. 1982). A defendant's duty to warn is confined to risks either known or knowable by the exercise of reasonable care. *Id*.

[14] Additionally, the KPLA contains a statutory presumption that a product is not defective "if the design, methods of manufacture, and testing conformed to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared." KRS § 411.310.

Similar to Prather's strict liability duty to warn claim, this claim, judged under negligence principles, also fails. The Court is not persuaded that Defendant knew or should have known of the PCIP's allegedly defective and dangerous condition at the time of Prather's surgery. As discussed, the state of medical science at the time of the 2001 surgery did not suggest a link between cartilage damage and the intra-articular infusion of an anesthetic. The law does not impart a duty to warn of the unknown. *See Rodriguez*, 2011 WL 31462, at *10 ([B]ecause there was no way to reasonably know of this risk, it is not logical to argue that the defendant should have warned doctors about chondrolysis."). Accordingly, the Court concludes that Defendant was not negligent for failing to warn doctors of the risk of shoulder degradation caused by the PCIP.

C.

Turning now to the failure to test theory, Prather argues that Defendant should be liable for failing to sufficiently test the PCIP to ensure that its use in the intra-articular joint space did not pose a risk of harm. It is unclear whether Kentucky law recognizes an independent duty to test.[15] No Kentucky cases explicitly impose such a duty, but a careful reading of the KPLA suggests testing may be indicative of whether the manufacturer satisfied its more general duty to exercise reasonable care. *See* KRS § 411.300 (defining a product liability action as "any brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, *testing*, listing, certifying, warning, instructing, marketing, advertising, packaging or labeling of any

[15] Other courts faced with similar cases have not recognized a separate duty to test. *See Rodriguez*, 680 F.3d at 574 (ruling that, under Tennessee law, a duty to test "collapses into the failure-to-warn claim"); *Rodriguez*, 2011 WL 31462, at *9 (stating that "it is clear that there is no broadly recognized 'duty to test' in Tennessee"); *Mack*, 2012 WL 3599458, at *11 n.7 ("There is no independent duty to test under Minnesota law, but it is generally subsumed within the duty to adequately warn.").

product")(emphasis added); KRS § 411.310(2) (stating that "it shall be presumed, until rebutted by a preponderance of the evidence to the contrary, that the product was not defective if the design, methods of manufacture, *and testing* conformed to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared, and the product was manufactured")(emphasis added). A failure to conduct adequate safety tests tends to show that a manufacturer did not exercise reasonable care in its production of the product. Accordingly, the Court will analyze whether Defendant possibly breached its duty of care by failing to sufficiently test the PCIP to ensure its safety.

Defendant maintains that it satisfied its duty of care by conducting a reasonable amount of testing to safeguard against known risks. Further, Defendant argues that to require manufacturers to develop methodologies and conduct research to discover a problem that no one in the medical community had reported before 2001 would be overly burdensome. The Court agrees. The link between an intra-articular pain pump and chondrolysis was remote at the time Defendant manufacturer the PCIP. As such, Defendant did not breach its duty to care by failing to conduct some theoretical test that could have unearthed possible evidence of chondrolysis. *See Rodriguez*, 690 F.3d at 574 ("The law does not require a company to test for hidden risks that neither it nor the medical community had a reasonable basis to suspect."); *Phillippi v. Stryker Corp.*, 2010 WL 26508596, *3 (E.D. Cal. July 1, 2010)(holding that there is no independent duty to test and even if there were, "it would be completely speculative as to what the consequences would be of any purported failure to fulfill this supposed duty").

Though Prather's expert Dr. Parisian suggests Defendant could have done additional testing, it is unclear whether such testing would have revealed a risk of chondrolysis. Defendant certainly

had an obligation to conduct some amount of testing, defined by what risks the medical community identified or suspected the product to have, in order to ensure the general safety of the product. However, Defendant did not have an obligation to spearhead medical research by testing for every conceivable risks posed by use of the PCIP. Imposing such an extraordinary, heightened duty of care would be inefficient; in most cases, additional testing would likely result in products that are marginally more safe, but unnecessarily more expensive. *See Rodriguez*, 2011 WL 31462, at *10 ("At the time that this product was marketed, no one knew of this specific risk, and it would not have been reasonable - at the time - to refer to a party as 'negligent' for failing to conduct additional testing and research to explore this unknown risk."). Therefore, Defendant cannot be held liable for a failure to test the PCIP for an unknown risk.

D.

Next, Prather contends that Defendant breached its duty of care by failing to submit sufficient information to the FDA with respect to the PCIP. Specifically, Prather alleges that Defendant failed to act as a reasonably prudent manufacturer when it manufactured the PCIP under a 510(k) clearance; since the PCIP had a different intended use than the predicate device, Sgarlato improperly claimed substantial equivalence and should have pursued the more rigorous PMA application route. Prather argues that Defendant then had a duty to warn physicians that the FDA did not properly clear the intra-articular placement of the PCIP.

First, it is worth emphasizing Defendant's role, or rather lack thereof, in the FDA submission process. Prather has failed to present any evidence that Defendant was or should have been involved in Sgarlato's 510(k) application, or that an allegedly improper 510(k) clearance would have triggered a duty to warn. *See Lohr*, 518 U.S. at 493 ("The 510(k) process is focused on equivalence, not

safety."). Moreover, it is undisputed that in March 1999, Sgarlato received 510(k) clearance to market the PCIP "to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative management of pain following surgery." ECF No. 266-10. The FDA determined that Sgarlato demonstrated substantial equivalence between the PCIP and the predicate device. Certainly the FDA had the options to deny Sgarlato's application or request additional information. However, that was not the case. The FDA cleared the PCIP for the precise way in which Dr. Savoie used it in Prather's surgery. Accordingly, Prather's negligence claim concerning the PCIP's regulatory submission fails.

E.

Even if Prather could create a factual issue on the duty and breach element of her negligence product liability claim, it would nonetheless fail as a matter of law for lack of causation. In Kentucky, a plaintiff pursuing claims for strict liability, negligence, or breach of warranty bears the burden of establishing that the product was the factual and legal cause of her injuries. *Morales*, 71 F.3d at 537. "Further, under Kentucky law, causation or proximate cause is defined by the substantial factor test: was the defendant's conduct a substantial factor in bringing out plaintiff's harm?" *Id*. A plaintiff may prove causation by circumstantial evidence, but "the evidence must be sufficient to tilt the balance from possibility to probability." *Id*.

Prather has failed to show that any alleged breach on the part of Defendant directly or proximately caused her injury. Here, the evidence indicates that Dr. Savoie's use and placement of the PCIP were decisions entirely of his own. Sgarlato originally developed the PCIP as a pain pump implant for the foot. Dr. Savoie, with his colleagues, adapted the PCIP for use in the shoulder's intra-articular joint space. At no time did Defendant promote any particular use or placement of the

PCIP. In fact, the record strongly suggests that Defendant's conduct did not have a meaningful effect on any of Dr. Savoie's medical decisions.[16] As such, Prather has failed to show that Defendant's manufacturing of the PCIP was the proximate cause of her injuries.

Prather highlights testimony in which Dr. Savoie stated that had he been warned of the risk of chondrolysis, he in all likelihood would not have used the PCIP in the June 2001 surgery. However, as thoroughly analyzed above, the medical field was unaware of such a risk, and the Court will not burden Defendant with the daunting task of discovering a later-known medical phenomenon. In sum, Defendant's negligence claims fail as a matter of lack for lack of legal causation.

V.

In their briefs, the parties devote little argument and analysis to Prather's claims for breach of express and implied warranties. These claims are somewhat derivative of the strict and negligence product liability claims in that they similarly require Prather to establish that her injury resulted from a defective or unreasonably dangerous product, *McCoy*, 47 F. Supp. 2d at 839, and that Defendant's failure to warn was the proximate cause of Prather's injury. *Holbrook v. Rose*, 458 S.W.2d 155, 157 (Ky. 1970). The Court's previous findings that the PCIP was neither defective nor unreasonably dangerous, and that Prather cannot sufficiently demonstrate legal causation, foreclose

[16] The Court in *Phillippi* aptly summarized the discretion that is distinct in the medical field:

> It is without controversy that the decision to use Stryker's infusion pump in the fashion that it was used during Plaintiff's surgery was solely and exclusively Dr. Younger's, who received no direction or instruction from Stryker as to the placement of the catheter, the type of anesthetic utilized, the amount of anesthetic utilized, the rate at which the anesthetic was administered via the pump, or the duration of time during which the anesthetic was administered. Because all these variables were within the doctor's discretion, Stryker cannot be liable as a matter of law for an injury which, assuming that medical causation were established, would be due solely to the doctor's decision on these factors.

Phillippi, 2010 WL 2650596, at *3.

Prather's ability to prove a meritorious warranty claim. Accordingly, these claims are similarly dismissed as a matter of law.

VI.

Lastly, in her Complaint Prather alleges causes of action based on fraudulent misrepresentation, negligent misrepresentation, fraudulent concealment and fraud. In a Kentucky action for fraud, the party claiming harm must establish the following six elements by clear and convincing evidence:

> (1) that defendant made a material representation; (2) that it was false; (3) that when he made it he knew it was false, or made it recklessly, without any knowledge of its truth and as a positive assertion; (4) that he made it with the intention of inducing plaintiff to act, or that it should be acted upon by the plaintiff; (5) that plaintiff acted in reliance upon it; and (6) that plaintiff thereby suffered injury.

Crescent Grocery Co. v. Vick, 240 S.W. 388, 389 (Ky. Ct. App. 1922).[17]

Defendant argues that the fraud and misrepresentation claims should be dismissed because there is no evidence that Defendant made any false representations to, or withheld knowable information from, Dr. Savoie or Prather. The Court agrees. Again, it is worth highlighting that Defendant was a contract manufacturer for Sgarlato. Defendant did not market the PCIP, but rather sold the PCIP to Sgarlato pursuant to the distribution agreement. The record does not indicate that Dr. Savoie had *any* interaction with Defendant whatsoever.

Prather hinges this claim on the allegation that Lisa Sgarlato, a sales representative for Sgarlato, made misrepresentations in conversations with Dr. Savoie that induced him to use the

[17] "The tort of negligent misrepresentation differs from fraudulent misrepresentation only in that the former tort demands only that a false representation or concealment be made negligently, rather than recklessly or with knowledge of its falsity." *Clark v. Danek Med., Inc.*, 64 F. Supp. 2d 652, 657 (W.D. Ky. 1999). Moreover, to maintain a claim for fraudulent concealment, the plaintiff must sufficiently allege that defendant had a duty to disclose a material fact and failed to do so, and that as a result, the plaintiff suffered a loss. *Rivermont Inn, Inc. v. Bass Hotels & Resorts, Inc.*, 113 S.W.3d 636, 641 (Ky. Ct. App. 2003).

PCIP in the manner that he did. Prather maintains that Ms. Sgarlato made these misrepresentations with Defendant's "full knowledge, implied consent and by virtue of their manufacture of the PCIP." ECF No. 271. The inferential jumps required to make such a conclusion are attenuated at best. The record unequivocally establishes that Defendant did not make any representations that the PCIP should be implanted in the intra-articular joint space following arthroscopic shoulder surgery and that Dr. Savoie made that decision independently. *See* ECF No. 266-12 (When asked if Lisa Sgarlato explained to him how to use the PCIP, Dr Savoie responded, "I don't remember anybody actually explaining to me how to use it."); *see also Rodriguez*, 680 F.3d at 575 ("[I]t makes no difference that Stryker knew surgeons would use its pump in the joint space or even encouraged them to do so since Rodriguez has failed to show that Stryker knew or should have known that the use was dangerous. The FDA approved Stryker's pain pump for use at the intra-operative site, and none of Rodriguez's evidence indicates that Stryker marketed its pump beyond the approved use."). In short, Dr. Savoie did not rely on any alleged representations made by Sgarlato and appears to be entirely unfamiliar with Defendant. Consequently, Defendant is entitled to summary judgment on each of Prather's claims premised on fraud and misrepresentation.

Being otherwise sufficiently advised,

IT IS HEREBY ORDERED that Defendant’s Motion for Summary Judgment is SUSTAINED and all of Plaintiff’s claims are DISMISSED WITH PREJUDICE.

This is a final and appealable order.

April 1, 2013

John G. Heyburn II, Judge
United States District Court

cc: Counsel of Record