IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
NEWARK VICINAGE

CATHY HARTNEY, on behalf of herself and all others similarly situated, Plaintiffs, v. ZOETIS, INC. Defendant.	Case No. 2:24-cv-9698

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, Cathy Hartney ("Plaintiff"), by and through undersigned counsel, and on behalf of herself and all other similarly situated as set forth below, brings the following Class Action Complaint against Defendant, Zoetis, Inc. ("Defendant"), to recover monetary damages, injunctive relief, and other remedies for violations of state statutes and common law.

INTRODUCTION

1. Bedinvetmab, sold under the brand name Librela in the United States and Europe, is a canine monoclonal antibody used for the control of pain associated with osteoarthritis in dogs. Librela has been associated with thousands of reported adverse events in dogs including lethargy, drooling, shaking, behavior changes, hiding, urinary incontinence, inappetence, increased or decreased thirst, ataxia, hind-end weakness, inability to walk, new or worsening seizures, organ damage, worsening osteoarthritis symptoms, worsening pain, and even death.

2. Librela is a long-acting drug that is administered orally or by injection on a monthly basis. There is no available antidote if a pet has an adverse reaction to this long-acting drug.

3. Defendant Zoetis, Inc., ("Defendant"), the manufacturer of Librela, failed to adequately inform consumers (pet owners) about the dangers of Librela and misled consumers by representing that Librela is safe for use in dogs when it is not.

4. At no point has Defendant adequately disclosed the dangers of Librela to consumers in the United States. To the contrary, Defendant has maintained and represented that Librela is safe for use in dogs.

5. The misrepresentations by Zoetis that Librela was safe and effective has resulted in millions upon millions of dollars in damages for pet owners, including, but not limited to, the costs of Librela, veterinary expenses related to the injuries to dogs injured by Librela and in some cases death of the dog. Plaintiff's dog, Jake, a poodle mix, was diagnosed with coxofemoral osteoarthritis. Below is a photograph of Jake:

6. Plaintiff's veterinarian prescribed and administered an injection of Librela to Jake on or around May 16, 2024.

7. Plaintiff consented to the Librela injection for Jake because, consistent with Defendant's representations, Plaintiff believed Librela was safe and effective for use in dogs like Jake, who had no known medical concerns other than osteoarthritis.

8. At the time Plaintiff consented to the Librela injection for Jake, and based on the false and misleading claims, warranties, representations, media advertising, and/or other marketing by Defendant, Plaintiff was unaware that Librela had a propensity to cause significant injuries to dogs when used as directed, and therefore was not, as represented by Defendant, safe and effective.

9. Plaintiff would not have purchased Librela if the Defendant had not represented that Librela was safe and effective for use in dogs.

10. Within days following the first administration of the Librela, Plaintiff's dog, Jake began experiencing markedly increased thirst, significantly decreased appetite (inappetence), drastically limited mobility (e.g. inability to get up to avoid urinating and defecating on himself), and apparent worsening pain.

11. Plaintiff grew concerned as a result of Jake's symptoms. Plaintiff undertook various efforts to resolve the health conditions that Jake was experiencing, which developed after Jake received injections of Librela, including additional visits to the veterinarian. Unfortunately, these efforts were unsuccessful, and as a result of the symptoms caused by the injections of Librela in May 2024, Jake's condition had become so dire and his quality of life so poor that there was only one humane option. Tragically, he had to be euthanized.

12. Plaintiff spent money ($113.50 + $60 for the exam fee + $8 biohazard fee for need disposal) on the Librela injection, which did not conform to the product labeling. Plaintiff incurred costs and expenses from subsequent veterinary bills in an attempt to treat the adverse events to Librela, and end-of-life expenses when that was unsuccessful. Plaintiff was harmed economically

by the loss of her pet, and also suffered extreme emotional stress and anguish from losing her beloved Jake. Plaintiff did not receive the product she intended to purchase: a pet medication that was fit for its ordinary purpose—to treat Jake's pain associated with osteoarthritis in a safe and effective manner. She did not receive the benefit of her bargain. Plaintiff subsequently filed adverse event reports with both the Defendant and the FDA.

13. Plaintiff's injuries include but are not limited to: the damage to and loss of her beloved pet Jake; out-of-pocket medical expenses (including the price of the drug and drug administration, cost of subsequent treatment attempts, and end-of-life costs); and other damages. These damages were a direct result of the harm caused by the use of Librela.

JURISDICTION

14. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. §§ 1332(d)(2) and (6) of the Class Action Fairness Act of 2005 ("CAFA") because: (i) there are 100 or more class members, (ii) there is an aggregate amount in controversy exceeding $5,000,000, exclusive of interest and costs, and (iii) there is minimal diversity because at least one plaintiff and one defendant are citizens of different states.

15. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

PARTIES

16. Plaintiff Cathy Hartney ("Plaintiff") is a resident and citizen of the State of Florida.

17. Defendant Zoetis, Inc. ("Zoetis" or "Defendant") is a Delaware corporation headquartered in Parsippany, New Jersey.

18. Zoetis touts that it "discovers, develops, manufactures and markets veterinary vaccines and medicines, with a focus on both farm and companion animals"[1] and touts itself as "the leading animal health company."[2] In 2023, the company generated annual revenues of $8.54 billion.[3] Zoetis directly markets pet pharmaceutical drugs in approximately 45 countries and sells its products in more than 100 countries around the world.[4] Zoetis's vast manufacturing network includes 29 sites in 11 different countries. As of 2023, the company had more than 14,000 employees worldwide.[5]

FACTUAL ALLEGATIONS

19. Veterinarians use a wide variety of products to benefit the health and safety of pets and the consumer market for pet medication is substantial.

20. According to a report regarding the Economic and Social Contributions of the Animal Health Industry, published by the Animal Health Institute in December 2022, the global animal health market was estimated to be $39.9 billion in 2021.[6] The United States accounted for nearly one-third of the global market, generating an estimated $13 billion in sales.[7] In the United States, animal health products make up about 2% of the total biopharmaceutical spending ($13 billion in sales of animal health products compared to $574 billion for human medicines).[8]

21. Pet owners rely on animal health products to keep their pets healthy and prevent or treat a host of symptoms, diseases, and conditions.

22. A study from the Human Animal Bond Research Institute (HABRI) shows that the

[1] https://investor.zoetis.com/news/news-details/2013/Zoetis-Closes-Initial-Public-Offering/default.aspx
[2] https://www.zoetisus.com/about-us
[3] *Id*.
[4] *Id*.
[5] *Id*.
[6] https://ahi.org/wp-content/uploads/AHI-Primer-December-2022-Final-w-Infographic.pdf
[7] https://ndpanalytics.com/wp-content/uploads/All-Factsheets-Combined.pdf
[8] https://ahi.org/animal-health-industry/industry-snapshot/

human-animal bond is strong and that pets positively impact their owners' health.[9] Animal health is a priority for most pet owners because they view pets as more than just property. According to the research, approximately 95% of dog and cat owners consider their pets as members of their family and about 86% say they would pay whatever it takes if their pet needed extensive veterinary care.[10]

23. This mindset is reflected in consumer spending on pet products and services. According to the Bureau of Labor Statistics, Americans spent nearly $103 billion on their pets in 2021. On average, the 90.5 million pet-owning households across the country each spent $1,137 on their pets, including $393 on veterinary services such as routine visits, surgery, treatments, and vaccinations, and $263 on pet purchases and supplies, including medicine.[11]

24. Dogs often suffer from many of the same illnesses and diseases that afflict humans, including osteoarthritis. Osteoarthritis is a chronic joint disease characterized by loss of joint cartilage, thickening of the joint capsule and new bone formation around the joint (osteophytosis), and it ultimately leads to pain and limb dysfunction.[12] As the condition worsens, bones may rub together, causing pain and decreased mobility.

25. Osteoarthritis is the most common form of arthritis in dogs, affecting approximately a quarter of the population.[13] Pain from osteoarthritis impacts how dogs move and feel, and it can decrease dogs' willingness to play, affecting their quality of life.

26. Librela belongs to a class of drugs that target and block a protein, called nerve growth factor ("NGF"), that plays a key role in signaling pain.[14] Researchers have found elevated

[9] https://habri.org/pressroom/20220116
[10] *Id.*
[11] https://ahi.org/wp-content/uploads/AHI-Primer-December-2022-Final-w-Infographic.pdf
[12] https://www.acvs.org/small-animal/osteoarthritis-in-dogs/
[13] *Id*.
[14] https://curacore.org/vet/2023/11/23/why-do-some-dogs-appear-to-develop-neurologic-problems-after-anti-nerve-growth-factor-monoclonal-antibody-injections/

levels of NGF in animals with osteoarthritis. Thus, they hypothesized that blocking NGF could reduce pain.[15] However, NGF has important protective, supportive, and reparative functions throughout the body, affecting the eye, the gut, and the nervous system. Therefore, according to one veterinarian, "we block [NGF] at our peril, or more specifically, perhaps at our patients' peril."[16]

27. Librela was approved for medical use in the European Union in November 2020[17] and approved in the United States in May 2023.[18] Librela and a similar treatment for cats (Solensia) were the first monoclonal antibody drugs for pets approved in the United States for controlling osteoarthritis pain.[19] The drugs, which promised to relieve painful arthritis in animals, became an important product for Zoetis, the world's largest animal-health company by sales.

28. Since Librela's approval in 2023, health regulators in the U.S. and Europe have received thousands of reports of adverse effects. The FDA received more than 3,800 reports of side effects concerning the drugs through the end of 2023. The European Medicines Agency received more than 12,300 reports of side effects involving Librela since 2021, when the drug went on sale in Europe.[20] FDA adverse event reports are all transmitted to the manufacturer Zoetis. Upon information and belief, Zoetis has also directly received thousands of adverse event reports as well.

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[15] *Id*.
[16] *Id*.
[17] "Librela EPAR." European Medicines Agency (EMA). 21 February 2022.
[18] "Zoetis Announces U.S. FDA Approval of Librela (bedinvetmab injection) to Control Osteoarthritis (OA) Pain in Dogs" (Press release). Zoetis. 5 May 2023.
[19] The bedinvetmab product is marketed in Australia and New Zealand as Barensa.
[20] https://www.wsj.com/health/pharma/dog-cat-arthritis-drugs-bcdddea6

29. The European Database of Suspected Adverse Drug Reaction Reports (Eudra Vigilance) currently contains nearly 20,000 reports of adverse event reports regarding Librela, the majority of which are classified as "systemic disorders."[21]

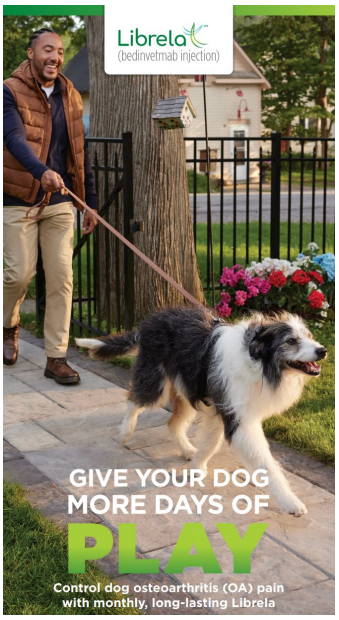
30. Adverse effects described online by consumers include, but are not limited to, those symptoms listed in ¶ 1.

31. Prior to approval of this NGF inhibitor (Librela) for use in dogs, the adverse effects of NGF inhibitors in humans were well-documented. More than a decade prior to approval of Librela for use in dogs, pharmaceutical companies were attempting to develop NGF inhibitor medications for human use. However, in 2011, the FDA paused testing of the NGF inhibitor drug class for humans because of evidence linking the drugs to worsening joint damage and other adverse events. Several drug manufacturers including AbbVie, AstraZeneca, and Johnson & Johnson stopped working on NGF inhibitors following the FDA action. Eli Lilly and Pfizer forged ahead seeking approval for tanezumab, an NGF drug for the treatment of osteoarthritis in humans. However, in 2021, Eli Lilly and Pfizer stopped global clinical development of tanezumab after the FDA and the European Medicines Agency rejected requests for approval of the drug.[22]

32. Librela is marketed directly to consumers through an extensive marketing campaign directing pet owners to "Ask your vet about Librela" and advising pet owners to look for certain signs of undiagnosed osteoarthritis and "If your dog is showing any of these behaviors, speak to a veterinary professional" about starting Librela.

33. The following are examples of Zoetis' direct-to-consumer marketing campaign.

[21] https://dap.ema.europa.eu/analytics/saw.dll?Dashboard
[22] https://finance.yahoo.com/news/pfizer-eli-lillys-osteoarthritis-drug-040715348.html?fr=sycsrp_catchall



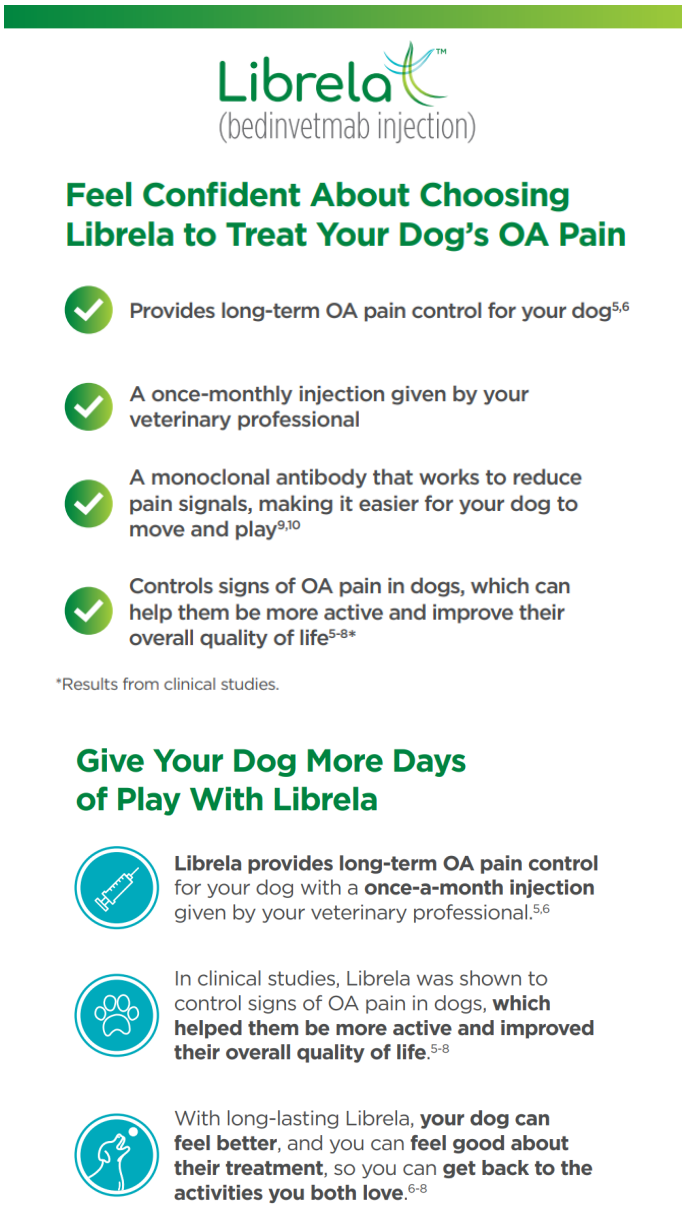
Is Your Dog Showing Signs of OA Pain?

An OA diagnosis can be missed in some dogs because the signs may be subtle or overlooked as normal changes related to aging

Nearly 40% of dogs show signs of OA pain, but less than half are actually diagnosed[3,4]

Your dog could be suffering from OA pain if they're displaying the following behaviors:

If your dog is showing any of these behaviors, speak to a veterinary professional.



34. Defendant's advertising and promotional materials for Librela represented that the product was safe for use in dogs without disclosing many significant adverse effects associated with the product. For example, Zoetis' direct-to-consumer marketing materials indicated that, "In a clinical study, the most common side effects in dogs taking Librela vs. placebo (no medicine) were urinary tract infection, bacterial skin infection, and dermatitis, **and were similar for dogs taking placebo**" (emphasis added).

35. The product warning label for Librela is inadequate in that it failed to warn consumers and veterinarians about the potential for significant adverse events following administration, including the risk of neurological problems, organ damage, and death, along with many other adverse events listed in ¶ 1.

WARNINGS

User Safety Warnings

Not for use in humans. Keep this and all drugs out of reach of children. For use in dogs only.

Hypersensitivity reactions, including anaphylaxis, could potentially occur in the case of accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet, vial or carton to the physician.

Pregnant women, women trying to conceive, and breastfeeding women should take extreme care to avoid accidental self-injection.

The importance of Nerve Growth Factor in ensuring normal fetal nervous system development is well-established and laboratory studies conducted on nonhuman primates with human anti-NGF antibodies have shown evidence of reproductive and developmental toxicity.

PRECAUTIONS

Administration of monoclonal antibodies may be associated with hypersensitivity reactions and delayed hypersensitivity reactions. If anaphylaxis or other hypersensitivity reaction occurs, discontinue use and institute appropriate therapy.

The safe use of this product with other monoclonal antibodies has not been evaluated. Use with caution in dogs with known hypersensitivity to other immunoglobulin therapy.

Evaluations were not made to determine if interactions occurred between LIBRELA and veterinary vaccines.

Treatment with LIBRELA may result in the formation of anti-bedinvetmab antibodies and potentially the loss of product effectiveness (see **IMMUNOGENICITY**).

The safe use of anti-NGF monoclonal antibodies with concurrent non-steroidal anti-inflammatory drugs (NSAIDs) has not been established in dogs. In human clinical trials, rapidly progressing osteoarthritis (RPOA) has been reported in a small number of patients receiving humanized anti-NGF monoclonal antibody therapy. The incidence of these events increased in human patients receiving NSAID treatment long term in combination with an anti-NGF monoclonal antibody. RPOA has not been characterized or reported in dogs.

The safety and effectiveness of LIBRELA has not been evaluated in dogs less than 12 months of age.

LIBRELA has not been studied in dogs that have a history of cruciate ligament rupture within six months before initial product use as these cases were excluded from the field studies.

Long term effects which may occur more than 9 months after the use of LIBRELA have not been evaluated.

NGF is expressed within the heart and vasculature, and the long-term effects of reduced NGF in dogs with cardiac disease are unknown.

Primates receiving high doses of anti-NGF monoclonal antibodies had anatomical changes in postganglionic cell bodies (reduced size and number of neurons). The change in cell body size returned to normal after anti-NGF monoclonal antibody administration was discontinued. NGF is involved in the normal development of sensory and sympathetic nerve fibers in developing animals. This may be important with use of LIBRELA in young growing dogs.

ADVERSE REACTIONS

The safety of LIBRELA was assessed in a masked, controlled 84-day US field study evaluating the effectiveness of LIBRELA for the control of pain associated with osteoarthritis. Enrollment included 272 dogs, 135 dogs treated with LIBRELA and 137 dogs treated with a negative control (sterile saline). The enrolled dogs were at least 1 year of age (1 to 17 years old), weighed between 1.8 to 62.7 kg and were of various breeds or non-purebred. Dogs were dosed at 28-day intervals and received up to three injections. The most common adverse reactions reported during the study are summarized in Table 2 below.

Table 2. Number (%) of Dogs with Adverse Reactions Reported in the US Field Study

Adverse Reaction*	LIBRELA n (%) (Total N = 135)	Negative Control n (%) (Total N = 137)
Urinary tract infection	15 (11.1)	11 (8.0)
Bacterial skin infection	11 (8.1)	9 (6.6)
Dermatitis	10 (7.4)	8 (5.8)
Dermal mass	8 (5.9)	5 (3.6)
Erythema	6 (4.4)	5 (3.6)
Dermal cyst(s)	4 (3.0)	2 (1.5)
Pain on injection	4 (3.0)	2 (1.5)
Inappropriate urination**	4 (3.0)	1 (0.7)
Histiocytoma	3 (2.2)	0 (0.0)

*An adverse reaction may have occurred more than once in a dog; only the first occurrence was counted.
** Of these, two dogs treated with LIBRELA were among those reported with a urinary tract infection.

The safety of LIBRELA was also evaluated in a masked, controlled 84-day European field study evaluating the effectiveness of LIBRELA for the control of pain associated with osteoarthritis. Enrollment included 281 dogs, 138 dogs were treated with LIBRELA and 143 treated with a negative control (sterile saline). The enrolled dogs were at least 1 year of age (1 to 17.5 years old), weighed between 1.7 to 66 kg and were of various breeds or non-purebred. Dogs were dosed at 28-day intervals and received up to three injections. The most common adverse reactions reported during the study are summarized in Table 3 below.

Table 3. Number (%) of dogs with Adverse Reactions Reported in the European Field Study

Adverse Event Reported*	LIBRELA n (%) (Total N = 138)	Negative Control n (%) (Total N = 143)
Increased Blood Urea Nitrogen (BUN)**	19 (13.8)	7 (4.9)
Lethargy	5 (3.6)	0 (0.0)
Emesis	4 (2.9)	1 (0.7)
Anorexia	3 (2.2)	0 (0.0)
Lameness	3 (2.2)	1 (0.7)
Cough	3 (2.2)	1 (0.7)

*An adverse reaction may have occurred more than once in a dog; only the first occurrence was counted.
** Two dogs treated with LIBRELA suffered serious adverse events and were euthanized during or after study completion: A 13-year old Bichon Frise had pre-existing increased urine protein-creatinine ratio and heart failure that worsened during study; the dog also had an increase in creatinine during the study and was diagnosed with renal failure and was euthanized 3 days after completing the study. An 8-year-old mixed breed dog had pancreatitis and was euthanized on Day 74. The remainder of the dogs that had elevations in the BUN did not have any obvious adverse events associated with this finding.

One dog in the LIBRELA group was diagnosed with pyelonephritis on Day 15; this dog had pre-existing increased serum BUN and creatinine and a recent history of urinary tract infection that was not confirmed resolved prior to enrollment. Non-steroidal anti-inflammatory drugs (NSAIDs) and acetaminophen were initiated on Day 7 for osteoarthritis-associated joint pain but NSAIDs were discontinued on Day 10 due to anorexia and gastroenteritis; azotemia worsened at Day 13 and the dog received no further LIBRELA treatment.

One dog in the LIBRELA group with a history of atopy, developed mild alopecia and mild erythema on the injection site on Days 5 and 23. Both episodes of alopecia and erythema resolved with treatment.

A total of 89 dogs were enrolled in a 6-month, single arm, open labeled, uncontrolled continuation of the EU field study and received monthly subcutaneous injections of LIBRELA. The study provided additional field safety information.

One dog experienced acute gastroenteritis and recovered following treatment for abdominal pain, fever, vomiting, and anorexia. One large breed dog enrolled for stifle osteoarthritis developed acute forelimb lameness that was diagnosed as elbow dysplasia. Two dogs presented with rear limb paresis of unknown etiology, one of whom responded to ongoing NSAID treatment and one who did not.

36. Since its release, there have been thousands of reports of serious adverse incidents involving Librela, of which Defendant knew or should have known.

37. The actual number of adverse events associated with Librela administrations in dogs is likely higher, as not all exposures and injuries would have been reported to the company and or the FDA.

38. On November 20, 2023, the FDA's Center of Veterinary Medicine notified Zoetis that the Librela website made false or misleading claims about the efficacy of Librela. The FDA warned Zoetis that as a result of those claims, the website misbrands Librela within the meaning of the Federal Food, Drug and Cosmetic Act, making its distribution violative of federal regulations. The FDA informed Zoetis that, "These violations are especially concerning from a public health perspective because the promotional communications create a misleading impression regarding the effectiveness of Librela, which is a veterinary drug in a novel therapeutic class."[23]

39. In contrast with the information and warnings that Defendant provided to consumers, Defendant was aware, or should have been aware, that Librela could cause neurological injuries (e.g., ataxia, convulsions, and tremors), and failed to warn consumers that the product should be discontinued if neurological injuries manifest after using the product.

40. Defendant also failed to warn consumers of other adverse events (see ¶ 1) that had been reported in dogs after using Librela, and failed to recommend discontinuing Librela if those events occurred.

41. Because Librela is a monthly injection or administration, significant damage can occur during the period of time that Librela remains in the system of an animal experiencing such

[23] https://www.fda.gov/media/174818/download

adverse events. There is currently no antidote should a dog experience a significant adverse event after administration of Librela, although the drug is designed to exert an effect for a full month.

42. Nowhere on the product packaging or labeling were there warnings or other representations indicating that Librela may cause life-threatening severe adverse side effects.

43. Had Defendant disclosed the existence of the serious safety risks associated with the use of Librela, Plaintiff and the Putative Class Members would not have purchased Librela for their dogs and would have acted differently. Consequently, Plaintiff and the Putative Class Members did not receive the benefit of their bargain.

44. Defendant failed to adequately study the effects of the Librela on dogs before placing Librela into the stream of commerce and there is a dearth of reliable independent scientific literature evaluating the safety and efficacy of Librela. Further, the relevant studies concerning the purported success of bedinvetmab have significant design flaws.

45. The Defendant's claims about the safety and efficacy of Librela are based primarily on two company-sponsored studies, Corral (2021)[24] and Krautmann (2021).[25]

46. The Corral (2021) study contains the following disclaimer: "All authors were employees of Zoetis while engaged in this research."

47. Similarly, in Krautmann (2021), eleven of the thirteen co-authors were employed by Zoetis, Inc. "These studies were sponsored by Zoetis, Parsippany, NJ, USA. All co-authors are employees of Zoetis, Parsippany, NJ, USA or Charles River Laboratories Montreal, ULC, Senneville, Quebec, Canada."

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[24] Corral, Maria J., et al., "A prospective, randomized, blinded, placebo-controlled multisite clinical study of bedinvetmab, a canine monoclonal antibody targeting nerve growth factor, in dogs with osteoarthritis." *Veterinary Anaesthesia and Analgesia*, 48 (2021). https://doi.org/10.1016/j.vaa.2021.08.001.

[25] Krautmann, M., et al., "Laboratory safety evaluation of bedinvetmab, a canine anti-nerve growth factor monoclonal antibody, in dogs." *The Veterinary Journal*, 276 (2021). https://doi.org/10.1016/j.tvjl.2021.105733

48. In 2023, Dr. Katrin Kronenberger from the University of Edinburgh Royal (Dick) School of Veterinary Studies published a report in the journal *Veterinary Evidence* that detailed a long list of methodological flaws in the Corral and Krautmann studies.[26]

49. For example, Dr. Kronenberger states that the authors of the Corral (2021) study "do not describe individual site blinding methodology and do not discuss statistical management of missing data, particularly methods for handling the implementation of rescue medication. Furthermore, incomplete follow–up minimised data interpretability."[27]

50. Furthermore, the authors in Corral (2021) measured pain using the Canine Brief Pain Inventory, but "did not adhere to scale administrative guidelines (Brown et al., 2008) by collecting data at enrolment and using these as the baseline for comparison with scores obtained at later time points, despite standardization guidance to avoid using scores collected on the first appointment given concerns about regression (Brown et al., 2008; and Friedman et al., 2015)."[28]

51. Krautmann (2021) fares no better. The authors of that study "do not describe randomised allocation, and the blinding of outcome assessors was incomplete. Sample sizes were small and were further reduced in each of the three studies in this preclinical trial, limiting statistical power and potentially impacting the detection of adverse health effects (AHEs)."[29]

52. Further, in that study, "Four of those dogs were 'deemed unsuitable' with no further explanation for their removal or why replacement dogs were 'deemed eligible'. It is difficult to determine what effect this replacement had on randomisation or magnitude, or direction of effects."[30]

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[26] Kronenberger, K. "In dogs diagnosed with osteoarthritis, how safe and effective is long-term treatment with bedinvetmab in providing analgesia?" *Veterinary Evidence*, 8:1 (2023). https://doi.org/10.18849/ve.v8i1.598
[27] Kronenberger (2023), p. 11.
[28] Kronenberger (2023), p. 12.
[29] Kronenberger (2023), p. 12.
[30] Kronenberger (2023), p. 12.

53. Due to Defendant's misrepresentations and omissions regarding the safety and efficacy of Librela, Plaintiff and the Putative Class Members did not receive the product they intended to purchase—that is, a pet medication that was fit for its ordinary purpose to treat osteoarthritis safely.

54. In short, Defendant entirely omitted several dangerous safety concerns associated with Librela—omitting key information from consumers and misrepresenting the safety and efficacy of the product.

55. Defendant still denies any problems with Librela or its labeling. In fact, Zoetis issued a statement to the Veterinary Information Network (VIN) News Service stating that "We remain confident in the safety and effectiveness of Librela (and Solensia) for controlling osteoarthritis pain in dogs (and cats, respectively), when used according to the label."[31]

56. Accordingly, Defendant has not only omitted safety information from Librela warning labels but continues to mislead consumers into believing Librela is safe and effective. Consumers are unable to make informed risk-benefit assessments about the use of Librela to treat their pets without adequate and accurate information about both risks and efficacy.

CLASS DEFINITION AND ALLEGATIONS

57. Pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3) and 23(c)(4), Plaintiff brings this action on behalf of herself and the following proposed Class:

> All persons in the United States who purchased Librela during the Class Period and whose pet developed one or more of the symptoms listed in ¶ 1, within six (6) months from the date of an administration of Librela.

58. The Class Period begins from the length of the greatest applicable statute of limitations to the present.

[31] https://news.vin.com/default.aspx?pid=210&catId=614&Id=12137959

59. Excluded from the Class are: (i) Defendant, any entity in which any Defendant has a controlling interest or which has a controlling interest in any Defendant, and Defendant's legal representatives, predecessors, successors and assigns; (ii) Defendant's employees, officers, directors, agents, and representatives and their family members; (iii) governmental entities; (iv) all persons who make a timely election to be excluded from the class; (v) judge(s) and staff to whom this case is assigned, and any member of the judge's or judges' staffs' immediate family; and (vi) plaintiffs' counsel and plaintiff's counsel's staff, and any member of counsel's or counsel's staff's immediate family.

60. Certification of Plaintiff's claims for class-wide treatment is appropriate because Plaintiff can prove the elements of her claims on a class-wide basis using the same evidence as would be used to prove those elements in individual actions alleging the same claims.

61. **Numerosity – Federal Rule of Civil Procedure 23(a)(1)**. Members of the proposed Class are so numerous that the individual joinder of all absent Class members is impracticable. Class members are thousands of consumers who have purchased thousands of Librela injections or doses during the Class Period. Further information regarding the number of Class members is ascertainable by appropriate discovery. Plaintiff is informed and so believes, based upon the nature of the trade and commerce involved, that the proposed Class includes many thousands of Class members who are geographically diverse so that joinder of all Class members is impracticable.

62. **Typicality – Federal Rule of Civil Procedure 23(a)(3)**. Plaintiff's claims are typical of the claims of putative members of the Classes in that each purchased Librela for use on a pet and each member of the Classes owns a pet who suffered an injury caused by the administration of Librela. Plaintiff and the Class members were comparably injured through

Defendant's uniform course of misconduct described herein. Plaintiff and Class members all suffered common injuries and damages as a result of Defendant's false, deceptive, and misleading acts and practices in the sale of Librela. By advancing her claims, Plaintiff will also advance the claims of all Class members because Defendant's unlawful conduct caused and continues to cause all Class members to suffer similar harm.

63. **Adequacy – Federal Rule of Civil Procedure 23(a)(4)**. Plaintiff will fairly and adequately protect the interests of the Class members. Plaintiff's interests and the interests of all other members of each respective class are identical, and Plaintiff is cognizant of her duties and responsibilities to the Class members. Further, the interests of the Class members are not conflicting or divergent but, rather, are common. Accordingly, Plaintiffs can fairly and adequately represent the interests of the class. Moreover, Plaintiff's counsel are competent and experienced in litigating class actions, including litigation of this kind. Plaintiff and counsel intend to vigorously prosecute this case and will fairly and adequately protect the Class members' interests.

64. **Commonality and Predominance – Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3)**. This action involves common questions of law and fact, which predominate over any questions affecting individual Class members. Among the questions of law or fact common to the proposed Class are:

a. whether Defendant failed to warn consumers regarding the known or knowable safety risks Librela poses to dogs, as described herein;

b. whether Defendant failed to fully disclose material information to consumers concerning certain serious safety risks posed by Librela to dogs;

c. whether Defendant's representations and omissions concerning Librela involved representations and omissions of material fact;

d. whether Defendant concealed from consumers the safety risks posed by Librela to dogs, as described herein;

e. whether Defendant breached warranties with consumers when they marketed and sold Librela as being safe and effective for pets, which posed risks known to Defendant but unknown and undisclosed to consumers, as described herein;

f. whether Defendant engaged in unfair, unconscionable, or deceptive trade practices by selling and/or marketing Librela that poses safety risks pets, as described herein;

g. whether Defendant breached express warranties to Class members;

h. whether Defendant breached implied warranties of merchantability to Class members;

i. whether Defendant was negligent in selling Librela to consumers;

j. whether Defendant's conduct was unjust and in violation of principles of justice, equity, and good conscience;

k. whether Plaintiff and Class members conferred financial benefits on Defendant by purchasing Librela;

l. whether it is unjust for Defendant to retain the benefits conferred by Plaintiff's and Class members' overpayments for Librela;

m. whether Plaintiff and the Class members are entitled to damages, including compensatory, exemplary, and statutory damages, and the amount of such damages and the amount thereof; and

n. whether Plaintiff and Class members are entitled to equitable relief, including but not limited to a preliminary and/or permanent injunction.

65. **Superiority – Federal Rule of Civil Procedure 23(b)(3)**. A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The quintessential purpose of the class action mechanism is to permit litigation against wrongdoers even when damages to an individual plaintiff may not be sufficient to justify individual litigation. Here, the damages suffered by Plaintiff and the Class are relatively small compared to the burden and expense required to individually litigate their claims against Defendant, and thus, individual litigation to redress Defendant's wrongful conduct would be impracticable. Individual litigation by each Class member would also strain the court system, create the potential for inconsistent or contradictory judgments, and increase the delay and expense to all parties and the court system. By contrast, the class action device presents far fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

66. **Declaratory and Injunctive Relief – Federal Rule of Civil Procedure 23(b)(2)**. Class certification is also appropriate under Rule 23(b)(2) because Defendant has acted and refused to act on grounds generally applicable to the Class as a whole, such that final injunctive relief is appropriate with respect to the class as a whole. In addition to all of the other relief sought, Plaintiff asserts claims for injunctive relief and restitution arising from Defendant's false, misleading, and deceptive advertising and Defendant's failure to disclose the material risks of use of Librela on dogs.

67. **Certification of Particular Issues – Federal Rule of Civil Procedure 23(c)(4)**. This action is also properly maintainable under Rule 23(c)(4) in that particular issues common to

the Class, as described above in part, are most appropriately and efficiently resolved via class action, and would advance the disposition of this matter and the parties' interests therein.

FIRST CLAIM FOR RELIEF
VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT
N.J.S.A. 56:8-1 et seq.
(By Plaintiff Individually and on Behalf of the Class)

68. Plaintiff reasserts the allegations set forth in the factual allegations paragraphs above and incorporates such allegations by reference herein.

69. Plaintiff brings this claim on behalf of the Class against Defendant for violation of the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-1, et seq. ("NJCFA" or the "Act").

70. The NJCFA is a consumer protection law prohibiting businesses from engaging in any unconscionable, fraudulent, or deceptive practices.

71. NJCFA declares unlawful the act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate…whether or not any person has in fact been misled, deceived or damaged." N.J.S.A. 56:8-2.

72. In addition, the NJCFA makes unlawful "the advertisement of merchandise as part of a plan or scheme not to sell the item or service so advertised…" N.J.S.A. 56:8-2.2.

73. Plaintiff and the members of the Class are "persons" and the purchase of Librela was a "sale," as those terms are defined under the Act. N.J.S.A. § 56:8-1.

74. Defendant manufactures, distributes, markets, advertises and sells Librela, which constitutes "merchandise" within the meaning of the NJCFA. N.J.S.A. § 56:8-1.

75. Defendant violated and continues to violate NJCFA by engaging in the conduct described herein, which are unconscionable, deceptive, unfair acts or practices proscribed by NJCFA. Defendant's acts and practices, including their omissions, were likely to, and did, in fact, deceive and mislead members of the public, including consumers acting reasonably under the circumstances, to their detriment.

76. Defendant represented in the Librela packaging, labeling, marketing, advertising, and promotion that Librela provides a safe means to treat osteoarthritis in dogs. Defendant has continued to tout the safety of Librela even though the product has been linked to numerous pet deaths and incidents involving pet harm.

77. Contrary to these representations, Librela poses an unreasonable safety risk to dogs.

78. Defendant omitted, concealed, and failed to disclose to consumers that Librela poses serious safety risks to dogs, including that Librela was inherently defective; unreasonably dangerous; not fit to be used for its intended purpose and/or caused serious health problems. Rather than disclose this information, Defendant marketed Librela as safe for its intended purpose.

79. Defendant engaged in the following unconscionable, unfair, deceptive, and unconscionable practices:

a. Defendant manufactured, distributed, marketed, advertised and sold Librela, which posed serious safety risks to pets (as evidenced by the numerous reports of injuries and deaths), and which serious safety risks existed when the product left Defendant's control and at the point of sale;

b. Defendant knew, or otherwise should have known, that Librela posed serious safety risks to pets, but omitted and failed to disclose or concealed these risks from consumers.

c. Defendant knew the serious safety risks posed by Librela were unknown to consumers and would not be easily discovered by Plaintiff and members of the Class, and would defeat their ordinary, foreseeable and reasonable expectations concerning the performance of Librela.

d. Defendant warranted that Librela provided a safe means to treat the symptoms of osteoarthritis in dogs when, in fact, Librela poses serious safety risks to dogs; and

e. Defendant represented to consumers, including Plaintiff and members of the Class, that Librela was safe and fit for the use for which it were intended, despite the fact that Defendant either knew or otherwise should have known, that Librela was unsafe and posed serious safety risks to consumers' pets.

80. Contrary to Defendant's warranties and representations that Librela was safe and suitable for its intended use, Librela is unsafe as designed, manufactured, marketed, and sold. Librela poses serious safety risks to dogs.

81. Defendant had exclusive knowledge of material facts concerning the serious safety risks posed by Librela to dogs.

82. Defendant either knew, or otherwise should have known, that Librela posed serious safety risks to pets, including Plaintiff's dog and the Class members' dogs based upon: (1) their own internal testing, data, and surveys; (2) numerous consumer complaints lodged directly with Defendant and/or filed with the FDA and transmitted to Defendants; (3) numerous consumer complaints lodged to retailers; (4) numerous consumer complaints on online for a; (4) safety and efficacy testing done by Defendant, its predecessors, or other drug manufacturers regarding nerve growth factor (NGF) inhibitor drugs, whether brought to market or withdrawn from development due to safety concerns, regardless of target species.

83. Despite Defendant's knowledge of material facts concerning the existence of the serious safety risks posed by Librela, Defendant actively concealed the serious safety risks from consumers by failing to disclose the serious safety risks to consumers.

84. Despite Defendant's knowledge of material facts concerning the existence of the serious safety risks posed by Librela, Defendant denied the existence of the serious safety risks to dogs.

85. Defendant's deceptive acts and practices, including their representations and omissions, were material, in part, because they concerned an essential aspect of the product, including its intended use and safety profile. Such facts would naturally affect the conduct of purchasers, and a reasonable person would have considered those facts to be important in deciding whether to purchase Librela and/or allow the product to be used on their pet. Rather than disclose this information, Defendant marketed and labeled Librela as a safe means to treat pain associated with osteoarthritis in dogs.

86. Defendant's misrepresentations and omissions regarding the inherently defective and unreasonably dangerous nature of Librela were and are directed at consumers in a uniform manner.

87. Defendant's practices described herein had the capacity to deceive consumers acting reasonably under the circumstances and were in fact made with the intent that consumers rely on such practices. Consumers, including Plaintiff and the members of the Class, would not have purchased Librela on the same terms if the true facts concerning the risks associated with use of Librela had they known that the product posed serious safety risks to them and their pets.

88. Defendant's violations described herein present a continuing risk to Plaintiff and the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

89. Plaintiff has suffered an ascertainable loss, including but not limited to the cost of $181.50 for the Librela injection and related veterinary costs, the cost of subsequent treatment for her pet's adverse reaction to Librela and his end-of-life care, and property damage due to the damage to and death of Jake.

90. Defendant's unconscionable, deceptive and/or unfair practices have caused actual damages to Plaintiff and the Class.

91. As a direct and proximate result of Defendant's unfair or deceptive acts or practices, Plaintiff and the members of the Class have been damaged and are entitled to recover actual damages to the extent permitted by law in an amount to be proven at trial.

92. Furthermore, Plaintiff and other members of the Class are entitled to treble damages pursuant to N.J.S.A. § 56:8-19.

93. Additionally, Plaintiff and the members of the Class seek an order enjoining Defendant's unfair, unlawful, and/or deceptive practices, and awarding Plaintiffs' attorneys' fees and any other just and proper relief available under FDUTPA and applicable law.

SECOND CLAIM FOR RELIEF
VIOLATION OF THE NEW JERSEY PRODUCTS LIABILITY ACT
NJ Rev Stat § 2A:58C-2
(By Plaintiff Individually and on Behalf of the Class)

94. Plaintiff reasserts the allegations set forth in the factual allegations paragraphs above and incorporates such allegations by reference herein.

95. Defendant designed, manufactured, and sold Librela, an unsafe pet pharmaceutical product that creates a risk of adverse reactions in dogs (see ¶ 1).

96. Librela was not reasonably fit, suitable, or safe for its intended purpose because the product failed to contain adequate warnings for all of the risks of the potential adverse reactions (see ¶ 1).

97. That Librela was risky to the health of dogs was, at all times material hereto, an unreasonably dangerous defect and/or condition. The failure of Defendant to warn on its package and/or product labeling of the dangerousness of Librela, as well as Defendant's omissions of the defect, also constituted an unreasonably dangerous defect and/or condition.

98. These unreasonably dangerous defects and/or conditions existed at the time Librela left Defendant's control.

99. Defendant knew or should have known about the dangers Librela posed, but did not inform consumers of the risks, has downplayed safety issues, and has denied that its product was the cause of the adverse effects described above.

100. Librela came in sealed packages, and its packaging did not change from the time it left Defendant's possession through the time they arrived in veterinarians' offices to be delivered to consumers.

101. The unreasonably dangerous defects and/or conditions of Librela proximately caused injury and death to animals, constituting property damage to Plaintiff and the members of the Class beyond and in addition to the damages from purchasing the mislabeled Librela.

102. Accordingly, Defendant is strictly liable for the property damages caused to Plaintiffs and any other members of the Class, as a result of the use of the unreasonably dangerous Librela, including specifically the illness and deaths of any animals and the expenses incurred therewith.

THIRD CLAIM FOR RELIEF
BREACH OF EXPRESS WARRANTY
(By Plaintiff Individually and on Behalf of the Class)

103. Plaintiff reasserts the allegations set forth in the factual allegations paragraphs above and incorporates such allegations by reference herein.

104. The Uniform Commercial Code, including U.C.C. § 2-313 covers express warranties. That section provides that "any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." U.C.C. § 2-313(1)(a). Further, "[a]ny description of the goods which is made part of the basis of the bargain creates an express warranty that the good shall conform to the description." Id. § 2-313(1)(b).

105. Defendant marketed, sold, and/or distributed Librela, and Plaintiff and members of the Class purchased Librela.

106. Defendant represented and described in their marketing, advertising, and promotion of Librela that the drug provided a safe means of treating pain associated with osteoarthritis in dogs. However, Defendant failed, or otherwise refused, to disclose that the product posed certain serious safety risks to consumers and their pets.

107. Defendant's representations were of a kind that would naturally induce Plaintiff and members of the Class to purchase Librela.

108. Accordingly, Defendant's representations and omissions that Librela provided a safe means of treating pain associated with osteoarthritis in dogs, while refusing to disclose the serious safety risks posed by the product to consumers and their pets, became part of the basis of the bargain between Defendant on the one hand, and Plaintiff and the members of the Class on the other.

109. Librela did not conform to Defendant's representations, descriptions, and warranties that the product provided a safe means of treating pain associated with osteoarthritis in dogs, because at all relevant times Librela posed serious, continuous safety risks to pets. This constitutes a breach of the product's express warranties.

110. As a direct and proximate result of Defendant's breaches of their express warranties and their failure to conform to Librela's representations and descriptions, Plaintiff and the members of the Class have been damaged in an amount to be proven at trial.

111. Plaintiff and the members of the Class have suffered damages in that they did not receive the safe product for which they paid and which Defendant warranted it to be. Plaintiff and the members of the Class would not have purchased Librela on the same terms if the true facts concerning the risks associated with the use of the drug had been disclosed.

FOURTH CLAIM FOR RELIEF
BREACH OF IMPLIED WARRANTY
(By Plaintiff Individually and on Behalf of the Class)

112. Plaintiff reasserts the allegations set forth in the factual allegations paragraphs above and incorporates such allegations by reference herein.

113. The Uniform Commercial Code, including U.C.C. § 2-314 covers the implied warranty of merchantability. That section provides that "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." U.C.C. § 2-314(1).

114. At all relevant times, Defendant was a merchant with respect to Librela, which was sold to Plaintiff and the members of the Class, and Defendant was in the business of selling such products.

115. Librela, manufactured and sold by Defendant, came with an implied warranty that it would be merchantable and fit for the ordinary purpose for which such a product would be used, including impliedly warrantying on the label for Librela that the product was merchantable and fit for the ordinary purposes for which they were sold—namely, as a safe means of treating pain associated with osteoarthritis in dogs.

116. Defendant marketed, sold, and/or distributed Librela, and Plaintiff and the members of the Class purchased Librela.

117. Defendant breached their implied warranty of merchantability pursuant to U.C.C. § 2-314 because Librela was not safe and posed serious safety risks to pets, thereby failing of their ordinary and intended purpose.

118. When Defendant sold Librela, the product was unsafe, was not merchantable, did not pass without objection in the trade as a safe drug for the purpose of treating pain associated with osteoarthritis in dogs, was not of adequate quality within that description, was not fit for the ordinary purposes for which such goods are used, was not adequately labeled, and did not conform to the promises or affirmations of fact made on the packaging and/or label. See U.C.C. § 2-314(2).

119. U.C.C. § 2-315, covers the implied warranty of fitness for particular purpose. That section provides that "where the seller . . . has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose" U.C.C. § 2-315.

120. The Librela drug sold by Defendant came with an implied warranty that it would be suitable and appropriate for a particular purpose: to treat pain associated with osteoarthritis in dogs. Defendant marketed, sold, and/or distributed Librela for this particular purpose.

121. Plaintiff and the members of the Class purchased Librela for a particular purpose: to treat pain associated with osteoarthritis in dogs and to provide such treatment in a safe manner.

122. At all relevant times, Defendant had advanced skills and judgment relating to Librela based on their knowledge and experience gained through years of designing, developing, and testing Librela and similar products intended for use on and by pets. At all relevant times, Defendant was in a better position of skill, judgment, knowledge, and experience as sellers of pet pharmaceutical products than of those consumers who would consider purchasing or would purchase Librela.

123. Plaintiffs and the members of the Class relied on Defendant's skill, judgment, knowledge, and experience relating to Librela in allowing the product to be used on their pets. Likewise, Plaintiff and the members of the Class relied on Defendant to use their skill, judgment, knowledge, and experience in furnishing Librela to consumers for purchase and use.

124. Defendant had reason to know that Plaintiff and the members of the Class were likely to purchase and would purchase, Librela for this particular purpose—to provide a safe means of treating pain associated with osteoarthritis in dogs—as that was its intended and marketed purpose. Further, Defendant had reason to know that Plaintiff and the members of the Class were likely to rely on Defendant's advanced skill, judgment, knowledge, and experience relating to Librela in selecting the product for sale and furnishing a safe product for purchase by consumers and for use on and by pets.

125. When Defendant sold Librela, the product was unsafe and was not fit for the particular purchase for which they were purchased—namely, as a safe means of treating pain associated with osteoarthritis in dogs.

126. Defendant breached the implied warranty of fitness for a particular purpose pursuant to U.C.C. § 2-315 because Librela was not safe and posed serious safety risk to pets, thereby failing the particular purpose for which they were sold and purchased.

127. Librela is not fit for its intended use—or any use—because they have dangerous propensities when used as intended and pose serious safety risks to dogs.

128. As a direct and proximate result of Defendant's breaches of (1) the implied warranties of merchantability and (2) the implied warranties of fitness for a particular purpose, Plaintiff and the members of the Class have been damaged in an amount to be proven at trial. Plaintiff and the members of the Class have suffered damages in that they did not receive (1) the merchantable product that was fit for its ordinary purpose for which they paid and which Defendant warranted it to be, and (2) a product that was fit for the particular purpose for which they paid and which Defendant warranted it to be. Plaintiff and the members of the Class would not have purchased Librela on the same terms if the true facts concerning the risks associated with the use of Librela had been disclosed.

FIFTH CLAIM FOR RELIEF
NEGLIGENCE
(By Plaintiff Individually and on Behalf of the Class)

129. Plaintiff reasserts the allegations set forth in the factual allegation paragraphs above and incorporates such allegations by reference herein.

130. Defendant, directly or indirectly, caused Librela to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff and the members of the Class.

131. At all times relevant, Defendant had a duty to exercise reasonable care in the marketing, advertisement, and sale of Librela. Defendant's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks

of using Librela and appropriate, complete, and accurate warnings concerning the potential adverse effects of exposure to Librela, and, in particular, its active ingredient bedinvetmab.

132. At all times relevant, Defendant knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Librela and its active ingredient bedinvetmab.

133. Defendant knew, or otherwise should have known, that their Librela marketing and advertising statements as to Librela's safety and efficacy were false based upon: (1) their own internal testing, data, and surveys; (2) numerous consumer complaints lodged directly with Defendant and/or lodged with the FDA and conveyed to Defendant; (3) numerous consumer complaints lodged to retailers; and (4) numerous consumer complaints on online fora.

134. Accordingly, at all times relevant, Defendant knew or, in the exercise of reasonable care, should have known that their marketing and advertising statements for Librela were false and/or misleading in that they failed to disclose the true efficacy and serious adverse events to pets as a result of taking Librela.

135. Defendant also knew or, in the exercise of reasonable care, should have known that purchases of Librela were unaware of the risks and the magnitude of the risks associated with use of and/or exposure to Librela (bedinvetmab).

136. Defendant omitted, concealed, and failed to disclose to consumers that Librela poses serious safety risks to pets, including adverse events listed in ¶ 1. Rather than disclose this information, Defendant marketed Librela as safe for its intended purpose.

137. As such, Defendant breached the duty of reasonable care and failed to exercise ordinary care in the marketing, promotion, advertisement, packaging, sale, and distribution of Librela, in that Defendant marketed, promoted, and sold a product containing bedinvetmap, knew or had reason to know of the true efficacy and safety profile of the product, knew or had reason to

know that a consumer's pet's exposure to the product created a significant risk of harm and because of dangerous side effects to the pet, and failed to adequately disclose or warn consumers of the true efficacy and safety profile of the product.

138. In breach of their duties, Defendant negligently:

a. Failed to conduct adequate research and testing to determine the extent to which exposure to Librela was likely to cause harm to the animals who used it;

b. Failed to conduct adequate research and testing to determine the extent to which Librela was likely to cause or contribute to causing neurological or other damage that was both permanent and cumulative and the extent to which repeated exposures were likely to cause or contribute to cause clinically significant neurological or other injuries;

c. Failed to conduct adequate research and testing to determine the true efficacy of Librela;

d. Failed to warn consumers through their marketing and advertising statements that Librela could cause serious injuries to pets, including but not limited to causing neurologic injury that was both permanent and cumulative, or other injuries listed in ¶ 1.

139. Despite the ability and means to investigate, study, and test Librela and to provide adequate warnings, Defendant has failed to do so. Indeed, Defendant has wrongfully concealed information and have further made false and/or misleading statements concerning the safety and/or exposure to Librela and bedinvetmab.

140. Defendant was negligent in the following respects:

a. Promoting, advertising, selling, and/or distributing Librela without thorough and adequate pre-and post-market testing;

b. Promoting, advertising, selling, and/or distributing Librela while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of exposure to bedinvetmab, and, consequently, the risk of serious harm associated with use of and exposure to Librela;

c. Failing to undertake sufficient studies and conduct necessary testing and adverse event analysis to determine whether Librela was safe for its intended use;

d. Failing to provide adequate instructions, guidelines, and safety precautions to those consumers and their pets who Defendant could reasonably foresee would use and be exposed to Librela;

e. Failing to disclose to Plaintiff, Class members, users/consumers, and the general public that use of and exposure to Librela presented severe risks of neurological injury and other grave injuries in dogs;

f. Failing to warn Plaintiffs and Class members, consumers, and the general public that Librela's risk of harm was unreasonable and that there were safer and effective alternative treatments available to Plaintiffs and other consumers;

g. Systematically suppressing or downplaying evidence about the risks, incidence, and prevalence of the side effects of Librela and bedinvetmap;

h. Representing that Librela was safe for its intended use when, in fact, Defendant knew or should have known that the product was not safe for their intended purpose;

i. Failing to make and/or submit any changes to Librela's labeling or other promotional materials that would alert the consumers and the general public of the risks of Librela and bedinvetmab;

j. Advertising, marketing, and recommending the use of Librela while concealing and failing to disclose or warn of the dangers known by Defendant to be associated with or caused by the use of or exposure to Librela and bedinvetmab;

k. Continuing to disseminate information to its consumers, which indicates or implies that Defendant's Librela was safe for use on dogs; and

l. Continuing the manufacture and sale of its products with the knowledge that Librela was unreasonably unsafe and dangerous.

141. Defendant knew, or otherwise should have known, that it was foreseeable that consumers' pets, including Plaintiff's and the Class members' pets, would suffer injuries as a result of Defendant's failure to exercise ordinary care in the marketing, promotion, labeling, distribution, and sale of Librela.

142. Plaintiff and the members of the Class did not know the nature and extent of the injuries that could result from the intended use of and/or exposure to Librela and bedinvetmab.

143. Defendant's negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff and the members of the Class suffered, as described herein, including the injuries suffered by Plaintiff and the Class members' pets.

144. Defendant's conduct, as described above, was reckless. Defendant risked the lives of consumers' pets, with full knowledge of the dangers of Librela. Defendant made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiff and the members of the Class. Defendant's reckless conduct therefore warrants an award of punitive damages.

145. As a proximate result of Defendant's wrongful acts and omissions in placing Librela into the stream of commerce without adequate research and without adequate and accurate disclosure of the hazardous and neurotoxic nature of Librela (bedinvetmab) through its marketing and advertising statement for Librela, Plaintiff and the members of the Class have suffered economic damages and property damages as a result of the physical injuries and/or death suffered by their pets. Plaintiff and the members of the Class have suffered damages (including significant expenses for medical care and treatment of their pets) in an amount to be determined.

SIXTH CLAIM FOR RELIEF
UNJUST ENRICHMENT
(By Plaintiff Individually and on Behalf of the Class)

146. Plaintiff reasserts the allegations set forth in the factual allegations paragraphs above and incorporates such allegations by reference herein.

147. As described herein, Defendant represented in the Librela packaging, labeling, marketing, advertising, and promotion that the drug provides a safe means of treating pain associated with osteoarthritis in dogs. Defendant has continued to tout the safety of Librela even though Librela has been linked to pet death and neurological and other injuries in dogs.

148. Contrary to these representations, Librela poses an unreasonable safety risk to pets.

149. Defendant omitted, concealed, and failed to disclose to consumers that Librela poses serious safety risks to pets, including that Librela was inherently defective; unreasonably

dangerous; not fit to be used for its intended purpose and/or caused serious health problems. Rather than disclose this information, Defendant marketed Librela as safe for their intended purpose.

150. Due to its misrepresentations and omissions, Defendant has knowingly and unjustly been enriched at the expense of and to the detriment of Plaintiff and the Class members by collecting excess profits to which it is not entitled.

151. Defendant has unjustly retained those ill-gotten gains and should be required to disgorge this unjust enrichment.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the members of the Class described in this Complaint, respectfully request the Court to enter an Order:

A. Certifying the proposed class under Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), and, in the alternative, (c)(4) as set forth above;

B. Declaring that Defendant is financially responsible for notifying the Class members of the pendency of this suit;

C. Declaring that Defendant has committed the violations of law alleged herein;

D. Providing for any and all injunctive relief the Court deems appropriate;

E. Awarding statutory damages, including treble damages, in the maximum amount for which the law provides;

F. Awarding monetary damages, including but not limited to any compensatory, incidental, or consequential damages in an amount that the Court or jury will determine, in accordance with applicable law;

G. Providing for any and all equitable monetary relief the Court deems appropriate;

H. Awarding punitive or exemplary damages in accordance with proof and in an amount consistent with applicable precedent;

I. Awarding Plaintiff and the members of the Class their reasonable costs and expenses of suit, including attorneys' fees;

J. Awarding pre-and post-judgment interest to the extent the law allows; and

K. Providing such further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury on all claims so triable.

Dated: October 9, 2024

PARAFINCZUK WOLF

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