IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JAMES P. WILSON and JACQUELYN H. WILSON,

Plaintiffs,

v.

SYNTHES USA PRODUCTS, LLC, SYNTHES SPINE COMPANY, LP, SYNTHES SPINE, INC., SYNTHES USA HQ, INC., and SYNTHES NORTH AMERICA, INC.,

Defendants.

CIVIL ACTION
NO. 14-4724

MEMORANDUM OPINION

Schmehl, J. /s/ JLS **July 15, 2015**

Before the Court is the motion to dismiss of Defendants, Synthes USA Products, LLC, Synthes Spine Company, LP, Synthes Spine, Inc., Synthes USA HQ, Inc., and Synthes North America, Inc. ("Defendants"). Plaintiffs, James P. Wilson and Jacquelyn H. Wilson ("Plaintiffs") have opposed the motion, and Defendants have filed a reply and a "Notice of Supplemental Authority." Further, Plaintiffs have filed their own "Notice of Supplemental Authority." Having read the parties' briefing, I will grant Defendants' motion to dismiss in part and deny it in part.

I. BACKGROUND

Plaintiffs filed this products liability action against Defendants in the Philadelphia County Court of Common Pleas on March 14, 2014, and on August 14, 2014, Defendants removed the matter to this Court. Thereafter, Defendants filed a Motion to Dismiss, claiming Plaintiffs' Complaint does not set forth a plausible cause of action against Defendants and therefore, should be dismissed. Specifically, Plaintiffs' Complaint asserts

four claims against Defendants: 1) strict liability; 2) negligence; 3) negligence *per se*; and 4) loss of consortium. (See Compl.)

II. STATEMENT OF FACTS

On March 16, 2010, James Wilson's doctor implanted two N-Hance spinal fixation rods manufactured by Defendants in an attempt to repair Mr. Wilson's back injuries. (Compl. ¶ 13.) In March of 2012, imaging studies showed that the N-Hance rods had failed and that both rods implanted in Mr. Wilson's back had broken in a similar manner. (Compl. ¶ 14.) Plaintiffs allege, in short, that a properly designed and manufactured spine implant should not bend, fracture or break once implanted, and that the N-Hance implants did so because of problems at the manufacturing plant and because of an inherently defective design that made the rods prone to breakage. (Compl. ¶¶ 15-17.)

III. STANDARD OF REVIEW

To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must allege facts that " 'raise a right to relief above the speculative level.' " Victaulic Co. v. Tieman, 499 F.3d 227, 234 (3d Cir.2007) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007.) In determining whether a complaint is sufficient, the court must accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading, the plaintiff may be entitled to relief. Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) (citing Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008)).

Although "conclusory" or "bare-bones allegations" will not survive a motion to dismiss, Fowler, 578 F.3d at 210, a complaint may not be dismissed merely because it

appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits. Phillips, 515 F.3d at 231. Nonetheless, to survive a Rule 12(b)(6) motion, the complaint must provide "enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." Id. at 234 (quoting Twombly, 550 U.S. at 556) (internal quotations omitted).

IV. DISCUSSION

Defendants move to dismiss Plaintiffs' claims due to allegedly insufficiently pled manufacturing defect claims and negligence claims. Defendants also argue that Plaintiffs' strict liability claims should be dismissed, claiming that Pennsylvania law bars the application of strict liability to an allegedly defective medical device. Defendants also argue that Pennsylvania law does not recognize a negligent marketing claim. For the reasons that follow, I will dismiss Plaintiffs' strict liability and negligent marketing claims. The remainder of Plaintiffs' claims will be permitted to remain.

A. Strict Liability Claims.

Defendants claim that Plaintiffs' strict liability claims must be dismissed because Pennsylvania law does not recognize a strict liability cause of action against the manufacturer of a medical device, such as the N-Hance rods used on Mr. Wilson. (Def's Mtn, p. 3.) Defendants argue that "[p]roduct liability claims against a medical device company, under Pennsylvania law, can only be brought under a theory of negligence, not strict liability." (Id.) Defendants contend that the Pennsylvania Supreme Court has held that prescription drugs are "unavoidably unsafe" and are therefore excluded from strict liability claims under *Comment k* to the Restatement (Second) of Torts § 402A (Hahn v. Richter, 673 A.2d 888, 891 (Pa. 1996)), and that this reasoning has been consistently

applied by Pennsylvania state and federal courts to medical device cases, leading to a finding that plaintiffs may not assert strict liability claims against medical device manufacturers. (Defs' Mtn, p. 4.)

> Comment k of the Restatement (Second) of Torts, §402A states:
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> > 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…Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

Restatement (Second) of Torts, § 402A, comment k. Pennsylvania has adopted comment k of the Restatement (Second) §402A to exempt prescription drugs from the imposition of strict liability on manufacturers selling these drugs. Hahn v. Richter, 673 A.2d 888, 889-90 (Pa. 1996); Soufflas v . Zimmer, Inc., 474 F.Supp.2d 737, 749 (E.D. Pa. 2007) (Robreno. J.) (internal quotation omitted). Although the Pennsylvania Supreme Court has not yet addressed whether comment k extends to prescription medical devices, the Pennsylvania Superior Court has held that there is "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." Creazzo v. Medtronic, Inc.. 903 A.2d 24, 31 (Pa. Super. 2006). Further, numerous federal courts have applied the Superior Court's reasoning in Hahn to medical device cases, finding that plaintiffs may not assert strict liability claims against manufacturers of medical devices. Horsmon v. Zimmer Holdings, Inc., 2011 WL 5509420 (W.D. Pa. Nov. 10, 2011); Soufflas v. Zimmer, Inc., 474 F. Supp.2d at 749-750; Parkinson v. Guidant Corp., 315 F.Supp.2d 741, 747 (W.D. Pa. 2004); Kester v. Zimmer Holdings, Inc., No. 10-523, 2010 WL 2696467, at * 9 (W.D. Pa., June 16, 2010) (McVerry, J.); Geesey v. Stryker Corp., 2010 WL 3069630 (E.D. Pa. Aug. 4, 2010) (Slomsky, J.); Runner v. C.R. Bard, et al, No.

14-5259, 2015 WL 3513424 (E.D. Pa. June 3, 2015) (Dalzell, J.). But see Bergstresser v. Bristol-Myers Squibb Co., No. 12-1464, 2013 WL 1760525, *3 (M.D. Pa. Apr. 24, 2013) (allowing a strict liability claim based upon an alleged manufacturing defect in a prescription drug to proceed); Dougherty v. C.R. Bard, Inc., 2012 WL 2940727 at *2 (E.D. Pa. July 18, 2010) (finding that strict liability claims involving a manufacturing defect in prescription drug and device cases are not clearly barred in Pennsylvania); Tatum v. Takeda Pharmaceuticals North America, Inc., No. 12-1114, 2012 WL 5182895, *2 (E.D. Pa. Oct. 19, 2012) (concluding that strict liability claims for manufacturing defects in a prescription drug are not prohibited"); Killen v. Stryker Corp., No. 11-1508, 2012 WL 4498865, *4 (W.D. Pa. Sept. 28, 2012) (denying a motion to dismiss the plaintiff's strict liability claim for a manufacturing defect in a medical device case); Kline v. Zimmer Holdings, No. 13-513, 2013 WL 3279797 (W.D. Pa. June 27, 2013) (permitting a strict liability manufacturing defect claim to proceed against a medical device manufacturer).

Defendants rely on Terrell v. Davol, No. 13-5074, 2014 WL 3746532 (E.D. Pa. July 30, 2014), a recent case in which Judge Slomsky acknowledged that there is a split among federal courts regarding the application of strict liability in medical device cases and that some courts have allowed strict liability manufacturing defect claims only to proceed. Terrell v. Davol, 2014 WL 3746532 at *5. In analyzing this issue, Judge Slomsky reviewed the relevant case law and determined that the Pennsylvania Supreme Court had recently resolved this split in Lance v. Wyeth, 85 A.3d 434, 453 (Pa. 2014), where it reiterated the long-standing principle that all strict liability claims are barred in prescription drug cases, and failed to exempt a manufacturing defect claim from this bar.

Terrell, 2014 WL 3746532, at *5. Judge Slomsky then predicted that the Pennsylvania Supreme Court would conclude that all strict liability claims are also barred in medical device cases. Id.

Plaintiffs argue that in finding no strict liability for medical devices, Terrell was wrongfully decided, and that instead, I should follow the analysis found in Kline v. Zimmer Holdings, 2013 WL 3279797, *5 (W.D. Pa. June 27, 2013), which permitted a strict liability manufacturing defect claim to proceed against a medical device manufacturer. Plaintiffs fail to provide any real explanation as to why the holding in Kline should apply to the instant matter as opposed to the holding in Terrell.[1] Plaintiffs only argument seems to be that medical devices can be "altered or manufactured in different ways to render them more fit for their purposes," and therefore should be "subjected to equal or *greater* liability than most products." (Pls' Response, p. 4.) (emphasis in original). I find this attempt to distinguish medical devices from prescription drugs to be unpersuasive, as both medical devices AND prescription drugs could be manufactured in different ways to make them more fit for their purpose. Prescription drugs and medical devices are similar in that both are unreasonably dangerous, but should not be subjected to strict liability because they benefit certain members of society. See Terrell, supra at *4. Like prescription drugs, medical devices are known to cause possible harm, but the risks are outweighed by the benefits they provide for patients who need them. Clearly, the public policy arguments as to both are very similar. Further, the decision in Kline v. Zimmer Holdings, which Plaintiffs would have me rely upon, pre-dates the decision of the Pennsylvania Supreme Court in Lance v. Wyeth, which

[1] Both cases involved an allegedly defective medical device. Kline involved a hip replacement part, while Terrell dealt with a mesh implant inserted as part of a hernia repair.

reiterated a bar on all strict liability claims in Pennsylvania as to prescription drugs.[2] Lance, 85 A.3d at 453. Accordingly, I conclude that Defendants' argument is correct, and comment k of the Restatement (Second) §402A serves to impose a ban on all strict liability against medical device manufacturers. Accordingly, I will grant Defendants' Motion to Dismiss as to Plaintiffs' strict liability claims.

B. Negligence Claims

Next, Defendants argue that Plaintiffs have failed to adequately plead their negligence claims under Fed. R. Civ. P. 8(a)(2), and that Plaintiffs have relied on "conclusory and boilerplate allegations, devoid of any factual support." (Defs' Mtn, pp. 5-6.) Specifically, Defendants take issue with Plaintiffs' pleading of their manufacturing defect, negligent marketing, negligent design and failure to warm claims. I will analyze each of these issues in turn.

1. Manufacturing defect claim

Defendants contend that the allegations in Plaintiffs' Complaint regarding a manufacturing defect are deficient because they fail to identify how the device deviated from the manufacturer's intended design or how the device deviated from other identical products. (Defs' Mtn, p. 9.) Plaintiffs' Complaint alleges that "Defendants also failed to exercise reasonable care in the manufacture, distribution and sale of the N-Hance System, because Defendants' failed to inspect the devices before placing them in interstate

[2] The Kline court relied in part on Dougherty v. C.R. Bard, 2012 WL 2940727, at *4 (E.D. Pa., July 18, 2012) an Eastern District of Pennsylvania case in which the Court declined to bar a manufacturing defect claim against the manufacturer of a medical device. Id. at 4. The Dougherty court discussed the Pennsylvania Superior Court decision in Lance v. Wyeth, where the Superior Court found there were no state law cases barring strict-liability manufacturing defect claims against a manufacturer of prescription drugs or devices. 4 A.3d 160, 164-65 (Pa. Super. 2010). However, the Superior Court decision in Lance which was relied upon by the Dougherty court was subsequently partially overturned on appeal to the Pennsylvania Supreme Court, when the Court stated that there is a bar in Pennsylvania as to strict liability for all prescription drugs. Lance, 85 A.3d at 453.

commerce." (Compl., ¶ 38.) Plaintiffs' Complaint further alleges that Defendants breached their duty and were negligent by "manufacturing the N-Hance System in a defective condition, manufacturing the N-Hance System such that the product failed, and manufacturing the N-Hance System such that it failed to perform its intended purpose." (Compl. ¶ 39 (a) – (c)).

Although these allegations of Plaintiffs' Complaint are not extremely specific, I find that when the complaint is read as a whole, there is sufficient specificity as to the alleged manufacturing defect to meet the Rule 8 requirement of a "short and plain statement of the claim." Specifically, paragraphs 18 through 26 of Plaintiffs' Complaint, when viewed "in the light most favorable to the non-moving party," contain enough factual specificity regarding the defect in this matter to allow this claim to proceed. Therefore, I will deny Defendants' Motion to Dismiss on the manufacturing defect claim.

2. Negligent marketing claim

Next, Defendants claim that Plaintiffs' Complaint is unclear as to what kind of negligence claim they are asserting for "marketing and/or selling a defective and unreasonably dangerous product," as Pennsylvania "recognizes only a very narrow claim for negligent marketing when a manufacturer over-promotes a drug that nullifies adequate warnings." (Defs' Mtn, p. 13.) Plaintiffs do not argue that their broad negligent marketing claim should be permitted to remain, and their Complaint contains no allegations regarding Defendants' alleged "over-promotion" of the N-Hance System that would be recognized in Pennsylvania as a valid negligent marketing claim. Accordingly, I will grant Defendants' Motion to Dismiss as to any negligent marketing claim being alleged by Plaintiffs.

3. Negligent design claim

Defendants claim that for a negligent design theory to survive a motion to dismiss, "at a minimum, federal pleading standards require Plaintiffs to specify the nature of the alleged product defect," and that Plaintiffs here have failed to identify the alleged design defect in the Synthes device. (Defs' Mtn, pp. 14-15.)

As to the negligent design claim, Plaintiffs' Complaint states as follows:

> Defendants defectively designed the N-Hance device, including the device implanted in Plaintiff, by allowing unlimited and unrestricted manipulations of the device during formation prior to implant. Each bend during the formation process causes surface fractures that ultimately reduce the integrity of the device. As the device becomes weaker, it is more susceptible to premature failure, like the N-Hance device implanted in James Wilson.

(Compl., ¶ 17.)

I find this paragraph of Plaintiffs' Complaint is sufficiently specific to identify the alleged design defect in Defendants' product. No greater specificity is required, and I will therefore deny Defendants' Motion to Dismiss as to the negligent design claim.

4. Failure to warn claim

Defendants also move to dismiss Plaintiffs' failure to warn claim, alleging that Plaintiffs failed to address how Defendants breached a duty to Plaintiffs' doctor and how a better warning would have affected his doctor's choice of device. (Defs' Mtn, p. 16.) It is well-established that a "manufacturer's duty to warn is directed to physicians." Lance v. Wyeth, 85 A.3d 434, 438 n. 6 (Pa. 2014). Plaintiffs' Complaint alleges that Defendants were negligent by failing to adequately warn health care providers that the N-Hance system could fail, failing to adequately warn health care providers of storage and handling requirements, and by failing to adequately warn health care providers of

manufacturing defects. (Compl., ¶ 39 (e) – (g)). When the Complaint is read together as a whole, I find that these allegations are sufficiently pled in order to allege that defendants failed to exercise reasonable care in informing Plaintiffs' doctors of any alleged defects in the N-Hance system, thereby depriving Plaintiff of advice from a fully informed physician. Accordingly, Defendants' Motion is denied as to Plaintiff's failure to warn claim.

C. Negligence *Per Se* Claims

Lastly, Defendants argue that Plaintiffs' negligence *per se* claim fails as a matter of law, as "Plaintiffs' claim for negligence *per se* is based on Synthes' alleged violations of the Federal Food, Drug and Cosmetic Act ("FDCA") and it implementing regulations," and that the FDCA "forbids private causes of action." (Defs' Mtn at pp. 17-18, citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). I will deny Defendants' Motion to Dismiss as to Plaintiffs' negligence *per se* claims without prejudice, and allow Defendants to reassert this issue at the time of summary judgment, if warranted.

V. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss Plaintiff's Complaint is granted in part and denied in part.