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

ASHLEY KNAPP,	)	
	)	
PLAINTIFF,	)	
v.	)	**Case No.: 3:20-cv-00191**
	)	
ZOETIS INC,	)	
	)	
DEFENDANT.	)	
	)	

FIRST AMENDED COMPLAINT

COMES NOW, Plaintiff Ashley Knapp (herein "Knapp" or "Plaintiff") and makes the following allegations against Defendant Zoetis Inc. (herein "Zoetis"):

INTRODUCTION AND PARTIES

1. Knapp brings this lawsuit seeking recovery against Zoetis relating to its equine medical product Excede, for failure to warn, defective design and/or manufacture, breach of express warranty, breach of implied warranty.

2. Knapp is a citizen and resident of the City of Richmond in the Commonwealth of Virginia.

3. Zoetis is the largest global animal health company. It is incorporated in the State of Delaware and its principal place of business and global headquarters located at 10 Sylvan Way in Parsippany, New Jersey. Zoetis is authorized to transact business in the Commonwealth of Virginia pursuant to a certificate of authority issued by the Virginia State Corporation Commission. Zoetis, with Virginia corporate ID F194381, maintains a registered agent in Glen Allen, Virginia, regularly transacts business in the Commonwealth of Virginia, and has subjected itself to the jurisdiction of Virginia courts. On information

and belief, Zoetis is additionally authorized to, and does, operate throughout the United States.

4. Zoetis manufactures and distributes an injectable, extended release antibiotic for equines with the brand name Excede.

5. Plaintiff is an owner of a horse in the United States who suffered a life-threatening reaction to Excede within the last ten (10) years.

JURISDICTION AND VENUE

6. Jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332(a) because there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000, exclusive of interest and costs.

7. Venue is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Plaintiff's claim occurred in this District. Plaintiff resides in this District and, as shown above and below, Zoetis transacts business in this District and her horse was administered Excede within this District.

FACTUAL ALLEGATIONS

8. Knapp owns a now eleven-year old Hanoverian gelding horse known as "Boom Balou" (herein "Boomer"). Boomer was at all relevant times stabled at a boarding facility known as Linmoorland Farm located in Gloucester, Virginia.

9. On or about the morning of August 13, 2016, Boomer was brought into the barn by the stable staff at Linmorland after overnight turnout.

10. The staff noticed that all four of Boomer's legs were swollen; however, no cuts, abrasions, or scratches were noticed. Boomer was eating, drinking, defecating, and urinating normally.

11. An equine veterinarian was called immediately to examine, diagnose, and treat Boomer. It was determined that Boomer's swollen legs were likely the result of an infection or some other malady typically treatable through the use of antibiotics.

12. As a part of the treatment, the veterinarian administered an injection of Excede to Boomer.

13. Within an hour, 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.

14. The veterinarian was called back to the barn immediately.

15. When she returned, Boomer was becoming increasingly lethargic and was unable to raise his head normally. The veterinarian observed that Boomer's gums had turned white, and a toxic line had appeared. She also observed that no gut sounds were present and that his respiratory rate had increased.

16. The veterinarian referred Boomer to Blue Ridge Equine in Charlottesville, Virginia for emergency treatment, and he was shipped immediately to Blue Ridge.

17. The treating veterinarian at Blue Ridge diagnosed Boomer with a reaction to the Excede injection, and he ruled out colic as a source of Boomer's symptoms.

18. 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.

19. After being shipped home on August 15, 2016, Boomer was observed standing abnormally with his hind legs underneath him, which is an indication of pain and

discomfort. Boomer also exhibited signs of neck soreness. Over the ensuing days, a large of patch of swelling and leathery skin spread over most of the left side of Boomer's neck. The swelling began to harden, and firm lumps were felt under the skin.

20. On August 18, 2016, Ms. Knapp notified Zoetis of Boomer's severe reaction to the Excede injection.

21. Dr. Maureen Dower of Zoetis disclosed that a similar reaction had occurred on or about October 29, 2014 to a horse located in Vermont.

22. In addition, numerous other similar reactions, including ones with fatal outcomes, have occurred throughout the country and have been reported to Zoetis since at least 2012 and continuing through 2020, including several recent severe or fatal reactions in the Charlottesville and Middleburg areas of Virginia and in Pennsylvania.

23. Despite the knowledge of these severely debilitating and/or fatal reactions, Zoetis did not disclose or adequately warn of Excede's danger to horses prior to Boomer's reaction. In or about January 2020, Zoetis changed its warning label to include the type of reaction that Boomer suffered.

24. Since Boomer's treatment for the Excede reaction in 2016, he has experienced persistent lameness, and the musculature in his neck has been permanently damaged.

25. Consistent veterinary treatment, with a variety of modalities, has been unable to return Boomer to the soundness necessary for a performance horse.

26. Prior to the Excede injection and reaction, Boomer was a successful, young show hunter.

27. As a result of the permanent lameness and physical damage caused by the Excede injection, Boomer can no longer be ridden or used as a show horse.

28. From 2010 through December 2018, nearly 600 adverse reaction reports were made by Zoetis to the FDA for Excede reactions experienced by horses in the United States. Upon information and belief, additional significant adverse reactions also occurred during 2019 and 2020.

29. Reactions have included fatalities, 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. Ms. Knapp's horse, Boomer, experienced both a severe anaphylactic response and a severe site reaction. At the time, Boomer was given Excede, the product carried no warnings, let alone adequate ones, concerning the above possible reactions and the hazardous properties causing same.

30. In many of these instances, whether the end result was a fatality or not, 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 who have not, and will not, fully recover. In the case of Boomer, veterinary bills totaled approximately $6,500.00.

31. Zoetis was made aware of these adverse reactions, and the resulting veterinary costs and diminished value of the afflicted horses.

32. The fair market value of horses that compete within the hunter/jumper discipline is driven by the physical and athletic ability to perform and, in the case of

hunters, is also driven by the horse's physical appearance and lack of blemishes or scarring. Ms. Knapp's horse, Boomer, had a pre-injury fair market value of $90,000.00.

33. The fair market value of a horse that experiences a significant medical issue or complication, like a severe drug reaction, muscle damage, or scarring, is significantly diminished. In certain instances, the residual value of a damaged performance horse is essentially zero.

34. Despite knowledge of the numerous adverse reactions suffered by horses who were administered Excede, Zoetis refused to revise Excede's warning label and prescribing information to reflect the significant negative post-approval experience. Consequently, the majority of would-be consumers and prescribing veterinarians were left with no way of knowing the considerable risk associated with the administration of Excede.

35. Excede is an antibiotic expressly marketed as treating equine respiratory infections with a "two dose, one solution" treatment for sick horses. Zoetis further markets Excede as doing in two doses what would otherwise take ten.[1]

36. Excede is also prescribed by veterinarians for off-label uses as well, a fact known by Zoetis. Most antibiotics prescribed by equine veterinarians are for off-label or extra-label use, which is permissible under federal law. Zoetis was aware that equine veterinarians used Excede off-label for treating conditions including the type of condition Boomer had on August 13, 2016, and that some horses experience the same type of adverse reaction that Boomer suffered as a result of the off-label use of Excede for those types of conditions.

[1] *See* https://www.zoetisus.com/products/horses/excede.aspx (last visited 11.18.19)

37. Excede works through an "extended release formulation" which upon winning FDA approval in 2010, Zoetis touted as a "true innovation." Because of Excede's extended release formulation, Zoetis claimed it made treatment of horses easier and more effective because it would allow owners and veterinarians to administer treatment more easily and with less stress to the animal.[2]

38. The formulation, design, method of manufacture, and sources of the ingredients contained in Excede are proprietary and known only to Zoetis.

39. Excede, and other extended release veterinary medications, are of particular use when it comes to free roaming animals, like livestock who are not stabled and thus may be difficult to locate at any given time. For multiple categories of horses, be they performance horses like Boomer, racehorses, and/or other riding horses, location is rarely an issue because they are usually stabled, or have ready access to stabling, and can be provided medication more simply and consistently than roaming livestock. For such horses, administration of a ten-day course of non-extended release antibiotics remains a relatively easy task that has been accomplished in the horse industry for many decades.

40. Zoetis manufactures a non-extended release injectable ceftiofur antibiotic for equines called Naxcel, which has been safely used in horses for decades. Upon information and belief, the use of Naxcel has not resulted in the type of severe reactions caused by Excede.

41. The only significant difference between Naxcel and Excede is the extended release delivery system found in Excede, which was designed by Zoetis utilizing a caprylic acid and cottonseed oil based suspension.

[2] *See* https://www.zoetisus.com/news-and-media/fda-approves-pfizer-animal-healths-excede-ceftiofur-crystalline-free-acid-sterile-suspension-for-horses.aspx (last visited 11.18.19)

42. Cottonseed oil is not used as a suspension in other regularly used, approved equine medications. Cottonseed oil that is not refined or is improperly refined contains substances that are toxic to horses.

43. Nevertheless, despite viable alternatives and the known concerns regarding the negative post-approval experiences suffered by hundreds of horses, Zoetis refused to make any alterations to Excede's label prior to January 2020 and continues to market the product as being superior to traditional courses of antibiotic treatment for stabled horses.

COUNT I
Negligence
(Failure to Warn)

44. The foregoing allegations are hereby incorporated by reference as if fully set forth herein.

45. At all relevant times herein, Zoetis was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the injectable animal antibiotic with brand name Excede, including the Excede that was used on Boomer and other horses across the country.

46. Zoetis had a duty to exercise reasonable care in the design, manufacture, sale, and/or distribution of Excede into the stream of commerce, including a duty to ensure that its products, specifically Excede, did not pose a significantly increased risk of harm and adverse events to the animals on which its products were used.

47. Zoetis failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Excede into interstate commerce in that Zoetis knew or

should have known that Excede could cause severely debilitating and/or fatal reactions in horses.

48. Zoetis had a duty to exercise ordinary care in the labeling and provision of prescribing information for Excede, including a duty to provide adequate warnings of the known risks of the administration of Excede, to veterinarians and consumers.

49. At all times relevant, Defendant was well aware of the dangers posed by Excede when used in both on- and off-label manners.

50. At all times relevant, Plaintiff and her veterinarians were not aware of the dangers and risks associated with the administration of Excede to stabled horses.

51. Defendant's warning label and treatment indication(s) for Excede made no mention of such aforementioned dangers and risks, and specifically failed to warn of the danger and/or risk of the type of reactions suffered by Boomer. Even after receiving hundreds of adverse reaction reports made over the course of many years, Zoetis intentionally, willfully, recklessly and maliciously refused to revise its prescribing information and refused to publish the negative post-approval experience of which it was aware in order to adequately warn of the risks of Excede, including the specific risk of a reaction of the type suffered by Boomer.

52. As a direct result of Zoetis' negligent, willful, wanton, and malicious conduct, which was in reckless disregard for the rights of Knapp, Knapp has sustained damage to Boomer in that he has diminished monetary value as a performance horse and/or as a recreational riding horse. She has sustained substantial veterinary expenses for Boomer's lifesaving and recuperative treatment; has sustained veterinary expenses to try to reverse or mitigate the debilitating effects of the reaction, and to try to return Boomer to

his prior sound condition; and will sustain in the future expenses associated with the care and maintenance of Boomer for the remainder of his life without being able to use Boomer for his intended purpose.

Count II
Negligence
(Defective Design and Manufacture)

53. The foregoing allegations are hereby incorporated by reference as if fully set forth herein.

54. At all relevant times herein, Zoetis was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the injectable animal antibiotic with brand name Excede, including the Excede that was used on Boomer and other horses across the country.

55. Zoetis had a duty to exercise reasonable care in the design and manufacture of Excede, which was placed by Zoetis into the stream of commerce, including a duty to ensure that its products, specifically Excede, did not pose a significantly increased risk of harm and adverse events to the animals on which its products were used.

56. Zoetis failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of Excede into interstate commerce in that Zoetis knew or should have known that Excede could cause severely debilitating and/or fatal reactions in horses.

57. Despite the fact that Zoetis knew or should have known that Excede, and specifically its extended release delivery system, poses a serious risk of harm to horses,

Zoetis continues to manufacture and market Excede for use by consumers and end-users including Knapp and myriad other horse owners. Alternative effective antibiotics that do not pose the same risk of harm to horses exist and are available to consumers and end-users including Knapp and myriad other horse owners.

58. The Excede antibiotic, and specifically the design and/or manufacture of its extended release delivery system, was unreasonably dangerous for the use in horses to which it would ordinarily be put and for its foreseeable purposes, and the unreasonably dangerous condition existed when the Excede antibiotic left Zoetis' hands.

59. The Excede antibiotic extended release formulation was unreasonably dangerous because the extended release delivery system was imprudently designed and/or manufactured. Upon information and belief, Zoetis has not modified the formulation or method of manufacture for Excede despite knowing of its dangerousness.

60. As a direct result of Zoetis' negligent, willful, wanton, and malicious conduct, in reckless disregard for the rights of Knapp, Knapp has sustained damage to Boomer in that he has diminished monetary value as a performance horse and/or as a recreational riding horse. She has sustained substantial veterinary expenses for Boomer's lifesaving and recuperative treatment; has sustained veterinary expenses to try to reverse or mitigate the debilitating effects of the reaction, and to try to return Boomer to his prior sound condition; and will sustain in the future expenses associated with the care and maintenance of Boomer for the remainder of his life without being able to use Boomer for his intended purpose.

COUNT III
Breach of Express Warranty
(Virginia Commercial Code)

61. The foregoing allegations are hereby incorporated by reference as if fully set forth herein.

62. Zoetis expressly warranted that the Excede antibiotic was safe and reasonably fit for its intended use in the treatment of horses through its information containing affirmations of statements of facts, promises, and descriptions regarding the product. Such affirmations, promises, and descriptions include, but are not limited, to:

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."

63. Knapp and/or her veterinarian chose the Excede antibiotic based upon Zoetis' express warranties and representations regarding the safety and fitness of Excede.

64. The Excede antibiotic manufactured and sold by Zoetis did not conform to Zoetis' express representations because an injection of Excede caused serious harm, stress, and permanent damage to Knapp's horse when used as recommended and directed.

65. As a direct result of Zoetis' breach of warranty, Knapp has sustained damage to her horse in that it no longer has significant monetary value as a show horse; has sustained veterinary expenses for the treatment of her horse to save its life; has sustained veterinary expenses to try to reverse or mitigate the debilitating effects of the reaction, and to try to return the horse to its prior sound condition, which efforts have been unsuccessful; and will sustain in the future expenses associated with the care and maintenance of the horse for the remainder of its life without being able to use the horse for its intended purpose.

COUNT IV
Breach of Implied Warranty
(Virginia Commercial Code)

66. The foregoing allegations are hereby incorporated by reference as if fully set forth herein.

67. At the time Zoetis designed, manufactured, marketed, sold, and distributed the Excede antibiotic for use by Knapp, Zoetis knew of the use for which Excede was intended and impliedly warranted that it was of merchantable quality and safe for such use and reasonably safe.

68. The Excede antibiotic was, in fact, unfit and unmerchantable and unreasonably dangerous for its foreseeable and intended uses and was defective in manufacture, imprudently designed, not accompanied by adequate warnings concerning its hazardous properties, and not in compliance with requirements pertaining and relating to the creation of implied warranties of merchantability.

69. The unreasonably dangerous condition of the Excede antibiotic as alleged herein existed when it left Zoetis' hands.

70. Knapp is not required to give notice to Zoetis of her breach of warranty claims under Va. Code §8.2-607(3)(a). Nevertheless, on or about January 16, 2018, prior to the institution of this action and in addition to the notice given on or about August 18, 2016, Knapp gave written notice to Zoetis regarding Boomer's reaction as well as the danger and unfitness of Excede. Zoetis did not respond to the January 16, 2018 correspondence.

71. As a direct result of Zoetis' breach of warranty, Knapp has sustained damage to her horse in that it no longer has significant monetary value as a show horse; has sustained veterinary expenses for the treatment of her horse to save its life; has sustained veterinary expenses to try to reverse or mitigate the debilitating effects of the reaction, and to try to return the horse to its prior sound condition, which efforts have been unsuccessful; and will sustain in the future expenses associated with the care and maintenance of the horse for the remainder of its life without being able to use the horse for its intended purpose.

WHEREFORE, Knapp respectfully requests that, as to all Counts, she be awarded judgment against Zoetis as follows:

a. damages in the amount of no less than $500,000;

b. punitive damages in the amount of $350,000; and

c. all other relief that this Court deems just and proper.

Jury trial demanded.

ASHLEY KNAPP,

/s/ Tamara L. Tucker
By Counsel

Tamara L. Tucker (VSB No. 39805)
Tucker Law Firm, PLC
690 Berkmar Circle
Charlottesville, VA 22901
833-388-2537 phone & fax
tamara.tucker@tuckerlawplc.com

Harris D. Butler, III, (VSB No. 26483)
Zev H. Antell (VSB No. 74634)
Butler Curwood, PLC
140 Virginia Street, Ste 302
Richmond, Virginia 23219
Telephone: (804) 648-4848
Facsimile: (804) 237-0413
Email: harris@butlercurwood.com
zev@butlercurwood.com

Counsel for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2021, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

Michael H. Gladstone
McCandlish Holton
1111 East Main Street, Suite 2100
Richmond, VA 23218
Tel: 804-775-3813
Fax: 804-775-3800
Email: mgladstone@lawmh.com

Joseph H. Blum
Sean Wajert
Shook Hardy & Bacon LLP
Two Commerce Square
2001 Market Street Suite 3300
Philadelphia,PA 19103
Email: jblum@shb.com
swajert@shb.com

Attorneys for Defendant Zoetis, Inc.

By: /s/ *Tamara L. Tucker*
Tamara L. Tucker (VSB No. 39805)
Tucker Law Firm, PLC
690 Berkmar Circle
Charlottesville, VA 22901
833-388-2537 phone & fax
tamara.tucker@tuckerlawplc.com
Attorney for Plaintiff Ashley Knapp, et al.