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

FOGE, McKEEVER LLC; TODD M. ROONEY; and ELDON S. THOMPSON,	)	
Plaintiffs,	)	
v.	)	No.: 2:20-cv-01462-RJC
ZOETIS INC.,	)	
Defendant.	)	

OPINION

Robert J. Colville, United States District Judge

Presently pending before the Court is a Motion to Dismiss filed on behalf of Zoetis Inc. ("Zoetis") (ECF No. 13). The matter has been fully briefed and is ripe for disposition.

I. Background and Factual Allegations

This products liability action was brought by Plaintiffs Foge, McKeever LLC (hereinafter "FML"), Todd M. Rooney and Eldon S.Thompson (collectively "Owners") as a result of the sudden death of their filly racehorse after receiving injections of a drug developed and manufactured by defendant Zoetis Inc.

The allegations in the Amended Complaint (ECF No. 12) ("Am. Compl.") are as follows. Plaintiffs owned a 3-year old Standardbred filly known as Saratoga Gia ("SG"), at all relevant times stabled at the Meadows Racetrack located in Washington County, Pennsylvania. (Am. Compl. ¶ 9). On or about April 7, 2020, via an equine veterinarian, SG received an injection of Excede (ceftiofur crystalline-free acid) manufactured and distributed by defendant Zoetis to address a minor puncture wound. (Am. Compl. ¶ 10). The Owners' equine veterinarians relied upon representations made by Zoetis concerning the efficacy and safety of Excede in

recommending the use of Excede. (Am. Compl. ¶ 11). On or about April 11, 2020, per Zoetis' specific recommendations, SG was administered a second dosage of Excede via an equine veterinarian. (Am. Compl. ¶ 12). Almost immediately after the second administration of Excede, SG experienced a severe reaction to the drug, causing her to collapse to the floor of the stall and never get up. (Am. Compl. ¶ 13). Due to the extreme distress caused by the administration of Excede, SG was provided with continuous veterinary care up to including her transport on April 13, 2020, to the Galbreath Equine Center, of the Ohio State University ("OSU"), in Columbus, Ohio, for additional emergency treatment. (Am. Compl. ¶ 14). Despite the emergency treatment, on April 15, 2020, SG passed away while under the care of OSU; SG died as a result of the administration of Excede, as directed. (Am. Compl. ¶ 15). The Owners notified Zoetis of SG's death caused by the Excede injections. (Am. Compl. ¶ 16). Prior to the Excede injections, SG was a promising and successful racehorse. (Am. Compl. ¶ 17).

Upon information and belief, Zoetis is acutely aware of similar adverse equine reactions to the injection of Excede in horses, but willfully, intentionally, maliciously and negligently ignored the risks associated with injections of the drug and failed to adequately warn of those dangers. (Am. Compl. ¶ 18). Numerous other similar adverse reactions, including those with fatal outcomes, have occurred throughout the United States and elsewhere, and have been reported to Zoetis since at least 2012 and continuing through 2020. (Am. Compl. ¶ 19). Upon information and belief, from 2010 through at least 2020, nearly 600 adverse reaction reports were made by Zoetis to the Federal Drug Administration ("FDA") for Excede reactions experienced by horses in the United States. (Am. Compl. ¶ 20). Zoetis was fully aware that adverse reactions to the administration of Excede have included fatal reactions, internal hemorrhaging, anaphylaxis, and other systemic-type reactions. (Am. Compl. ¶ 21). In many of

these instances, the affected horses were provided with extensive and expensive veterinary care and treatment, and the owners of the animals have absorbed veterinary costs as well as the diminished or ruined value associated with the horses who have died. In the case of SG, veterinary bills, other expenses and lost income (including, without limitation, lost breeding income) exceed $1.8 million dollars. (Am. Compl. ¶ 22). Upon information and belief, many of the horses who have suffered adverse reactions to the administration of Excede are performance animals. (Am. Compl. ¶ 23).

It is further alleged that Zoetis was aware of the adverse reactions to Excede, and the resulting veterinary costs and diminished or eliminated value of the afflicted horses. (Am. Compl. ¶ 24). Despite its knowledge of the severely debilitating and/or fatal reactions to the administration of Excede, Zoetis has neither disclosed nor adequately warned of Excede's danger to horses and has refused to adequately revise its warning label and prescribing information to reflect the significant negative effects of Excede. As a result, consumers, including the Owners, and treating veterinarians are left with no way of knowing of the considerable risks associated with the administration of Excede. (Am. Compl. ¶ 25). Had the Owners' equine veterinarians been adequately warned of Excede's dangers they would not have used Excede on SG and recommended a different course of treatment. (Am. Compl. ¶ 26). The Owners' equine veterinarians have ceased using Excede due to its dangerous propensities. (Am. Compl. ¶ 27).

Excede is an antibiotic expressly marketed as treating equine infections with a "two dose, one solution" treatment for ill horses. (Am. Compl. ¶ 28). Zoetis further markets Excede as doing in 2 doses what would otherwise take 10. (Am. Compl. ¶ 29). Excede is also prescribed by veterinarians for off-label uses. (Am. Compl. ¶ 30). Excede allegedly works

through an extended release formulation, which, upon gaining FDA approval in 2010, Zoetis touted as a "true innovation." (Am. Compl. ¶ 31). Because of Excede's extended release formulation, Zoetis claims that its treatment of horses is easier and more effective because it allows owners and veterinarians to administer treatment with less stress to the animal. (Am. Compl. ¶ 32). Excede is extensively promoted and marketed for use with stabled animals, such as SG. (Am. Compl. ¶ 33). For performance horses such as SG, administration of a 10-day course of nonextended release antibiotics is a relatively easy task that has been accomplished in the horse industry for many decades. (Am. Compl. ¶ 34).

It is further alleged that despite viable alternatives, and the known risks regarding the negative post-approval experiences suffered by, at least, hundreds of horses, Zoetis has willfully, intentionally, maliciously, and negligently refused to make alterations to Excede's label to adequately warn consumers of the dangers of Excede and continues to extensively market the product as being superior to traditional courses of antibiotic treatment for injured horses. (Am. Compl. ¶ 35).

Plaintiffs' Amended Complaint contains claims for Negligence (Counts I-III), Strict Liability (Counts IV-VI), Breach of Express Warranty (Count VII), Breach of the Implied Warranty of Merchantability (Count VIII), Fraudulent Misrepresentation and Concealment (Count IX), and Negligent Misrepresentation (Count X) against Zoetis for the loss of their horse. They claim entitlement to actual, compensatory, consequential and punitive damages as a result of Zoetis' allegedly defective design and manufacture of Excede. (Am. Compl. at ¶ 22).

II. Standard of Review

A motion to dismiss filed pursuant to Federal Rule of Civil Procedure 12(b)(6) 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 likely 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 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)).

"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.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554 (2007)). "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." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). The Supreme Court of the United States has explained:

> 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).

III. Discussion

A. Counts I, II, and II: Negligence

Plaintiffs assert products liability claims premised on negligent failure to warn, negligent defective design, and negligent manufacturing defect. Defendant moves to dismiss these claims, alleging Plaintiffs have failed to allege facts with sufficient plausibility. In products liability

claims sounding in negligence, Pennsylvania courts follow the Restatement (Second) of Torts. *Smith v. Howmedica Osteonics Corp.*, 251 F. Supp. 3d 844, 852–53 (E.D. Pa. 2017). Manufacturing defects are governed by Section 395 and design defects are governed by Section 398. *Lance v. Wyeth*, 624 Pa. 231, 85 A.3d 434, 445 n.13 (2014) ("[T]his Court has rather roundly endorsed the substantive principles reflected in both Sections 395 and 398...as having been 'adopted in practically all jurisdictions.'") Negligent failure to warn claims are governed by Section 388. *Baldino v. Castagna*, 505 Pa. 239, 478 A.2d 807, 810 (1984).

1. Count I: Negligent Failure to Warn

To assert a viable negligent failure to warn claim, a plaintiff must allege facts sufficient to plausibly show that the defendant "fail[ed] to exercise reasonable care to inform those for whose use the product is supplied of the facts which make it likely to be dangerous." *Id.* Federal courts in Pennsylvania have found such claims viable where plaintiffs' complaints contained factual allegations as to the content of the warnings defendants should have provided. *See, e.g., Terrell v. Davol, Inc*., 2014 WL 3746532, at *9-10 (E.D. Pa. July 30, 2014) (allowing negligent failure to warn claim where plaintiff alleged what information should have been given to her medical providers, setting forth an extensive list); *Houtz v. Encore Medical Corp.*, 2014 WL 6982767, at *4–5, (M.D. Pa. Dec. 10, 2014) (allowing claim where plaintiff alleged that manufacturer should have warned her/her doctors that a specific component of the device was defective and had a high risk of failure).

Defendant argues that Plaintiffs' negligent failure to warn allegations[1] are inadequate and conclusory and fail to allege causation, i.e. that the prescribing veterinarians would not have

[1] Plaintiffs allege "Zoetis failed to warn consumers and end-users, including the Owners and their equine veterinarians of the dangers posed by Excede." Am. Compl. at ¶ 43. Because Excede is regulated and approved by the FDA, its use is limited to those who can write prescriptions, i.e., veterinarians, not end-users and owners.

prescribed and administered the drug if they had been given sufficient warning. Defendant argues that Plaintiffs have failed to describe the warnings on the label, and to the extent Plaintiffs offer allegations of what was missing from the label, said allegations are inadequate.

Plaintiffs directs this Court to paragraphs 11, 26, and 42 of their Amended Complaint. (ECF No. 17 at 7). These allegations, however, do not specify what information was missing from Defendant's warnings or how and why the warnings were inadequate. Without this information, Plaintiffs have not plausibly stated a connection between their alleged injuries and Defendant's failure to warn. Plaintiff's negligent failure to warn claim is therefore dismissed.

2. Count II: Negligent Defective Design

To plead a viable claim for negligent design, a plaintiff must plead facts to plausibly show that the defendant failed to exercise reasonable care in the adoption of a safe design. *Smith*, 251 F. Supp. 3d at 854. Here, Defendant moves to dismiss this claim on the grounds that the allegations in Plaintiffs' Amended Complaint fail to identify any specific design defect or available reasonable alternative. Plaintiffs plead their negligent design claim based on the availability of a safer, feasible alternative design, and also, the bare legal conclusion that Defendant was negligent in their design. (Am. Comp. ¶¶ 34, 56). Plaintiffs allege the drug's extended release formulation is unreasonably dangerous. (Am. Comp. ¶ 48).

We find that Plaintiffs' allegations that Zoetis was negligent in the design lack adequate specificity as to why the design was flawed, or whether the duty of care in design was violated by releasing the drug into the marketplace knowing it was harmful. Moreover, Plaintiffs have not alleged what alternative formulation would be feasible and adopted by Zoetis. Conclusory allegations that a product was negligently designed are not, on their own, sufficient to plead a viable claim. *See, e.g.*, *Smith*, 251 F. Supp. 3d at 854 (dismissing negligent design claim where

"[t]he only explicit reference to the product's design is the conclusory allegation that [d]efendants were negligent in such design").

Because Plaintiffs fail to allege facts sufficient to plausibly state a negligent design claim, this claim is dismissed.

3. Negligent Manufacturing Defect

To plead a viable negligent manufacturing claim, "it is necessary to allege some facts that would plausibly suggest that the manufacturer failed to exercise a reasonable standard of care during the 'manufacturing process.'" *Smith*, 251 F. Supp. 3d at 853. Conclusory allegations that a product was negligently manufactured are not, on their own, sufficient to plead a viable claim. *Id.* (holding that "[w]ithout any factual allegation as to the nature of what went wrong during the manufacturing process, there is no plausible road to recovery for negligent manufacturing.

Defendant moves to dismiss Plaintiffs' negligent manufacturing claim on the grounds that it is insufficient to simply allege, in conclusory fashion, that the product departed from its intended design and contained a manufacturing defect. Plaintiffs allege that Excede was negligently manufactured. (Am. Comp. ¶ 60). Defendant argues Plaintiffs must allege facts that plausibly suggest how the manufacturer failed to exercise reasonable care during the manufacturing process, and further, must allege factual allegations as to what went wrong during that process. Defendant also argues Plaintiffs fail to allege causation. Plaintiffs argue that these matters can be inferred from the pleadings, i.e. that the horse became ill after a second dose, and that discovery is needed in order to support this claim. Yet "[w]ithout any factual allegation as to the nature of what went wrong during the manufacturing process," Plaintiffs cannot plausibly state a claim for negligent manufacturing. *Smith*, 251 F. Supp. 3d at 853.

After a careful review of the Amended Complaint, we find Plaintiffs have not alleged facts concerning Defendant's manufacturing process. Plaintiffs' negligent manufacturing claim is therefore dismissed.

B. Counts IV, V and VI: Strict Liability

At Counts IV, V and VI Plaintiffs assert strict liability claims premised on failure to warn, defective design and defective manufacture. Defendant moves to dismiss these strict liability claims on the basis that, under Pennsylvania law, such claims are not legally cognizable against a prescription drug manufacturer under Section 402A of the Restatement (Second) of Torts, comment k. The Pennsylvania Supreme Court has held broadly that "Comment k [to § 402A of the Restatement (Second) of Torts] ... denies application of strict liability to products such as prescription drugs." *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888, 889 (1996).[2] The Pennsylvania Supreme Court reiterated its broad statement in *Lance v. Wyeth*, 624 Pa. 231, 85 A.3d 434 (2014), holding that "for policy reasons, this Court has declined to extend strict liability into the prescription drug arena." *Id.* at 438; *see also Bell v. Boehringer Ingelheim Pharm., Inc*., No. 17-1153, 2018 WL 928237, *3 (W.D. Pa. Feb. 15, 2018). This has been applied to strict liability as to manufacturing defects, defective design, and failure to warn. *Hahn*, 673 A.2d at 890; *Keen v. C.R. Bard, Inc*., No. 13-5361, 2020 WL 4873634, at *7 (E.D. Pa. Aug. 19, 2020 *McGrain v. C.R. Bard, Inc*., No. 21-1539, 2021 WL 3288601, *4 (E.D. Pa. July 30, 2021)

[2] In *Hahn*, the Court applied comment k of the Restatement (Second) of Torts § 402A to hold that prescription drugs are categorically immune from strict liability because they are "[u]navoidably unsafe" but are nonetheless justified for some patients. 673 A.2d at 889–91 (quoting Restatement (Second) of Torts § 402A cmt. k). When read in conjunction with *Hahn*, comment k, which lacks textual restrictions, and embodies similar policy concerns, would dictate there be no strict liability for unavoidably unsafe products such as prescription drugs for animals.

Accordingly, Plaintiff's strict liability claims for failure to warn (Count IV), defective design (Count V) and manufacturing defect (Count VI) are barred as a matter of law, and Counts IV-VI are dismissed with prejudice.,

C. Breach of Warranty

1. Count VII: Breach of Express Warranty

At Count VII Plaintiffs assert a claim for breach of express warranty. Defendant argues that under Pennsylvania law, an express warranty arises out of the representations or promises of the seller. 13 Pa. Cons. Stat. § 2313; *see also Sowers v. Johnson & Johnson Medical, Inc*., 867 F. Supp. 306, 313 (E.D. Pa. 1994). To create an express warranty, "the seller must expressly communicate the terms of the warranty to the buyer in such a manner that the buyer understands those terms and accepts them." *Eiser v. Brown & Williamson Tobacco Corp*., 2006 WL 933394, at *5 (Pa. Super. Ct. Jan. 19, 2006) (quoting *Goodman v. PPG Indus., Inc*., 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004)). To plausibly plead an express warranty claim, some level of meaningful detail is required. *See, e.g., Luke v. Am. Home Prods. Corp.*, 1998 WL 1781624, at *6 (Pa. Ct. Com. Pl. Nov. 18, 1998) (dismissing express warranty claim because complaint failed to state "what the warranty allegedly covered, when it was made[,] and to whom it was directed").

Here, Plaintiff alleges certain representations made by Zoetis in their labeling, inserts and informational materials, (Am. Compl. ¶ 92),[3] that the Plaintiffs relied on such information (Am. Compl.¶ 93), and that Zoetis breached its express warranties because Excede does not conform to its statements and representations because an injection of the drug causes serious

[3]Plaintiffs allege:
a. "Excede provides peace of mind knowing that the antibiotic has been demonstrated to be safe and effective in horses."
b. "In a safety study, swelling [at the injection site] completely resolved within 7 days in the majority of cases."
c. "Excede makes the treatment process less stressful for you and your horse."
d. "Excede may cause some transient swelling and edema around injection site."
e. "No cases of necrosis, abscess or drainage were reported in the clinical studies."

harm even when used as recommended and directed by Zoetis. (Am. Comp. ¶ 97). To the extent it is alleged Defendant expressly warranted that Excede was safe and effective, such conclusory allegations do not suffice. *In re Avandia Mktg. Sales Practices & Prod. Liab. Litig.*, 588 F.App'x 171, 177 (3d Cir. 2014). As to the allegations that studies were referenced in labeling, inserts and other materials, and that the drug may cause "side effects," there is no allegation that Zoetis would *not* cause other another side effect besides swelling. Furthermore, Plaintiffs have not alleged where and when these representations were made. Such conclusory and non-fact specific allegations as to the terms of an alleged express warranty do not state a claim.

Because Plaintiffs have not plausibly stated a claim for breach of express warranty, Count VII is dismissed.

2. Count VIII: Breach of Implied Warranty

At Count VIII, Plaintiffs assert a claim for breach of the implied warranty of merchantability. An implied warranty of merchantability arises whenever goods are sold by a person who is a merchant with respect to goods of that kind. *See* 13 Pa. Cons. Stat. § 2314. The essence of the warranty of merchantability is that the item sold is fit for the ordinary purposes for which such goods are used. *Wisniewski v. Great Atlantic and Pacific Tea Company*, 226 Pa.Super. 574, 323 A.2d 744, 746–747 (1974); 13 Pa. Cons. Stat. § 2314(b)(3). The Pennsylvania Supreme Court has indicated that, while implied warranty of merchantability claims are not identical to strict liability claims, they are "co-extensive." *Williams v. West Penn Power Co.*, 502 Pa. 557, 467 A.2d 811, 815 n.16 (1983). When applying Pennsylvania law, the Third Circuit has endorsed the general understanding that the elements of the two theories of liability are "essentially the same." *Gumbs v. Int'l Harvester, Inc.*, 718 F.2d 88, 94 (3d Cir. 1983) (citations omitted) (interpreting the identical provision of the Uniform Commercial Code);

see also Reese v. Ford Motor Co., 499 F. App'x 163, 166 (3d Cir. 2012) (citing *Gumbs* and reaching the same conclusion with respect to 13 Pa. Cons. Stat. § 2314).

In *Makripodis ex rel. Makripodis v. Merrell-Dow Pharms., Inc.*, 361 Pa.Super. 589, 523 A.2d 374, 594 (1987), the Pennsylvania Superior Court applied this principle in the prescription drug arena. The *Makripodis* court held that "the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for 'ordinary purposes,' " affirming the lower court's dismissal of the claim. *Id.* (relying on Comment k).

We find that, just as Plaintiffs' strict liability claims are barred as a matter of law, their "co-extensive" breach of implied warranty of merchantability claim is barred. *Crockett v. Luitpold Pharm., Inc.*, No. 19-275, 222020 WL 433367, at *5 (E.D. Pa. Jan. 28, 2020).

Count VIII will therefore be dismissed with prejudice.

D. Counts IX and X: Misrepresentations

1. Count IX: Fraudulent Misrepresentation/Concealment

Allegations of fraud trigger the heightened pleading requirement of Rule 9(b) of the Federal Rules of Civil Procedure. *In re Burlington Coat Factory Sec. Litig.*, 113 F.3d 1410, 1417 (3d Cir. 1997). Rule 9(b) provides, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). The purpose of Rule 9(b) is to "give defendants notice of the claims against them, provide[ ] an increased measure of protection for their reputations, and reduce[ ] the number of frivolous suits brought solely to extract settlements." *In re Supreme Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 270 (3d Cir. 2006).

A complaint alleging fraud "must state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the 'precise misconduct with which [it is] charged.'" *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (quoting *Lum v. Bank*

of Am., 361 F.3d 217, 223-24 (3d Cir. 2004)). Plaintiffs may meet this particularity requirement by supporting their allegations "with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Properties, Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002) (internal quotations omitted). Plaintiffs must "inject[ ] precision and some measure of substantiation into [the] allegations of fraud." *Lum*, 361 F.3d at 224.

Here, Plaintiffs allege that the drug was represented as being "safe and effective" and safe for the use of stabled horses. (Am. Compl. ¶¶ 111-113). Plaintiffs summarily allege Zoetis actively concealed known risks and dangers of the drug, and concealed other information from labels and written and promotional materials. There are no allegations as to the specific advertisement relied upon by an unspecified, prescribing physician. These allegations, as to fraudulent misrepresentation or fraudulent concealment, lack the necessary specificity to allege a claim sounding in fraud, and hence, Count IX will be dismissed.

2. Count X: Negligent Misrepresentation

Count X alleges negligent misrepresentation. Under Pennsylvania law, to prove negligent misrepresentation, a plaintiff must prove: "(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known of its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation." *Bortz v. Noon*, 556 Pa. 489, 729 A.2d 555, 561 (Pa.1999) (citing *Gibbs v. Ernst*, 538 Pa. 193, 647 A.2d 882, 890 (Pa.1994)).

Additionally, Rule 9(b) states, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The United States

Court of Appeals for the Third Circuit has noted that Rule 9(b) "requires plaintiffs to plead with particularity the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges*." Kester v. Zimmer Holdings, Inc*., Civ. No. 2:10–CV–00523, 2010 WL 2696467, *12 (W.D. Pa. June 16, 2010) (quoting *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984)). Although allegations of time, date or place satisfy the particularity requirements, a plaintiff can also satisfy the pleading requirements by pleading with a "degree of precision or some measure of substantiation into the fraud allegation." *Id.* (quoting *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007)).

In this case, we find that Plaintiffs have not met the pleading requirements under Rule 8, 9 or Rule 12. They allege broadly that they relied upon representations about the nature and quality of the product (Am. Compl. ¶ 127) and do not specify the specific advertisement that a prescribing physical may have viewed. The allegations contained in Count X and the preceding paragraphs of the Amended Complaint incorporated by reference, do place the Defendants on notice of the misconduct at issue. Therefore, we will dismiss Count X of Plaintiffs' Amended Complaint.

E. Leave to Amend

Leave to amend "should ... 'be freely given when justice so requires.'" *See Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc.*, 482 F.3d 247, 252 (3d Cir. 2007) (quoting Fed. R. Civ. P. 15(a)). The Third Circuit has held that "[d]ismissal without leave to amend is justified only on the grounds of bad faith, undue delay, prejudice, or futility." *Alston v. Parker*, 363 F.3d 229, 236 (3d Cir. 2004).

For the reasons stated herein, Plaintiffs' claims for strict liability and breach of implied warranty of merchantability are barred as a matter of law. As such, amendment of these claims would be futile. Plaintiff's claims premised on negligence, breach of express warranty, fraudulent misrepresentation, and negligent misrepresentation, however, suffer from mere pleading inadequacies. Therefore, Plaintiff is granted leave to amend these claims, provided there are facts to support the requisite amendments.

IV. Conclusion

For the reasons stated herein, the Motion to Dismiss will be granted. The claims alleged as to strict liability at Counts IV, V, and VI, as well as implied warranty of merchantability at Count VIII are precluded and dismissed with prejudice. Plaintiffs are granted leave to amend their claims based negligence (Counts I, II, III), breach of express warranty (Count VII), fraudulent misrepresentation (Count IX), and negligent misrepresentation (Count X).

An appropriate order will be entered.

BY THE COURT:

s/*Robert J. Colville*
Robert J. Colville
United States District Judge

DATED: September 30, 2021

cc/ecf: All counsel of record