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

MELANIE ATKINSON,	**CIVIL ACTION NO. 19-0277**
v.	
LUITPOLD PHARMACEUTICALS, INC., et al.	
TAMMIE COMBS,	**CIVIL ACTION NO. 19-3888**
v.	
LUITPOLD PHARMACEUTICALS, INC., et al.	

MEMORANDUM OPINION

Plaintiffs Melanie Atkinson and Tammie Combs bring these actions[1] against Defendants American Regent, Inc.,[2] Daiichi Sankyo, Inc., Daiichi Sankyo Co., Ltd., Daiichi Sankyo US Holdings, Inc., Vifor Pharma Ltd., Vifor Pharma Participations Ltd., Vifor (International) AG, and Relypsa, Inc.,[3] for purported adverse effects suffered after receiving injections of Injectafer, a medication prescribed to treat iron deficiency anemia. Defendants American Regent, Inc., Daiichi Sankyo, Inc., and Daiichi Sankyo U.S. Holdings, Inc. (collectively, "Defendants") move to dismiss the Complaints pursuant to Federal Rules of Civil Procedure 8(a) and 12(b)(6).

I. BACKGROUND[4]

The background and allegations in this matter have already been recounted at length.

[1] Plaintiffs' cases are two of twenty-five cases currently before this Judge concerning the Injectafer product.

[2] Effective January 1, 2019, Luitpold Pharmaceuticals, Inc. merged with American Regent, Inc..

[3] Plaintiffs also bring these actions against Vifor Pharma Management Ltd. Vifor Pharma Management Ltd. was recently dismissed for lack of personal jurisdiction in a related Injectafer case. See Crockett v. Luitpold Pharms., Inc., 2020 WL 3096527 (E.D. Pa. June 11, 2020).

[4] These facts are drawn from the Complaints and, for the purposes of the motions to dismiss, will be taken as true. See Kost v. Kozakiewicz, 1 F. 3d 176, 183 (3d Cir. 1993).

See Atkinson v. Luitpold Pharms., Inc., 2020 WL 1330705, at *1-*2 (E.D. Pa. Mar. 23, 2020). Injectafer is an iron replacement injection medication brought to market in the United States by Defendants for the treatment of iron deficiency anemia in adults who have intolerance to oral iron.

Injectafer is one of several products available for intravenous iron but is the only such product available in the United States formulated with the unique ferric carboxymaltose ("FCM") compound. Prior to its approval in the United States, FCM was available on the European and other markets under the brand name Ferinject—designed, manufactured, promoted, and sold by Defendant Vifor (International) AG.[5] During FCM's presence on the European and United States markets, dozens of case reports and medical publications emerged that revealed the link between FCM and a condition called severe hypophosphatemia ("Severe HPP"), an abnormally low level of phosphate in a person's blood. Defendants had been on notice of the link between FCM and clinically important hypophosphatemia since the FDA alerted them of the condition in July 2006 during their application request for new drug approval in the United States, but these studies, of which Defendants were also on notice, revealed an increasing number of case reports of intravenous-iron patients developing Severe HPP. In one study, all 18 cases of life-threatening Severe HPP developed after administration of FCM. In another study, of the 78 patients taking FCM, 51% developed HPP, including 13% with Severe HPP. Another study found that use of FCM was associated with a 20-fold higher risk of Severe HPP than another intravenous iron drug on the market. A study comparing Injectafer to another intravenous iron drug noted that extreme HPP and prolonged HPP lasting more than five weeks were noted exclusively in Injectafer patients, at 10% and 29.1%, respectively. Defendants also

[5] Vifor (International) AG licensed and continues to license FCM to all other Defendants.

had knowledge of the link between Injectafer and Severe HPP from their own clinical studies.

Plaintiffs were prescribed Injectafer and, subsequent to their treatment with Injectafer, they were diagnosed with HPP. They filed these suits, alleging that they suffered and likely will continue to suffer severe and permanent injuries and damages as a result of taking Injectafer.

This Court previously ruled on Defendants' motion to dismiss Atkinson's First Amended Complaint. See Atkinson, 2020 WL 1330705. In her opposition brief, Atkinson abandoned her claims for negligent design defect, negligent misrepresentation, breach of express warranty, breach of implied warranty, and breach of consumer protection laws, and those claims were therefore dismissed with prejudice. Id. at *3. Atkinson's claims for negligence, negligent failure to warn, fraud, strict liability failure to warn, and gross negligence were dismissed with prejudice insofar as they were based on a failure to warn theory. Id. at *8. However, she was granted leave to amend her negligence and gross negligence claims based on a failure to test theory. Id. at *9.

Atkinson has filed a Second Amended Complaint. Atkinson and Combs are both Texas Plaintiffs, and insofar as they are bringing similar claims, they will be addressed below together. Defendants have now moved to dismiss all claims, in whole or in part.

II. LEGAL STANDARD

When evaluating a complaint on a motion to dismiss, factual allegations are scrutinized under Rules 8(a) and 12(b)(6) to determine if the allegations and inferences proposed from those allegations are plausible. See Ashcroft v. Iqbal, 556 U.S. 662, 683 (2009). "To 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.'" See id. at 678 (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)).

"In light of Twombly, 'it is no longer sufficient to allege mere elements of a cause of action; instead a complaint must allege facts suggestive of [the proscribed] conduct.'" Great W. Mining & Mineral Co. v. Fox Rothschild LLP, 615 F.3d 159, 177 (3d Cir. 2010) (quoting Phillips v. Cty. of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008)). "[R]ote recitals of the elements of a cause of action, legal conclusions, and mere conclusory statements" are disregarded. James v. City of Wilkes-Barre, 700 F.3d 675, 679 (3d Cir. 2012). The relevant question is not whether the claimant "will ultimately prevail . . . but whether [the] complaint [is] sufficient to cross the federal court's threshold." Skinner v. Switzer, 562 U.S. 521, 531 (2011).

III. ANALYSIS

Both Plaintiffs allege negligent failure to test and gross negligence (and seek punitive damages). Combs additionally alleges design defect, sounding in both strict liability and negligence.

A. Negligent Failure to Test

Defendants argue that Plaintiffs' negligent failure to test claim is actually a failure to warn claim, masquerading as failure to test so as to circumvent the Texas statute that preempts failure to warn claims against pharmaceutical manufacturers, see Tex. Rev. Civ. Stat. Ann. § 82.007,[6] and furthermore that the claim is inadequately pled.

This Court has previously held that a negligent failure to test claim is a cause of action independent of a failure to warn. See Atkinson, 2020 WL 1330705, at *8-*9; see also Bates v. Dow Agrosciences LLC, 544 U.S. 431, 444 (2005) (addressing failure to warn and failure to test

[6] Section 82.007(a)(1) states:

> In a products liability action alleging that an injury was caused by a failure to provide adequate warnings of information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants . . . are not liable with respect to the allegations involving failure to provide adequate warnings or information. . . .

as distinct theories of recovery in a Texas tort case). A pharmaceutical manufacturer has an independent duty to "not only keep abreast of scientific knowledge, discoveries, and advances, but, more importantly, test and inspect its product." Romero v. Wyeth LLC, 2012 WL 12547105, at *4 (E.D. Tex. May 30, 2012) (citing Borel v. Fibreboard Paper Prods. Corp., 493 F.3d 1076, 1089-90 (5th Cir. 1973)); but see Morris v. PLIVA, Inc., 713 F.3d 774, 778 (5th Cir. 2013) (noting that any "useful reporting" resulting from adequate testing would "ostensibly consist of some sort of warning"). The extent of research conducted by the manufacturer "must be commensurate with the dangers involved." Atkinson, 2020 WL 1330705, at *9 (citing Romero, 2012 WL 12547105, at *4).[7]

Here, Plaintiffs have pled that Defendants had a duty to conduct adequate testing of Injectafer and breached that duty, despite Defendants' knowledge of existing risks of Severe HPP "from the available adverse event reports, literature, clinical studies, and case studies that had built up over years of ferric carboxymaltose and, specifically, Injectafer use in the European and US marketplaces." Accepting Plaintiff's factual allegations as true, Defendants were on notice of the link between FCM and HPP as early as July 2006, at which time the FDA issued Defendants a non-approvable letter in response to their application to introduce Injectafer to the U.S. market, which cited "clinically important hypophosphatemia" as a safety concern. Beyond this knowledge, Plaintiffs point to multiple studies, some of which Defendants were on notice of and some of which Defendants themselves conducted. Plaintiffs' Complaints refer to a study identifying that use of FCM "was associated with a 20-fold higher risk" for Severe HPP than another intravenous iron drug on the market. Another study indicated that over half of the

[7] Defendants' reliance on Rojas is unavailing. See Rojas v. Teva Pharms. USA, Inc., 920 F. Supp.2d 772 (S.D. Tex. 2013). Rojas was a generic drug case in which the court subsumed the failure to test analysis within failure to warn, see id. at 778-79, which this Court has declined to do. See *Atkinson*, 2020 WL 1330705, at *9.

patients treated with FCM experienced HPP, with 13% experiencing Severe HPP. Yet another study indicated that "58.8% of Injectafer users versus only .9% of Feraheme users" developed Severe HPP. This study also indicated that extreme HPP and Severe HPP lasting longer than five weeks were noted exclusively in Injectafer users at 10% and 29.1%, respectively.

Plaintiffs allege that despite their knowledge of the risk, Defendants' breached their duty to Injectafer patients by failing to "establish and maintain an adequate post-marketing surveillance program" and failing to conduct "clinical trials, preclinical trials, surveys and prospective studies, to investigate Injectafer's . . . propensity to cause Severe Hypophosphatemia[,]" as well as failing to engage in testing how to "offset or mitigate" the negative effects of Injectafer. Defendants' alleged negligence led to the introduction of Injectafer at its recommended dosing into the United States market, which has caused direct injury to Plaintiffs. These facts plausibly allege negligence under a failure to test theory. Accordingly, Defendants' motion to dismiss Atkinson's and Combs's negligence claims shall be denied.

B. Gross Negligence

Defendants argue that Plaintiffs' claims for gross negligence should be dismissed, because the allegations are derivative of their unsuccessful failure to test claim and cannot stand alone. Without a successful claim for gross negligence, Defendants assert that punitive damages are unavailable. See Tex. Rev. Civ. Stat. Ann. § 41.003 (punitive damages are only available if the plaintiff can prove the defendant acted with "fraud, malice, or gross negligence").

To state a claim for gross negligence under Texas law, a plaintiff must allege facts indicating that "the defendant knew about the peril, but his acts or omissions demonstrate that he did not care." Louisiana-Pac. Corp. v. Andrade, 19 S.W.3d 245, 247 (Tex. 1999). A claim for

gross negligence has both objective and subjective components. Objectively, "from the standpoint of the actor, the act or omission must involve an extreme degree of risk, considering the probability and magnitude of the potential harm to others." Great Plains Tr. Co. v. Morgan Stanley Dean Witter & Co., 313 F.3d 305, 314 (5th Cir. 2002). Additionally, the defendant "must have actual, subjective awareness of the risk involved, but nevertheless proceed with conscious indifference to the rights, safety, or welfare of others." Id.

Here, Plaintiffs have alleged that in "fail[ing] to conduct adequate testing . . . Defendants ignored or disregarded years of data and reports on the relationship between [FCM] and Severe [HPP,]" despite having "knowledge and awareness of the extensive body of information available." This extensive body of information came in the form of "adverse event reports, literature, clinical studies, and case studies," as well as Defendants' own clinical studies. The Complaints include the results of some of these clinical studies and are discussed in detail, supra.

Accepting Plaintiff's allegations as true, Defendants failed to conduct further testing despite their knowledge of the existing medical literature identifying a strong link between FCM and Severe HPP. Considering these facts, Defendants evinced sufficient indifference to state a claim for gross negligence. See Fearrington v. Boston Sci. Corp., 410 F. Supp.3d 794, 808-09 (S.D. Tex. 2019) (permitting claim for punitive damages where the plaintiff alleged failures to adequately research or anticipate possible risks "despite knowledge that they would cause catastrophic injuries in some individuals"). Because Plaintiffs' gross negligence claims survive, so does Plaintiffs' basis for punitive damages. See Tex. Civ. Prac. & Rem. Code Ann. § 41.003.[8]

[8] Plaintiffs assert that Pennsylvania law is applicable to the question of punitive damages. Without deciding at this time whether Texas or Pennsylvania law applies, it is noted that the pleading standard for punitive damages is similar in Pennsylvania. See Hutchison v. Luddy, 870 A.2d 766, 770 (Pa. 2005) (noting that punitive damages are awarded for outrageous conduct "because of the defendant's evil motive or his reckless indifference to the rights of others"); see also Piazza v. Young, 403 F. Supp.3d 421, 443 (M.D. Pa. 2019) (deeming punitive damages analysis a "fact-intensive inquiry" and noting the court's practice of routinely declining to dismiss punitive damages claims at the motion to dismiss stage).

C. Design Defect

Defendants argue that Combs's strict liability design defect claim must be dismissed because it is barred under Comment k of the Second Restatement of Torts, Section 402A.[9] Plaintiff responds that design defect claims are permissible, arguing that Section 82.007's presumption that an FDA-approved medication contains an adequate warning is only applicable to failure to warn claims, and that Comment k should not be applied to bar the design defect claim here.

In deciding Defendants' motion to dismiss Combs's strict liability design defect claim, the Court is guided by the law of the case doctrine, which limits relitigation of "a previously decided issue" so as to "promote finality, consistency, and judicial economy." Hamilton v. Leavy, 322 F.3d 776, 786-87 (3d Cir. 2003). Law of the case doctrine is applicable where a court adheres to a prior ruling in a closely related case. See Pension Benefit Guar. Corp. v. White Consol. Indus. Inc., 1999 WL 680185, at *34 (W.D. Pa. July 21, 1999), *aff'd on other*

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[9] Comment k addresses "[u]navoidably unsafe products" and states:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k (1965) (emphasis in original).

grounds, 215 F.3d 407 (3d Cir. 2000); see also Brown v. New York, 975 F. Supp.2d 209, 220 (N.D.N.Y. 2013) (applying the doctrine to claims previously adjudicated by the same court in related cases).

This Court previously held that Atkinson was unable to rebut the presumption of an adequate warning imposed by Texas statute, and a manufacturer of a product with a presumed-adequate warning could not be held liable under a theory of strict liability design defect pursuant to Comment k; therefore, Atkinson's strict liability design defect claim was dismissed with prejudice. See Atkinson, 2020 WL 1330705, at *8-*9.[10] Applying law of the case doctrine, Combs's same strict liability design defect claim here shall be dismissed with prejudice.

Defendants also seek dismissal of Combs's negligent design defect claim,[11] arguing that it is duplicative of a failure to warn claim and that Combs fails to satisfy the requirement of identifying a safer alternative as required by Texas law.[12]

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[10] Applying Texas law, this Court found that manufacturers cannot be strictly liable for pharmaceutical design defects if "proper warning is given," pursuant to Comment k of the Second Restatement of Torts, Section 402A. Atkinson, 2020 WL 1330705, at *9. Texas provides a pharmaceutical manufacturer with a presumption that an FDA-approved medication has an adequate warning, see Section 82.007(a)(1), which is rebuttable if the plaintiff proves that the defendant "withheld from or misrepresented" to the FDA material information relevant to the product. Tex. Rev. Civ. Stat. Ann. § 82.007(b)(1). However, the Supreme Court's decision in Buckman preempted Plaintiff's ability to rebut that presumption. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). The Fifth Circuit subsequently held that plaintiffs could only rebut the presumption of an FDA-approved medication's adequate warning if the FDA itself found the defendant was fraudulent in obtaining FDA approval. See Lofton v. McNeil Consumer & Specialty Pharms., 672 F.3d 372, 381 (5th Cir. 2012).

Given that the FDA has not made a finding of fraud against Defendants, this Court held that Atkinson was unable to rebut the presumption of an adequate warning imposed by Texas statute. See Atkinson, 2020 WL 1330705, at *8-*9. As such, the strict liability design defect claim in Atkinson was dismissed with prejudice given that Defendants cannot be held liable on a theory of strict liability design defect for products that contain adequate warnings pursuant to Comment k. Id.

[11] Unlike the strict liability design defect claim in Atkinson's First Amended Complaint, which was dismissed with prejudice as a matter of law, the negligent design defect claim was dismissed because it was voluntarily abandoned by Plaintiff. See Atkinson, 2020 WL 1330705, at *3. Law of the case doctrine therefore applies to Combs's strict liability design defect claim but not to her negligent design defect claim.

[12] Defendants' argument that Combs's negligent design defect claim is duplicative of a failure warn claim is not supported by citation to any binding case law.

Negligent design claims are "conceptually distinguishable from . . . strict liability claims." Am. Tobacco Co., Inc. v. Grinnell, 951 S.W.2d 420, 437 (Tex. 1997). A negligent design defect claim focuses not on the condition of the product, but the care given by the manufacturer in designing the product. Id. By its clear terms, Comment k is limited to strict liability claims. See Restatement (Second) of Torts § 402A cmt. k (stating that if a product is "properly prepared and marketed, and proper warning is given," it "is not to be held to strict liability for unfortunate consequences attending their use" (emphasis added)). Comment k makes no mention of negligence. Thus, the "immunity provided by Comment k" to pharmaceutical manufacturers does not apply to design defect claims based in negligence. See Friske v. ALZA Corp., 2011 WL 13233327, at *13 (N.D. Tex. Apr. 29, 2011) (analyzing language of Comment k); see also Lake-Allen v. Johnson & Johnson, L.P., 2009 WL 2252198, at *3 (D. Utah July 27, 2009) (declining to find that state's adoption of Comment k barred prescription drug negligent design defect claims in addition to strict liability claims).

However, Texas common law requires plaintiffs alleging design defects to prove that a safer alternative design of the product in question was feasible. Hernandez v. Tokai Corp., 2 S.W.3d 251, 256, 258 (Tex. 1999). Plaintiffs must plead facts that suggest a plausible alternative design. See Rodriguez v. Gilead Scis., Inc., 2015 WL 236621, at *3 (S.D. Tex. Jan. 16, 2015). A proposed alternative cannot be a completely different product. See Caterpillar, Inc. v. Shears, 911 S.W.2d 379, 385 (Tex. 1995) ("A motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle."). Moreover, competitive products are unacceptable as alternative designs, "even when the other product has the same general purpose as the allegedly defective product." Massa v. Genentech, 2012 WL 956192, at *7 (S.D. Tex. Mar. 19, 2012) (citation omitted) (finding plaintiff's argument that defendants "always had the

option of using an alternative chemical compound in their psoriasis treatment" insufficient); see also Brockert v. Wyeth Pharms., Inc., 287 S.W.3d 760, 770-71 (Tex. App. 2009) (rejecting proposed alternative of removing problematic compound from medication because it would be an "entirely different" medication).

Here, Plaintiff's Complaint summarily refers to a potential alternative as follows: "At the time Injectafer was developed and designed, there existed safer alternative intravenous iron medications that were known to Defendants and available on the marketplace and comparatively safer than the Injectafer product." Outside of Plaintiff's proffered alternatives that are entirely different products already on the market, see Massa, 2012 WL 956192, at *7, the facts as alleged are conclusory and insufficient to meet the threshold of plausibility required at the motion to dismiss stage. Accordingly, Plaintiff's negligent design defect claim shall also be dismissed with prejudice.[13]

An appropriate order follows.

August 6, 2020

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.

[13] Although courts should freely grant leave to amend "when justice so requires . . . a court may deny leave to amend when such amendment would be futile." Budhun v. Reading Hosp. & Med. Ctr., 765 F.3d 245, 259 (3d Cir. 2014). This litigation has been ongoing for over a year and Combs already amended her Complaint once following this Court's opinion in Atkinson. As such, dismissal with prejudice is appropriate.