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

WILLIAM L. BELL, JR,	)	CIVIL ACTION NO. 17-1153
	)	
Plaintiff,	)	
	)	
	)	
v.	)	
	)	
	)	
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, AND; AND ELI LILLY & COMPANY,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

Conti, Chief District Judge

I. Introduction

Plaintiff William L. Bell, Jr. ("Bell") alleges that he developed an acute kidney injury as a direct result of taking the prescription drug Jardiance. Bell alleges numerous claims under Pennsylvania law. This court has subject-matter jurisdiction based on diversity of citizenship.

Defendants Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI")[1] and Eli Lilly & Company ("Lilly") filed a motion to dismiss all but counts 4 and 9 (ECF No. 10), arguing that Pennsylvania law broadly bars all non-negligence claims asserted against prescription drug manufacturers. Defendants also argue that the entire complaint should be dismissed for failing to comply with federal pleading standards. Lilly filed a separate motion to dismiss all claims

[1] Two other Boehringer entities named as defendants have not yet been served.

against it (ECF No. 7), arguing that because BIPI is the sole holder of the Jardiane New Drug Application ("NDA") filed with the Food and Drug Administration ("FDA") Lilly never had authority to change Jardiance's labeling or design. The motions are fully briefed and ripe for disposition. The parties agreed to stay the case pending the court's resolution of these motions. (ECF No. 15).

II. Factual Background

As set forth in the complaint, in July 2014, defendants submitted an NDA to the FDA for Jardiance. Complaint ¶ 20 (ECF No. 1). In August 2014, the FDA approved Jardiance for the treatment of Type II diabetes. *Id*. ¶ 21. Jardiance is the tradename for the drug empagliflozin, which is a member of the gliflozin class of sodium-glucose cotransporter 2 ("SGLT2") inhibitors. *Id.* ¶ 22. SGLT2 inhibitors are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. *Id.* ¶ 24. Excess glucose is not metabolized. Instead, it is excreted through the kidneys. *Id.* ¶ 24. Jardiance is indicated for only improved glycemic control in type 2 adult diabetics, but defendants market it for off label purposes, including weight loss, reduced blood pressure and improved glycemic control in type 1 diabetes. *Id.* ¶ 25. Since the release of Jardiance, the FDA has received a significant number of reports of diabetic ketoacidosis. *Id.* ¶ 26. Bell alleges that defendants knew about the significant risk of diabetic ketoacidosis but did not adequately warn consumers or the medical community about the severity of such risks. *Id.* ¶ 30.

On June 13, 2015, Bell began taking Jardiance per his doctor's instructions, primarily to treat diabetes. *Id.* ¶ 32. Bell relied on defendants' claims that Jardiance was safe and effective for the treatment of diabetes. *Id.* ¶ 35. On August 31, 2015, Bell suffered acute renal failure.

Id. ¶ 37. Bell does not plead any other facts about his medical condition.[2]

The complaint asserts the following causes of action: (1) products liability – design defect (strict liability); (2) products liability – failure to warn (strict liability); (3) willful and wanton misconduct or gross negligence; (4) negligence; (5) breach of express warranty; (6) breach of implied warranty; (7) fraudulent misrepresentation; (8) negligent misrepresentation; (9) negligent design; (10) fraudulent concealment; and (11) fraud.

III. Standard of Review

A motion to dismiss tests the legal sufficiency of the complaint. *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). In deciding a motion to dismiss, the court is not opining on whether the plaintiff will be likely to prevail on the merits; rather, when considering a motion to dismiss, the court accepts as true all well-pled factual allegations in the complaint and views them in a light most favorable to the plaintiff. *U.S. Express Lines Ltd. v. Higgins*, 281 F.3d 383, 388 (3d Cir. 2002). While a complaint does not need detailed factual allegations to survive a Federal Rule of Civil Procedure 12(b)(6) ("Rule 12(b)(6)") motion to dismiss, a complaint must provide more than labels and conclusions. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). A "formulaic recitation of the elements of a cause of action will not do." *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). "Factual allegations must be enough to raise a right to relief above the speculative level" and "sufficient to state a claim for relief that is plausible on its face." *Id.* "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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at

[2] The complaint appears to be copied from another case with a female plaintiff, as there are multiple references to "her" and "she." *See, e.g.*, Complaint Introduction and ¶ 46.

556).

> 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.'"

Id. (quoting *Twombly*, 550 U.S. at 556) (internal citations omitted).

Two working principles underlie *Twombly*. *Id.* First, with respect to mere conclusory statements, a court need not accept as true all of the allegations contained in a complaint. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Twombly*, 550 U.S. at 555.) Second, to survive a motion to dismiss, a claim must state a plausible claim for relief. *Id.* at 679. "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.* (citing 490 F.3d at 157-58). "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)). A court considering a motion to dismiss may begin by identifying pleadings that are not entitled to the assumption of truth because they are mere conclusions.

> While legal conclusions can provide the framework of the complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.

Id.

IV. Legal Analysis

A. Pennsylvania Law Regarding Claims Against Manufacturers of Prescription Drugs

This case is governed by Pennsylvania law. Defendants argue that under Pennsylvania law, product liability claims against pharmaceutical manufacturers can only be brought under a negligence theory.

1. Strict liability claims

In *Hahn v. Richter*, 673 A.2d 888, 889-90 (Pa. 1996), the Pennsylvania Supreme Court held that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the **only** recognized basis of liability." *Id*. at 890 (emphasis added). The Pennsylvania Supreme Court explained in *Hahn* that the Restatement (Second) of Torts § 402A, comment k "denies application of strict liability to products such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." *Id*. For example, the rabies vaccine commonly leads to serious consequences when injected, but because the disease itself leads to death, the marketing and use of the vaccine is fully justified. *Id*. at 890 n.2. That kind of product, properly prepared and accompanied by proper directions and warning, is not defective and is not unreasonably dangerous. *Id*.

Bell argues that *Hahn* is "antiquated" and this court should instead follow the principles set forth in *Tincher v. Omega Flex, Inc*., 104 A.3d 328 (Pa. 2014), a case involving stainless steel tubing. *Tincher* did not address pharmaceutical drugs and did not overrule *Hahn*. *See id.* at 382 (recognizing that under *Hahn*, a manufacturer is immune from strict liability defective design claims premised upon sale of prescription drugs without adequate warnings). In addition, Bell

argues that this court should follow *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), which recognized a negligent design defect claim against a prescription drug manufacturer. *Lance* described *Hahn* as having a "truncated analysis" that offered a "poor foundation for extrapolation." *Id*. at 452 n.21. The court emphasized in *Lance*, though, "that we are not revisiting *Hahn*." *Id*. The court reiterated that "for policy reasons this Court has declined to extend strict liability into the prescription drug arena. . . ." *Id*. at 264.

With respect to state law claims, this court is bound by the law as set forth by the Pennsylvania Supreme Court. *Hahn* is still good law and is controlling on cases involving prescription drugs. In *Hahn,* the supreme court rejected strict liability theories in the prescription drug context. Bell's strict liability claims in counts 1 and 2 of the complaint must be dismissed.

2. Breach of warranty claims

In *Hahn,* the Pennsylvania Supreme Court did not specifically address breach of warranty claims. Its holding that negligence is the "only" recognized basis of liability, *id.* at 890, similarly precludes a claim against a prescription drug manufacturer based on an alleged breach of warranty. In *Salvio v. Amgen, Inc*., 810 F. Supp. 2d 745 (W.D. Pa. 2011), the court explained:

> Pennsylvania state and federal courts have interpreted *Hahn* broadly to bar all non-negligence based claims asserted against a manufacturer of prescription drugs. *Leonard v. Taro Pharmaceuticals USA, Inc*., No. 10–1241, 2010 WL 4961647, at *5, 2010 U.S. Dist. LEXIS 127892, *12 (W.D. Pa. Dec. 2, 2010) (citing *Aaron v. Wyeth*, No. 07–927, 2010 WL 653984, at *11, 2010 U.S. Dist. LEXIS 14581, *30–1 (W.D. Pa. Feb. 19, 2010) (dismissing breach of express and implied warranty claims under *Hahn*); *Kline v. Pfizer, Inc*., No. 08–3238, 2008 WL 4787577, at *3, 2008 U.S. Dist. LEXIS 101655, *7 (E.D. Pa. Oct. 31, 2008) (dismissing breach of express and implied warranty claims under *Hahn*); *Colacicco v. Apotex, Inc*., 432 F.Supp.2d 514, 548 (E.D. Pa. 2006) (dismissing breach of implied warranty claim under *Hahn*)).

Salvio, 810 F. Supp.2d at, 755–56; *accord Rowland v. Novartis Pharmaceuticals Corp*., 34 F. Supp.3d 556, 568-69 (W.D. Pa. 2014). Bell's claims for breach of express and implied

warranties in counts 5 and 6 of the complaint will be dismissed.

3. Fraud claims

Counts 7, 10 and 11 of Bell's complaint allege that defendants knowingly represented that Jardiance was safer than alternative medications and failed to make truthful representations regarding the risks of taking Jardiance. The case law is split regarding claims for fraudulent misrepresentation, fraudulent concealment and fraud.

Some courts hold that *Hahn* broadly bars all non-negligence based claims asserted against a manufacturer of prescription drugs. In *Leonard v. Taro Pharm. USA, Inc*., No. 10CV1341, 2010 WL 4961647 (W.D. Pa. Dec. 2, 2010), the court reasoned that a claim of intentional misrepresentation or fraud is "a non-negligence based claim akin to strict liability for failure to warn, and is barred by *Hahn* and its progeny." *Id*. at *5. Other courts have recognized fraud-based claims. In *Tatum v. Takeda Pharm. N. Am., Inc*., No. CIV.A. 12-1114, 2012 WL 5182895 (E.D. Pa. Oct. 19, 2012), the court pointed out that *Hahn* required a seller of prescription drugs to warn not only of risks of which he reasonably should have knowledge, but also warn of risks of which he did, in fact, have knowledge. *Id*. at *4; *see Hahn*, 673 A.2d at 890 (a seller must warn of risks of which he "**has** or reasonably should have knowledge") (emphasis added). *Accord Cutruzzula v. Bayer Healthcare Pharm. Inc*., No. CV 14-1474, 2015 WL 8488670, at *5 (W.D. Pa. Nov. 17, 2015), report and recommendation adopted, No. CV 14-1474, 2015 WL 8492767 (W.D. Pa. Dec. 10, 2015) (refusing to dismiss fraud claims if they contain allegations of affirmative misrepresentations that go beyond a mere failure to warn).

The court is persuaded that Pennsylvania law recognizes a cause of action for fraudulent marketing of prescription drugs. *Hahn* does not preclude claims where the plaintiff alleges that the seller had actual knowledge of the risks of prescription drugs and intentionally concealed

them. The fraud claims in counts 7, 10 and 11 of Bell's complaint are not barred by *Hahn* as a matter of law.[3]

4. Negligent misrepresentation claim

Count 8 of Bell's complaint alleges negligent misrepresentation. Although the court in *Leonard* dismissed a fraudulent misrepresention claim, it held that a claim for negligent misrepresentation is not barred by *Hahn*. 2010 WL 4961647, at *5 (quoting *Colacicco*, 432 F. Supp.2d at 548). This court agrees with that analysis. Because count 8 of Bell's complaint sounds in negligence, it is not barred by *Hahn*.

5. Gross negligence claim

In count 3 of the complaint, Bell alleges that defendants acted with willful and wanton conduct or gross negligence and seeks punitive damages. "[T]here is no separate cause of action under Pennsylvania law for gross negligence." *Spence v. ESAB Group, Inc*., 623 F.3d 212, 215 n. 2 (3d Cir. 2010) (citing *Hunter v. Squirrel Hill Assocs. ., LP*, 413 F.Supp.2d 517, 520 n. 2 (E.D.Pa. 2005) ("While Pennsylvania courts acknowledge differing standards of care, they do not recognize degrees of negligence as separate causes of action.")). *See also Floyd v. Brown & Williamson Tobacco Corp*., 159 F.Supp.2d 823, 828 (E.D.Pa.2001) (dismissing plaintiff's separately pleaded claim for gross negligence); *Salvio*, 810 F. Supp.2d at 756 (same); *Kline v. Pfizer, Inc*., No. CIV.A.08-3238, 2008 WL 4787577, at *3 (E.D. Pa. Oct. 31, 2008) (same).

The dismissal of a stand-alone gross negligence claim does not preclude Bell from pursuing damages (including punitive damages) if he is able to demonstrate that defendants were grossly negligent. As explained in *Daly v. New Century Trans, Inc*., No. 1:11-CV-2037, 2012 WL 4060687 (M.D. Pa. Sept. 14, 2012):

[3] As will be discussed below, fraud claims are subject to rigorous pleading standards.

> Although not recognized as a separate cause of action, gross negligence has been recognized by Pennsylvania and federal courts interpreting Pennsylvania law as "a form of negligence where the facts support substantially more than ordinary carelessness, inadvertence, laxity, or indifference." Thus, Pennsylvania law acknowledges differing standards of care, but does not recognize degrees of negligence as separate causes of action.

Id. at *4 (citations omitted) (recognizing that allegations of gross negligence could support a claim for punitive damages). In count 4, Bell asserts a claim of negligence which is sufficient to encompass gross negligence. In accordance with these standards, Count 3 of Bell's complaint will be dismissed as a separate cause of action because it is subsumed within the negligence claims.

In summary, counts 1, 2, 3, 5 and 6 of Bell's complaint are not recognized by controlling Pennsylvania law. Counts 1, 2, 5 and 6 will be dismissed with prejudice, without leave to amend. *Salvio*, 810 F. Supp.2d at 757 (denying leave to amend non-negligence claims as futile). Count 3 is being dismissed but it is not dismissed on the merits; it is dismissed because it is not a separate claim.

B. Federal Pleading Standards

Defendants contend that even if some of the claims asserted by Bell are theoretically cognizable, the complaint in this case fails to allege sufficient facts to make any claim plausible. Defendants, therefore, seek dismissal of the entire complaint.

Bell argues that the claims are sufficiently pled. For example, Bell points to allegations that Jardiance was more dangerous than other risks associated with treatment of diabetes (although factual details are not provided), the benefits of Jardiance were outweighed by the risks, there are other (unspecified) design alternatives that have a better safety profile (although what those designs are, and how the safety profile is better are not pled), and Jardiance was more dangerous that the expectations of ordinary consumers and physicians (again, with no factual

details provided).

Factual details are almost entirely lacking. The complaint appears to be copied from another source, because it refers to "her" and "she." *See supra* note 2. There are no factual details about when Bell contracted diabetes, whether he has type I or type II diabetes, whether he has other medical conditions, who his treating physicians were, why he decided to take Jardiance, what alternatives to Jardiance were discussed, whether he read the warnings, how long he took Jardiance or at what dose or why he believes his acute renal failure was caused by Jardiance.

A close examination of the complaint reveals that the vast majority of its averments are bald legal conclusions or a formulaic repackaging of the elements of the claim. Bell did not plead the roles of each defendant. Bell did not plead how each defendant's conduct in the design of Jardiance, how warnings about Jardiance fell below the required standard of care or how each defendant's alleged breaches of duty caused Bell's injury. Bell did not explain how and why the design or warnings were defective. In paragraphs 22-24 of the complaint, Bell describes how SGLT2 inhibitors like Jardiance work. The complaint does not plead any facts, however, about why this design is defective. Bell conclusorily alleged that "several alternative safer products" exist (Complaint ¶ 29) but did not identify those products or explain why they are safer.

In *House v. Bristol-Myers Squibb Co*., No. 3:15-894, 2017 WL 55876 (W.D. Ky. Jan. 4, 2017), and *Fleming v. Janssen Pharmaceuticals, Inc*., 186 F. Supp. 3d 826, 835 (W.D. Tenn. 2016), the courts dismissed very similar complaints asserting products liability claims against manufacturers of similar drugs for failing to plead sufficient facts. In *Fleming*, the court explained:

> The only assertion as to how the product design was defective is a description of how the class of products works. (See Compl. ¶ 24 ("SGLT2 inhibitors ... are

> designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease.").) The Court cannot reasonably infer from the generic description of SGLT2 inhibitors' mechanism of action that Invokana was defective or unreasonably dangerous. The facts are also insufficient as to the alleged defect as the cause of Plaintiff's injuries. Plaintiff asserts, for example, that "[a]s a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of INVOKANA, Plaintiff suffered severe and permanent physical and emotional injuries." (Compl. ¶ 48.) Under Rule 12(b)(6), such "unadorned, the-defendant-unlawfully-harmed-me accusation[s]" are insufficient to state a claim.

186 F. Supp.3d at 835-36. The court dismissed the failure to warn claim because the plaintiff failed to allege facts showing that the drug was unreasonably dangerous. *Id*. at 836.

In *House*, the court similarly concluded that it could not infer defectiveness from a generic description of how SGLT2 inhibitors work. *House*, 2017 WL 55876 at *4. The court characterized the following allegations as formulaic legal conclusions that were insufficient to meet the *Twombly-Iqbal* standard: (a) the drugs "contained unreasonably dangerous design defects and were not reasonably safe as intended to be used"; (b) the drugs "were defective in design and formulation, making use of the drugs more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of diabetes"; (c) defendants "could have designed their respective [drugs] to make them less dangerous"; and (d) there "was a practical, technically feasible safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing" the function of the drugs. *Id*. at *3-4. The court dismissed the failure to warn claim as similarly based on only conclusory statements. *Id*. at *4.

The allegations in Bell's complaint are substantially identical to those held to be insufficient in *Fleming* and *House*. *See Salvio*, 810 F. Supp.2d at754 (describing complaint as "little more than a list of legal conclusions regarding Defendants' failure to test, market, warn,

design, and manufacture"). There are simply no actual facts pled about how each defendant was negligent in Jardiance's design or warnings or how each defendant's alleged breaches of the standard of care caused Bell's injuries. Bell's complaint will likewise be dismissed.

Fraud claims are subject to the more rigorous standards of Federal Rule of Civil Procedure 9(b) and must be pled with particularity. *See House*, 2017 WL 55876 at *8 (dismissing fraud-based claims described at a high level of generality). The fraud-based claims in counts 7, 10 and 11 of Bell's complaint fall far short of the Rule 9 standard and must be dismissed.

In sum, the complaint fails to plead sufficient facts to make any claim "plausible," as required by the Federal Rules of Civil Procedure. The complaint, therefore, will be dismissed in its entirety.

C. Federal Preemption

Lilly filed a separate motion to dismiss, arguing that because BIPI is the sole holder of the NDA, Lilly had no ability to change Jardiance's label or design. Lilly reasons that because federal law required it to follow the NDA, Bell's contrary state law claims are preempted.

Lilly cites *Warren v. Boehringer Ingelheim Pharmaceuticals*, Inc., No. 16-1326, 2017 WL 3970666 (S.D. Ind. Sept. 8, 2017) (involving Jardiance), and *Germain v. Teva Pharmaceuticals, USA, Inc*., 756 F.3d 917 (6th Cir. 2014), which concluded that a manufacturer who does not hold the NDA has no ability to change the warning label or the design of the drug. In *Warren*, the court held that Lilly could not comply with any duty imposed by state law to change the design or labeling of Jardiance, and therefore, state law claims against Lilly were preempted. *Warren*, 2017 WL 3970666 at *16. *Accord Yates v. Ortho-McNeil-Janssen Pharm., Inc*., 808 F.3d 281, 298 (6th Cir. 2015) (a "post-approval design defect claim is clearly

preempted by federal law").

Bell, in response, explains that his "claims focus on the initial design of Jardiance **prior to** FDA approval." ECF No. 17 at 5 (emphasis added); *see* ECF No. 17 at 6 ("Plaintiff's claims are premised on Eli Lilly's duty to initially design a reasonably safe product."). Bell apparently recognizes that he cannot pursue post-FDA approval claims against Lilly.

The case law regarding preemption of pre-approval design claims is not fully developed. Impossibility preemption is a demanding defense on which defendants bear the burden of proof. *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). The United States Court of Appeals for the Third Circuit has not addressed preemption in the prescription drug context. *But see Sikkelee v. Precision Airmotive Corp*., 822 F.3d 680, 702-03 (3d Cir. 2016) (holding at the summary judgment stage that federal law did not preempt a products liability claim in the aviation industry and discussing preemption principles in the "analogous preapproval scheme for pharmaceutical labeling"). In *Warren*, the court refused to dismiss a claim against BIPI based on the original design of Jardiance before FDA approval. *Warren*, 2017 WL 3970666 at *10, 15. *Accord Estate of Cassel v. Alza Corp*., No. 12-771, 2014 WL 856023 (W.D. Wis. Mar. 5, 2014) (holding that a pre-FDA approval design defect claim survived summary judgment because defendants failed to meet their burden to establish the preemption defense as a matter of law). In *Yates*, the court held that a pre-FDA approval design claim was preempted, but did so at the summary judgment stage, not on a motion to dismiss. 808 F.3d at 289, 299-300 (holding that the plaintiff's argument regarding a pre-approval duty to design a safer drug was "too attenuated"). The court recognized in *Yates*, however, that "[a]s a general matter, plaintiffs injured by brand-name prescription drugs retain state-law tort remedies against the manufacturer of those drugs, provided it is not impossible for the drug manufacturer to comply with both state and federal

law." *Id*. at 294.

As explained above, the complaint contains no factual details about Lilly's actions or how the design of Jardiance was allegedly defective prior to FDA approval. Without knowing what Lilly's actions were, the court cannot evaluate whether those actions create a conflict between Pennsylvania law and federal law. Given the lack of factual allegations in Bell's complaint and the unsettled state of preemption law, the court reserves ruling on the preemption issue at this time. Lilly's motion will be denied without prejudice.

V. Leave to Amend

Bell affirmatively requested leave to amend the complaint in the event that the motions to dismiss were granted. Pursuant to Rule 15, leave to amend should be freely granted. When a complaint is subject to dismissal under Rule 12(b)(6), district courts should generally permit an opportunity to amend unless an amendment would be inequitable, or otherwise unjust by way of futility, bad faith, or undue delay. *Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006). There has been no undue delay.

As explained above, it is clear that Bell will be unable to correct the shortcomings identified in this opinion as to counts 1, 2, 5 and 6 because those claims are not recognized by controlling Pennsylvania law and as to count 3 because it is subsumed into the negligence claims. Leave to amend those claims is denied because amendment would be futile. Amendment of the negligence and fraud-based claims asserted by Bell in counts 4, 7, 8, 9, 10 and 11 is not necessarily futile. Those claims are being dismissed for failure to comply with the required pleading standards.

Bell may file an amended complaint on or before March 8, 2018. The court cautions that if Bell chooses to file an amended complaint, it will be important for him to assure that the complaint contains all factual allegations needed to render the claims "plausible," against each defendant, because the court is unlikely to permit a further "bite at the apple." Bell must ensure that any fraud-based claims comply with the particularity standard in Rule 9. It will also be important for Bell to plead how the design or warnings were faulty. *See Salvio*, 810 F. Supp.2d at 750-51 (taking judicial notice of the package warning label); ECF No. 11 at 9 n.5 (purporting to quote from Jardiance's warning label regarding impaired renal function).

VI. Conclusion

In accordance with the foregoing, Defendants' joint motion to dismiss (ECF No. 10) will be GRANTED, and Lilly's separate motion to dismiss (ECF No. 7) will be DENIED WITHOUT PREJUDICE. Counts 1, 2, 3, 5 and 6 are dismissed without leave to amend. Counts 4, 7, 8, 9, 10 and 11 are dismissed with leave to amend. An appropriate order will be entered.

February 15, 2018

/s/ Joy Flowers Conti
Joy Flowers Conti
Chief United States District Judge