IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

MICHAEL SICH and ELLEN BITTERLICH, his wife,	:	
Plaintiffs,	:	Civil No. 1:17-cv-02828 (RBK/KMW)
v.	:	**OPINION**
PFIZER PHARMACEUTICAL, PFIZER INCORPORATED, et al	:	
Defendants.	:	

KUGLER, United States District Judge:

This matter arises upon defendant Pfizer Incorporated's ("Defendant") motion to dismiss plaintiffs Michael Sich and Ellen Bitterlich's ("Plaintiffs") suit for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). For the reasons set forth in the opinion below, this motion is **GRANTED WITHOUT PREJUDICE**, and Plaintiffs are permitted to submit an amended complaint as to only the claims arising under the New Jersey Products Liability Act ("PLA") within 14 days.

I. BACKGROUND

Plaintiffs allege that Defendant's drug, Dep-Medrol, caused Mr. Sich severe physical injuries. *See* Compl. at 1. In February 2015, Mr. Sich visited Reconstructive Orthopedics where a physician's assistant administered an injection of Dep-Medrol in his left knee. *Id.* Later that month, Mr. Sich returned to Reconstructive Orthopedics for an appointment with Dr. Scott Schoifet and received a second injection. *Id.* at 2. Within hours, Mr. Sich began experiencing

symptoms including elevated temperature, sensitivity, swelling, rashes, and hives. *Id.* Within a week, Mr. Sich underwent open debridement and two operations, and required seventeen days of inpatient treatment. *Id.* Plaintiffs then sued in New Jersey State Court, but Defendant removed the case on diversity grounds. *See* Notice of Removal (Doc. No. 1). Mr. Sich alleges that the "medication supplied by Defendant [] was defective" and caused his injuries. *Id.*

Plaintiffs seek relief under a number of theories. *See* Compl. First, Plaintiffs allege a design defect, a failure to warn, and manufacturing defects under the PLA. *Id.*; N.J.S.A. § 2A:58C. Second, Plaintiffs allege breach of actual and implied warranties, negligence, and "other causes of action allowed by law." Compl. at 4. Finally, Plaintiffs allege loss of consortium on behalf of Ms. Bitterlich. *Id.* at 5.

II. STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows a court to dismiss an action for failure to state a claim upon which relief can be granted. When evaluating a motion to dismiss, "courts accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quoting *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). In other words, a complaint survives a motion to dismiss if it contains 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); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

To make this determination, a court conducts a three-part analysis. *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010). First, the court must "tak[e] note of the elements a plaintiff must plead to state a claim." *Id.* (quoting *Iqbal*, 556 U.S. at 675). Second,

the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* at 131 (quoting *Iqbal*, 556 U.S. at 680). Finally, "where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Id.* (quoting *Iqbal*, 556 U.S. at 680). This plausibility determination is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. A complaint cannot survive where a court can only infer that a claim is merely possible rather than plausible. *Id.*

III. ANALYSIS

Plaintiffs' Strict Products Liability, Negligence, Breach of Implied Warranty, and Loss of Consortium Claims Are Subsumed by the PLA.

The PLA is "both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *In re Lead Paint Litigation*, 924 A.2d 484, 436-37 (N.J. 2007) (citing N.J.S.A. § 2A:58C-1(b)(3) (defining "product liability action")). The statute's reach includes "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. § 2A:58C-1(b)(3).

Here, Plaintiffs allege injuries sustained as a result of Mr. Sich's use of Depo-Medrol. *See* Compl. The PLA, as a result, applies—this is a products liability case. But "negligence, strict liability and implied warranty have been consolidated into a single product liability cause of action" by the PLA. *Clements v. Sanofi-Aventis, U.S. Inc.*, 111 F. Supp. 3d 586, 596 (D.N.J. 2015) ("New Jersey law no longer recognizes breach of implied warranty, negligence, and strict liability as viable separate claims for harms deriving from a defective product."); *Fid.*

& Guar. Ins. Underwriters, Inc. v. Omega Flex, Inc., 936 F. Supp. 2d 441, 446-51 (D.N.J. 2013); *Green v. Gen. Motors Corp.*, 709 A.2d 205, 209 (N.J. Super. 1998). Furthermore, the PLA subsumes loss of consortium claims arising in products liability contexts. *Chester v. Boston Sci. Corp.*, No. CV 16-02421, 2017 WL 751424, at *4 (D.N.J. Feb. 27, 2017). Therefore, Plaintiffs' strict products liability, negligence, breach of implied warranty, and loss of consortium claims are subsumed by the PLA and must be dismissed as a matter of law.

Because the PLA subsumes these claims, it would be futile to include them in the amended complaint.

Plaintiffs PLA and Breach of Express Warranty Claims Fail to Meet The Fed. R. Civ. P. 12(b)(6) Pleading Standard and Must be Dismissed Without Prejudice With Leave to Amend.

A. Design Defect

Under New Jersey law, the plaintiff must show that the "product was defective, that the defect existed when the product left the defendant's control, and that the defect caused injury to a reasonably foreseeable user." *Feldman v. Lederle Labs.*, 97 N.J. 429, 449 (N.J. 1984); *see Donlon v. Gluck Grp., LLC*, No. 09-5379, 2011 WL 6020574, at *3 (D.N.J. Dec. 2, 2011). The plaintiff must demonstrate that the "product [was] manufactured as intended but the design render[ed] the product unsafe." *Pollander v. Desimone BMW of Mt. Laurel, Ltd.*, No. A-3204-10T3, 2012 WL 127563, at *3 (N.J. Super. Ct. App. Div. Jan. 18, 2012). Plaintiffs must also provide—pursuant to a risk-utility analysis—an alternative design that is both practical and feasible. *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 560-61 (N.J. 1998); *Schraeder v. Demilec (USA) LLC*, No. 12-6074, 2013 WL 5770970, at *2 (D.N.J. Oct. 22, 2013).

Plaintiffs have failed to reach this bar. Plaintiffs have alleged that as a result of a defect in the product, "including its sterility and/or formulation, Plaintiff Michael Sich was injected with

toxic substances and injured." Compl. at 3. That is not enough—Plaintiffs have failed to plead facts that satisfy each of the necessary elements of a design defect claim, they have simply alleged injury.

B. Failure to Warn

A manufacturer is liable for harm caused by a failure to warn if the product does not contain an adequate warning or instruction. N.J.S.A. § 2A:58C-4. A warning is adequate if it is "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product." *Id.*; *Banner v. Hoffman-La Roche Inc.*, 891 A.2d 1229, 1236 (N.J. Super. App. Div. 2006) (*cert. denied*, 921 A.2d 447 (N.J. 2007)).

Plaintiffs' allegations fail to meet this standard. Plaintiffs allege that "[a]s a direct and proximate result of" Defendant's failure to warn, "Plaintiff Michael Sich was injected with toxic substances and was injured." Compl. at 3. Plaintiffs offer nothing further, and thus do not reach the requisite plausibility requirement.[1] *Iqbal*, 556 U.S. at 680.

C. Manufacturing Defect

A manufacturing defect exists if a product "deviated from the design specification, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae." N.J.S.A. § 2A:58C-2(a). A plaintiff must prove "that the product was defective, that the defect existed when the product left the manufacturer's control, and that the defect proximately caused injuries to the plaintiff, [who

[1] Because Plaintiffs have not alleged or pleaded *any* facts related to the warning label, this Court does not reach the questions of (1) whether the learned intermediary doctrine applies and if Mr. Sich's healthcare provider was adequately warned of any relevant dangers; and (2) whether the warning label is protected by the rebuttable presumption of adequacy afforded to FDA-approved prescription medication under the PLA. N.J.S.A. § 2A:58C-4.

must be] a reasonably foreseeable or intended user." *McMahon v. Gen. Dynamics Corp.*, 933 F. Supp. 2d 682, 695 (D.N.J. 2013) (citing *Myrlak v. Port Authority of N.Y. and N.J.*, 723 A.2d 45, 52 (N.J. 1999)).

Plaintiffs have alleged that as a "direct and proximate result of . . . manufacturing defects including its sterility and/or formulation, Plaintiff Michael Sich was injected with toxic substance and was injured." Compl. at 3. Plaintiffs have not, however, explained how the drug differed from the requisite standard or how it was allegedly defective. This claim thus lacks the factual support that it needs to reach the *Twombly* / *Iqbal* plausibility standards—conclusory statements are not enough. 550 U.S. at 570; 556 U.S. at 680.

D. Breach of Express Warranty

An express warranty is an "affirmation of fact or promise made by the seller . . . which relates to the goods and becomes part of the basis of the bargain." N.J.S.A. § 12A:2-313(a). Plaintiffs must allege: (1) that Defendant made an affirmation, promise, or description about the product; (2) that this affirmation, promise, or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description. *Mendez v. Shah*, 28 F. Supp. 3d 282, 294 (D.N.J. 2014); *Fid. & Guar. Ins. Underwriters, Inc.*, 936 F. Supp. 2d at 451.

Plaintiffs have failed to present an affirmation, promise, or description about the product made by Defendant. They have additionally failed to allege how this missing affirmation, promise, or description became a part of the basis of the bargain for the product, nor how the product ultimately did not conform to that affirmation, promise, or description. As such, the breach of express warranty claim constitutes a categorical allegation and nothing more. *Iqbal*, 556 U.S. at 678.

IV. CONCLUSION

Because the complaint as pleaded does not present facts, accepted as true, that give rise to any plausible entitlement to relief, Defendant's motion to dismiss is **GRANTED WITHOUT PREJUDICE** and Plaintiffs are permitted 14 days to submit an amended complaint correcting the deficiencies noted above.

Dated: 10/04/2017

s/Robert B. Kugler
ROBERT B. KUGLER
United States District Judge