IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

ASHLEY KNAPP,

Plaintiff,

v. **Civil Action No. 3:20cv191**

ZOETIS INC.,

Defendant.

MEMORANDUM OPINION

This matter comes before the Court on Defendant Zoetis Inc's ("Zoetis") Motion to Dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6)[1] ("Motion to Dismiss"), (ECF No. 27). Plaintiff Ashley Knapp responded in opposition to the Motion to Dismiss, (ECF No. 30), and Zoetis replied, (ECF No. 31).

The matter is ripe for disposition. The Court dispenses with oral argument because the materials before it adequately present the facts and legal contentions, and argument would not aid in the decisional process. The Court exercises jurisdiction pursuant to 28 U.S.C. §§ 1332(a) and (d).[2] For the reasons that follow, the Court will deny the Motion to Dismiss.

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[1] Rule 12(b)(6) allows dismissal for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6).

[2] Knapp, a citizen of Virginia, brings this class action against Zoetis, a citizen of Delaware and New Jersey. (ECF No. 24 ¶¶ 2, 3, ECF No. 24.) The Complaint seeks damages of $850,000.00. (ECF No. 24, at 14.) The Court exercises diversity jurisdiction over Knapp's individual claims arising under Virginia law. *See* 28 U.S.C. § 1332(a) ("The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between . . . citizens of different States.").

I. Factual and Procedural Background[3]

This four-count products liability action arises from a veterinarian's use of Excede, a Zoetis-developed equine antibiotic, on Knapp's horse Boomer. Knapp alleges that after the veterinarian administered Excede to Boomer, the horse developed serious medical complications leading to "persistent lameness" and permanent damage to the "musculature in his neck." (ECF No. 24 ¶ 24.) Knapp alleges that Zoetis had knowledge of similar negative reactions to Excede between 2012 and 2020, but "has not disclosed or adequately warned of Excede's danger to horses." (ECF No. 24 ¶¶ 22–23.)

This Court earlier entered a Memorandum Opinion and Order dismissing without prejudice several of Knapp's claims[4] and striking Knapp's class action claims.[5] (*See* ECF Nos. 20, 21.) Knapp filed her Amended Complaint, (ECF No. 24), and Zoetis moved to dismiss the Amended Complaint, (ECF No. 27).

A. Factual Background[6]

Zoetis, the world's largest "global animal health company," "manufactures and distributes an injectable, extended release antibiotic for equines with the brand name Excede."

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[3] For the purpose of the Rule 12(b)(6) Motion to Dismiss, "a court 'must accept as true all of the factual allegations contained in the complaint' and 'draw all reasonable inferences in favor of the plaintiff.'" *Kensington Volunteer Fire Dep't, Inc. v. Montgomery Cnty., Md.*, 684 F.3d 462, 467 (4th Cir. 2012) (quoting *E.I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d 435, 440 (4th Cir. 2011)).

[4] The Court held, however, that Knapp's Breach of Express Warranty claim survived Zoetis's original Motion to Dismiss. Accordingly, Zoetis does not presently move to dismiss Count III (Breach of Express Warranty) and has filed an answer to it.

[5] In her Amended Complaint, Knapp does not bring any class action claims.

[6] The Court recounts similar facts to those stated in its earlier Opinion granting in part and denying in part Zoetis's Motion to Dismiss Knapp's original Complaint. Where relevant, facts that Knapp added in her Amended Complaint are included.

(ECF No. 24 ¶¶ 3–4.) Zoetis markets Excede "as treating equine respiratory infections with a 'two dose, one solution' treatment." (ECF No. 24 ¶ 35.) Veterinarians also prescribe Excede "for off-label uses." (ECF No. 24 ¶ 36.)

1. Boomer Experiences an Adverse Reaction to Excede

Knapp owns Boomer, an eleven-year-old Hanoverian gelding horse, who "was at all relevant times stabled at a boarding facility known as Linmoorland Farm located in Gloucester, Virginia." (ECF No. 24 ¶ 8.) On August 13, 2016, Boomer began to suffer from leg swelling while at Linmoorland Farm. A veterinarian was immediately called "to examine, diagnose, and treat Boomer" and "[a]s a part of the treatment, the veterinarian administered an injection of Excede to Boomer." (ECF No. 24 ¶¶ 11–12.) Within an hour of treatment with Excede, "Boomer began to show signs of extreme pain, including abnormal vocalization (screaming whinny), abnormal sweating, spinning in his stall, striking out, buckling of the hind end and inability to walk normally, stretching and turning his neck repeatedly, and biting at the air with his teeth bared." (ECF No. 24 ¶ 13.) The veterinarian returned to the stable and observed that Boomer was becoming "increasingly lethargic and was unable to raise his head normally. . . . [His] gums had turned white, and a toxic line had appeared." (ECF No. 24 ¶ 15.) The veterinarian referred Boomer to Blue Ridge Equine, a nearby animal hospital, "for emergency treatment." (ECF No. 24 ¶ 16.) There, the treating veterinarian "diagnosed Boomer with a reaction to the Excede injection, and . . . ruled out colic as a source of Boomer's symptoms." (ECF No. 24 ¶ 17.) "Boomer was treated for his symptoms at Blue Ridge for two days, and during the course of that treatment, an ultrasound detected a pocket of fluid on the neck at the injection site." (ECF No. 24 ¶ 18.)

Boomer returned to Linmoorland Farm two days later, on August 15, 2016, and "was observed standing abnormally with his hind legs underneath him, which is an indication of pain and discomfort." (ECF No. 24 ¶ 19.) "Over the ensuing days, a large patch of swelling and leathery skin spread over most of the left side of Boomer's neck." (ECF No. 24 ¶ 19.)

Knapp states that prior to treatment with Excede "Boomer was a successful, young show hunter" but that he has since "experienced persistent lameness, and the musculature in his neck has been permanently damaged." (ECF No. 24 ¶¶ 24, 26.) "Consistent veterinary treatment . . . has been unable to return Boomer to soundness necessary for a performance horse." (ECF No. 24 ¶ 25.)

2. Excede Causes Similar Adverse Reactions in Other Horses

On August 18, 2016, five days after the first injection, Knapp "notified Zoetis of Boomer's severe reaction to the Excede injection." (ECF No. 24 ¶ 20.) In response, Dr. Maureen Dower of Zoetis informed Knapp "that a similar reaction had occurred on or about October 29, 2014 to a horse located in Vermont." (ECF No. 24 ¶ 21.) "[N]umerous other similar reactions, including ones with fatal outcomes, have occurred throughout the country and have been reported to Zoetis since at least 2012 and continued through 2020, including several recent severe or fatal reactions in the Charlottesville and Middleburg areas of Virginia and in Pennsylvania." (ECF No. 24 ¶ 22.) From 2010 through December 2018, "nearly 600 adverse reaction reports were made by Zoetis to the [Food and Drug Administration ("FDA")] for Excede reactions experienced by horses in the United States," and that "[u]pon information and belief, additional significant adverse reactions also occurred during 2019 and 2020." (ECF No. 24 ¶ 28.)

Knapp states that equine reactions to Excede "have included fatal reactions, internal hemorrhaging, anaphylaxis, other systemic-type reactions, and site reactions ranging from debilitating to minor with complications that have included, but are not limited to, swelling, muscle damage, pain, and scarring at the injection site." (ECF No. 24 ¶ 29.) "Boomer[] experienced both a severe anaphylactic response and a severe site reaction." (ECF No. 24 ¶ 29.) Knapp reports that, while the severity of the reaction and symptoms varied in each individual case, "[i]n many of these instances . . . the affected horses were provided with extensive and expensive veterinary care and the owners of the animals have had to absorb those costs as well as the diminished value associated with those horses." (ECF No. 24 ¶ 30.)

Excede uses an "extended release delivery system." (ECF No. 24 ¶ 41.) According to Zoetis's marketing, through this innovative system, "Excede [can do] in two doses what would otherwise take ten" doses of other medication. (ECF No. 24 ¶ 35.) The extended-delivery system "utilize[es] a caprylic acid and cottonseed oil based suspension." (ECF No. 24 ¶ 41.) According to Knapp, "[c]ottonseed oil is not used as a suspension in other regularly used, approved equine medications," and that "[c]ottonseed oil that is not refined or is improperly refined contains substances that are toxic to horses." (ECF No. 24 ¶ 42.) "Upon [Knapp's] information and belief, the use of Naxcel," another antibiotic produced by Zoetis that appears to treat the same symptoms but that does not employ an extended-release delivery system, "has not resulted in the type of severe reactions caused by Excede." (ECF No. 24 ¶ 40.)

3. Zoetis Becomes Aware of Excede's Harmful Effects

Knapp alleges that "Zoetis was made aware of these adverse reactions, and the resulting veterinary costs and diminished value of the afflicted horses." (ECF No. 24 ¶ 31.) Despite this knowledge, "Zoetis refused to revise Excede's warning label and prescribing information to

reflect the significant negative post-[FDA] approval experience." (ECF No. 24 ¶ 34.) As a result, "the majority of would-be consumers and prescribing veterinarians are left with no way of knowing of the considerable risk associated with the administration of Excede." (ECF No. 24 ¶ 34.)

Zoetis also made a number of affirmations about and descriptions of Excede, including that:

> 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.

Knapp states that Excede "did not conform to Zoetis'[s] express representations because an injection of Excede caused serious harm, stress, and permanent damage to Knapp's horse when used as recommended and directed." (ECF No. 24 ¶ 64.)

B. Procedural History

On March 31, 2021, the Court dismissed without prejudice all but one of the claims in Knapp's original Complaint (the count for Breach of Express Warranty) and struck Knapp's class action allegations. (ECF Nos. 20, 21.) On April 20, 2021, Knapp filed her Amended Complaint, bringing four counts against Zoetis under Virginia law:

Count I: **Negligent Failure to Warn.**

Count II: **Negligent Design and Manufacture.**

Count III: Breach of Express Warranty.

Count IV: Breach of Implied Warranty.

Knapp seeks $500,000 in compensatory damages and $350,000 in punitive damages. The matter is fully briefed. For the reasons articulated below, the Court will deny the Motion to Dismiss.

II. Standard of Review: Federal Rule of Civil Procedure 12(b)(6)

"A motion to dismiss under Rule 12(b)(6) tests the sufficiency of a complaint; importantly, it does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Republican Party of N.C. v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992) (citing 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1356 (1990)). To survive Rule 12(b)(6) scrutiny, a complaint must contain sufficient factual information to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also* Fed. R. Civ. P. 8(a)(2) ("A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief."). Mere labels and conclusions declaring that the plaintiff is entitled to relief are not enough. *Twombly*, 550 U.S. at 555. Thus, "naked assertions of wrongdoing necessitate some factual enhancement within the complaint to cross the line between possibility and plausibility of entitlement to relief." *Francis v. Giacomelli*, 588 F.3d 186, 193 (4th Cir. 2009) (citations omitted).

A complaint achieves facial plausibility when the facts contained therein support a reasonable inference that the defendant is liable for the misconduct alleged. *Twombly*, 550 U.S. at 556; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This analysis is context specific and requires "the reviewing court to draw on its judicial experience and common sense." *Francis*, 588 F.3d at 193. The Court must assume all well pleaded factual allegations to be true and

determine whether, viewed in the light most favorable to the plaintiff, they "plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 678–79; *see also Kensington*, 684 F.3d at 467 (finding that the court in deciding a Rule 12(b)(6) motion to dismiss "'must accept as true all of the factual allegations contained in the complaint' and 'draw all reasonable inferences in favor of the plaintiff'" (quoting *Kolon Indus., Inc.*, 637 F.3d at 440)). This principle applies only to factual allegations, however, and "a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Iqbal*, 556 U.S. at 679

III. Analysis

Zoetis moves to dismiss Count I (Failure to Warn), Count II (Negligent Design and Manufacture), and Count IV (Breach of Implied Warranty),[7] and moves to strike Knapp's request for punitive damages in the Amended Complaint.[8] Because Knapp sufficiently identifies a defect with Excede, and because the Amended Complaint otherwise satisfies the elements of negligence and breach of implied warranty under design defect, manufacturing defect, and failure to warn theories, the Court will deny Zoetis's Motion to Dismiss Counts I, II, and IV.

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[7] As United States District Judge Robert E. Payne of this Court recently observed, "[t]he basic analytical framework applicable to products liability claims in Virginia is the same whether a plaintiff is bringing a negligence or breach of implied warranty action." *Benedict*, 295 F. Supp. 3d at 637; *see also Holiday Motor Corp. v. Walters*, 790 S.E.2d 447, 455 (2016) ("the standard of safety of goods imposed on . . . the manufacturer of a product is essentially the same whether the theory of liability is labeled warranty or negligence. The product must be fit for the ordinary purposes for which it is to be used") (internal citation omitted). Because Knapp's claims for Negligence and Breach of Implied Warranty rise and fall together, the Court addresses them jointly.

[8] Although Zoetis moves to "dismiss" Knapp's request for punitive damages, such a motion is properly brought under a motion to strike pursuant to Federal Rule of Civil Procedure 12(f). *Nedrick v. Southside Regional Med. Ctr.*, No. 3:19cv202, 2020 WL 534052, at *3 (E.D. Va. Feb. 3, 2020). Thus, the Court will consider this portion of Zoetis's Motion to Dismiss as a Motion to Strike.

Moreover, Knapp properly alleges an entitlement to punitive damages under Counts I, II, III, and IV. As a result, as with Count III before, the Court will deny the Motion to Dismiss Counts I, II, or IV of Knapp's Amended Complaint and will not strike her request for punitive damages with respect to all four Counts.

A. Knapp States Claims Under Design Defect, Manufacturing Defect, and Failure to Warn Theories

1. Legal Standard: Negligence and Breach of Implied Warranty

"The basic analytical framework applicable to products liability claims in Virginia is the same whether a plaintiff is bringing a negligence or breach of implied warranty action." *Benedict*, 295 F. Supp. 3d at 637. To recover for negligence or breach of implied warranty, a plaintiff must show: "(1) that the goods were unreasonably dangerous either for the use to which they would ordinarily be put or for some other reasonably foreseeable purpose, and (2) that the unreasonably dangerous condition existed when the goods left the defendant's hands." *Porter v. DePuy Orthopaedics, Inc.*, No. 3:19cv7, 2019 WL 3979656, at *7 (E.D. Va. Aug. 6, 2019) (internal citations omitted); *see also Abbot by Abbot v. Am. Cynamamid Co.*, 844 F.2d 1108, 1114 (4th Cir. 1988); *Morgen Indus. v. Vaughan*, 471 S.E.2d 489, 492 (Va. 1996); *Ball v. Takeda Pharms. Am., Inc.*, 963 F. Supp. 2d 497, 504–05 (E.D. Va. 2013), *aff'd*, 587 F. App'x 78 (4th Cir. 2014). "A product is 'unreasonably dangerous'" if it is "[1] imprudently designed," "[2] defective . . . in assembly or manufacture," or, "[3] not accompanied by adequate warnings about its hazardous properties." *Abbot by Abbot*, 844 F.2d at 1114. That is, Virginia law recognizes three types of products liability actions: design defect, manufacturing defect, and failure to warn. *Powell v. Diehl Woodworking Machinery, Inc.*, 198 F. Supp. 3d 628, 633 (E.D. Va. 2016).

a. Design Defect

A plaintiff asserting a defective design claim must first "show that the manufacturer 'owes [and breached] a legally recognized duty to design' a product in a certain way to ensure that the product 'is reasonably safe for the purpose for which it is intended." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 280 (4th Cir. 2021) (quoting *Holiday Motor Corp. v. Walters*, 790 S.E.2d 447, 454–55 (2016)). "Whether such a duty exists is a question of law for the court, not the jury, . . . and is informed by three kinds of evidence: (1) governmental safety standards; (2) industry practices; and (3) reasonable consumer expectations." *Id.* (citing *Evans v. Nacco Materials Handling Grp., Inc.*, 810 S.E.2d 462, 472 (Va. 2018)). "[T]he manufacturer breaches [the duty to construct a product in a particular manner] if the product does not conform to that standard." *Id.* (citing *Holiday Motor*, 790 S.E.2d at 455 & n.14).

A plaintiff asserting defective design or manufacture must also "allege facts that would permit the Court to conclude that a . . . design defect existed." *Ball*, 963 F. Supp. 2d at 505. "A bare allegation of a 'defect' is no more than a legal conclusion." *Id.* (collecting cases). Therefore, even at the pleadings stage, a plaintiff must allege sufficient facts "indicating how a product may have been [designed] improperly." *Dodson v. C.R. Bard, Inc.*, No. 3:20cv596, 2020 WL 7647631, at *4 (E.D. Va. Dec. 23, 2020); *see also Porter,* 2019 WL 3979656, at *8 (plaintiff must "allege facts specifying a plausible defect in the implants' manufacture or design").

Finally, a plaintiff must state facts showing that "an alternative design is safer overall than the design used by the manufacturer." *Evans*, 810 S.E.2d at 471. However, "an alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product." *Torkie-Tork*, 739 F. Supp. 2d at 900. Whether a design would so fundamentally alter a product is 'typically a question of fact, not law." *Id.*

b. Manufacturing Defect

"A manufacturing defect exists when a product fails to conform to its intended design." *Dodson*, 2020 WL 7647631, at *4. "Thus, to succeed on a claim of negligent manufacture, the plaintiff must allege that the defendant did not make the product as intended." *Id.* Again, a plaintiff must also "allege facts that would permit the Court to conclude that a manufacturing . . . defect existed." *Ball*, 963 F. Supp. 2d at 505.

c. Failure to Warn

Under Virginia law, to state a claim for failure to warn, a plaintiff must allege sufficient facts to show that the defendant:

> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied[;] . . .
>
> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition[;] and[,]
>
> (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Funkhouser v. Ford Motor Co., 736 S.E.2d 309, 313 (Va. 2013) (en banc) (quoting *Featherall v. Firestone Tire & Rubber Co.*, 252 S.E.2d 358, 366 (Va. 1979)). The Virginia Supreme Court has expressly rejected a standard that would require a manufacturer to warn a plaintiff if the manufacturer *should have* known about a dangerous condition with its product. *Owens-Corning Fiberglas Corp. v. Watson*, 413 S.E.2d 630, 634–35 (Va. 1992). Instead, a plaintiff must demonstrate that the defendant *knew or had reason to know* of a dangerous condition. *Id.* at 635. As another court in this district has explained, "[t]he 'reason to know' standard requires that the defendant has knowledge of facts from which a reasonable person could infer the fact in question instead of merely having a duty to ascertain the existence of facts that would lead to that inference," which would be the case under a "*should have* known" standard. *Valley Proteins,*

Inc. v. Mid-South Boiler & Engineering Co., Inc., No. 2:17cv19, 2017 WL 11507175, at *3 (E.D. Va. May 12, 2017).

In Virginia, a plaintiff may show that the defendant knew or had reason to know of a defect by "present[ing] evidence of similar incidents, provided the prior incidents occurred 'under substantially the same circumstances, and had been caused by the same or similar defects and dangers as those in issue.'"[9] *Funkhouser*, 736 S.E.2d at 313–14 (quoting *Roll 'R' Way Rinks, Inc. v. Smith*, 237 S.E 2d 157, 160 (Va. 1977)).

As the Virginia Supreme Court clarified during post-trial review of a case, "two avenues . . . to establish substantial similarity in a failure to warn claim against a manufacturer" exist: (1) through identification of the accident's cause, which must be attributable to the manufacturer, or (2) through the elimination of other potential causes that are not attributable to the manufacturer." *Id.* at 315. As to the first option, the Virginia Supreme Court held that a plaintiff "must demonstrate that the [similar incidents] were caused by the same or similar defect." *Id.*

Finally, pursuant to the "learned intermediary doctrine, in a case involving prescription drugs, the manufacturer owes a duty only "to warn the physician who prescribes the drug." *Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 44 (Va. 1980); *see Higgins v. Forest Lab'ys*, 48 F. Supp. 3d 878, 886–87 (W.D. Va. 2014) (surveying cases). A plaintiff must also allege that adequate warnings would have altered the physician's decision to prescribe the drug. *Talley v. Danek Med., Inc.*, 179 F.3d 154, 163–64 (4th Cir. 1999).

[9] Although the *Funkhouser* court addressed the issue of failure to warn through the narrower issue of admissibility of certain testimony, as the *Funkhouser* partial concurrence and partial dissent correctly identifies, in so doing, the majority necessarily opined on the substance of proper elements under a failure to warn theory. *Funkhouser*, 736 S.E.2d at 285–86.

2. Knapp Adequately Alleges a Design Defect

The Amended Complaint sufficiently states negligence and breach of implied warranty claims under a design defect theory. First—as is relevant to *all* of Knapp's product's liability claims—Knapp adequately pleads that Zoetis could reasonably foresee that veterinarians would treat horses with Excede off-label for the type of symptoms Boomer experienced. Second, Knapp plausibly alleges a design defect theory in particular: she states—at least at this early stage—that Zoetis owed and breached a duty to consumers to design safe products, Excede likely suffered from a defect in its cottonseed oil-based suspension system, and Naxcel is a safe, alternative design.

a. Boomer's Off-Label Use Was a Reasonably Foreseeable Application of Excede

As an initial matter, Knapp adequately states that Boomer's off-label use of Excede was a "reasonably foreseeable purpose," a predicate element to each of Knapp's products liability claims. *Porter*, 2019 WL 3979656, at *7. Knapp notes that "Excede is also prescribed by veterinarians for off-label uses . . . , a fact known by Zoetis." (ECF No. 24 ¶ 36.) Indeed, Knapp alleges that "Zoetis was aware that equine veterinarians used Excede off-label for treating conditions including the type of condition Boomer had on" the day of the incident. (ECF No. 24 ¶ 36.) In support, she avers that "[m]ost antibiotics prescribed by equine veterinarians are for off-label or extra-label use . . ." (ECF No. 24 ¶ 36.) These statements, alongside Knapp's allegation that "nearly 600 adverse reaction reports were made by Zoetis to the FDA for Excede reactions" from 2010 to 2018, when read favorably and viewed as true, plausibly create a reasonable inference that Zoetis could reasonably foresee that a veterinarian would treat Boomer with Excede for the maladies from which he suffered in 2016.

b. Knapp Plausibly Alleges That Zoetis Was Unreasonably Dangerous Pursuant to a Design Defect Theory

Reading her allegations favorably, the Court finds that Knapp adequately alleges that (1) Zoetis owed—and breached—a duty to consumers to design a reasonably safe product; (2) Excede suffered from a design defect; and, (3) a safe, alternative design to Excede exists. In other words, Knapp states a claim under a design defect theory.

First, there can be no question that reasonable consumer expectations impose upon Zoetis a duty to manufacture Excede in such a way that does not cause severe and debilitating allergic reactions such as that purportedly suffered by Boomer.[10] And Zoetis plainly breached that duty by manufacturing and distributing a dose of Excede that caused such reactions.

Second, using only reasonable inferences from the facts alleged, the Court concludes that Knapp sufficiently alleges facts showing "that a . . . design defect existed." *Ball*, 963 F. Supp. 2d at 505. To be sure, Knapp does not—and, quite frankly, cannot at this stage[11]—state a defect in the medication with granular specificity. Nevertheless, she states sufficient facts to *plausibly* show that unrefined or improperly refined cottonseed oil caused Boomer's adverse reaction. Specifically, she alleges that (1) from 2010 to 2018, Zoetis reported nearly 600 cases of adverse reactions to Excede, some of which included similar symptoms to Boomer's; (2) Excede employs an "extended release" delivery system that sets it apart from other medication that

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[10] Although Zoetis points out that Knapp does not allege "violations of industry standards or FDA regulations," (ECF No. 28, at 11), such allegations are merely two of the three options available to show unreasonably dangerous design, *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 899–900 (E.D. Va. 2010) ("FDA approval of a drug does not preempt an action for defective design.").

[11] As Knapp identifies, "[t]he formulation, design, method of manufacture, and sources of the ingredients contained in Excede are proprietary and known only to Zoetis." (ECF No. 24 ¶ 38.)

utilizes "cottonseed oil based suspension"; (3) "[c]ottonseed oil that is not refined or is improperly refined contains substances that are toxic to horses;" and, (4) "[u]pon information and belief, the use of [non-extended release medication manufactured by Zoetis] Naxcel has not resulted in the type of severe reactions caused by Excede," (ECF No. 24 ¶¶ 28–29, 40–42.) Such facts plausibly allege that defective cottonseed oil caused Boomer's adverse reaction.

Clearly, it is not insignificant that the *600* adverse reaction reports from 2010 to 2018 went to a government agency, the *FDA*. *Sardis*, 10 F.4th, at 280 (including government safety standards when assessing a legally recognized duty to design).

The Court now finds the case at bar distinguishable from *Ball*. There, the plaintiff brought (among other things) a defective design claim against the manufacturer and distributer of a drug called Dexilant. *Ball*, 963 F. Supp. 2d at 500. Ball alleged that after her doctor prescribed Dexilant to treat her gastric problems, the drug "caused her fallopian tubes to close, as well as the development of a condition known as 'Stevens-Johnson Syndrome.'"[12] *Id.* Ball alleged that "medical studies and scientific research ha[d] shown impaired fertility (including damage to the fallopian tubes) following the use of ingredients found in Dexilant. *Id.* Nevertheless, the Court found that Ball had failed to allege "any facts that would permit the Court to conclude that a manufacturing or design defect existed, or that such a defect was the proximate cause of plaintiff's alleged injuries." *Id.* at 505.[13]

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[12] At the time of Ball's adverse reaction, Dexilant's label specifically "identifie[d] Stevens-Johnson syndrome as a potential 'adverse reaction' that could result from use of the prescription drug." *Ball*, 963 F. Supp. 2d at 504.

[13] Moreover, it is likely the *Fields* court faced more generalized factual assertions as to the alleged defect than are alleged here. 2014 WL 1513289. The specific factual allegations in *Fields* are not evident in the Opinion.

Crucially, however, the *Ball* plaintiff did not tangibly identify the likely defect by contrasting Dexilant with other medications. Instead, she merely stated that certain ingredients that had been linked to closed fallopian tubes were also present in Dexilant. The *Ball* court was left to guess, then, whether such stray ingredients were indeed the cause of her conditions. Here however, Knapp highlights one distinct aspect of Excede's design: it adopts a delivery system—not used "in other regularly used, approved equine medications"—that employs cottonseed oil. (ECF No. 24 ¶¶ 41, 42.) Knapp contrasts Excede with Naxcel, which does not employ cottonseed oil, and which "has not resulted in the type of severe reactions caused by Excede." (ECF No. 24 ¶¶ 40, 41.) Thus, in alleging that Excede employs a wholly *unique* ingredient, and that Excede appears *uniquely* likely to cause adverse reactions (triggering almost 600 reports between 2010 and 2018), Knapp plausibly states that Excede has been defectively designed. *Cf. Dodson*, 2020 WL 7647631, at *4 (finding manufacturing defect claim "merely conceivable as opposed to plausible" when, "from the facts pled, *it appear[ed] just as likely that another explanation, including conditions of the human body or external forces, caused the fracturing.*" (emphasis added))

Finally, Knapp alleges facts to raise a reasonable inference that a safe, alternative design to Excede exists. Again, she identifies Naxcel, "a non-extended release injectable ceftiofur antibiotic for equines." (ECF No. 24 ¶ 40.) According to Knapp, Naxcel "has been safely used in horses for decades," and, "[u]pon information and belief, the use of Naxcel has not resulted in the type of severe reactions caused by Excede." (ECF No. 24 ¶ 40.) Moreover, "[t]he only significant difference between Naxcel and Excede is the extended release delivery system." (ECF No. 24 ¶ 41.) Such allegations suffice to state a claim, at this early stage, that Naxcel is a safe and alternative design.

Although Zoetis argues that "Naxcel cannot stand as a feasible alternative design," and that it is a "completely different . . . antibiotic" because it lacks the Excede's defining "slow-release suspension," this contention fails to persuade the Court. (ECF No. 28, at 13.) In making such an argument, Zoetis attempts to insert a fact not included in the Amended Complaint: that a lack of slow release suspension would fundamentally alter Excede. Such questions are typically left to the jury, as they are inherently fact-bound. *Torkie-Tork*, 739 F. Supp. 2d at 900. At the very least, such an argument would require looking outside the Amended Complaint to new facts, which the Court cannot do at the 12(b)(6) stage.

Torkie-Tork is instructive. There, the plaintiff took a medication called Prempro to reduce "severe menopausal symptoms." 739 F. Supp. 2d at 897. She was later diagnosed with breast cancer "of a type that was caused by hormones such as those contained in Prempro." *Id.* at 898. The plaintiff argued, among other things, that a "change in the dosage of the drug itself" was a safe, alternative design. *Id.* at 900. After discovery at the Summary Judgment stage, the Court agreed, opining that "it may well be that the dosage of a drug is a fundamental characteristic of the drug, since a lower dosage may well alter or affect the positive impact the drug is designed to have on the human body." *Id.* "Nevertheless," the Court concluded, "the decision properly rests with a jury to determine whether an alternative dosage of Prempro would so fundamentally alter the drug as to render it an entirely different product." *Id.*

So too here. Certainly, removing the suspended release system *could* transform Excede into a fundamentally different product. But, reading the Amended Complaint favorably at this procedural juncture, the Court concludes that Knapp sufficiently alleges that Naxcel is a reasonable, alternative design. Accordingly, Knapp plausibly states a claim that Excede was unreasonably dangerous under a design defect theory.

3. Knapp Adequately Alleges a Manufacturing Defect

For similar reasons as the Court articulated *supra*, Knapp sufficiently states a claim that Excede was negligently manufactured. To state a manufacturing defect claim, "the plaintiff must allege that the defendant did not make the product as intended," and must set forth "facts that would permit the Court to conclude that a manufacturing . . . defect existed." *Ball*, 963 F. Supp. 2d at 505. In addition to stating a claim, at this procedural juncture, that a design defect may have caused Boomer's reaction, Knapp also sets forth adequate facts to show that a defect in Excede's *manufacturing* process may have been the root cause of Boomer's harm. She identifies that (1) Excede utilizes a cottonseed oil based suspension, (2) unrefined or improper refined cottonseed oil "contains substances that are toxic to horses," and (3) Naxcel—which does not employ cottonseed oil—has not caused such reactions. Drawing reasonable inferences from Knapp's favorably read factual allegations, the Court concludes that Knapp alleges a claim that Excede was negligently manufactured.

4. Knapp Adequately Alleges Negligence Under a Failure to Warn Theory

Finally, Knapp plausibly pleads that Zoetis owed and breached a duty to warn her veterinarian. As an initial matter, assuming that the learned intermediary doctrine applies to veterinary medication, Knapp clearly states that Zoetis failed to warn her veterinarian of Excede's purported dangers. She avers that "[a]t all times relevant, Plaintiff and her veterinarians were not aware of the dangers and risks associated with the administration of Excede to stabled horses." (ECF No. 24 ¶ 50.) And, despite Zoetis's contention that Knapp "does not plead that the alleged inadequate warning affected the veterinarian's decision to treat Boomer with Excede for an off-label purpose," (ECF No. 28, at 7), the Amended Complaint belies this argument. Knapp states that she "and/or her veterinarian chose the Excede antibiotic

based upon Zoetis's express warranties and representations" that Excede was "safe and effective in horses." (ECF No. 24 ¶¶ 62(a), 64 (emphasis added).) It is abundantly reasonable to infer from these facts that the veterinarian would *not* have prescribed Excede if she felt it was unsafe. Thus, Zoetis's attempt to sever liability through the learned intermediary doctrine fails.

For similar reasons as articulated above, Knapp also sufficiently pleads that Zoetis knew or had reason to know that Excede caused dangerous adverse reactions. Knapp alleges that at least a significant number of the 600 adverse reaction reports occurred under substantially the same circumstances and were caused by the same or similar defects. She avers that the other incidents "included fatalities, internal hemorrhaging, anaphylaxis, other systemic-type reactions, and site reactions ranging from debilitating to minor." (ECF No. 24 ¶ 29.) And she states that "Boomer[] experienced both a severe anaphylactic response and a severe site reaction." (ECF No. 24 ¶ 29.) Indeed, "*Dr. Maureen Dower of Zoetis disclosed [to Knapp] that a similar reaction [to Boomer's] had occurred on or about October 29, 2014 to a horse located in Vermont.*" (ECF No. 24 ¶ 21 (emphasis added).) Finally, Knapp notes that Naxcel, which does not include the purportedly defective cottonseed oil, "has not resulted in the type of severe reactions caused by Excede." (ECF No. 24 ¶ 40.) This Court can thus reasonably infer at this early stage that—at the very least—a sufficient number of the adverse reactions arose under the same circumstances and involved similar defects such that Zoetis at least had reason to know that Excede was dangerous.

Although the Virginia Supreme Court in *Funkhouser* faulted the plaintiff for not granularly identifying the defect in the product, the procedural posture here differs from that in *Funkhouser*. There, the question before the court was whether "proffered evidence of fires in seven other Windstar vans was inadmissible to establish that Ford had notice and actual

knowledge of a defective condition." *Funkhouser*, 736 S.E.3d at 280. The parties had already engaged in extensive discovery and had an opportunity to investigate the precise cause of the fires, as *Funkhouser* reviewed the case post-trial. Here, on the other hand, Knapp need only allege facts to *plausibly* show that Zoetis knew or had reason to know of a dangerous condition—which she has done.

The Amended Complaint also plainly satisfies the final two elements of a failure to warn theory. Knapp alleges that Zoetis had no reason to believe that Knapp or her veterinarians would realize Excede's danger (and Zoetis does not argue otherwise). Knapp clearly states that "at the time[] Boomer was given Excede, the product carried no warnings" concerning "possible reactions" or "hazardous properties." (ECF No. 24 ¶ 29.) Therefore, Knapp sufficiently states that Excede was unreasonably dangerous under a failure to warn theory.

5. Knapp Adequately Alleges that Excede's Dangerous Conditions Existed When It Left Zoetis's Control

Having stated a claim that Excede was unreasonably dangerous (under all three possible theories of liability), Knapp need only further allege that the dangerous condition existed when it left Zoetis's hands. As articulated above, she makes such a showing. Knapp states that Zoetis manufactured Excede using a unique cottonseed oil-based suspension system and suggests that this cottonseed oil likely caused Boomer's adverse reaction. From such statements, the Court can reasonably infer that the purported defect in the cottonseed oil existed at the time the drug left Zoetis's control. Accordingly, because Knapp plausibly proffers that (1) Excede was unreasonably dangerous, and (2) its dangerous condition existed when it left Zoetis's hands, Knapp sufficiently alleges products liability through negligence and breach of implied warranty. The Court therefore denies the Motion to Dismiss Counts I, II, and IV.

C. The Court Will Not Strike Knapp's Request for Punitive Damages Under Counts I, II, III, and IV

At this early stage in the case, Knapp sufficiently alleges entitlement to punitive damages under all four of her Counts. As a threshold matter, the Court concludes that Knapp's Breach of Express and Implied Warranty claims sound in tort, not contract. Moreover, Knapp alleges facts, read favorably and presumed true, to plausibly show that Zoetis acted willfully or wantonly in negligently designing, manufacturing, and warning about Excede, and in breaching its warranties.

1. Knapp's Breach of Express and Implied Warranty Claims Sound in Tort

As a preliminary matter, this Court must determine whether Knapp's claims for Breach of Express and Implied Warranty sound in tort law.[14] The Court concludes that they do.

a. Legal Standard: Distinguishing Between Causes of Action for Tort and Contract

A plaintiff cannot collect punitive damages under a breach of contract claim. *Kamlar Corp. v. Haley*, 299 S.E.2d 514, 518 (Va. 1983). However, in Virginia, "a single act or occurrence can . . . support causes of action both for breach of contract and for breach of a duty arising in tort, thus permitting a plaintiff to recover both for the loss suffered as a result of the breach and traditional tort damages, including, where appropriate, punitive damages. *Dunn Const. Co. v. Cloney*, 682 S.E.2d 943, 946 (Va. 2009). Yet, "[t]o avoid turning every breach of contract into a tort, . . . [the Virginia Supreme Court] adhere[s] to the rule that, in order to recover in tort, 'the duty tortiously or negligently breached must be a common law duty, not one

[14] Count I (failure to warn) and Count II (negligent design and manufacture) indisputably sound in tort law.

existing between the parties solely by virtue of the contract.'" *Id.* (quoting *Foreign Mission Bd. v. Wade*, 409 S.E.2d 144, 148 (1991). In other words, "the determination of whether a cause of action sounds in contract or tort depends on the source of the duty violated.[15] *Id.* at 946.

The Virginia Supreme Court has established a test to determine whether an action properly sounds in contract or in tort:

> If the cause of complaint be for an act of omission or non-feasance which, without proof of a contract to do what was left undone, would not give rise to any cause of action (because no duty apart from contract to do what is complained of exists) then the action is founded upon contract, and not upon tort. If, on the other hand, the relation of the plaintiff and the defendants be such that a duty arises from that relationship, irrespective of the contract, to take due care, and the defendants are negligent, then the action is one of tort.

Richmond Metro. Auth. v. McDevitt St. Bovis, Inc., 507 S.E.2d 344, 347 (Va. 1998) (quoting *Oleyar v. Kerr, Trustee*, 225 S.E.2d 398, 399–400 (Va. 1976). In other words, Virginia law draws a line between nonfeasance under a contract on one hand, and misfeasance or malfeasance on the other. *Tingler v. Graystone Homes, Inc.*, 834 S.E.2d 244, 256 (Va. 2019). Tort liability arises under misfeasance and malfeasance, but only contract liability arises under nonfeasance. *Id.* In general, "courts have adhered to the line thus drawn." *Id.* (quotation marks and citation omitted).

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[15] Further, "[t]he law of torts provides redress only for the violation of certain common law and statutory duties involving the safety of persons and property, which are imposed to protect the broad interests of society." *Kaltman v. All Am. Pest Control, Inc.*, 706 S.E.2d 864, 870 (Va. 2011) (citation omitted). On the other hand, "[l]osses suffered as a result of the breach of a duty assumed only by agreement, rather than a duty imposed by law, remain the province of the law of contracts." *Id.* (citation omitted).

b. Knapp's Breach of Express and Implied Warranty Claims Involve Affirmative Acts and Breaches of Duties Not Connected to Any Contract

As a preliminary matter, the Amended Complaint does not refer to any independent contract between Knapp (or her veterinarian) and Zoetis. But even presuming Knapp's Implied and Express Warranty claims imply a contractual obligation, those claims sound in tort.

Kaltman v. All Am. Pest Control, Inc. illustrates the line the Virginia Supreme Court has drawn. There, a homeowner contracted with a pesticide contractor "to apply chemicals to control . . . pests" in the home. 706 S.E.2d 864, 867 (Va. 2011). However, instead of using chemicals permitted for use in residential buildings, the contractor applied "concentrations of . . . a toxic ingredient . . . not licensed for residential use." *Id.* at 866–67. The Virginia Supreme Court held that such actions permitted recovery under tort law because by erroneously applying toxic chemicals, the contractor "breached common law and statutory duties independent of the company's contractual duty to control pests." *Id.* at 870. As the court explained in a subsequent case, "the gist of [*Kaltman*] was clear: it was the contractor's affirmative act of using a dangerous pesticide, not the failure to use a safe pesticide, that mattered." *Tingler*, 834 S.E.2d at 257.

Here, Knapp alleges such affirmative acts that give rise to tort liability.[16] With respect to her Implied Warranty claim, she states that Zoetis "defective[ly] . . . manufacture[d]" Excede, "imprudently designed" it, and failed to provide "adequate warnings concerning its hazardous properties." (ECF No. 24 ¶ 68.) And with respect to her Express Warranty claim, Zoetis

[16] The Court need not decide whether she alleges *mis*feasance or *mal*feasance, as both provide for tort liability. Both misfeasance and malfeasance require an affirmative act, which Knapp alleges here.

represented that Excede was, among other things, "safe and effective in horses," and that Excede "did not conform to Zoetis's express representations" because it "caused serious harm, stress, and permanent damage to Knapp's horse." (ECF No. 24 ¶¶ 62(a), 64.) Knapp does not allege that Zoetis wholly failed to perform any duties owed to her under any specific contract through which she might have obtained the drug. Instead, she avers that Zoetis affirmatively performed in such a way that injured her horse. Even presuming the Express and Implied Warranty claims might somehow imply a contractual obligation, this "affirmative act" is precisely one that sets misfeasance and malfeasance apart from nonfeasance, and that provides grounds for tort liability. *Tingler*, 834 S.E.2d at 257.

Moreover, in providing an allegedly unsafe medication, Zoetis breached duties wholly independent from any specific contract between Knapp (or her veterinarian) and Zoetis. The common law imposes a duty on Zoetis to manufacture and distribute products that are reasonably safe for their intended or otherwise reasonably foreseeable use. *Abbot by Abbot*, 844 F.2d, at 1114. Further, Virginia law does not require that a plaintiff asserting a breach of warranty claim show privity of contract. Instead, as relevant here, the defendant's duty to provide its products in accordance with its express warranties runs to anyone "whom [the defendant] might reasonably have expected to use, consume, or be affected by the goods." Va. Stat. § 8.2-318; (*see* ECF No. 20, at 27 (concluding that Knapp need not allege privity of contract to state a Breach of Express Warranty claim).) Thus, the Amended Complaint states that Zoetis "breached [its] common law and statutory duties" to provide supply reasonably safe products and comply with its express

warranties. *Kaltman*, 706 S.E.2d at 870. Knapp's Breach of Express and Implied Warranty claims accordingly sound in tort.[17]

2. Knapp States Entitlement to Punitive Damages

With that threshold question addressed, the Court now turns to the more substantive issue before it: whether Knapp's allegations as to Zoetis's conduct suffice to state an entitlement to punitive damages. The Court answers in the affirmative.

a. Legal Standard: Punitive Damages

In Virginia, "[n]egligence which is so willful or wanton as to evince a conscious disregard of the rights of others, as well as malicious conduct, will support an award of punitive damages." *Owens-Corning*, 413 S.E.2d at 640 (quoting *Booth v. Robertson*, 374 S.E.2d 1, 3 (1988)). "Willful and wanton negligence is defined as 'acting consciously in disregard of another person's rights or acting with reckless indifference to the consequences, with the defendant aware, from his knowledge of existing circumstances and conditions, that his conduct probably would cause injury to another." *Id.* (quoting *Griffin v. Shively*, 315 S.E2d 210, 213 (Va. 1984)). Generally, Virginia courts do not "favor[]" the "imposition of punitive damages."

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[17] This Court acknowledges that the Fourth Circuit has concluded that "[o]nly if the breach [of contract] establishes the elements of 'an independent, willful tort,' may it support an award for punitive damages." *A & E Supply Co., Inc. v. Nationwide Mut. Fire Ins. Co.*, 798 F.2d 669, 672 (4th Cir. 1986); *accord Kamlar Corp. v. Haley*, 299 S.E.2d 514, 518 (Va. 1983). For the purposes of that inquiry, "an 'independent tort' is one that is factually bound to the contractual breach but whose legal elements are distinct from it." *Id.*

However, these cases dealt with claims that first clearly and unambiguously sounded in contract. The court then determined whether, *in addition* to that claim that was clearly rooted in contract law, the plaintiff had stated another independent tort. *See, e.g., A & E Supply Co.*, 798 F.2d at 672. Here, on the other hand, this Court addresses the predicate question of whether these claims primarily sound in contract or tort in the first place. Knapp does not allege a separate, independent tort from her breach of contract claim. Instead, this Court concludes that her Breach of Express and Implied Warranty claims *themselves* sound in tort law.

Id. at 639. Indeed, such damages "should be awarded only in cases of the most egregious conduct." *Id.* (quoting *Philip Morris Inc. v. Emerson*, 368 S.E.2d 268, 283 (Va. 1988)).

b. Knapp Alleges Facts Sufficient to Support a Reasonable Inference That Zoetis Acted Willfully or Wantonly

Although Knapp's averments as to Zoetis's willful or wanton conduct are relatively sparse, they still suffice, at this stage, to allow the issue of punitive damages to go forward.

The Virginia Supreme Court has suggested that it requires some level of intentionality or failure to take *any* preventative measures to impose punitive damages on a defendant. For instance, in *Philip Morris, Inc. v. Emerson*, the Virginia Supreme Court considered a case involving the negligent disposal of the highly toxic gas pentaborane. 368 S.E.2d 268, 271. Texaco, Inc. conducted experiments with the gas. *Id.* at 271. Eventually, Texaco disposed of its pentaborane by placing it in pressurized cylinders and burying those cylinders (alongside others containing different gases) in a pit—a highly dangerous practice. *Id.* at 272, 283. Texaco apparently marked the pits with pipes and to have noted their location on a map. *Id.* at 283. The company then sold this facility to Philip Morris, Inc. "but failed to disclose . . . that it had buried chemicals in a number of pits on the property." *Id.* at 272. After Philip Morris discovered the cylinders and contacted Texaco, Texaco "gave Philip Morris the minimal information it found, but [otherwise] refused to assist further." *Id.*

Philip Morris then contacted several firms about disposing the cylinders. Ultimately, it chose A-Line Industries, co-owned by James Kachur. *Id.* at 273–74. During disposal—which a Philip Morris employee generally oversaw—Kachur and another associate opened one of the cylinders, which happened to contain pentaborane, without masks or gloves. *Id.* Kachur then "drained a small amount of clear liquid [from the cylinder] into an open beaker." *Id.* He, his

associate, and rescue personnel were exposed to the gas. *Id.* Kachur died from exposure, and others became ill. *Id.*

The *Emerson* court first concluded as a matter of law that Texaco did not act with sufficient willfulness or wantonness to warrant punitive damages. It reasoned that "Texaco's burial of the cylinders in pits, marking the pits with pipes[,] and noting their location on a map indicated that some attention, even though insufficient to constitute reasonable care, was being given to the danger." *Id.* at 284. Moreover, "[t]he fact that [Texaco] later supplied additional information concerning the chemicals [was] evidence of Texaco's concern for the safety of others." *Id.* Likewise, the court found that "Philip Morris's efforts to neutralize the contents of the cylinders, although negligent as a matter of law, showed some concern for the safety of others," and that a supervisor's "presence during most of the [disposal] work gave evidence of a degree of care taken by Philip Morris." *Id.* at 284. The *Emerson* court thus concluded that, "as a matter of law, . . . the evidence fail[ed] to prove that [Texaco and Philip Morris's] acts and omissions constitute[d] willful and wanton negligence." *Id.*

On the other hand, the court concluded that a jury *could* find that Kachur had acted with willful or wanton negligence. The court pointed out that Kachur "drained an unknown chemical from a pressurized chamber into an open beaker and carried the beaker into [the laboratory's] office." *Id.* Kachur "knew he was hired to dispose of dangerous chemicals. In fact, he knew that at least two of the cylinders contained pentaborane, and he should have treated all the remaining unmarked cylinders as though they contained equally dangerous chemicals." *Id.* Additionally, "Kachur knew that oxygen masks were essential for protection, yet he exposed himself [and others] to a chemical which was emitting an odor and obviously reacting in some

fashion with the outside air." *Id.* Thus, the court found that "there was sufficient evidence of Kachur's wanton negligence to support the jury's award of punitive damages." *Id.*

Although Knapp's averments are far less detailed than the facts established in *Emerson*,[18] she still sufficiently alleges, viewing the Amended Complaint favorably and presuming its proffered facts true at this procedural juncture, that Zoetis knew about the danger Excede posed to horses and nevertheless continued to (1) manufacture and distribute Excede without warning labels, and (2) expressly advertise Excede as "safe" without warnings of adverse reactions. First, she avers that Zoetis reported to the FDA (and therefore knew about) nearly 600 adverse reactions by horses to Excede from 2010 to 2018. Second, she contends that Zoetis made specific affirmations about Excede, including that it had "been demonstrated to be safe and effective in horses."[19] (ECF No. 24 ¶ 62(a).) Finally, she claims that "[d]espite knowledge of the numerous adverse reactions suffered by horses who were administered Excede," Zoetis continued to manufacture and distribute Excede and "refused to revise Excede's warning label and prescribing information to reflect the significant negative post-approval experience." (ECF No. 24 ¶ 34.) The Amended Complaint therefore states a claim that survives a Motion to Strike that Zoetis acted willfully or wantonly with respect to all four Counts in the Amended Complaint.

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[18] Indeed, this is necessarily so, as *Emerson* involved evidence adduced at trial. Here, on the other hand, the Court merely has before it a Motion to Dismiss an Amended Complaint. Discovery has not commenced here. Knapp need only allege sufficient facts to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. 570.

[19] Knapp also claims that she "and/or her veterinarian chose the Excede antibiotic based upon Zoetis's express warranties and representations regarding the safety and fitness of Excede." (ECF No. 24 ¶ 63.)

IV. Conclusion

For the foregoing reasons, the Court will deny Zoetis's Motion to Dismiss Knapp's Amended Complaint, including Zoetis's included Motion to Strike Punitive Damages. (ECF No. 27.)

An appropriate Order shall issue.

Date: 3-31-2022
Richmond, Virginia

/s/
M. Hannah Lauck
United States District Judge