Estes v. Lanx, Inc. et al Doc. 111

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
ABERDEEN DIVISION

ROCKY ESTES PLAINTIFF

V. CAUSE NO.: 1:14CV052-SA-DAS

LANX, INC., et al. DEFENDANTS

MEMORANDUM OPINION

Plaintiff filed this suit against Lanx, Inc., for negligence, products liability for design defect, products liability for manufacturing defect, breach of express and implied warranties, fraudulent concealment, and negligent misrepresentation. Defendant filed a Motion for Summary Judgment [94] that no genuine disputes of material fact exist as to those claims. After reviewing the record, motion, response, rules, and authorities, the Court finds as follows:

Factual and Procedural Background

In 2011, Rocky Estes underwent spinal fusion surgery wherein the Lanx Telluride Spinal Fixation System was implanted to fuse his L5-S1 vertebrae. Within five months, two pedicle screws fractured. A revision surgery was performed on June 28, 2012, to remove the broken screws and replace the Telluride Spinal Fixation System with new orthopedic hardware.

Estes seeks compensation for injuries, pain and suffering, and his extensive past and future medical treatment on the basis that the pedicle screw was negligently designed or manufactured, that Lanx breached warranties as to the pedicle screws, and that Lanx failed to obtain FDA clearance for the Telluride System.

Lanx filed a Motion for Summary Judgment on those claims.

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Summary Judgment Standard

Summary judgment is warranted under Rule 56(a) of the Federal Rules of Civil Procedure when the evidence reveals no genuine dispute regarding any material fact and the moving party is entitled to judgment as a matter of law. The rule "mandates the entry of summary judgment, after adequate time for discovery and upon motion, 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, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986).

The party moving for summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Id.* at 323, 106 S. Ct. 2548. The nonmoving party must then "go beyond the pleadings" and "set forth 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 324, 106 S. Ct. 2548 (citation omitted). In reviewing the evidence, factual controversies are to be resolved in favor of the nonmovant, "but only when . . . both parties have submitted evidence of contradictory facts." *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc). Importantly, conclusory allegations, speculation, unsubstantiated assertions, and legalistic arguments have never constituted an adequate substitute for specific facts showing a genuine issue for trial. *TIG Ins. Co. v. Sedgwick James of Wash.*, 276 F.3d 754, 759 (5th Cir. 2002); *SEC v. Recile*, 10 F.3d 1093, 1097 (5th Cir. 1997); *Little*, 37 F.3d at 1075.

Discussion and Analysis

Plaintiff's causes of action can be summarized into three broader sub-categories: (1) claims concerning the specific pedicle screw and/or spinal fixation system used in Estes' 2011

surgery; (2) claims regarding warranties allegedly made by Lanx; and (3) claims that the Telluride Spinal Fixation System was improperly placed on the market for sale without proper FDA clearance.

(1) Mississippi Products Liability Act and Negligence

As for the first category, claims centered around the specific medical device used on Estes, the Plaintiff pled these causes of action: negligence, defective design, and manufacturing defect. Lanx contends that Plaintiff cannot sustain a negligence action on the basis that the Mississippi Products Liability Act precludes common law negligence.

a. Design Defect under the MPLA

Defendant contends Plaintiff's MPLA design defect claim should be dismissed as no feasible alternative design has been offered into evidence. Plaintiff failed to respond. The Mississippi Supreme Court has summarized the design defect elements under the MPLA as follows:

> The danger presented by the product's design was known or should have been known to the manufacturer [or seller] (i.e., the danger was foreseeable); (2) the product failed to function as expected (as a result of a design characteristic); (3) an alternative design existed that would not impair the product's usefulness or desirability; and (4) the alternative design would have to a reasonable probability prevented the harm.

Phillips 66 Co., 94 So. 3d at 1060 (quoting *Williams v. Bennett*, 921 So. 2d 1269, 1274 (Miss. 2006) (internal quotation marks omitted)). Plaintiff put forth no evidence as to an alternative design. Accordingly, the Court finds that no genuine issue of material fact has been produced as to Plaintiff's design defect claim and that claim is dismissed. *See Gilley v. Protective Life Ins. Co.*, 17 F.3d 775, 781 n.13 (5th Cir. 1994) ("We have held that an argument is waived if the party fails to make the argument in response to summary judgment.").

b. *Failure to Warn under the MPLA*

For a plaintiff to prevail on a failure-to-warn claim in Mississippi, he must prove by a preponderance of the evidence that at the time the product left the control of the manufacturer, designer, or seller:

> (i) . . . The product was defective because it failed to contain adequate warnings or instructions . . . ; and
>
> (ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and
>
> (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.

MISS. CODE ANN. § 11-1-63(a)(i)(2), (ii) (iii). On such a claim, a plaintiff must also prove the following:

> (c)(i) . . . [A]t the time the product left the control of the manufacturer, designer[,] or seller, the manufacturer, designer[,] or seller knew or in light of reasonably available knowledge should have known about the danger that caused the damage for which recovery is sought and that the ordinary user or consumer would not realize its dangerous condition[; and]
>
> (ii) An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device[,] or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device[,] or other product.

MISS. CODE ANN. § 11-1-63(c).

Thus, "[a] manufacturer is liable under a failure-to-warn theory if the product 'failed to contain adequate warnings,' the inadequate warnings 'rendered the product unreasonably

dangerous to the user or consumer,' and the inadequate warnings 'proximately caused the damages for which recovery is sought.'" *Union Carbide Corp. v. Nix, Jr.*, 142 So. 3d 374, 385 (Miss. 2014). The Fifth Circuit in interpreting Mississippi law has stated:

> Under the learned intermediary doctrine, which is codified in the Mississippi Products Liability Act, a manufacturer of a prescription drug has no duty to warn the end user of the drug's possible adverse effects. *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688 (Miss. 1988). The manufacturer's duty to warn runs only to the prescribing physician, who acts as an intermediary between the manufacturer and the patient. *Id*. The learned intermediary doctrine applies to medical devices as well as prescription drugs. *Moore v. Mem. Hosp. of Gulfport*, 825 So. 2d 658, 662 n.6 (Miss. 2002).

Smith v. Johnson & Johnson, Inc., 483 F. App'x 909, 913-14 (5th Cir. 2012) (per curiam). "In order to make out a case for failure to warn under the learned intermediary doctrine, the plaintiff must establish that the treating physician, or a reasonable physician in the treating physician's position, would not have used the product had he received an adequate warning." *Id*. at 914 (citing *Thomas v. Hoffman—LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992)).

Plaintiff alleges Lanx had a duty to inform the hospital and the attending physician that the Lanx Telluride Spinal Fixation System had not been cleared, or that a standalone 510(k) had not been submitted to the FDA, and that this failure caused his injuries.[1] In support of this claim, Plaintiff states that "Dr. Crosby has confirmed that had he known that Lanx Telluride Spinal Fixation System had not been cleared or that a standalone 510(k) had not been submitted to the FDA and the Telluride System had not been cleared by the FDA he would not have used the Telluride System in the surgical procedure he performed on Estes." No record citation is provided by Plaintiff, and no support is found therein, to substantiate this claim. Thus, Plaintiff

[1] Although the Amended Complaint [90] does not assert a failure to warn theory of liability under the MPLA, and the Court generally will not consider claims raised only in response to summary judgment, the Court analyzes them herein because dismissal of these claims is necessary after their consideration. *See Roberts v. Lubrizol Corp.*, 582 F. App'x 455, 461 (5th Cir. 2014) (quoting *Cutrera v. Bd. of Supervisors of La. State Univ.*, 429 F.3d 108, 113 (5th Cir. 2005); *see also Green v. JP Morgan Chase Bank, N.A.*, 562 F. App'x. 238, 240 (5th Cir. 2014).

has failed to put forth evidence that the treating physician would not have used this product had he known of the alleged lack of FDA clearance for the device or components of the product. Additionally, the treating physician did indicate in his deposition that he was aware of the risks of spinal fusion surgery and implantation of fusion devices, including the possibility of device failure. Even knowing those risks, Dr. Crosby testified he still used the Lanx Telluride Spinal Fixation System. Plaintiff's failure to warn claim is dismissed.

c. *Manufacturing Defect under the MPLA*

For a plaintiff to prevail on a manufacturing defect claim in Mississippi, he must prove by a preponderance of the evidence that at the time the product left the control of the manufacturer or designer:

> (i) The product was defective because it deviated in a material way from the manufacturer's or designer's specifications or from otherwise identical units manufactured to the same manufacturing specifications, . . .; and
>
> (ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and
>
> (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.

MISS. CODE ANN. § 11-1-63(a)(1)(i)-(iii).

"[M]anufacturing defect claims involve allegations not that the entire product line in question was defectively designed, but rather that the specific product purchased by the consumer was manufactured in a way which deviated from the design specifications." *Hickory Springs Mfg. Co. v. Star Pipe Prods., Ltd.*, 991 F. Supp. 2d 778, 782 (N.D. Miss. 2014).

"[A] product is not 'defective' under § 11-1-63(a)(i)(1) unless it is shown to be out of compliance with the manufacturer's specifications." *Cooper Tire & Rubber Co. v. Tuckier*, 826 So. 2d 679, 693 (Miss. 2002) (citing *Leverette v. Louisville Ladder Co.*, 183 F.3d 339, 341 (5th

Cir. 1999) (holding that expert's testimony that ladder had manufacturing defect was properly excluded in products liability action under Mississippi law where expert failed to assess whether ladder met manufacturer's specifications)).

Plaintiff's Amended Complaint suggests that the "Lanx Pedicle Screws were not made in accordance with the Defendants' [sic] specifications or performance standards." However, Plaintiff never states how the pedicle screws at issue deviated from the manufacturing specification. In fact, Plaintiff puts forth no manufacturing specifications at all. Plaintiff further contends that proof of malfunction creates a genuine issue of material fact as to a manufacturing defect under the MPLA. Moreover, Plaintiff alleges that Defendant spoliated the evidence by failing to collect or maintain the broken pedicle screws after their removal from the Plaintiff.

The Court finds that Plaintiff's assertion that proof of malfunction is enough to sustain a question of fact in manufacturing defect cases under the MPLA is erroneous. Plaintiff's citations on this issue indicate the converse of Plaintiff's contentions. *See Shelter Ins. Co. v. Mercedes-Benz USA, LLC*, 236 F. App'x 45, 47-48 (5th Cir. 2007) (holding that evidence that only the battery malfunctioned, without proof of an actual deviation from manufacturer specifications, was not enough to prove an essential element of the plaintiff's claim); *Tuckier*, 826 So. 2d at 693 ("[A] product is not 'defective' under § 11-1-63(a)(i)(1) unless it is shown to be out of compliance with the manufacturer's specifications."). Accordingly, without evidence of any manufacturer specifications, Plaintiff has failed to put forth evidence as to an element of the manufacturing defect claim that he would have to prove at trial. Therefore, Lanx's motion for summary judgment as to this claim is granted.

d. *Negligence*

Plaintiff's Amended Complaint additionally alleges that Lanx breached its duty of reasonable care in that it negligently "designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled, and/or sold" the Lanx Telluride System and its component, the Lanx Pedicle Screw. Despite the allegations not being in his complaint, the Plaintiff, in response to Defendant's Motion for Summary Judgment asserts that Lanx was additionally negligent in releasing the Telluride Spinal Fixation System into commerce without proper FDA clearance.

The Mississippi Legislature amended the Mississippi Products Liability Act (MPLA) in 2014 to apply to "any action for damages caused by a product, *including, but not limited to, any action based on a theory of strict liability in tort, negligence or breach of implied warranty*" and details the requirements to find "[t]he manufacturer, *designer* or seller" liable in such actions. MS LEGIS 383 (2014), 2014 Miss. Laws Ch. 383 (H.B. 680) (amended text emphasized). This amendment seems to signal the Mississippi Legislature's intent for all claims brought for damage caused by a product to be analyzed under the MPLA. *See Little v. Smith & Nephew, Inc.*, No. 1:15-CV-028-GHD, 2015 U.S. Dist. Lexis 75666, *12-13 (N.D. Miss. June 11, 2015). However, that version of the MPLA went into "force from and after July 1, 2014." *See* 2014 Miss. Laws WL No. 48 (H.B. 680). "[I]f a statute is to apply 'effective from and after passage' it is not to apply to causes of action that have accrued prior to the passage of the statute." *Tie—Reace Hollingsworth ex rel McDonald v. City of Laurel*, 808 So. 2d 950, 954 (Miss. 2002). "A cause of action accrues only when it comes into existence as an enforceable claim; that is, when the right to sue becomes vested, and the theory that an injury has to happen before a tort is considered complete." *Oaks v. Sellers*, 953 So. 2d 1077, 1081 (Miss. 2007) (internal quotation marks and

citation omitted). Indisputably, this cause of action accrued prior to the 2014 amendments to the MPLA.

Under the previous version of the MPLA, a determination of whether a plaintiff's negligence claim can exist alongside his other MPLA claims requires this Court to navigate unsettled Mississippi law. The previous version of the MPLA states that it applies "in any action for damages caused by a product except for commercial damage to the product itself." *See* Laws 2004, 1st Ex. Sess., Ch. 1, § 3, eff. September 1, 2004, amended by Laws 2014, Ch. 383 (H.B. No. 680), § 1, eff. July 1, 2014. To date, the Mississippi Supreme Court has never clearly indicated whether negligence claims are abrogated by the MPLA, and as recently as 2012 declined to decide that issue. *See Phillips 66 Co. v. Lofton*, 94 So. 3d 1051, 1063 (Miss. 2012) ("[G]iven that we have found that [the plaintiff] met his evidentiary burden under MPLA, it is unnecessary for this Court to reach the issue of whether [his] negligence claim was subsumed under MPLA . . . ."). In interpreting Mississippi law that same year, the Fifth Circuit stated that negligence claims can be brought alongside strict liability claims, but "a party may not disguise a products liability claim as a negligence claim to avoid dismissal." *Murray v. GM, L.L.C.*, 478 F. App'x 175, 181 (5th Cir. 2012) (per curiam) (citing *McSwain v. Sunrise Med., Inc.*, 689 F. Supp. 2d 835, 844 (S.D. Miss. 2010)). *See McSwain*, 689 F. Supp. 2d at 846 (the plaintiff's "common law negligence claims fail because they are mere restatements of the claims brought under the MPLA, and . . . are not supported by sufficient evidence"); *Murray v. GM, LLC*, No. 3:10-CV-188-HTW-LRA, 2011 U.S. Dist. LEXIS 93845, 2011 WL 3684517, at *3 (S.D. Miss. Aug. 22, 2011) ("[W]hen a plaintiff's negligence claim cannot survive apart from his MPLA claim, regardless of how the plaintiff labels the claim . . . the claim is governed by the MPLA."); *McKee v. Bowers Window & Door Co.*, 64 So. 3d 926, 940 (Miss. 2011) (the plaintiffs'

"negligence claim fail[s] to present any new discussion or claim that does not relate back to the . . . products liability claim")).

With regard to specific claims, courts in Mississippi generally held that a negligence claim arising from defective design or failure to warn could not exist as a stand-alone claim because MPLA design defect claims and failure-to-warn claims necessarily required a negligence analysis. *See Hill v. Forest Labs., Inc.*, No. 2:06-CV-244-KS-MTP, 2014 U.S. Dist. LEXIS 78057, 2014 WL 2558756, at *2 (S.D. Miss. June 6, 2014) (the plaintiff's claim that defendant "negligently failed to warn of the alleged association between Lexapro and suicide" "was plainly a product liability claim within the scope of the MPLA"); *Hankins v. Ford Motor Co.*, No. 3:08-CV-639-CWR, 2011 U.S. Dist. LEXIS 143269, 2011 WL 6180410, at *4-5 (S.D. Miss. Dec. 13, 2011) (quoting *Palmer v. Volkswagen of America, Inc.*, 905 So. 2d 564, 599-600 (Miss. Ct. App. 2003) (internal quotation marks omitted) ("[W]hen a plaintiff claims defective design under the MPLA, a jury instruction on negligence is not necessary . . . because the risk-utility test [in the MPLA] requires the jury to reach a conclusion about the manufacturer's conduct[;] the test is a version of Judge Learned Hand's negligence calculus. Therefore, . . . a jury performing risk-utility analysis necessarily makes a negligence determination."); *McSwain*, 689 F. Supp. 2d at 846 ("The claim that [defendant] negligently failed to warn users of the danger of the chair without anti-tip tubes is a restatement of the failure to warn cause of action under the MPLA."); *Jowers v. BOC Group, Inc.*, No. 1:08-CV-036-KMO, 2009 U.S. Dist. LEXIS 53126, 2009 WL 995613, at *4 (S.D. Miss. Apr. 14, 2009) *aff'd in part, vacated in part on other grounds, and remanded sub nom., Jowers v. Lincoln Elec. Co.*, 617 F.3d 346 (5th Cir. 2010) ("[T]he greater weight of the somewhat-mixed authority holds that negligence-based claims of product defect [against a manufacturer] are abrogated by the MPLA."); *Lundy v.*

Conoco, Inc., No. 3:05-CV-477-WHB, 2006 U.S. Dist. LEXIS 82423, 2006 WL 3300397, at *2 (S.D. Miss. Nov. 10, 2006) ("The Court finds that the failure to warn/inadequate warnings claims, regardless of the fact that Plaintiffs labeled one claim 'products liability' and the other 'negligence', are both governed by the [MPLA]."); *Bennett v. Madakasira*, 821 So. 2d 794, 804 (Miss. 2002) ("Although a plaintiff in a prescription drug liability case may alternatively rely on strict liability and negligence principles, these principles merge into one inquiry; the adequacy of the defendant's warnings."); *Palmer*, 905 So. 2d at 600, *aff'd in part, rev'd in part on other grounds*, 904 So. 2d 1077 (Miss. 2005) ("[L]ike a claim of design defect, a claim of inadequate warnings under the MPLA requires the jury to perform negligence analysis in assessing liability. . . . [Thus], the court need not present the jury with a separate negligence instruction on inadequate warnings."). Therefore, it is clear that under the prior version of the MPLA, purported negligence claims that merely restate the elements of defective design or failure-to-warn claims brought under the MPLA are subsumed by the MPLA.

However, Mississippi case law interpreting the previous version of the MPLA is unclear as to whether a negligence claim arising from a manufacturing defect can exist as a stand-alone negligence claim. *See Little*, No. 1:15-CV-028-GHD, 2015 U.S. Dist. Lexis 75666, at *12-13. The Fifth Circuit has determined under Mississippi law that "[t]he risk-utility analysis [employed in defect design and failure-to-warn claims] applies to design defect cases, not manufacturing defect cases," thus hinting that a negligence claim premised on manufacturing defect might exist alongside an MPLA manufacturing defect claim. *See Leverette v. Louisville Ladder Co.*, 183 F.3d 339, 342 (5th Cir. 1999); *see also Joiner v. Genlyte Thomas Grp., L.L.C.*, No. 1:09-CV-00093-GHD, 2012 U.S. Dist. LEXIS 20966, 2012 WL 567201, at *4 (N.D. Miss. Feb. 21, 2012) (a negligence claim arising from manufacturing defect might exist alongside a separate MPLA

manufacturing defect claim). *But see Deese v. Immunex Corp*., No. 3:11-CV-373-DPJ-FKB, 2012 U.S. Dist. LEXIS 17342, 2012 WL 463722, at *5 (S.D. Miss. Feb. 13, 2012) ("It is unclear whether Mississippi law recognizes such a negligence claim separate and apart from the MPLA claims for negligent design or failure to warn.").

In addition to Plaintiff's manufacturing defect claim under the MPLA, Plaintiff's Amended Complaint could be liberally read to include a negligence action on the basis of manufacturing. Regardless of whether the MPLA subsumes that negligence action or not, the Court finds there are no genuine disputes of material fact concerning any manufacturing negligence, so summary judgment is appropriate as to that claim.

Plaintiff claims that the purpose of the Telluride Spinal Fixation System being implanted was to stabilize the spinal section to allow boney fusion. According to Dr. Crosby, Plaintiff's treating physician, achieving boney fusion takes between six and twenty-four months. The pedicle screws at issue here severed at five months. Plaintiff contends that evidence of the screws' malfunction is enough to show a breach of Lanx's duty. However, Plaintiff fails to elaborate or put forth expert testimony as to any particular manufacturing negligence on the part of Lanx. Plaintiff's expert testified that he had no opinions as to the manufacturing process as it applied to the particular screws. In follow up at the deposition, however, Lanx's counsel acknowledges that because the screws were not available, any opinion as to their defective construction would be inappropriate. Plaintiff contends that Lanx spoliated the evidence because it failed to save the broken pedicle screws after their removal.

Spoliation is "[t]he intentional destruction, mutilation, alteration, or concealment of evidence." Black's Law Dictionary 1531 (9th ed. 2009). But "[a] party can only be sanctioned for destroying evidence that it had a duty to preserve, and such duty arises when 'the party has

notice that the evidence is relevant to litigation or when a party should have known that the evidence may be relevant to future litigation.'" *Consol. Aluminum Corp. v. Alcoa, Inc.*, 244 F.R.D. 335, 339 (M.D. La. 2006) (quoting *Zubulake v. UBS Warburg, LLC*, 220 F.R.D. 212, 216 (S.D.N.Y. 2003)). When spoliation is the result of a litigant's bad-faith actions, it gives rise to an adverse inference that the evidence was detrimental to the spoliating party's case. *Vick v. Tex. Emp't Comm'n*, 514 F.2d 734, 737 (5th Cir. 1975). "The party requesting an adverse inference must first show that the documents in question exist or existed and were within the control of the opposing party." *Jobe v. ATR Mktg., Inc.*, 189 F.3d 466, at *6 n.3 (5th Cir. 1999) (unpublished table decision) (citation omitted). "Moreover, a party seeking to obtain an adverse inference based on non-production or destruction of documents must show bad faith." *Id*. (citing *Vick*, 514 F.2d at 737 ("[T]he circumstances of the act must manifest bad faith. Mere negligence is not enough, for it does not sustain an inference of consciousness of a weak case.")).

Dr. Fernandez performed the surgical removal of the Lanx Telluride System. Dr. Crosby and Allen Rasoul, a medical product distributor, were also present during the surgery. Rasoul distributed Lanx, as well as other medical devices, and was present at Estes' surgery to deliver the new system being implanted. Plaintiff contends because complaints regarding broken screws were most often reported by distributors, and not individual patients, Rasoul should have collected the broken screws and either returned them to Lanx, had the hospital maintain possession of them, or retrieve them for himself. It is undisputed, however, the screws were not recovered after surgery, and the screws were not destroyed by Lanx or Rasoul. Because Plaintiff has failed to put forth a genuine issue of material fact as to bad faith on the part of Lanx, no spoliation instruction is warranted. Without evidence or testimony regarding Lanx's alleged

manufacturing negligence, Plaintiff has not put forth any genuine issues of material fact as to that claim.

Aside from the negligence claims subsumed by the MPLA and the negligence in manufacturing claim, Plaintiff also makes negligence claims based on the alleged failure of Lanx to secure the appropriate clearance from the FDA. However, Plaintiff has not adequately shown a genuine issue of material fact as to causation against Lanx for its alleged releasing the Telluride System into commerce without FDA approval. It is well established that causation is an essential element of a negligence claim. *See Weathersby Chevrolet Co., Inc. v. Redd Pest Control Co., Inc.*, 778 So. 2d 130, 133 (Miss. 2001). Plaintiff's own expert testified that connecting the Plaintiff's injury with the alleged failure to properly file with the FDA would be improper as it was too speculative. Accordingly, despite whether there was any duty to Plaintiff to achieve proper FDA clearance or breach of that duty by Lanx, the negligence claim for allegedly failing to obtain proper FDA authorization cannot succeed as there is no causative link between that alleged failure and Plaintiff's injuries. Accordingly, Defendant's Motion for Summary Judgment as to Plaintiff's negligence claims identified is granted.

(2) Warranties

The second category of claims covers Plaintiff's breach of express warranty and breach of implied warranties. Defendant counters that because Lanx never made representations to Estes, that these causes of action are due to be dismissed.

a. *Breach of Express Warranty*

For a plaintiff to prevail on a breach of express warranty claim in an action for damages caused by a product in Mississippi, he must prove by a preponderance of the evidence that at the time the product left the control of the manufacturer, designer, or seller:

> (i) . . . The product breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product; and
>
> (ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and
>
> (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.

MISS. CODE ANN. § 11-1-63(a)(i)(4), (ii), (iii).

"[A]n express warranty is any affirmation of fact or promise which concerns the product and becomes part of the basis for the purchase of such a product. Fault does not need to be shown to establish a breach. The plaintiff need only show that the product did not live up to its warranty." *Scirocco*, 2015 U.S. Dist. LEXIS 66561, 2015 WL 2451225, at *4 (quoting *Forbes v. GMC*, 935 So. 2d 869, 876 (Miss. 2006) (quoting *Austin v. Will—Burt Co.*, 232 F. Supp. 2d 682, 687 (N.D. Miss. 2002), *aff'd*, 361 F.3d 862 (5th Cir. 2004) (internal quotation marks omitted)); *see also* MISS. CODE ANN. § 75-2-313(1)(a). The plaintiff must ultimately show that he relied on the alleged representation. *See* MISS. CODE ANN. § 11-1-63(a)(i)(4).

Plaintiff alleges the existence of an express warranty as follows:

> Defendant expressly warranted that the Lanx Telluride System and its component part of the Lanx Pedicle Screw were safe and fit for use by consumers and users including Plaintiff Rocky Estes for its intended purpose, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

In response to summary judgment, Plaintiff again spins his claim to reflect Lanx's alleged failure to get FDA clearance for the Telluride System or its components. However, Plaintiff has failed to allege any express warranty that Lanx made to him regarding its 510(k) submission to the FDA, or even any specific claim made by Lanx to Plaintiff regarding the safety of the Telluride System or the pedicle screw associated therewith. Moreover, Plaintiff has produced no evidence

or testimony creating a genuine issue of material fact that he relied on any representation by Lanx as to the safety or federal regulatory clearance. Accordingly, Defendant's Motion for Summary Judgment as to the breach of express warranty claim is granted.

b. *Breach of Implied Warranty of Merchantability*

To recover on a claim for breach of an implied warranty of merchantability, a plaintiff must demonstrate the following:

> (1) That a "merchant" sold "goods," and he was a merchant with respect to "goods of the kind" involved in the transaction, (2) which were not merchantable at the time of sale, and (3) injuries and damages to the plaintiff or his property, (4) caused proximately and in fact by the defective nature of the goods, and (5) notice to the seller of the injury.

Watson Quality Ford. Inc. v. Casanova, 999 So. 2d 830, 834 (Miss. 2008) (citing MISS. CODE ANN. § 75-2-314). With respect to the last element, the Mississippi Supreme Court has noted that "though there may have been a breach of the warranty of merchantability, the seller has a right to attempt cure. An opportunity for the seller to cure is a reasonable requisite of a buyer's right of recovery." *Id.* at 834-35.

Defendant asserts that because Plaintiff never allowed Lanx the chance to cure the alleged defect that Plaintiff's implied warranty of merchantability claim fails. Plaintiff failed to respond to this specific allegation of Lanx. Because opportunity to cure is a "requisite" to the buyer's right of recovery, and there is no testimony or proof that Plaintiff attempted to contact or contacted Lanx when it was discovered that the pedicle screw was broken, Lanx was not given an opportunity to cure and that claim is dismissed.

c. *Breach of Implied Warranty of Fitness for a Particular Purpose*

To recover on a claim for breach of an implied warranty of fitness for a particular purpose under Mississippi law, a plaintiff is required to demonstrate the following;

> (1) the seller at the time of the contracting had reason to know the particular purpose for which the goods were required; (2) the reliance by the plaintiff as buyer upon the skill or judgment of the seller to select suitable goods, and (3) the goods were unfit for the particular purpose.

Watson Quality Ford, Inc., 999 So. 2d at 835 (quoting *Garner v. S & S Livestock Dealers, Inc.*, 248 So. 2d 783, 785 (Miss. 1971) (internal quotation marks omitted) (citing MISS. CODE ANN. § 75-2-315)). "[N]o claim for breach of the implied warranty of fitness for a particular purpose will lie when a product is to be used for its ordinary purpose." *Id.* (citing *Ford Motor Co. v. Fairley*, 398 So. 2d 216, 219 (Miss. 1981)).

Aside from the fact that there is no allegation that the pedicle screw or Lanx Telluride Spinal Fixation System was not used for its ordinary purpose, there is no proof or testimony that Plaintiff relied on Lanx, the seller, in selecting to use that product. In fact, Estes testified that he relied solely on his treating physician Dr. Crosby to make that decision. Accordingly, Defendant's request for summary judgment as to the implied warranty for fitness for a particular purpose is granted.

d. *Negligent Misrepresentation*

Numerous Mississippi district courts have held that the MPLA subsumes common law negligent misrepresentation claims based on a defective product. *See Austin*, 2013 U.S. Dist. LEXIS 137480, 2013 WL 5406589, at *8; *Gardley—Starks*, 917 F. Supp. 2d at 602; *McSwain*, 689 F. Supp. 2d at 844-45; *Lashley v. Pfizer, Inc.*, 877 F. Supp. 2d 466, 471 (S.D. Miss. 2012); *Murray*, No. 3:10-CV-188 HTW-LRA, 2011 U.S. Dist. LEXIS 93845, 2011 WL 3684517, at *3 (S.D. Miss. Aug. 22, 2011), aff'd, 478 F. App'x 175 (5th Cir. 2012); *Walker v. George Koch Sons, Inc.*, 610 F. Supp. 2d 551, 562-63 (S.D. Miss. 2009). *See also Jowers*, 2009 U.S. Dist. LEXIS 53126, 2009 WL 995613, at *9 (discussing *R.J. Reynolds Tobacco Co. v. King*, 921 So. 2d 268 (Miss. 2005) (negligent misrepresentation claim may not be product liability claim if

affirmative representations were made in addition to and separate from those in connection with a failure-to-warn claim)). Because Plaintiff in the case *sub judice* alleges that Defendant made representations with respect to the screw that mirror his allegations concerning the alleged representations in his failure-to-warn claim, the Court finds that his negligent misrepresentation claim is subsumed by the MPLA and must be dismissed.

(3) Claims as to the FDA

Plaintiff's factual basis for the final category of claims centers on Lanx's FDA clearance for either the pedicle screws used in the Telluride Spinal Fixation System, or the Telluride Spinal Fixation System itself. Plaintiff's fraudulent concealment cause of action alleges liability for the fraudulent concealment or misrepresentation that the Lanx Telluride System had been properly approved by the FDA.

In a factually and legally similar case to this one, the United States Supreme Court in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-49, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001), held that federal law preempts state-law causes of action claiming that a medical device manufacturer made fraudulent representations to the FDA. 531 U.S. at 353, 121 S. Ct. 1012. *Buckman* involved orthopedic bone screws that the FDA approved in an expedited process as "substantially equivalent" to devices already on the market. 531 U.S. at 346, 121 S. Ct. 1012. Plaintiffs who suffered injuries after implantation of the screws brought suit alleging that the manufacturer misled the FDA. Like here, they further alleged that the misrepresentations were a "but for" cause of their injuries because, absent the misrepresentations, the product would never have reached the market. 531 U.S. at 343, 121 S. Ct. 1012.

The Supreme Court rejected the novel cause of action because the state law claim would conflict with the FDA's authority to punish fraud on the agency. As noted by the Court:

> [T]he § 510(k) process sets forth a comprehensive scheme for determining whether an applicant has demonstrated that a product is substantially equivalent to a predicate device. Among other information, the applicant must submit to the FDA "proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use," 21 CFR § 807.87(e) (2000), and a statement attesting to and explaining the similarities to and/or differences from similar devices (along with supporting data), see § 807.87(f). The FDA is also empowered to require additional necessary information. See § 807.87(l). Admittedly, the § 510(k) process lacks the PMA review's rigor: The former requires only a showing of substantial equivalence to a predicate device, while the latter involves a time-consuming inquiry into the risks and efficacy of each device. Nevertheless, to achieve its limited purpose, the § 510(k) process imposes upon applicants a variety of requirements that are designed to enable the FDA to make its statutorily required judgment as to whether the device qualifies under this exception.
>
> Accompanying these disclosure requirements are various provisions aimed at detecting, deterring, and punishing false statements made during this and related approval processes. The FDA is empowered to investigate suspected fraud, see 21 U.S.C. § 372; 21 CFR § 5.35 (2000), and citizens may report wrongdoing and petition the agency to take action, § 10.30. In addition to the general criminal proscription on making false statements to the Federal Government, 18 U.S.C. § 1001, (1994 ed., Supp. IV), the FDA may respond to fraud by seeking injunctive relief, 21 U.S.C. § 332, and civil penalties, 21 U.S.C. § 333(f)(1)(A); seizing the device, § 334(a)(2)(D); and pursuing criminal prosecutions, § 333(a). The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Agency.

Buckman, 531 U.S. at 348-49, 121 S. Ct. 1012. Indeed, the Court stated "that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration." 531 U.S. at 348, 121 S. Ct. 1012. Not only does federal law provide administrative tools to punish and deter fraud, but the agency's decision to employ those tools implicates its discretion and special competence.[2] Among the factors that make FDA enforcement "a somewhat delicate balance of statutory objectives," *id.*, 121 S. Ct. 1012, are the need for administrative efficiency and the possibility that tort liability based on inadequate

[2] The FDA has authority to investigate fraud, 21 U.S.C. § 372, consider citizen petitions, 21 C.F.R. § 10.30, and seek criminal and civil penalties particular to fraud-on-the-FDA, 21 U.S.C. § 332-33. *Buckman*, 531 U.S. at 349, 121 S. Ct. 1012.

disclosures would create "an incentive to submit a deluge of information," 531 U.S. at 351, 121 S. Ct. 1012. The Court concluded that authorizing tort liability for failure to comply with FDA disclosure requirements "would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." 531 U.S. at 353, 121 S. Ct. 1012; *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 375-76 (5th Cir. 2012).

The parties have failed to brief whether federal regulatory law impliedly preempts Plaintiff's causes of action based on Lanx's submissions to the FDA. Accordingly, the parties are ORDERED to SHOW CAUSE as to whether these claims and others are or are not preempted. Show Cause Responses are due JANUARY 8, 2016.

Conclusion

Accordingly, the Defendant's Motion for Summary Judgment [94] is GRANTED IN PART. Plaintiff has failed to bring forth genuine issues of material fact as to the following claims: (1) all negligence claims; (2) all claims under the MPLA; and (3) all warranty claims.

The parties shall have until January 8, 2016, to show cause as to why FDA regulations do or do not impliedly preempt Plaintiff's claims regarding Lanx's failure to procure the appropriate 510(k) clearance from the FDA before introducing the Telluride System and/or pedicle screw into commerce.

SO ORDERED, this the 23rd day of December, 2015.

/s/ Sharion Aycock
U.S. DISTRICT JUDGE