IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
VALDOSTA DIVISION

JESSICA KAKU and EMILLIANO KAKU,

Plaintiffs,

v.

ALPHATEC SPINE, INC.,

Defendant.

Civil Action No. 7:16-CV-9 (HL)

ORDER

Before the Court is Defendant Alphatec Spine, Inc.'s Motion to Dismiss (Doc. 7) and Defendant's Motion to Dismiss Plaintiffs' First Amended Complaint. (Doc. 13). For the reasons discussed herein, Defendant's Motion to Dismiss Plaintiffs' First Amended Complaint (Doc. 13) is denied, and Defendant's Motion to Dismiss (Doc. 7) is deemed moot.

I. FACTUAL BACKGROUND

This is a product liability action arising out of the alleged failure of two Alphatec Zodiac® polyaxial pedicle screws, implanted into Plaintiff Jessica Kaku's vertebrae, to remain intact following a transforaminal lumbar interbody fusion ("TLIF").[1] In January of 2014, Jessica Kaku sought treatment for lower back pain from Dr. James Goss at Valdosta Orthopedic Associates. Following a

[1] The facts are taken from the allegations in the First Amended Complaint (Doc. 10) and are accepted as true for purposes of this motion.

diagnosis of spondylolisthesis, Dr. Goss recommended that Mrs. Kaku undergo TLIF, a type of surgical spinal fusion. The goal of lumbar fusion is to create solid bone between two or more vertebrae to reduce pain from motion and nerve root inflammation. Pedicle screws are used to add extra support and strength to the fusion by locking the spine in place while the fusion heals.

Dr. Goss performed the TLIF procedure on Jessica Kaku on February 10, 2014. During the procedure, four pedicle screws were surgically implanted into two of Mrs. Kaku's vertebrae. The screws were designed, manufactured, marketed, distributed, sold, and supplied by Defendant. Following the surgery, Jessica Kaku experienced relief from her lower back and sciatic pain almost immediately and was able to return to work in the United States Air Force within three weeks.

On March 21, 2014, while sitting at her desk, Mrs. Kaku turned in her chair to throw a piece of paper in the trashcan and felt a sudden pop in her back, followed by the feeling of metal grinding. She later learned that the pop she felt was the sound of two of the pedicle screws breaking. The failure of the screws compromised the progress of Mrs. Kaku's fusion, and she was forced to undergo a second surgery on June 23, 2014 to remove the pedicle screws. Three of the screws were removed, but one of the screws could not be removed safely. As a result, that screw remains in Mrs. Kaku's vertebra. Since the second surgery, Mrs. Kaku has experienced continuous low back pain, more excruciating than the pain she endured prior to her first surgery.

The pedicle screws at issue in this lawsuit are Class II medical devices. Prior to marketing a Class II device, Section 510(k) of the Food, Drug and Cosmetic Act requires the submission of a premarket notification to the Food and Drug Administration ("FDA"). The 510(k) process allows the FDA to classify the device and determine whether it is substantially equivalent to another device already on the market. Thus, prior to marketing its pedicle screws, Defendant filed a premarket notification with the FDA.

On July 16, 2015, the FDA issued a warning letter to Defendant. The warning letter claims that an inspection revealed that pedicle screw implants and stainless steel instruments used during implant installation procedures were "adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 321(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820." Plaintiffs have not alleged that the warning letter pertains to the pedicle screws that were implanted in Jessica Kaku. However, Plaintiffs make clear that the deficiencies outlined in the letter were present at Defendant's manufacturing facilities at the time the pedicle screws implanted in Mrs. Kaku were manufactured.

Plaintiffs Jessica Kaku and Emilliano Kaku filed this lawsuit, alleging that Defendant is strictly liable for defectively designing, developing, engineering,

and/or manufacturing the pedicle screws that were implanted in Jessica Kaku. In addition to their strict liability claim, Plaintiffs have stated a claim for loss of consortium, punitive damages, and attorneys' fees. Defendant filed a Motion to Dismiss (Doc. 7) on March 22, 2016. Plaintiffs then filed their First Amended Complaint (Doc. 10) on April 4, 2016. Defendant now moves to dismiss Plaintiffs' First Amended Complaint, arguing that Plaintiffs have failed to state a claim upon which relief may be granted, that Plaintiffs' strict liability claim is preempted by the Medical Device Amendments of 1976 ("MDA"), and that the remaining claims must be dismissed because they are derivative of Plaintiffs' strict liability claim.

II. STANDARD OF REVIEW

When reviewing a claim pursuant to a Rule 12(b)(6) motion, the Court accepts the allegations in the claim as true and construes them in the light most favorable to the party asserting the claim. See Jackson v. BellSouth Telecomms., 372 F.2d 1250, 1262 (11th Cir. 2004). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007) (internal quotations and citations omitted). Instead, the complaint must set forth factual allegations "plausibly suggesting (not merely consistent with)" a violation of the law. Id. at 557.

Accordingly, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Twombly, 550 U.S. at 570). The Iqbal Court explained as follows:

> A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

556 U.S. at 678 (internal quotes and citations omitted).

"Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id. at 679 (citation omitted). "But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" Id. (quoting Fed. R. Civ. P. 8(a)(2)).

III. ANALYSIS

Defendant moves to dismiss Plaintiffs' First Amended Complaint, arguing that Plaintiffs' strict liability claim fails for lack of factual support. Even if the facts alleged were sufficient to state a claim for strict products liability, Defendant argues that this claim is preempted by the MDA. Finally, Defendant moves to

dismiss Plaintiffs' claims for loss of consortium, punitive damages, and attorneys' fees because they are derivative of Plaintiffs' strict liability claim.

A. Plaintiffs have stated a claim for relief for strict products liability

Defendant moves to dismiss Plaintiffs' strict liability claim, arguing that Plaintiffs have failed to state specific facts showing a product defect or causation. To state a claim for strict products liability, a plaintiff must allege that: (1) the defendant manufactured the allegedly defective product; (2) the allegedly defective product was not merchantable and reasonably suited for its intended use when the defendant sold it; and (3) the defective product proximately caused the plaintiff's injuries. Chi. Hardware & Fixture Co. v. Letterman, 510 S.E.2d 875, 877–78 (Ga. Ct. App. 1999). Under Georgia law, "[t]here are three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects." Banks v. ICI Americas, Inc., 450 S.E.2d 671, 672 (Ga. 1994). In all cases, the inquiry is the same: "whether a product was defective, and if so, whether the defect was the proximate cause of a plaintiff's injury." SK Hand Tool Corp. v. Lowman, 479 S.E.2d 103, 106 (Ga. Ct. App. 1996).

Count I of Plaintiffs' First Amended Complaint, for strict products liability, contains the following allegation:

> The Alphatec pedicle screws implanted in Plaintiff, as designed, developed, engineered, manufactured, distributed, marketed, and sold by Alphatec, were not merchantable or reasonably suited for their intended use at the time said screws were sold. Specifically,

> the Alphatec pedicle screws failed to perform as intended and designed by breaking within six (6) weeks of implantation into Plaintiff Jessica Kaku's vertebrae. Because said failure occurred prior to the fusion healing fully, the screws were incapable of serving their intended purpose of providing the necessary stability to the vertebral column during this critical period of recovery.

(Doc. 10, ¶ 31).

Defendant argues that Plaintiffs have not identified whether the allegedly defective pedicle screws suffered from a design defect, a manufacturing defect, some failure to warn-based theory of liability, or all three.[2] As a result, Defendant contends that it has been put "in the untenable position . . . of trying to guess at the varying potential claims and facts in support, and swat them down on a piecemeal basis." (Doc. 17, p. 2). Defendant believes that Plaintiffs' allegations fall short of the requirements of Twombly, Iqbal, and their progeny.

The Court disagrees. Contrary to Defendant's assertion that Plaintiffs have failed to identify a specific defect in the pedicle screws, Plaintiffs have alleged that Defendant defectively designed and manufactured the pedicle screws. (Doc. 10, ¶ 30). Plaintiffs claim that the screws broke within six weeks of implantation, and were thus unable to serve their intended purpose of providing the necessary stability to Jessica Kaku's vertebral column during this critical period of recovery. (Doc. 10, ¶ 31). This is not a situation where, as Defendant contends, the First Amended Complaint is so completely devoid of

[2] There is no mention of any failure to warn-based theory of liability in the First Amended Complaint (Doc. 10) or in Plaintiffs' Response to Defendant's Motion to Dismiss (Doc. 15). As a result, the Court concludes that Plaintiffs are proceeding on theories of defective design and defective manufacturing.

reference to a specific defect that Defendant is left "guess[ing] at the varying potential claims and facts in support." (Doc. 17, p. 2).

A bald assertion that the pedicle screws were defective in design and manufacture when they left Defendant's hands, that they were unreasonably dangerous, and that the foreseeable risks outweighed the benefits of using them during fusion would be insufficient to survive a motion to dismiss. See, e.g., Moore v. Mylan, Inc., 840 F.Supp.2d 1337, 1344–45 (N.D. Ga. 2012). But Plaintiffs have done much more here. They have alleged that four pedicle screws, manufactured by Defendant, were implanted into Jessica Kaku's vertebrae; that two of the screws broke within six weeks of the surgery; that the screws broke while Mrs. Kaku was turning in her chair to throw away a piece of paper; that the purpose of the screws was to provide the necessary stability to the vertebral column so that fusion could occur; and that because the screws were defective in design and manufacture, the screws were "incapable of serving their intended purpose." (Doc. 10, ¶¶ 13, 15–17, 31).

Although it is not clear from the allegations whether Plaintiffs believe it was a design defect or a manufacturing defect that caused the screws to break, when "[t]he very nature of a products liability action" makes it not obvious which of many alleged defects might have caused the plaintiff's injury, the plaintiff may set out various alternative or hypothetical sources of his injury. See Bailey v. Janssen Pharmaceutica, Inc., 288 F. App'x 596, 605 (11th Cir. 2008). "Nothing in Rule 8(a), Twombly, Iqbal, or any other binding precedent requires a plaintiff to

specifically plead facts that establish every element (e.g. causation) in order to state a claim." Edwards v. Wis. Pharmacol Co., 987 F.Supp.2d 1340, 1345–46 (N.D. Ga. 2013). What is required, under both Georgia law and the Federal Rules of Civil Procedure, is an allegation of specific defects from which the Court can draw a reasonable inference that at least one of the defects caused the plaintiff's injuries. Cf. Coney v. Mylan Pharm., Inc., No. 6:11-cv-35, 2012 WL 170143, at *6 (S.D. Ga. Jan. 19, 2012) (dismissing plaintiff's claims because he failed to assert any specific defects from which the court could draw a reasonable inference of causation). Plaintiff has satisfied that requirement here.

Defendant argues that, in evaluating whether Plaintiffs have alleged facts sufficient to state a claim for strict products liability, the Court should disregard the FDA Warning Letter discussed in the First Amended Complaint. (Doc. 13, p. 7). Defendant notes that Plaintiffs have not alleged that the products at issue in the letter are the same as those which were used in Jessica Kaku's surgery, and as a result Defendant believes the letter is irrelevant to this lawsuit. (Doc. 13, p. 7). Although Plaintiffs do not contend that the pedicle screws implanted in Mrs. Kaku are the subject of the warning letter, Plaintiffs do assert that "[t]he deficiencies noted in the Warning Letter existed at Alphatec's manufacturing facilities . . . at the time the Alphatec screws implanted into Plaintiff Jessica Kaku were manufactured." (Doc. 10, ¶ 29). This allegation "permit[s] the [C]ourt to infer more than the mere possibility of misconduct." Iqbal, 556 U.S. at 678.

Defendant further argues that the facts in the First Amended Complaint are insufficient to state a claim for strict products liability because they rely on a theory of res ipsa loquitur. Defendant asserts that res ipsa loquitur "is inapplicable in a case like this because Alphatec did not have exclusive control over the pedicle screws." (Doc. 13, p. 6).

> Res ipsa loquitur is a rule of evidence to be applied in cases where there is no evidence of consequence showing negligence on the part of the defendant. The doctrine authorizes, but does not require, the jury to infer facts from the circumstances in which the injury occurred, thereby filling the evidentiary gap.

Kmart Corp. v. Larsen, 522 S.E.2d 763, 765 (Ga. Ct. App. 1999). As a preliminary matter, res ipsa loquitur is a negligence doctrine and has "no application" in a strict liability case such as this one. Lang v. Federated Dept. Stores, Inc., 287 S.E.2d 729, 731 (Ga. Ct. App. 1982). However, "the inferences which are the core of the doctrine" are still applicable in strict liability cases; "the plaintiff is not required to eliminate all other possibilities or to prove the case beyond a reasonable doubt." Id.

It is true that, in order to impose strict liability against a manufacturer of a defective product, the product must "reach the user or consumer without substantial change in the condition in which it is sold." Talley v. City Tank Corp., 279 S.E.2d 264, 269 (Ga. Ct. App. 1981) (citation and internal quotation marks omitted). However, the fact that a manufacturer did not have exclusive control over a product before its defect became apparent is not a bar to recovery for strict products liability. See id. ("In some cases it may be a jury question as to

whether the product's original design has been merely slightly or somewhat modified. In such cases, the jury must determine whether the original manufacturer's design was defective and, if so, whether the proximate cause of the injuries sustained was the original defective design or the subsequent modification.").

Because Plaintiffs have adequately alleged that the pedicle screws suffered from a design or manufacturing defect, and because Plaintiffs have provided facts from which the Court can draw a reasonable inference that at least one of the defects caused Jessica Kaku's injuries, Plaintiffs have stated a claim for relief for strict products liability. Defendant is not entitled to dismissal of Count I of Plaintiffs' First Amended Complaint on this ground.

B. Plaintiffs' strict liability claim is not preempted by the Medical Device Amendments of 1976

In 1976, Congress enacted the MDA to address the perceived inadequacy of existing law to protect consumers from "increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used." S.Rep. No. 33, 94th Cong., 2d Sess. 5, reprinted in 1976 U.S. Code Cong. & Admin. News 1070, 1075. The Act classifies devices into one of three categories based on the risk that the device poses to the public. Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by "general controls." 21 U.S.C. § 360c(a)(1)(A). Devices that are potentially more harmful are designated Class II devices. Although they

may be marketed without advance approval, manufacturers of such devices must comply with federal performance regulations known as "special controls." § 360c(a)(1)(B). Finally, devices that either "presen[t] a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated Class III. § 360c(a)(1)(C). The Alphatec Zodiac® polyaxial pedicle screws are Class II devices. (Doc. 10, ¶ 21).

Class II devices are subject to the requirements of 21 U.S.C. § 360(k), which "imposes a limited form of review on every manufacturer intending to market a new device by requiring it to submit a 'premarket notification' to the FDA (the process is also known as a '§ 510(k) process,' after the number of the section in the original Act)." Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996). "If the FDA concludes on the basis of the § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis . . . ." Id. Notably, the Supreme Court has held that "[t]he 510(k) process is focused on *equivalence*, not safety." Id. at 493 (citation and quotation marks omitted) (emphasis in original). "As a result, substantial equivalence determinations provide little protection to the public." Id. (citation and quotation marks omitted).

The MDA includes an express preemption clause:

> **(a) General rule.** Except as provided in subsection (b)[3] of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The FDA's regulation interpreting section 360k, issued in 1978, advises that:

> State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

21 C.F.R. § 808.1(d).

Defendant argues that Plaintiffs' strict liability claim imposes duties inconsistent with the MDA, and is thus preempted. (Doc. 13, p. 10). Specifically, Defendant contends that this claim imposes a duty on Defendant to "create an 'indestructible' pedicle screw that could not fracture or cause injury." (Doc. 13, p. 10). Such a duty "would create a state law requirement that is different from, and in addition to, the federal requirements" governing Class II medical devices.

[3] Subsection (b) provides a means for a state or political subdivision thereof to apply for an exemption to preemption when compelling local conditions require a more stringent requirement. See 21 U.S.C. § 360k(b).

(Doc. 13, p. 11). As a result, Defendant argues that Plaintiffs' strict liability claim is preempted.

Defendant's argument is unpersuasive. As a preliminary matter, Plaintiffs' strict liability claim does not impose a duty on Defendant to create an "indestructible" pedicle screw. Rather, Plaintiffs allege that the pedicle screws implanted into Jessica Kaku's vertebrae were defective in that they broke during the fusion process, in which "it is critical that the screws remain intact." (Doc. 15, p. 13). Plaintiffs argue that the defective screws were "not merchantable and reasonably suited to the use intended," and accordingly, Defendants are strictly liable for the injuries sustained as a result of the failed pedicle screws. There is nothing in Georgia law or in the First Amended Complaint that requires a product manufacturer to produce an "indestructible" product.

Further, as Plaintiffs argue in their response to Defendant's Motion to Dismiss, Defendant's preemption argument is belied by the United States Supreme Court's decision in Medtronic, Inc. v. Lohr. Lohr, which reached the Supreme Court on appeal from the Eleventh Circuit Court of Appeals, held that the requirements of the § 510(k) process "were not sufficiently concrete to constitute a pre-empting federal requirement." 518 U.S. at 493. The Court reasoned that the 510(k) process does not "require" medical devices "to take any particular form for any particular reason." Id. Further, in examining the text of the statute and the legislative history, the Court explained that "[t]here is no suggestion in either the statutory scheme or the legislative history that the §

510(k) exemption process was intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents." Id. at 494.

In its Reply Brief (Doc. 17), Defendant attempts to distinguish Lohr from the facts at issue in this case. Defendant argues that Lohr was an *express* preemption case and that the Supreme Court "made no pronouncement regarding whether there was a conflict between the state and federal requirements." (Doc. 17, p. 9). Here, Defendant contends that Plaintiffs' strict liability claim is preempted by "*implied impossibility*." (Doc. 17, p. 5) (emphasis added). Defendant cites two cases in support of its argument: PLIVA v. Mensing, 564 U.S. 604 (2011), and Mutual Pharmaceutical Co. v. Bartlett, 133 S.Ct. 2466 (2013).

Both PLIVA and Bartlett concern "complex" federal drug labeling requirements. PLIVA, 564 U.S. at 612; see also Bartlett, 133 S.Ct. at 2470. PLIVA considered whether laws in Minnesota and Louisiana were preempted by drug labeling requirements promulgated under federal law. PLIVA, 563 U.S. at 611–12. At the heart of the Court's analysis was "whether, and to what extent, generic manufacturers may change their labels after initial FDA approval." Id. at 613. The Court summarized the state and federal requirements as follows:

> State tort law places a duty directly on all drug manufacturers to adequately and safely label their products. . . . [T]his duty required the Manufacturers to use a different, stronger label than the label they actually used. Federal drug regulations, as interpreted by the

> FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels.

Id. at 617. Ultimately, the Court concluded that the state law labeling requirements were preempted, because "state law imposed a duty on the Manufacturers to take certain action, and federal law barred them from taking that action." Id. at 624.

In Bartlett, the Supreme Court considered whether federal regulations preempted New Hampshire law which "imposes a duty on manufacturers to ensure that the drugs they market are not unreasonably unsafe." 133 S.Ct. at 2470. The Court held that the New Hampshire law was preempted because "state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law under PLIVA." Id.

Defendant argues that the facts at issue here are more akin to those at issue in PLIVA and Bartlett than they are to Lohr. As previously discussed, Lohr held that the requirements of the § 510(k) premarket notification process were not sufficiently concrete to constitute a pre-empting federal requirement. Defendant asserts that the Court's holding in Lohr concerned whether state law defective design claims were *expressly* preempted by the requirements of federal law. Here, Defendant urges, the Court should consider whether Plaintiffs' strict liability claim is *impliedly* preempted, due to the impossibility of complying with both state and federal law.

Defendant points the Court to 21 C.F.R. § 807.81(a)(3), which requires that a manufacturer submit a premarket notification submission to the FDA 90 days before the manufacturer proposes to introduce an altered product into the market if:

> (3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:
>
> (i) A change or modification in the device that *could significantly affect the safety or effectiveness of the device*, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.
>
> (ii) A major change or modification in the intended use of the device.

21 C.F.R. § 807.81(a)(3) (emphasis added). Defendant's position is that this regulation requires prior FDA approval of any change that might be required in order to comply with state law. Defendant argues that the Supreme Court's decision in PLIVA established that "there is a federal-state law conflict where state law 'demand[s] a safer label' and the only unilateral step a manufacturer can take is to 'communicate with the FDA about the possibility of a safer label.'" (Doc. 17, pp. 9–10) (citing PLIVA, 564 U.S. at 619). According to Defendant, "[t]hat same irreparable conflict exists [here,] where state law demands a safer design and the only unilateral step a § 510(k) device manufacturer can take is to submit a notification to the FDA requesting approval for a design change." (Doc. 17, p. 10). Because Defendant could not independently do under federal law

what Georgia law requires of it, Defendant argues that Plaintiffs' strict products liability claim is impliedly preempted by impossibility.

The Court disagrees. The Court concedes that 21 C.F.R. § 807.81(a)(3) concerns a situation where safety is inherently at issue, unlike the premarket notification submission under § 510(k). However, it is not clear that 21 C.F.R. § 807.81(a)(3) applies under the circumstances. Whether any changes to the pedicle screws, made to comply with Georgia law, would "significantly affect the safety" of the screws is a question of fact, not of law. There are no facts in the First Amended Complaint suggesting that changes which "significantly affect the safety" of the screws needed to be made in order to comply with Georgia's strict products liability statute. As a result, the Court cannot say that it was impossible for Defendant to comply with both state and federal law. Defendant is not entitled to dismissal of Plaintiffs' strict products liability claim on these grounds.

C. Plaintiffs have stated a claim for relief for loss of consortium, punitive damages, and attorneys' fees

Defendant moves to dismiss Counts II, III, and IV of the First Amended Complaint. Defendant's sole argument in support of dismissing these claims is that they are all derivative of Plaintiffs' strict liability claim. (Doc. 13, p. 10 n.4). The Court has determined that Plaintiffs have stated a claim for relief for strict products liability. Accordingly, Defendant is not entitled to dismissal of Counts II, III, and IV.

IV. CONCLUSION

For the reasons discussed, Defendant's Motion to Dismiss Plaintiffs' First Amended Complaint (Doc. 13) is **DENIED**. Defendant's Motion to Dismiss (Doc. 7) is deemed **MOOT**. Plaintiffs' claims may proceed for further factual development.

SO ORDERED, this the 28th day of March, 2017.

/s/ Hugh Lawson
HUGH LAWSON, SENIOR JUDGE

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