UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

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VALERIE PALMIERI, DIANE GORDON, TERI IPPOLITO, PATTI MASTRIC, GAYLE MORASKI, HOLLY REEVES, and AMY TUCKER, <i>individually and on behalf of all others</i> <i>similarly situated</i> , Plaintiffs,	SECOND AMENDED CLASS ACTION COMPLAINT JURY TRIAL DEMANDED
V.	No. 2:19-CV-22024
INTERVET INC. d/b/a MERCK ANIMAL HEALTH, a subsidiary of MERCK & CO., INC.,	The Honorable Julien Xavier Neals
Defendant.	

Plaintiffs Valerie Palmieri, Diane Gordon, Teri Ippolito, Patti Mastric, Gayle Moraski, Holly Reeves, and Amy Tucker (collectively, "Plaintiffs"),¹ individually and on behalf of all others similarly situated (collectively, the "Class," as more fully defined below), bring this class action complaint against Defendant Intervet Inc., d/b/a Merck Animal Health, a subsidiary of Merck & Co., Inc. ("Intervet" or "Defendant"). Plaintiffs make the following allegations upon personal knowledge as to their own acts, upon information and belief, and their attorneys' investigation as to all other matters, alleging as follows:

I. <u>NATURE OF THE ACTION</u>

1. Bravecto is the trade name for the drug fluralaner, which includes a pesticide called isoxazoline. In May 2014, the U.S. Food and Drug Administration ("FDA") approved the marketing and sale of Bravecto tablets for dogs and Bravecto topical solutions for cats and dogs (collectively, "Bravecto") for the treatment and prevention of flea and tick infestations. Bravecto is produced and marketed by Defendant Intervet Inc. d/b/a Merck Animal Health, which is a subsidiary of Merck & Co., Inc.

2. Like other pesticides used to kill bugs, consumers purchase flea and tick products, including collars, shampoos and topical applications directly from retail stores, like PetSmart or Walmart. Although products used to prevent ticks and fleas on pets are not a treatment for a medical condition, manufacturers have also created topical products that require a veterinarian's prescription similar to "prescription pet food," which has not received the FDA's approval as a "drug." Chewable tablets and topical applications, like Bravecto, are the most recent development in products used to treat flea and ticks that require a prescription from a veterinarian.

¹ Plaintiffs have amended their complaint in accordance with the Court's June 1, 2021 Order (ECF No. 41). Reference to prior versions of websites and other materials is sometimes made in this complaint given that Plaintiffs alleged that their causes of action arose when that language was operative.

3. Similar to other flea and tick treatments, Defendant advertises and markets Bravecto directly to consumers—including to the Plaintiffs—nationally as a safe chewable tablet for dogs or a topical application that prevents and kills ticks and fleas for up to three months, while competing products provide only one month of protection. Bravecto is advertised directly to consumers on television, online through its own website, through displays in veterinarian offices, information provided to veterinarians, and through other retailers' websites.

4. Bravecto is a pesticide that when used, is absorbed into the host animal's blood stream and subsequently causes toxicity in insects that bite those animals, such that the insects experience uncontrolled neural activity and, eventually, death. Because of the method by which it kills insects, Bravecto also presents a risk of neurological toxicity in the animals that ingest it. Unfortunately, Defendant failed to adequately disclose this risk to consumers, including Plaintiffs and the other Class members and their veterinarians.

5. As a result of Defendant's failure to disclose the known risk, reasonable consumers purchased Bravecto and paid a particular price for it without knowing the significant risk of neurological toxicity.

6. On September 20, 2018—more than four years after Defendant began marketing and selling Bravecto—the FDA issued an alert (the "FDA Press Release") on the potential neurological adverse events associated with isoxazoline medications to treat flea and ticks, including Bravecto.² In that press release, the FDA stated that it was requesting that manufacturers change their labels from their current inadequate notices of such risks to "highlight neurological

² FDA, Animal Drug Safety Communication: FDA Alerts Pet Owners and Veterinarians About Potential for Neurologic Adverse Events Associated with Certain Flea and Tick Products (Sept. 20, 2018), <u>https://www.fda.gov/animal-veterinary/cvm-updates/animal-drug-safety-communication-fda-alerts-pet-owners-and-veterinarians-about-potential-neurologic</u> (last visited July 1, 2020) (the "FDA Press Release").

events because these events were seen consistently across the isoxazoline class of products" and "provide veterinarians and pet owners with the information they need to make treatment decisions for each pet on an individual basis." The FDA Press Release also indicated that certain manufacturers—but not Defendant—had made the requested label change.

7. Defendant now discloses a risk of some neurologic adverse reactions including tremors, ataxia, and seizures from Bravecto.³

Despite touting the three-month, long lasting duration of Bravecto, on July 9,
 2020, Defendant introduced a less potent, one-month dose of Bravecto.⁴

9. The FDA, European government agencies, and likely Defendant, have received thousands of reports relating to adverse events from isoxazoline products, including Defendant's, Bravecto. A significant number of these adverse events relate to neurological symptoms.

10. In fact, in June 2021, because of increased reporting of adverse events to regulators and in the media, the FDA issued another press release alerting consumers of the risk of adverse events relating to flea and tick products and encouraging them to read all labels, packaging and inserts relating to those products to be aware of possible adverse reactions.⁵ The FDA simultaneously also issued a press release explaining how to report adverse reactions.⁶

³ Bravecto, FAQ, <u>https://us.bravecto.com/faq</u> (last visited July 1, 2020); Merck, Bravecto, <u>https://www.merck-animal-health-</u>

<u>usa.com/pdfs/canine/BravectoDogPI_152451%20R11_8.5x11.pdf</u> (last visited June 26, 2020).

⁴ Business Wire, Merck Animal Health Receives U.S. FDA Approval of BRAVECTO® (fluralaner) Monthly Chews, July 9, 2020,

https://www.businesswire.com/news/home/20200709005926/en/Merck-Animal-Health-Receives-U.S.-FDA-Approval-of-BRAVECTO%C2%AE-fluralaner-Monthly-Chews (last visited June 21, 2021).

⁵ FDA, Safe Use of Flea and Tick Products, current as of June 22, 2021 <u>https://www.fda.gov/consumers/consumer-updates/safe-use-flea-and-tick-products-pets</u> (last visited Jun. 22, 2021).

⁶ FDA, How to Report Problems Flea and Tick Products, current as of June 17, 2021

11. Consumers of Bravecto—including Plaintiffs and the other Class members—paid a premium for Bravecto, based on its purportedly safe extended prevention and control of flea and tick infestations, as compared to other products. Defendant, however, misrepresented or omitted the risk of neurological adverse reactions caused by Bravecto.

12. Defendant's omission of critical information from the Class members is further demonstrated by its attempts to "buy off" certain Class members—by offering them a check in exchange for silence and agreeing not to hold Defendant responsible for the problems cause by Bravecto while continuing to deny its role in consumers' pets' illnesses. These attempts to buy silence have likely negatively impacted other consumers and Class members.

13. Every consumer who purchased Bravecto without being informed of the facts about its health and safety risks prior to purchase was injured at the point of sale when, instead of obtaining a safe flea and tick medication, as was represented to them before their purchase by way of Defendant's failure to did not disclose the risk of neurological adverse events, which was—a substantial factor in their decision to make their purchase at the price that they paid for Bravecto,— they selected Defendant's unreasonably dangerous and defective product instead.

14. Further, consumers who purchased Bravecto experienced consequential damages in the form of veterinarian treatment of their pets who were harmed as a result of Bravecto's undisclosed safety issues.

15. By omitting the dangers that Bravecto poses to pets—specifically, risk of neurologic adverse reactions including tremors, ataxia, and seizures - and by thus misrepresenting the safety of Bravecto, Defendant defrauded Plaintiffs and the other Class members, deprived them

https://www.fda.gov/consumers/consumer-updates/how-report-problems-flea-and-tick-products (last visited Jun. 22, 2021).

of the benefit of their bargain, and/or was unjustly enriched at Plaintiffs' and the other Class members' expense. Plaintiffs, individually and on behalf of the other Class members they seek to represent, seek monetary damages, statutory penalties, and injunctive relief as set forth herein.

II. JURISDICTION AND VENUE

16. Jurisdiction is proper in this Court pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because at least one Class member is of diverse citizenship from the Defendant, there are more than 100 class members, and the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs. This Court has supplemental jurisdiction over Plaintiffs' state law claims under 28 U.S.C. § 1367.

17. This Court has personal jurisdiction over Defendant because Defendant is headquartered in the State of New Jersey and has purposefully availed itself of the privilege of conducting business in the State of New Jersey. Some, if not most, of the actions giving rise to the Complaint took place in this District, including but not limited to Defendant's manufacturing, distribution, advertising and representations regarding Bravecto, and Defendant's use of a call center to receive complaints from customers regarding adverse reactions. Most, if not all, of Plaintiffs' claims arise out of Defendant operating, conducting, engaging in, or carrying on a business or business venture in this State, or having an office or agency in this State, committing a tortious act in this State, and causing injury to property in this State arising out of Defendant's own acts and omissions outside this State. At or about the time of such injuries, Defendant was engaged in solicitation or service activities within this State, or else products, materials, or things processed, serviced, or manufactured by Defendant anywhere were used or consumed within this State in the ordinary course of commerce, trade, or use.

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a), because a substantial part of the events or omissions giving rise to these claims occurred in this District, Defendant has caused harm to class members residing in this District, and Defendant is a resident of this District under 28 U.S.C. § 1391(c)(2), because it is subject to personal jurisdiction in this District.

III. <u>PARTIES</u>

Plaintiffs



Plaintiff Palmieri's dog Jake

19. Plaintiff Valerie Palmieri is a resident and citizen of the State of Connecticut, residing in Monroe, Connecticut. Ms. Palmieri purchased the Bravecto product to treat her pet dog Jake on or around November 13, 2016. Ms. Palmieri viewed Defendant's packaging and materials and the display featuring Bravecto in her veterinarian's office and discussed the products with her veterinarian prior to her purchase that represented the products as safe and effective flea and tick medication and that did not disclose any risk of neurological adverse reactions. These representations about Bravecto and the absence of any warning about neurological adverse

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reactions were a substantial factor in her decision to purchase Bravecto and pay the price she paid for it. Ms. Palmieri would not have given the Bravecto product to her pet, or would have paid significantly less for it, if Defendant had disclosed such risks. After administering Bravecto, Ms. Palmieri's dog Jake vomited, stopped eating, exhibited other symptoms of lethargy, and was diagnosed as having had a seizure. Jake continues to suffer additional neurological episodes, which has resulted and will continue to result in in veterinary and medical expenses.



Plaintiff Gordon's dog Charlie

20. Plaintiff Diane Gordon is a resident and citizen of the State of Illinois, residing in Aurora, Illinois. Ms. Gordon purchased the Bravecto product to treat her pet dog Charlie in May and September 2015 that purported to provide three months of flea and tick protection—until December 2015 based upon application in September 2015. Ms. Gordon viewed Defendant's packaging and materials and the display featuring Bravecto in her veterinarian's office and

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discussed the product with her veterinarian prior to her purchase that represented the products as safe and effective flea and tick medication and that did not disclose any risk of neurological adverse reactions. These representations about Bravecto and the absence of any warning about neurological adverse reactions were a substantial factor in her decision to purchase Bravecto and pay the price she paid for it. Ms. Gordon would not have given the Bravecto product to her pet, or would have paid significantly less for it, if Defendant had disclosed such risks. After administering Bravecto, Ms. Gordon's dog Charlie suffered at least two seizures, and passed away on or around November 1, 2015.



Plaintiff Ippolito's dog Cooper

21. Plaintiff Teri Ippolito is a resident and citizen of the State of Florida, residing in Lutz, Florida. Ms. Ippolito purchased the Bravecto product to treat her pet dog Cooper on or around June 1, 2016. Ms. Ippolito viewed Defendant's packaging and discussed the products with her veterinarian prior to her purchase that represented the products as safe and effective flea and tick medication and that did not disclose any risk of neurological adverse reactions. These representations about Bravecto and the absence of any warning about neurological adverse reactions were a substantial factor in her decision to purchase Bravecto and pay the price she paid

for it. Ms. Ippolito would not have given the Bravecto product to her pet, or would have paid significantly less for it, if Defendant had disclosed such risks. After administering Bravecto, Ms. Ippolito's dog Cooper immediately had trouble standing up, became disoriented, and started pacing and slobbering. After nearly a year of suffering, Ms. Ippolito was forced to euthanize Cooper.



Plaintiff Mastric's dogs Trey and Duncan

22. Plaintiff Patti Mastric is a resident and citizen of the State of Florida, residing in New Smyrna, Florida. Ms. Mastric purchased the Bravecto product to treat her pet dog Duncan and Trey on or around June 3, 2015. Ms. Mastric viewed Defendant's packaging and materials and the display featuring Bravecto in her veterinarian's office and discussed the products with her veterinarian prior to her purchase of the Bravecto product, which was represented as safe and effective flea and tick medication and that did not disclose any risk of neurological adverse reactions. These representations about Bravecto and the absence of any warning about neurological adverse reactions were a substantial factor in her decision to purchase Bravecto and pay the price she paid for it. Ms. Mastric would not have given the Bravecto product to her pet, if Defendant had disclosed such risks. After administering Bravecto, Ms. Mastric's dog Duncan collapsed and died less than 24 hours after administration of Bravecto, and her dog Trey became unresponsive and suffered neurological issues and seizures for almost four years before passing away during a seizure on May 8, 2019. In the interim period of time, Ms. Mastric incurred veterinary and medical bills.



Plaintiff Moraski's dog Summer

23. Plaintiff Gayle Moraski is a resident and citizen of the State of Connecticut, residing in Winsted, Connecticut. Ms. Moraski purchased the Bravecto product to treat her pet dog Summer in or around August 2015 and made her most recent purchase on September 22, 2018, of a year's supply consisting of four doses purporting to be effective for three months. Ms. Moraski continued to use the product until September 2019, discontinuing use when her dog began suffering seizures. Ms. Moraski never received notice that Bravecto could cause neurological adverse events including from Defendant or her veterinarian nor did she see or hear about the FDA press release issued relating to this risk from Bravecto. Ms. Moraski viewed Defendant's packaging and materials and the display featuring Bravecto in her veterinarian's office that

represented the products as safe and effective flea and tick medication and that did not disclose any risk of neurological adverse reactions, and she discussed the product with her veterinarian prior to her purchase. These representations about Bravecto and the absence of any warning about neurological adverse reactions were a substantial factor in her decision to purchase Bravecto and pay the price she paid for it. Ms. Moraski would not have given the Bravecto product to her pet, or would have paid significantly less for it, if Defendant had disclosed such risks. On September 21, 2019, after taking Bravecto, Summer suffered numerous seizures, and was diagnosed with focal seizures. As a result, she has had to pay medical and veterinary expenses.



Plaintiff Reeves' dog Remi

24. Plaintiff Holly Reeves is a resident and citizen of the State of Texas, residing in Houston, Texas. Ms. Reeves purchased the Bravecto product in March and September of 2018 to treat her pet dog Remi in March, June, and September of 2018, discontinuing its use after her dog began suffering seizures. Ms. Reeves viewed Defendant's packaging and materials and the display featuring Bravecto in her veterinarian's office that represented the products as safe and effective flea and tick medication and that did not disclose any risk of neurological adverse reactions, and discussed the product with her veterinarian prior to her purchase. These representations about Bravecto and the absence of any warning about neurological adverse reactions were a substantial factor in her decision to purchase Bravecto and pay the price she paid for it. Ms. Reeves would not have given the Bravecto product to her pet, or would have paid significantly less for it, if Defendant had disclosed such risks. Soon after being administered Bravecto, Remi began experiencing seizures in October of 2018, and continues to experience seizures approximately once per month, often in clusters lasting for several days. No other cause for Remi's seizures could be determined after extensive blood tests, and she continues to have seizures and must take seizure medication for the rest of her life. As a result, Ms. Reeves has veterinary and medical expenses that she otherwise would not have had.



Plaintiff Amy Tucker's dog Duchess

25. Plaintiff Amy Tucker is a resident of the State of New York, residing in Delmar, New York. Ms. Tucker purchased the Bravecto product to treat her dogs Gizmo and Duchess in November of 2016. Ms. Tucker viewed Defendant's packaging and materials and the display featuring Bravecto in her veterinarian's office, reviewed information relating to Bravecto on Chewy.com and discussed the product with her veterinarian prior to her purchase of the Bravecto product, which was represented as a safe and effective flea and tick medication and that did not disclose any risk of neurological adverse reactions. These representations about Bravecto and the absence of any warning about neurological adverse reactions were a substantial factor in her decision to purchase Bravecto and pay the price she paid for it. Ms. Tucker would not have given the Bravecto product to her pets if Defendant had disclosed such risks. Within days after administering Bravecto, Duchess began to experience a loss of appetite and difficulty walking and standing upright. On December 9, 2016, Ms. Tucker was forced to euthanize Duchess due to the severe adverse effects she suffered, which were caused by Bravecto.

Defendant

26. Defendant Intervet identifies its address in Madison, New Jersey, including on its Bravecto packaging. Intervet's registered business address with the State of New Jersey is Kenilworth, New Jersey. Intervet does business under the name Merck Animal Health and is a subsidiary of Merck & Co., Inc. Intervet manufactures, distributes, markets, and sells Bravecto to consumers and veterinarians across the United States from its New Jersey headquarters.

IV. <u>COMMON FACTUAL ALLEGATIONS</u>

A. Bravecto can seriously harm pets. Rather than inform its consumers, Defendant hid the truth.

27. Since its launch in 2014 continuing today, thousands of consumers and veterinarians have reported adverse events relating to isoxazoline flea and tick treatments, including from Bravecto. Information obtained through public records requests to the FDA, and its European counterpart the European Medicines Agency ("EMA"), demonstrate that animals treated with isoxazoline medications experienced consistent neurological adverse reactions, including but not limited to, death, seizures, shaking/tremors/ataxia, neurological/cognitive issues, muscular/balance issues and vomiting/loss of appetite.

28. Plaintiffs' experiences are no different—after treating their pets with Bravecto, their beloved pets became seriously ill, demonstrating the same symptoms described above.

29. Defendant was aware (or, at the very least, was on notice) of these adverse neurological risks for several reasons.

- Bravecto is ingested or applied to animals and absorbed into their blood
 stream in order to penetrate nervous systems and cause death of insects—
 its functionality alone leads to a known risk; and
- Further, consumers issued numerous complaints concerning neurological adverse reactions following use of Bravecto since it was released to the market in 2014 and through at least late 2018.

30. While Defendant knew of these risks, it never disclosed them to consumers and their veterinarians. In contrast, it misrepresented Bravecto as a safe and effective flea and tick product, and omitted warnings about the risk of any adverse reactions to consumers and their veterinarians, representations upon which consumers based their purchase and paid the price they did for it. Defendant knew that these misrepresentations and undisclosed risks deprived consumers and their veterinarians of the ability to make an informed decision as to whether to purchase Bravecto at the price at which it was offered and to use it on their pets.

31. Consumers were deprived of the ability to make informed purchasing decisions concerning the medical treatment, health, and welfare of their pets and—as demonstrated above—in some instances were unknowingly poisoning their pets with toxic medications.

32. According to a parasitology expert at the College of Veterinary Medicine at the University of Illinois Urbana-Champaign, "Isoxazoline class medications bind to chloride channels in nerve and muscle cells, which blocks the transmission of neuronal signals, causing

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parasites to become paralyzed and die." The expert also stated that, "[isoxazoline class medications] can still cause toxicity in mammals, depending on the animal's physiological state, health, and history."⁷

33. Defendant's own study on Bravecto published on May 31, 2016, which was not made available to consumers (nor would consumers know to look for such a study having received no warning about such adverse events from Bravecto) determined that Bravecto has the ability to cross an animal's cell membranes to bind to them, which is what prevents it from being eliminated from their body except over a long period of time. However, this science can also present the risk to an animal's own nervous systems:

Fluralaner shows a relatively high apparent distribution ($V_z = 3.1$ L/kg in dogs and 3.5 L/kg in cats) into tissues following i.v. infusion. This is expected because the physicochemical properties of fluralaner with a molecular weight of 556.29, an unionized state at physiological pH (1–12), and a high logP_{ow} value of 5.35 favour the ability to cross cell membranes. . . For fluralaner, the main route of elimination is likely hepatic because the high plasma protein binding indicates minimal elimination via renal filtration. . . . The low clearance may be due to the high protein binding of fluralaner, which limits the unbound fraction of fluralaner in the vascular system that can be presented to clearing organs and/or due to a low intrinsic hepatic capacity to metabolize fluralaner.⁸

⁷ College of Veterinary Medicine, University of Illinois Urbana-Champaign, FDA Alert on Flea Medication (Oct. 22, 2018), <u>https://vetmed.illinois.edu/pet_column/fda-alert-on-flea-medications/</u> ("Only medications in the isoxazoline class of flea and tick medications are under investigation at this time. This includes Bravecto, Nexgard, Credelio, and Simparica (brand names for fluralaner, afoxolaner, lotilaner, and sarolaner).") (last visited June 26, 2020).

⁸ Kilp, S., Ramirez, D., Allan, M.J. et al. Comparative pharmacokinetics of fluralaner in dogs and cats following single topical or intravenous administration. Parasites Vectors 9, 296 (2016). https://doi.org/10.1186/s13071-016-1564-8

https://parasitesandvectors.biomedcentral.com/articles/10.1186/s13071-016-1564-8 (last visited June 29, 2020).

34. Defendant's Material Safety Data Sheet, which was last revised on June 24,

2011—well before the launch of Bravecto—disclosed the following with respect to the Bravecto Chewable Tablet⁹:

Hazard Identification

Emergency Overview

May cause allergic reactions in susceptible individuals,

May cause effects to:

gastrointestinal tract

cardiovascular system

respiratory system

kidney liver

Very toxic to aquatic organisms.

It also cautions to use protective gloves when handling Bravecto. The "SUBCHRONIC /

CHRONIC TOXICITY" section revealed that:

[i]n a 90 day study of CBPI in rats, the NOAEL was established orally at the highest dose of 400 mg/kg/body weight/day. In a 90 day study in rats, the NOAEL was established dermally at the highest dose of 500 mg/kg/body weight/day. The liver is the main elimination organ of CBPI and a sensitive target for effects as reflected by increased liver enzyme activity in blood plasma with decreased lipid and protein concentration, increased organ weight and increased hepatocellular fatty change as the main functional endpoints in rats. In the absence of any indicator of liver injury (Kupffer cell proliferation, necrosis, apoptosis, fibrosis, other degenerative changes, etc.) these changes are considered to represent reversible metabolic effects and hence are of non-adverse character.

35. In contrast to Bravecto and other isoxazoline products, other flea and tick treatments are only applied to an animal's skin on a monthly basis. The benefit of Bravecto is that is guaranteed for future performance—eliminating insects for a longer period of time than

⁹ MSDS Digital, Bravecto MSD (Jun. 24, 2011), <u>https://www.msdsdigital.com/bravecto-msds</u>.

traditional, topical treatments in a safe way. But Bravecto is not safe, and these other, safer treatments are not absorbed into the animal's blood stream. Instead, they are stored in the animal's oil glands on its skin such that when insects come in contact with the animal's coat, and not through biting them as with isoxazoline products, they die.¹⁰

36. Before the FDA approved Bravecto for market, safety studies and clinical trials indicated that isoxazoline drugs could cause neurologic adverse reactions in animals. For example, in September 2013, the FDA approved NexGard, the first isoxazoline product to be sold in the U.S. NexGard disclosed in connection with studies on the adverse effects of its product that seizures occurred in dogs that used its product (similar to Intervet's own studies involving Bravecto), stating in part:

In the U.S. field study, one dog with a history of seizures experienced a seizure on the same day after receiving the first dose and on the same day after receiving the second dose This dog experienced a third seizure one week after receiving the third dose. The dog remained enrolled and completed the study. Another dog with a history of seizures had a seizure 19 days after the third dose of NexGard. The dog remained enrolled and completed the study. A third dog with a history of seizures received NexGard and experienced no seizures throughout the study.¹¹

37. Despite observing a similar trend of adverse neurological reactions in NexGard, which is part of the same class of isoxazoline drugs as Bravecto, Defendant did not adequately disclose such adverse events as a precaution or warning to its consumers of the risk of serious adverse reaction including neurological reactions. Instead—as described herein—it elected to hide this important information from its consumers.

¹⁰ Frontline, FAQ, <u>https://frontline.com/plus/Pages/Faq.aspx</u> (last visited June 26, 2020).

¹¹ VIN News, Alert on pet flea control draws questions, few answers (Oct. 5, 2018),

https://news.vin.com/default.aspx?pid=210&Id=8745908&useobjecttypeid=10&fromVINNEW SASPX=1 (last visited June 26, 2020).

38. Over 32,000 adverse events relating to isoxazolines were reported to the FDA from January 2013 to September 2017, including instances of 2.47% of deaths and 5.34% seizures, 6.8% shaking/tremors/ataxia, 2.1% neurological/cognitive and 5.49% muscular/balance issues. Of these, nearly 17,000 related to Bravecto with reports of 2.5% deaths, 2.8% seizures, 3.6% shaking/tremors/ataxia, 1.6% neurological/cognitive and 4.2% muscular/balance issues. Possible neurological adverse events of seizures, ataxia, neurological/cognitive and balance issues accounted for 12.2% of the reports to the FDA about Bravecto during this time.

39. Over 7,000 adverse events relating to isoxazolines were reported to the European Medicines Agency from January 2013 to January 2017 and over 39,000 from 2013-2019. The reports up to 2017 included 22.66% deaths, 30.25% seizures, 6.9% ataxia or tremors, 7.51% loss of motor function, limb stiffness, inability to walk, and 1.39% loss of coordination/balance. Specifically, 4,351 of these reported adverse events related to Bravecto with 23.56% deaths, 18.73% seizures, 6.23% ataxia or tremors, 7.54% loss of motor function, limb stiffness, inability to walk, 1.56% loss of coordination/balance. Possible neurological adverse events of seizures, ataxia, inability to walk and loss of balance accounted for 34.06% of the reports to the EMA about Bravecto during this time. The reports dating to 2019, however, included 14.9% of deaths and 16.02% of seizures overall relating to isoxazolines, and specifically 23.7% deaths and 18.3% seizures relating to Bravecto.

40. Following a review of its adverse event reports, the EMA concluded in July 2017, that Defendant had to update its package leaflet to include convulsions as a new side effect to advise veterinarians and pet owners to use Bravecto with caution in dogs with epilepsy.¹² But

¹² EMA, Tick and flea control agent Bravecto continues to be acceptably safe to use, Aug. 17, 2017, <u>https://www.ema.europa.eu/en/news/tick-flea-control-agent-bravecto-continues-be-acceptably-safe-use</u> (last visited June 30, 2020).

Defendant continued to conceal these adverse effects as a warning from consumers in the United States.

41. Through its website "us.bravecto.com" specifically for "pet parents¹³," Defendant encourages consumers to contact "Merck Animal Health at <u>1-800-224-5318</u>" "to report a suspected adverse drug reaction, contact."¹⁴ However, when they do, it denies any link to the serious adverse reactions their pets experienced after using Bravecto—including those of several Plaintiffs. In the event that Defendant agreed to pay something toward the veterinarian bills incurred after a consumer's pet became ill after use of Bravecto, it would only do so if the consumer agreed to sign a release barring future claims and to not disclose information relating to Defendant or their pet's experience with Bravecto.

42. In addition to the thousands of reports of adverse events provided to government agencies and relayed to Defendant, some consumers have publicly shared their own experiences. In September 2015, an individual wrote to a syndicated newspaper column, "Dr. Michael Fox," about that person's experience with administering Bravecto, which ultimately led to the pet's death. That individual then started a Facebook group involving the adverse effects of Bravecto, which now has over 48,000 members.¹⁵ Upon information and belief, Defendant has tried on multiple occasions to shut down this Facebook group.

¹³ "This site [merck-animal-health-usa.com] is intended for veterinary professionals. Vist our" <u>website [us.bravecto.com] for pet parents.</u>" Merck Animal Health, Bravecto <u>https://www.merck-animal-health-usa.com/bravecto/fleas-ticks-12-week-</u> treatment?gclid=CjwKCAjwt8uGBhBAEiwAayu 9QSPVZpihV53csRjQxOg7onfbS9dOIvGyL KHzw04ZzJsjU0gaW74UBoCCGEQAvD_BwE&gclsrc=aw.ds (last visited Jun. 23, 2021).

¹⁴ Bravecto, <u>https://us.bravecto.com/faq</u> (last visited Jun. 23, 2021).

¹⁵ Problems with Oral Anti-Flea and Tick Drug, Herald Standard (Sept. 20, 2015), <u>https://www.heraldstandard.com/columns/national_advice/michael_fox/problems-with-oral-anti-flea--tick-drug/article_10b9c43c-3005-53b6-8d11-</u> 0455dca3fd74.html?fbclid=IwAR3inCcepTZ8nS8vQ6Go_VVGj8MNovtNgL8a4HXkQJTYptc

43. Furthermore, Defendant was not only aware of Dr. Fox's column regarding

Bravecto, but it responded publicly to it in March 2016, downplaying the seriousness of the reports:

Global safety surveillance of Bravecto use has provided additional compelling evidence of the safety of the product. Bravecto has been prescribed to more than 13 million dogs in 60 countries around the world, and the frequency of adverse event reports is classified as rare. In addition to noting that adverse events are rare, it is also important to note that such events consist most commonly of mild and transient gastrointestinal upset, which is noted on the product label.

As a responsible animal health company, we take every single report of a potential adverse event seriously. Whenever possible, we work with the pet owner and attending veterinarian to assemble as much clinical information as we can to help determine the cause of a pet's health issue, and to what degree the product may have been involved.

We report all findings to governing regulatory agencies around the world, so that they can make a fully informed, scientific assessment about whether an adverse event is product related. We do this so that accurate safety and efficacy information is updated and made available for veterinarians prescribing our products and pet owners.¹⁶

44. Several of the Plaintiffs attempted to contact Defendant to make sure that it knew

about the problems Bravecto caused for their pets. Like its dismissal of Dr. Fox and other individuals' complaints about Bravecto, Defendant denied that Bravecto could have been the cause of Plaintiff Palmieri's pet's adverse neurological reaction when she reported it to Defendant. Similarly, Plaintiff Gordon's complaint to Defendant went without acknowledgement.

45. Defendants have even tried to quietly settle with some individuals, requiring them to sign non-disclosure agreements, preventing the public from finding out the risk that Bravecto causes pets.

Ax-1LcMTezxk.

¹⁶ Company Maintains Flea Medication Safe for Pets, NewsTimes (Mar. 3, 2016), <u>https://www.newstimes.com/opinion/article/Company-maintains-flea-medication-safe-for-pets-6868127.php</u>.

46. Unlike Bravecto, however, other isoxazoline products, including Nexgard,¹⁷ Simparica (approved in February 2016), and Credelio (approved in January 2018), disclosed risks of neurological adverse reactions in the form of a warning to consumers on their websites and with their products when selling those products to consumers. Simparica, for example, disclosed as a warning with its products that it "*may cause abnormal neurological signs such as tremors, ataxia Seizures."¹⁸

47. Defendant knew of the adverse reactions that pets were experiencing as a result of taking Bravecto; however, it opted to misrepresent its products and not disclose that information to consumers as a warning. Instead, it routinely denied consumers' claims that Bravecto caused pets' injuries and neurological problems.

48. Plaintiffs and Class members purchased Bravecto without having a full understanding of the real, material, and potentially deadly risks the product posed to their pets.

49. Defendant's failure to disclose this material information risks Class members' pets' lives and caused injury to, and the deaths of, some of these pets. Defendant's failure to disclose the material risks associated with its Bravecto product—its conscious decision to omit those facts from its disclosures to consumers—was unconscionable and demonstrated a reckless indifference to Plaintiffs, Class members, and their pets.

50. As a result of Defendant's failure to fully disclose the neurological risks associated with Bravecto as a warning to consumers and continued misrepresentations about Bravecto's

¹⁷ FDA Press Release, <u>https://www.fda.gov/animal-veterinary/cvm-updates/animal-drug-safety-communication-fda-alerts-pet-owners-and-veterinarians-about-potential-neurologic</u>.

¹⁸ Simparico, <u>https://www.zoetispetcare.com/products/simparica-trio?section=compare-protection&gclid=EAIaIQobChMIq6KKocSo6gIVCa_ICh2KrACsEAAYASAAEgIssPD_BwE</u> (last visited June 29, 2020). Plaintiffs make no representation as to the adequacy of the warnings for these other drugs, and plead only that, by comparison, Bravecto was more lethal and contained less of a warning.

purported safety and efficacy, consumers suffered and continue to sustain damages resulting from Defendant's misconduct. Ongoing damages as a result of Plaintiffs' treating their pets with Bravecto include, but are not limited to, more frequent veterinarian visits and additional medications, some being required for the duration of the life of the pet. These are damages that would not have been incurred but for using Bravecto.

51. Additionally, some pet owners sustained damages related to euthanizing their pets that they would have not otherwise incurred had their pet not taken Bravecto.

52. And many pet owners—like Plaintiffs—sustained significant, psychological trauma related to their pets' reactions to Bravecto, including their pets' passing.

53. Plaintiffs and members of the proposed Classes have suffered injury as a result of Defendant's concealment, misrepresentations and/or deceptive and unfair trade practices, which were a substantial factor in deciding to purchase Bravecto at the price they paid, and they are entitled to relief.

54. Plaintiffs and members of the proposed Classes are also entitled to the damages that necessarily flow from their pets' ingestion of Bravecto—including increased veterinary bills and, in the worst instances, the cost of euthanizing their pets and disposing of their remains. Plaintiffs and members of the proposed Classes also have standing to pursue damages related to their emotional distress, as discussed herein.

55. Had Defendant disclosed the risks of adverse neurological reactions associated with Bravecto, Plaintiffs and the other Class members would have been aware of these risks and would not have purchased Bravecto, or would not have paid the price that they paid for it. In the future, if Defendant additionally disclosed these risks beyond the still-limited disclosures it only

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now presently makes, as described below, Plaintiffs and others would be in a position to make an informed decision as to whether to purchase Bravecto at the prices offered.

56. Plaintiffs and the other Class members did not receive the benefit of their bargain with Defendant. Rather, they purchased products that are of a lesser standard, grade, and quality than represented, with undisclosed health and safety risks, or a lack warning of the same. Plaintiffs and the other Class members did not receive products that met ordinary and reasonable consumer expectations regarding safety and efficacy.

B. Defendant's marketing corroborated the presumption of Bravecto's safety.

57. Plaintiffs and Class members had no reason to know that the adverse effects pets experienced after taking Bravecto should have been attributed to Bravecto, because Defendant failed to disclose those risks publicly to consumers and to their veterinarians, denied that its product caused any of the problems that pets experienced, and created materials directed at consumers that further represented to reasonable consumers that Bravecto was allegedly safe for pets.

58. Defendant's central marketing theme for Bravecto, which is directed to consumers through advertising on television, online, and displays in veterinarian's offices and in the information that it provides to their veterinarians, is the purported safety of its quick-acting, effective, and long-lasting benefits in preventing and controlling flea and tick infestations in dogs and cats, as compared to other products that require more frequent application.

59. Rather than making disclosures about potential adverse effects related to seizures in pets, Defendant touted and continues to tout Bravecto's "safety" front and center on its

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marketing materials, claiming that it is "FDA approved and proven safe for both dogs and cats for

12 weeks."19



60. Under the "FAQ" page of its website, Defendant states in response to the question "HOW SAFE IS BRAVECTO?" that "BRAVECTO has a wide margin of safety in dogs who weigh at least 4.4 lb. and cats who weigh at least 2.6 lb. It is also approved for puppies and kittens aged 6 months or older. BRAVECTO Chew is approved for use in breeding, pregnant, and lactating dogs."²⁰

61. In May 2014, the FDA approved Defendant's sale of Bravecto chewable tablets for dogs and topical solution for cats and dogs for the treatment and prevention of flea and tick infestations, based on information from Defendant.

62. Because Bravecto is more potent than other flea and tick preventative products, consumers are instructed to give one tablet or apply the topical solution every twelve weeks, unlike

¹⁹ Bravecto, <u>https://us.bravecto.com/</u> (last visited June 26, 2020).

²⁰ Bravecto FAQs, <u>https://us.bravecto.com/faq</u> (last visited June 26, 2020).

the common monthly application of other products. In addition to its potency to last three months, Defendant also touts Bravecto's immediate effectiveness in killing fleas and ticks.

63. Defendant formulated Bravecto—a pesticide—in both an ingestible, chewable tablet form for dogs, and a topical solution for dogs and cats. Bravecto poisons insects through their nervous systems causing uncontrolled neural activity and death. Because of Bravecto's formulation as a toxic pesticide that it is ingested or applied to the skin of animals to prevent and kill fleas and ticks, it presents a risk of neurological toxicity in the animals that are treated with it, which is not known to consumers (nor would consumers have reason to know about these risks).

64. At no time during the time period relevant to this action did Defendant's Bravecto packaging provide adequate warning of possible adverse neurological reactions. To wit, and by way of example:



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	(Ctenocenhalides & I'd)	of flea infestations
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· 这一是当时提到了1月1日个	tick infestations [Ixodes scopularis	(black-legged tick),
4月1日在他的现在分词是	Dermacentor variabilis (American	dog tick) and
公 里的自己的第三人称单数	Rhipicephalus sanguineus (brown do	a tick]] for 12 weeks
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3 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	weighing 4.4 pounds or greater.	age and older, and
31-201 Mar 19-10		
	Bravecto is also indicated for the tre	atment and control
	of Amblyomma americanum (lone st	ar tick) infectations
	for 8 weeks in dogs and puppies 6 i	months of a
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a share to be the share	Dosage and administration: Bra	avecto should be
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	chew tablet by mouth once every 1	2 weeks (3 months)
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65. Defendant's Bravecto packaging insert also omitted these risks by asserting that in a "well-controlled U.S. field study," "there were no serious adverse reactions":

BRAVECTO° (FLURALANER) Chews		A BANK STAN	T
Flavored chews for dogs.			F
Caution: Federal (USA) law restricts this drug to	use by or on the order of a licensed veterin	arian.	
Each chew is formulated to provide a m	inimum dose of 11.4 mg/lb (25 mg/kg) bod	oromethyl)-4,5-dihydroisoxazol-3-uil a	
The chemical name of fluralaner methyl-N-[2-oxo-2-(2,2,2-trifluoroethy	is (±)-4-[5-(3,5-dichlorophenyl)-5-(triflu /lamino) ethyl]benzamide.	0.011ca	
Indications:	d for the treatment and prevention of flea	infestations (Ctenocephalides felis), and	
the treatment and control of tick infest tick), and Rhipicephalus sanguineus (br weighing 4.4 pounds or greater.	own dog tick)] for 12 weeks in dogs and p	ouppies 6 months of age and older, and	In a one inter
Bravecto is also indicated for the trea 8 weeks in dogs and puppies 6 months	tment and control of Amblyomma amer- of age and older, and weighing 4.4 pounds	iconum (lone star tick) infestations for or greater.	For t Add repo
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	Percentage of Dogs with Adverse Ri Adverse Reaction (AR)	Bravecto Group: Percentage of	Active Control Group: Percentage	Reproductive Saf a dose of up to 1	
		Dogs with the AR During the 182-Day Study (n=224 dogs)	of Dogs with the AR During the 84-Day Study (n=70 dogs)	dogs in the contro	
	Vomiting	7.1	14.3	There were no o performance, sen	
	Decreased Appetite	6.7	0.0	One adult treated	
	Diarrhea	4,9	29	salivation was ob	
	Lethargy	5.4	7.1	The following ab examination: lim	
xazol-3-yl]-2-	Polydipsia	1.8	43	veterinary exami	
	Flatulence	1.3	0.0	treated group ha necropsy (days 5	
les felis), and	In a well controlled by	and the second second second	and a second	In a well-control	
merican dog id older, and estations for	For technical assistance or to report a si Additional information can be found a	uspected adverse drug reaction, contact	na and hyperemia of the upper lips within e day and had resolved without medical Merck Animal Health at 1-800-224-5318. Immation about adverse drug experience	antibiotics, and Storage Inform Do not store ab How Supplied: Bravecto is ava	
v to provide	SafetyHealth, Sa				
Peak fluralaner concentrations are achieved between 2 hours and 3 days following oral administration, and the elimination half-life ranges between 9.3 to 16.2 days. Quantifiable drug concentrations can be measured (lower than necessary for effectiveness) through 112 days. Due to reduced drug bioavailability in the fasted state, fluralaner should be administered with food.					
	Mode of Action:			Madison, NJ 07 Made in Austri	
d	Fluralaner is for systemic use and belon inhibitor of the arthropod nervous system channels (gamma-aminobutyric acid (GA		d benzamide derivatives. Fluralaner is an antagonism of the ligand-gated chloride	Copyright © 20	
	Effectiveness:		Law	All rights reser	
	Bravecto began to kill fleas within two h laboratory study, Bravecto killed fleas and on dogs by > 98% within 12 hours for effectiveness against adult fleas 48 hour, demonstrated > 93% effectiveness again 48 hours post-infestation for 12 weeks. 72 hours post-infestation for 8 weeks, but In a well-controlled U.S. field study, a sing flea allergy dematilis showed immovement	Addes includes ticks and reduced the nur 12 weeks. In a well-controlled laborator post-infestation for 12 weeks. In well st Dermocentor variabilis, kodes scopu Bravecto demonstrated ≥90% effectives if alled to demonstrate ≥90% effectives the dose of Bravecto reduced 8	nbers of live fleas and <i>bodes ricinus</i> ticks rry study, Bravecto demonstrated 100% I-controlled laboratory studies, Bravecto laris and Rhipicephalus sanguineus ticks eness against Amblyomma americanum ness beyond 8 weeks.		
	flea allergy dermatitis showed improvement of eliminating flea infestations. Palatability: In a well-controlled U.S. field voluntarily consumed Bravecto within 5 m when offered with food, and 6.8% refused	study, which included 559 doses ad	ministered to 224 dogs, 80.7% of dogs		
g until ng the	when offered with food, and 6.8% refused the dose or required forced administration. Animal Safety: Margin of Safety Study: In a margin of safety study, Bravecto was administered orally to 8- to 9-week-old pupples at 1, 3, and 5X the maximum label dose of 56 mg/kg at three, 8-week intervals. The dogs in the control group (0X) were untreated.				
is not	There were no clinically-relevant, treatment-related effects on physical examinations, body weights, food consumption, clinical pathology (hematology, clinical chemistries, coagulation tests, and urinalysis), gross pathology, histopathology, or organ weights. Diarrhea, mucoid and bloody feces were the most common observations in this study, occurring at a similar incidence in the treated and control groups. Five of the twelve treated dogs that experienced one or more of these signs did so within 6 hours of the first dosing. One dog in the 3X treatment group was observed to be dull, inappetant, with evidence of bloody diarrhea, vomiting, and weight loss beginning five days after the first treatment. One dog in the 1X treatment group vomited food 4 hours following the first treatment.				
s and d	vidence of bloody diarrhea, vomiting, and	weight loss beginning five days after	is observed to be dull, inappetant, with the first treatment. One dog in the 1X		

That in a "margin of safety study," "there were no clinically-relevant, treatment related effects":

And that in a "reproductive safety study," "there were no clinically-relevant, treatment related effects" even though "one adult treated dog suffered a seizure during the course of the study (46 days after treatment)." Notably, Defendant did *not* disclose that the observed seizure was at all

related to the use of Bravecto, was a risk of a serious adverse reaction from using Bravecto, or list

it in the precaution or warning section:

Reproductive Safety Study: Bravecto was administered orally to intact, reproductively- sound male and female a dose of up to 168 mg/kg (equivalent to 3X the maximum label dose) on three to four occasions at 8-week intervals. The dogs in the control group (OX) were untreated. There were no clinically-relevant, treatment-related effects on the body weights, food consumption, reproductive performance, semen analysis, litter data, gross necropsy (adult dogs) or histopathology findings (adult dogs and puppies). One adult treated dog suffered a seizure during the course of the study (46 days after the second treatment). Abnormal salivation was observed on 17 occasions: in six treated dogs (11 occasions) after dosing and four control dogs (6 occasions). The following abnormalities were noted in 7 pups from 2 of the 10 dams in only the treated group during gross necropsy examination; limb deformity (4 pups), enlarged heart (2 pups), enlarged spleen (3 pups), and cleft palate (2 pups). During veterinary examination at Week 7, two pups from the control group had inguinal testicles, and two and four pups from the treated group had inguinal and cryptorchid testicles, respectively. No undescended testicles were observed at the time of necropsy (days 50 to 71). In a well-controlled field study Bravecto was used concurrently with other medications, such as vaccines, anthelmintics. antibiotics, and steroids. No adverse reactions were observed from the concurrent use of Bravecto with other medications. in al Storage Information: Do not store above 86°F (30°C). 18. How Supplied: ce Bravecto is available in five strengths (112.5, 250, 500, 1000, and 1400 mg fluralaner per chew). Each chew is packaged yl individually into aluminum foil blister packs sealed with a peelable paper backed foil lid stock. Product may be packaged in 1, 2, or 4 chews per package. NADA 141-426, Approved by FDA Distributed by: Intervet Inc (d/b/a Merck Animal Health) Madison, NJ 07940 Made in Austria Copyright @ 2014 Intervet Inc, a subsidiary of Merck & Company Inc. All rights reserved

66. Plaintiffs and class members saw the Bravecto product and its packing and materials prior to purchase and use, as well as saw other advertising relating to Bravecto, including displays in veterinarians' offices, online advertisements and Bravecto's website and that of other online retailers of Bravecto, and discussed the product with their veterinarians. Defendant concealed the material risks to Plaintiffs' and class members' pets, and their veterinarians with whom they discussed the products, by failing to provide meaningful disclosures warning about the real and material safety risks pets face when taking Bravecto. As a result, Plaintiffs and class members would have no notice of these potential adverse risks.

67. Purchasers of medications and treatments for their pets rely upon companies that manufacture those medications and treatments to disclose the risks, so that they can make informed decisions. This special relationship that manufacturers of medicines and treatments have with pet owners is based upon the asymmetrical information that the parties have—pet owners rely and are reasonable in relying upon manufacturers of medications and treatments to ensure that their pets are safe. There was a complete imbalance in the information provided to Plaintiffs and Class members on one hand and what Bravecto knew on the other hand.

C. Complaints of neurological adverse events relating to isoxazoline flea and tick products prompted FDA to issue a warning requiring a label change.

68. During the time period relevant to this action, Defendant omitted or otherwise failed to disclose an adequate warning of the demonstrated risk of adverse neurological reactions from pets' being treated with Bravecto. Defendant failed to inform any of the Class members about the significant risks Bravecto posed to animals.

69. In failing to make these representations, consumers and their veterinarians did not have all of the facts relevant to inform their decision-making process about medications that could impact the health and safety of their pets.

70. Accordingly, because Bravecto is concealing this information, consumers and veterinarians do not have sufficient information to know that Bravecto is causing health problems with pets.

71. On September 20, 2018, more than four years after Defendant began marketing and selling Bravecto, the FDA issued its Press Release warning pet owners and veterinarians of the potential risk of neurological adverse events associated with isoxazoline medications to treat fleas and ticks, including Bravecto. As a result of the adverse events, the FDA requested that manufacturers change their labels, which it determined were previously not adequate, to disclose

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these risks, so that veterinarians and pet owners could make an informed decision as to whether

they want to use these treatments on their pets. The FDA Press Release stated, in pertinent part:

The U.S. Food and Drug Administration is alerting pet owners and veterinarians to be aware of the potential for neurologic adverse events in dogs and cats when treated with drugs that are in the isoxazoline class.

Since these products have obtained their respective FDA approvals, *data received by the agency as part of its routine post-marketing activities indicates that some animals receiving Bravecto (fluralaner) tablets for dogs, Bravecto (fluralaner) topical solution for cats and dogs*, Nexgard (afoxalaner) tablets for dogs, or Simparica (sarolaner) tablets for dogs, *have experienced adverse events such as muscle tremors, ataxia, and seizures*. Two additional products in this class, Credelio (lotilaner) tablets for dogs and Revolution Plus (selamectin and sarolaner topical solution) for cats, recently received FDA approval. These products are approved for the treatment and prevention of flea infestations, and the treatment and control of tick infestations. Revolution Plus, is also approved for prevention of heartworm disease, treatment and control of ear mite infestations and some gastrointestinal parasite infections.

The FDA is working with manufacturers of isoxazoline products to include new label information to highlight neurologic events because these events were seen consistently across the isoxazoline class of products. Revolution Plus, which was approved most recently, includes the new labeling information to highlight the potential for neurologic events in the isoxazoline class, and Merial has made the requested changes to Nexgard's labeling including adding the new class statement. Merial has since transferred ownership of Nexgard's approval to Boehringer Ingelheim.

The FDA carefully reviewed studies and other data on Bravecto, Bravecto Topical, Credelio, Nexgard, Simparica and Revolution Plus prior to approval, and these products continue to be safe and effective for the majority of animals. *The agency is asking the manufacturers to make the changes to the product labeling* in order to provide veterinarians and pet owners with the information they need to make treatment decisions for each pet on an individual basis. Veterinarians should use their specialized training to review their patients' medical histories and determine, in consultation with pet owners, whether a product in the isoxazoline class is appropriate for the pet.

Although FDA scientists carefully evaluate an animal drug prior to approval, there is the potential for new information to emerge after marketing, when the product is used in a much larger population. In the first three years after approval, the FDA

pays particularly close attention to adverse event reports, looking for any safety information that may emerge.²¹

72. The FDA Press Release indicated that certain manufacturers had made the requested label change. As of the date of the FDA Press Release, Defendant had not disclosed the risk of neurological adverse reactions from ingestion or application of Bravecto.

73. Defendant did not take corrective action to notify consumers and their veterinarians of the risk of neurological adverse events or perform a recall of its Bravecto products that were already in circulation at retailers and that did not contain a warning about the risk of this serious adverse reaction. Because of this, Defendant caused consumers, who did not hear or read about the FDA's press release, to continue to purchase and use Bravecto products substantially based upon, or in reliance upon, the misrepresentation of their safety and omitted the risk of neurological adverse events to their pets.

74. Now, only after the FDA issued the above statement, Defendant discloses for the first time, as a "Precaution" and "Important Safety Information" (not as an observation in a study) the risk of neurologic adverse reactions from using Bravecto, including tremors, ataxia, and seizures. Defendant, however, downplays and minimizes these risks as being uncommon and most prevalent in animals with a history of seizures, even though seizures have occurred in animals without any such history, like Plaintiffs' dogs. Prior labeling did not mention neurological adverse reactions like tremors, ataxia, and seizures.

²¹ FDA, Animal Drug Safety Communication: FDA Alerts Pet Owners and Veterinarians About Potential for Neurologic Adverse Events Associated with Certain Flea and Tick Products (Sept. 20, 2018), <u>https://www.fda.gov/animal-veterinary/cvm-updates/animaldrug-safety-communication-fda-alerts-pet-owners-and-veterinarians-about-potentialneurologic</u> (emphasis added) (last visited June 26, 2020).

75. Defendant's website for Bravecto specifically for consumers now discloses, in

pertinent part:

IMPORTANT SAFETY INFORMATION

BRAVECTO has not been shown to be effective for 12-weeks' duration in puppies or kittens less than 6 months of age. *Fluralaner is a member of the isoxazoline class. This class has been associated with neurologic adverse reactions including tremors, ataxia, and seizures.* BRAVECTO Chew: The most commonly reported adverse reactions include vomiting, decreased appetite, diarrhea, lethargy, polydipsia, and flatulence. BRAVECTO is not effective against lone star ticks beyond 8 weeks of dosing. *Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use with caution in dogs with a history of seizures or neurologic disorders.* BRAVECTO Topical Solution for Dogs: The most commonly reported adverse reactions include vomiting, hair loss, diarrhea, lethargy, decreased appetite, and moist dermatitis/rash. Bravecto is not effective against lone star ticks beyond 8 weeks of dosing. For topical use only. Avoid oral ingestion. *Seizures have been reported in dogs receiving isoxazoline class drugs, even in dogs without a history of seizures. Use caution in dogs with a history of seizures or neurologic disorders.*

BRAVECTO Topical Solution for Cats: The most commonly reported adverse reactions include vomiting, itching, diarrhea, hair loss, decreased appetite, lethargy, and scabs/ulcerated lesions. BRAVECTO is not effective against American dog ticks beyond 8 weeks of dosing. For topical use only. Avoid oral ingestion. The safety of BRAVECTO has not been established in breeding, pregnant and lactating cats. *Neurologic adverse reactions have been reported in cats receiving isoxazoline class drugs, even in cats without a history of neurologic disorders.* ²²

²² Bravecto, <u>https://us.bravecto.com/for-dogs</u> (emphasis added) (last visited June 26, 2020); Merck, Bravecto, <u>https://www.merck-animal-health-usa.com/pdfs/canine/BravectoDogPI_152451%20R11_8.5x11.pdf</u> (last visited June 26, 2020) ("Use with caution in dogs with a history of seizures. Seizures have been reported in dogs receiving fluralaner, even in dogs without a history of seizures (see Adverse Reactions and Animal Safety). . . . Adverse Reactions: In a well-controlled U.S. field study, which included a total of 165 households and 321 treated dogs (221 with fluralaner and 100 with a topical active control), there were no serious adverse reactions" and mentions two dogs without a history of seizures each experienced a seizure.); *Compare with* Chewy, Frontline, <u>https://www.chewy.com/frontline-plus-flea-tick-medium-breed/dp/34716</u> (last visited June 26, 2020) (discloses risk of temporary irritation to animal's skin where applied).

76. Defendant's television commercials²³ directed to consumers also now warn to "use caution in dogs with a history of seizures or neurological disorders":



77. Despite the increased disclosure of health risks relating to Bravecto as directed by the EMA and FDA, the EMA on February 24, 2020, issued its annual bulletin "to inform veterinarians and the general public of main outcome of pharmacovigilance or post-marketing surveillance activities for veterinary medicinal products during 2019 at the [EMA]." The bulletin revealed that the EMA continued monitoring of adverse events relating to Bravecto in 2020, stating in part:

²³ YouTube, Bravecto Television Commercial (2020), <u>https://www.youtube.com/watch?v=IUsz9_QcK5E</u> (last visited July 2, 2020).
Bravecto [Chewable] Tablets: *Neurological disorders*, hepatopathy, *death*, congenital eye disorders, potential birth defects in dogs, ataxia in cats, haemorrhagic diarrhoea as cases with death outcome have been reported after haemorrhagic diarrhoea in dogs

Bravecto Spot-on (Topical): Behavioural disorders, dyspnoea and hepatopathy in cats, *convulsions/seizures in cats and convulsions/seizures, tremors and ataxia in dogs*.

Bravecto Plus: Behavioural disorders, dyspnoea and hepatopathy in cats, *convulsions/seizures in cats*.²⁴

78. The EMA bulletin also noted the increased warnings for humans in 2019, relating

to Bravecto Spot-on and Bravecto Plus:

Update of section 4.5, special precautions, of the SPC to read as follows:

Contact with the product should be avoided and disposable protective gloves obtained with this product at the point of sale must be worn when handling the product for the following reasons: Hypersensitivity reactions have been reported in a small number of people, which can potentially be serious. Persons with a hypersensitivity to fluralaner or to any of the excipients should avoid any exposure to the product.

79. The EMA also stated that it was continuing to monitor through 2020, human

suspected adverse events relating to Bravecto Spot-on including: Hepatopathy, hypersensitivity

(especially generalised urticarial reaction/anaphylactic shock or anaphylaxis/oedema/dyspnoea/taste), and

dermatitis/eczema after contact with the treated animal, *neurological signs*, such as severe headache.

Monitor the effect of glove distribution.²⁵

80. On June 16, 2021, based on escalating reports of adverse events relating to flea

and tick products, the FDA issued another press release notifying consumers of the possibility of

²⁴ EMA, Veterinary Pharmacovigilance Public Bulletin 2019 at 4 (Feb. 24, 2020), <u>https://www.ema.europa.eu/en/documents/newsletter/public-bulletin-veterinary-</u>pharmacovigilance-

²⁰¹⁹_en.pdf?fbclid=IwAR1dyU6y7Hkt9rhjIg00a1d5154O9kH2MhbinMTWRAFSoOlQ2KLjYL iZsKU (emphasis added).

 $[\]overline{^{25}}$ Id. at 11-13 (emphasis added).

adverse events from the use of flea and tick products. The press release also encouraged consumers to report such events to government agencies and manufacturers and to read packaging and labeling of products to understand the risks and possible adverse events. The press release stated in pertinent part:

Although flea and tick products on the market have been used in millions of pets, *side effects or adverse events may and sometimes do occur*. It's strongly recommended that you involve your veterinarian when choosing a flea and tick product, especially if your pet has any health conditions. *You should also carefully read the label, the package insert, and any accompanying literature to make sure you're using the product correctly. You should also save the packaging for the product in case a problem does occur and you need to report it.*

* * *

• Read the label carefully before use. Even if you've used the product many times before, read the label because the directions or warnings may have changed. If you don't understand the wording, ask your veterinarian or call the manufacturer.

* * *

- Monitor your pet for side effects or adverse events after applying the product, particularly when using the product on your pet for the first time. Side effects might occur immediately or could happen sometime later.
- If your pet experiences a bad reaction from a flea and tick collar, remove the collar immediately.
- If your pet experiences a bad reaction from any flea or tick product (spot-on, shampoo, dip, or collar), call your veterinarian right away. Depending on the product used, your veterinarian may recommend that you immediately bathe the pet, if it's safe to do so, using mild dish soap and rinsing with large amounts of water.
- Call your veterinarian if your pet shows symptoms of illness after using a product. Look for dizziness, wobbliness, incoordination, poor appetite, depression, vomiting, diarrhea, or excessive salivation. *Some animals have had seizures and/or died*. ²⁶

²⁶ FDA, Safe Use Flea and Tick Products (June 16, 2021),

https://www.fda.gov/consumers/consumer-updates/safe-use-flea-and-tick-products-pets (last visited June 21, 2021) (emphasis added).

81. While Defendant now provides more information about Bravecto than in the past, given the information obtained by governmental entities, Plaintiffs are informed and believe that additional disclosures are necessary to inform consumers about the risks Bravecto pose to pets. Discovery is necessary to determine the appropriate scope of the warning to consumers.

82. Defendant's late-stage forced disclosure does not excuse it from liability for failing to previously disclose the material risks to health and safety of pets that Bravecto posed, which resulted in damages—compensatory, statutory, and punitive—given Defendant's previous reckless disregard for the lives of Class members' pets.

V. TOLLING OF THE STATUTE OF LIMITATIONS

Fraudulent Concealment

83. All applicable statutes of limitation have been tolled by Defendant's knowing, active, and ongoing fraudulent concealment and denial of the facts alleged herein at all times relevant to this action.

84. Since before its FDA-approval, and at least as soon after its market launch in 2014 when neurological adverse reactions were observed in the market after widespread use of Bravecto, Defendant knew of the material safety risks alleged herein. At all times relevant to this action, thousands of similar complaints have been reported alleging adverse neurological reactions as a result of using Bravecto.

85. Although the FDA approved Bravecto for sale in the United States in May 2014, it was not until September 20, 2018 that the FDA issued a public statement warning pet owners and veterinarians about potential neurological adverse events associated with the isoxazoline class of drugs used to treat and prevent flea and tick infestations, including Bravecto. At that time, the FDA requested that manufacturers of isoxazoline products change their products' labels to disclose

the risk of neurological events. Manufacturers of some isoxazoline products, including Revolution Plus and Nexgard, changed their label to include this information, but, as of the date of the FDA Press Release, Defendant had not changed Bravecto's label and did not recall the products in circulation to ensure that an adequate warning of the risk of neurological adverse reactions appeared on all of its product packaging.

86. As a result of Defendant's lack of corrective action or recall of Bravecto products currently in circulation and in consumers' homes, Class members who did not see or hear about the FDA's press release, such as Plaintiff Moraski, continued to purchase and use Bravecto products on their pets based on the representation they were safe flea and tick products without the risk of any serious adverse events including neurological ones.

87. Despite knowing about the material safety risks its Bravecto products caused to pets, Defendant concealed the nature of those risks. Defendant did not disclose the risk of neurological adverse reactions when such risks were clearly known, and, once the risks were disclosed, Defendant downplayed the severity of the risks, as demonstrated above.

88. Indeed, when Plaintiffs and Class members informed Defendant that its product harmed their pets—causing them neurological damage and other similar issues—Defendant routinely and uniformly denied that Bravecto was the cause, even when veterinarians disagreed. In some instances, Defendant also offered to provide aggrieved Class members cash in exchange for signing a non-disclosure agreement and that Bravecto did not cause their pets' injuries. Defendant's uniform practices were designed to ensure that Class members did not find out about the dangers Bravecto poses to pet populations across the United States.

89. Plaintiffs could not have known that Bravecto caused health problems with their pets, because Bravecto prevented the information from becoming known by pet owners and members of the public.

90. Any applicable statutes of limitation have, therefore, been tolled by Defendant's knowledge, active concealment, and denial of the facts alleged herein, all of which is ongoing.

Discovery Rule

91. Plaintiffs and the other Class members did not immediately discover—and could not have discovered through the exercise of reasonable diligence—the full and complete nature of the material safety risks from Bravecto.

92. Within the period of any applicable statutes of limitation, Plaintiffs and the other Class members could not have discovered, through the exercise of reasonable diligence, that Defendant was concealing the Bravecto risks and defects and misrepresenting Bravecto's safety (or lack thereof).

93. Prior to 2018, here was no reason for Plaintiffs or Class members to believe that Bravecto would harm their pets, or that it was the cause of the harm their pets suffered, because Defendant utterly failed to provide an adequate warning regarding the dangers Bravecto poses to pets.

94. Defendant prevented Plaintiffs and Class members from understanding that Bravecto was the cause of their pets' illnesses because it concealed information, tried to settle claims requiring the use of non-disclosure agreements, and did not inform the public about the dangers Bravecto poses to pets.

95. Any applicable statutes of limitation have, therefore, been tolled by operation of the discovery rule.

<u>Estoppel</u>

96. Defendant was under a continuous duty to disclose to Plaintiffs and the other Class members the true character, quality, and nature of the material safety risks posed by Bravecto.

97. Defendant actively concealed Bravecto's true character, quality, and nature and knowingly misrepresented—or omitted—facts about Bravecto's safety, quality, reliability, characteristics, and performance.

98. Defendant attempted to buy the silence of certain Class members, which would have also required them to submit to terms that would not allow other Class members to determine that Bravecto was harming other Class members' pets.

99. The imbalance of information prevented Plaintiffs and Class members from understanding that Bravecto causes pets injuries, and Defendant profited off of the imbalance of information because consumers would not have purchased Bravecto, or would have paid substantially less for it, had they known of the dangers Bravecto posed.

100. Plaintiffs and the other Class members reasonably relied upon Defendant's misrepresentations and/or active concealment of these facts.

101. Based on the foregoing, Defendant is estopped from relying on any statutes of limitation in defense of this action.

VI. <u>CLASS ACTION ALLEGATIONS</u>

102. The Class members' claims all derive directly from a uniform course of conduct by Defendant. Specifically, Defendant has engaged in uniform and standardized conduct in not disclosing, concealing, and omitting the serious, and dangerous, side effects of its medications. The objective facts—Defendant's failure to disclose, concealment, and omissions—are the same for all Class members. Accordingly, Plaintiffs bring this lawsuit as a class action on their own

behalf and on behalf of all other persons similarly situated as members of the proposed Classes pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) and/or (b)(2) and/or (c)(4). This action satisfies all requirements of those provisions, including numerosity, commonality, typicality, adequacy, predominance, and superiority.

The Nationwide Class

103. Plaintiffs bring this action and seek to certify and maintain it as a class action under Rules 23(a); (b)(2); and/or (b)(3); and/or (c)(4) of the Federal Rules of Civil Procedure on behalf of themselves and a Nationwide Class defined as follows:

All purchasers or users of Bravecto products in the United States or its territories between May 1, 2014 and the present.

The State Subclasses

104. Additionally, as further described herein, Plaintiffs bring claims based upon state laws on behalf of the following subclasses for the states of Connecticut, Florida, Illinois, Texas, and New York (collectively, the "Class" or "Classes"):

All purchasers or users of Bravecto products in that particular state between May 1, 2014, and the present.

105. Excluded from the Classes are: (a) any person who purchased Bravecto for resale and not for personal or household use, (b) any person who signed a release of any Defendant in exchange for consideration in excess of the cost of Bravecto, (c) Defendant, including any entity or division in which Defendant has a controlling interest, as well as its agents, representatives, officers, directors, employees, trustees, parents, children, heirs, assigns, and successors, and other persons or entities related to, or affiliated with Defendant, and (d) the Court and its staff, and their immediate families. Plaintiffs reserve the right to modify or amend these Nationwide and Statewide Class definitions as appropriate during the course of this litigation. 106. **Numerosity**: Federal Rule of Civil Procedure 23(a)(1). The members of the Nationwide Class and State Subclasses are so numerous and geographically dispersed that individual joinder of all class members is impracticable. While Plaintiffs believe that there are at least thousands of class members, the precise number is unknown to Plaintiffs but may be ascertained from purchase records, sales records, production records, and veterinarian records. Plaintiffs anticipate providing Court-approved, appropriate notice to class members, to be approved by the Court in accordance with Rule 23 of the Federal Rules of Civil Procedure.

107. Commonality and Predominance: Federal Rules 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, including, without limitation:

a. Whether Defendant omitted or otherwise misrepresented the safety risks with Bravecto to Plaintiffs and Class members;

b. Whether the defective nature of Bravecto constitutes a material fact that reasonable consumers would have considered in deciding whether to purchase the product;

c. Whether the Defendant knew or should have known about the Bravecto product safety defect, and, if so, how long the Defendant has known of the defect;

d. Whether Defendant had a duty to disclose the defective nature of Bravecto to Plaintiffs and Class members;

e. Whether Defendant's conduct tolls any or all applicable limitations periods by acts of fraudulent concealment, application of the discovery rule, or equitable estoppel;

f. Whether Defendant engaged in unfair, deceptive, unlawful and/or fraudulent acts or practices in trade or commerce by objectively misleading Plaintiffs and putative Class members;

g. Whether Defendant's conduct, as alleged herein, was likely to mislead a reasonable consumer;

h. Whether Defendant violated state consumer protection laws, and if so, what remedies are available under those statutes;

i. Whether Defendant's statements, concealments and omissions regarding Bravecto were material, in that a reasonable consumer could consider them important in purchasing Bravecto;

j. Whether Bravecto was unfit for the ordinary purposes for which it was used, in violation of the implied warranty of merchantability;

k. Whether Plaintiffs and the Classes are entitled to a declaratory judgment stating that Bravecto is defective and/or not merchantable;

l. Whether Defendant's unlawful, unfair, and/or deceptive practices harmed Plaintiffs and the Classes;

m. What aggregate amounts of statutory penalties are sufficient to punish and deter Defendant and to vindicate statutory and public policy;

n. Whether, as a result of Defendant's omissions and/or misrepresentations of material facts, Plaintiffs and Class members have suffered an ascertainable loss of monies and/or property and/or value; and

o. Whether Plaintiffs and Class members are entitled to monetary damages and/or other remedies and, if so, the nature of any such relief.

108. **Typicality: Federal Rule of Civil Procedure 23(a)(3)**. Plaintiffs' claims are typical of other Class members' claims because Plaintiffs were subjected to the same allegedly

unlawful conduct and damaged in the same way as Class members. The relief Plaintiffs seek is typical of the relief sought for the absent Class members.

Adequacy of Representation: Federal Rule of Civil Procedure 23(a)(4). Plaintiffs are adequate class representatives because their interests do not conflict with the interests of the other members of the Classes they seek to represent, Plaintiffs have retained counsel competent and experienced in complex class action litigation, and Plaintiffs intend to prosecute this action vigorously. The Class members' interests will be fairly and adequately protected by Plaintiffs and their counsel.

109. Declaratory and Injunctive Relief: Federal Rule of Civil Procedure 23(b)(2).

The prosecution of separate actions by individual class members would create a risk of inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for Defendant. Such individual actions would create a risk of adjudications that would be dispositive of the interests of other class members and impair their interests. Defendant has acted and/or refused to act on grounds generally applicable to the Classes, making final injunctive relief or corresponding declaratory relief appropriate. Additionally, Plaintiffs and Class members are pet owners who need flea and tick medicine and will be purchasing it for their pets in the future. Because Defendant manufactures medication and treatments under a variety of brand names, and new medications are continually being developed given the increased incidence of tick-borne and flea-borne diseases, Defendant could, in the future, market a flea and tick medication that does not disclose risks under a new brand name, and Plaintiffs and Class members could be deceived again. Injunctive relief is appropriate to prevent that from happening.

110. 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 damages or other financial detriment suffered by Plaintiffs and the other Class members are relatively small compared to the burden and expense that would be required to individually litigate their claims against Defendant, so it would be impracticable for Class members to individually seek redress for Defendant's wrongful conduct. Even if the Class members could afford litigation, the court system could not. Because of the relatively small size of the individual Class members' claims (compared to the cost of litigation), it is likely that only a few Class members could afford to seek legal redress for Defendant's misconduct. Individualized litigation creates a potential for inconsistent or contradictory judgments and increases 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 single adjudication, economies of scale, and comprehensive supervision by a single court. Class treatment of common questions of law and fact would be a superior method to multiple individual actions or piecemeal litigation in that class treatment will conserve the resources of the courts and the litigants, and will promote consistency and efficiency of adjudication.

VII. CLAIMS FOR RELIEF

<u>COUNT I</u> BREACH OF EXPRESS WARRANTY By All Plaintiffs on behalf of the Nationwide Class

111. Plaintiffs Palmieri, Gordon, Ippolito, Mastric, Moraski, Reeves, and Tucker ("Plaintiffs" for purposes of this Count) reallege and incorporate by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

112. Plaintiffs bring this claim on behalf of the Nationwide Class. In the alternative, Plaintiffs bring this claim on behalf of themselves and on behalf of the State Subclasses, under the laws of the states in which they reside and/or purchased Bravecto. Choice of law issues may be briefed after sufficient discovery.

113. Defendant constitutes a "merchant" and a "seller" in connection with its sales of Bravecto to Plaintiffs and the Nationwide Class as those terms are defined in the New Jersey Uniform Commercial Code. Plaintiffs and the Nationwide Class constituted "buyers" as that term is defined in the New Jersey Code. Bravecto products constituted "goods" as that term is defined in the New Jersey Code. Plaintiffs and Class members could buy the Bravecto product directly in the stream of commerce.

114. Under section 2-313 of title 12A of the New Jersey Revised Statutes, Defendant's statements of affirmations of fact, promises and descriptions made on Bravecto's packaging and advertising, which Defendant provided to Plaintiffs and the Nationwide Class, created written express warranties before or at the time of purchase, including that Bravecto was safe for pets to treat fleas and ticks.

115. State warranty laws from the states in which consumers purchased and used Bravecto are substantially similar to New Jersey's warranty law concerning the definitions of merchants, sellers, buyers, and goods.

116. State warranty laws from the states in which consumers purchased and used Bravecto are substantially similar to New Jersey's warranty law concerning the creation of promises based upon representations of safety.

117. These affirmations of facts and promises made by Defendant to Plaintiffs and the Nationwide Class related to Bravecto and became part of the bases of the bargains for the purchase

of Bravecto between them and Defendant, and thereby created express warranties that Bravecto would conform to those affirmations and promises.

118. Furthermore, the aforementioned descriptions of Bravecto were part of the bases of the bargains for the purchases of Bravecto between Defendant on the one hand and Plaintiffs and individual members of the Nationwide Class on the other. The descriptions created an express warranty that the goods would conform to those descriptions.

119. As previously noted, Defendant uniformly misrepresented the nature of Bravecto as safe without serious health risks. Instead, Bravecto is a toxic pesticide that presents a risk of neurological adverse reactions to animals. Bravecto did not conform to the affirmations, promises, and descriptions previously mentioned, resulting in breaches of Bravecto's express warranties.

120. Plaintiffs complied with all conditions precedent to filing this breach of warranty claim, including providing notice of the breach of warranty to Defendant, and at least one of the Plaintiffs provided notice on behalf of herself and the Nationwide Class, prior to filing this action. Alternatively, Defendant has been on notice since at least the commencement of this litigation of its breaches of warranty to Plaintiffs and the Nationwide Class, and Defendant has done nothing to remedy these breaches. Alternatively, notice need not have been given to Defendant, because it had actual notice of its breaches of warranty as to Plaintiffs and the Nationwide Class.

121. Plaintiffs believed the Bravecto products to be safe.

122. Plaintiffs believed that the Bravecto products would continue to be safe. Because Bravecto is not administered as often as topical treatments, Plaintiffs expected that the Bravecto products would continue to not only repel insects but also continue to be safe into the future after ingested.

123. Defendant created representations intending that consumers would rely upon them, and consumers would be reasonable in so relying—and did rely—upon those representations.

124. Defendant breached its warranties to consumers, because Bravecto products were supposed to be safe, but they contained material safety defects that made them unsafe.

125. Defendant did not disclose the safety defects inherent in the Bravecto product.

126. Defendant has known about the safety issues with its product but elected to omit those safety issues from its materials and representations to consumers. Accordingly, Defendant was already on notice of its breach of warranties.

127. When consumers—including Plaintiffs and Class members—contacted Defendant to complain about Bravecto and its impact on their pets, Defendant downplayed their concerns, informing them that Bravecto was not the cause for their pets' illnesses, all the while knowing that Bravecto has caused adverse health effects in pets.

128. Accordingly, providing Defendant with notice is ineffective at providing Defendant an opportunity to cure its breach of warranties. Allowing Defendant additional opportunity to cure its breach of warranties is unnecessary and would be futile here as Plaintiffs have already suffered harm.

129. As a direct and proximate result of Defendant's breach of express warranties, Plaintiffs and the Nationwide Class have suffered actual damages as follows:

a. Compensatory damages amounting to, among other things, the difference in value between the full purchase price of Bravecto and the actual value of it, pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure; and

b. Consequential damages pursuant to Rule 23(c)(4) of the Federal Rules of
Civil Procedure.

130. Plaintiffs and the Nationwide Class demand judgment against Defendant for damages, as set forth above, plus interest, costs, and such additional relief as the Court may deem appropriate or to which Plaintiffs and the Nationwide Class may be entitled.

<u>COUNT II</u> BREACH OF IMPLIED WARRANTY

By All Plaintiffs on behalf of the Nationwide Class

131. Plaintiffs Palmieri, Gordon, Ippolito, Mastric, Moraski, Reeves, and Tucker ("Plaintiffs" for purposes of this Count) reallege and incorporate by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

132. Plaintiffs bring this claim on behalf of themselves and the Nationwide Class. In the alternative, Plaintiffs bring this claim on behalf of themselves and on behalf of the State Subclasses, under the laws of the states in which they reside and/or purchased Bravecto. Choice of law issues may be briefed after sufficient discovery.

133. Plaintiffs purchased Bravecto for treatment of their pets believing the products to be of good, merchantable quality and safe for use in their pets.

134. Bravecto is a "good" within the meaning of the Uniform Commercial Code.

135. Plaintiffs and Class members are buyers as that term is defined by the Uniform Commercial Code. Defendant is a merchant with respect to the Bravecto product. Plaintiffs and Class members could purchase the Bravecto product directly in the stream of commerce.

136. Plaintiffs and Class members purchased the Bravecto products believing them to be safe to use for their pets. Defendant made an implied warranty with its consumers that the Bravecto products would be safe to use.

137. A warranty that Bravecto was in merchantable condition and fit for the ordinary purpose for which it is used is implied by law.

138. Bravecto, when it was sold and all times thereafter, was not in merchantable condition and not fit for the ordinary purpose for which it was intended—treatment of pets—given the serious safety defects contained in the product.

139. Bravecto was supposed to be safe for use for future performance—the effectiveness of the pill for a longer period of time versus topical appointment implied that the treatment would continue to not only repel insects into the future, but be safe well into the future.

140. Defendant has known about the safety issues with its product and that it was not merchantable but elected to omit those safety issues from its materials and representations to consumers. Accordingly, Defendant was already on notice of its breach of implied warranties.

141. When consumers—including Plaintiffs and Class members—contacted Defendant to complain about Bravecto and its impact on their pets, Defendant downplayed their concerns, informing them that Bravecto was not the cause for their pets' illnesses, all the while knowing that Bravecto has caused such adverse health effects in pets.

142. Accordingly, providing Defendant with notice is ineffective at providing Defendant an opportunity to cure its breach of implied warranties. Allowing Defendant additional opportunity to cure its breach of implied warranties is unnecessary and would be futile here as Plaintiffs have already suffered harm.

143. As a direct and proximate cause of Defendant's breach of the implied warranty of merchantability, Plaintiffs and Class members suffered injury in an amount to be proven at trial.

COUNT III NEW JERSEY CONSUMER FRAUD ACT By All Plaintiffs on behalf of the Nationwide Class

144. Plaintiffs Palmieri, Gordon, Ippolito, Mastric, Moraski, Reeves, and Tucker ("Plaintiffs" for purposes of this Count) reallege and incorporate by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

145. Plaintiffs bring this claim on behalf of themselves and the Nationwide Class.

146. Bravecto, which was designed, manufactured, advertised, marketed and sold by Defendant is considered "merchandise" within the meaning of the New Jersey Consumer Fraud Act. Plaintiffs and the Nationwide Class members are "persons" and "consumers" with the meaning of the New Jersey Consumer Fraud Act.

147. Defendant affirmatively misrepresented the Bravecto to consumers. These misrepresentations include, but are not limited to: (a) its false and misleading statements, representations, and depictions in its labeling, packaging, marketing, promotion and advertising for Bravecto as a safe and effective flea and tick product without the risk of any serious adverse reactions including neurological ones, (b) the fact that contrary to these representations that Bravecto is a toxic pesticide that may cause neurological adverse reactions and failed to provide adequate warning or notice of their health risks because of this; and (c) that because of these misrepresentations and omissions Plaintiffs and the Nationwide Class suffered damages.

148. Defendant's claims therefore were false, misleading and/or deceptive.

149. Defendant's affirmative misrepresentations and material omissions constituted an unconscionable commercial practice, deception, fraud, false promise, and/or misrepresentation as to the nature of the goods, in violation of the New Jersey Consumer Fraud Act.

150. As a result of Defendant's misrepresentations and material omissions, Plaintiffs and the Nationwide Class have suffered ascertainable losses of money and property, which they seek to recover consisting of the damages from purchasing a misrepresented and worthless Bravecto and the consequential damages from the injury and death of pets from the use of Bravecto and subsequent veterinarian bills incurred as a result.

151. Plaintiffs and other Nationwide Class members demand judgment pursuant to N.J.S.A. § 56:8-19 against Defendant for their ascertainable damages, statutory remedies made available under the Act, injunctive relief requiring Defendant to improve its disclosures to adequately inform consumers of the risk of serious adverse reactions.

152. Plaintiffs and the Nationwide Class further seek to enjoin such unlawful deceptive acts and practices as described above. Each of the Nationwide Class members will be irreparably harmed unless the unlawful action of Defendant is enjoined, in that Defendant will continue to falsely and misleadingly market, advertise and represent on its packaging and labeling that Bravecto is a safe and effective flea and tick product without the risk of serious adverse reactions. To that end, Plaintiffs and the Nationwide Class request an order granting them injunctive relief requiring removal of Bravecto from retail outlets and online, corrective disclosures and/or disclaimers on the labeling and advertising of Bravecto.

153. Absent injunctive relief, Defendant will continue to manufacture and sell unsafe and misrepresented Bravecto products without adequate warnings to consumers of their health risks.

154. In this regard, Defendant has violated, and continues to violate, the New Jersey Consumer Fraud Act, which makes deception, fraud, false promise, and/or misrepresentation of goods unlawful. As a direct and proximate result of Defendant's violation of the New Jersey

Consumer Fraud Act, as described above, Plaintiffs and the members of the Nationwide Class have suffered damages, as set forth above.

COUNT IV NEW JERSEY PRODUCTS LIABILITY ACT By All Plaintiffs on behalf of the Nationwide Class

155. Plaintiffs Palmieri, Gordon, Ippolito, Mastric, Moraski, Reeves, and Tucker ("Plaintiffs" for purposes of this Count) reallege and incorporate by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

156. Plaintiffs bring this cause of action on behalf of themselves and the Nationwide Class. If necessary, Plaintiffs bring this cause of action for product liability on behalf of themselves and the State Subclasses based upon the laws in the states in which they treated their pets with Bravecto. Choice of law principles may be briefed after sufficient discovery takes place.

157. Defendant designed, manufactured, and sold Bravecto, an unsafe toxic pesticide that creates a risk of neurological adverse reactions.

158. Bravecto was not reasonably fit, suitable, or safe for its intended purpose because it contains toxic pesticide and failed to contain adequate warnings of the risk of neurological adverse reactions.

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

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

161. Defendant knew about the dangers Bravecto posed, but elected not to inform consumers, downplay safety issues, and deny that its product was the cause of any adverse effects.

162. Bravecto came in sealed packages, and its packaging did not change from the time it left Defendant's possession through the time they arrived in stores or veterinarians' offices to be sold to consumers, and consumers purchased and took possession of it.

163. The unreasonably dangerous defects and/or conditions of Bravecto proximately caused injury and death to animals, constituting property damage to Plaintiffs and certain other members of the Nationwide Class beyond and in addition to the damages from purchasing the mislabeled and worthless Bravecto.

164. Accordingly, Defendant is strictly liable for the damages caused to Plaintiffs and any other members of the Nationwide Class, by the unreasonably dangerous Bravecto, specifically the illness and deaths of any animals and the expenses incurred therewith.

<u>COUNT V</u> Connecticut Unfair Trade Practices Act C.G.S.A. § 42-110g, et seq. By Plaintiffs Palmieri and Moraski on behalf of the Connecticut Subclass

165. Plaintiffs Palmieri and Moraski ("Plaintiffs" for purposes of this Count) reallege and incorporate by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

166. Plaintiffs assert this claim on behalf of themselves and the Connecticut Subclass.

167. Defendant is a "person" as defined by C.G.S.A. § 42-110a(3).

168. Defendant is engaged in "trade" or "commerce" as those terms are defined by

C.G.S.A. § 42-110a(4).

169. At the time of filing the amended complaint, Plaintiffs sent notice to the Attorney General and Commissioner of Consumer Protection pursuant to C.G.S.A. § 42-110g(c).

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170. Defendant advertised, offered, or sold goods or services in Connecticut, and engaged in trade or commerce directly or indirectly affecting the people of Connecticut.

171. Defendant engaged in deceptive acts and practices and unfair acts and practices in the conduct of trade or commerce, in violation of the C.G.S.A. § 42-110b, including omitting that Bravecto has serious and material safety risks that endanger the well-being and lives of Plaintiffs' and Class members' pets, and representing that the product was safe, while otherwise not providing corrective disclosures about the defects.

172. Defendant's representations and omissions were material because they were likely to deceive—and did in fact deceive—reasonable consumers.

173. Defendant intended to mislead Plaintiffs and Connecticut Subclass members and induce them to rely on its misrepresentations and omissions. Defendant's misrepresentations and omissions were a substantial factor in Plaintiffs and the Connecticut Subclass members' decision to purchase Bravecto at the price they paid for it. Had Plaintiffs and the Connecticut Subclass members known the truth about Bravecto, they may not have purchased it or paid the price they paid for it.

174. Had Defendant disclosed to Plaintiffs and Connecticut Subclass members that it uniformly misrepresented Bravecto as a "safe" flea and tick treatment while not making corrective disclosures, omitted material information regarding risk of neurological adverse reactions, and was otherwise engaged in deceptive, common business practices, Defendant would have been unable to continue in business and it would have been forced to disclose the uniform defects in Bravecto. Instead, Defendant represented that Bravecto was a safe flea and tick treatment without disclosing the risk of any serious adverse reactions. Plaintiff Palmieri and the Connecticut Subclass members

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acted reasonably in relying on Defendant's misrepresentations and omissions, the truth of which they could not have discovered.

175. Defendant acted intentionally, knowingly, and maliciously to violate the Connecticut Unfair Trade Practices Act, and recklessly disregarded Plaintiffs' and Connecticut Subclass members' rights. Defendant's knowledge of the adverse neurological reactions to Bravecto put Defendant on notice that the Bravecto was not as safe as advertised.

176. Accordingly, Defendant acted intentionally or with reckless disregard for the safety and well-being of Plaintiffs' and Connecticut Subclass members' pets.

177. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiffs and Connecticut Subclass members have suffered and will continue to suffer injury, ascertainable losses of money or property, and monetary and non-monetary damages, including from not receiving the benefit of their bargain in purchasing Bravecto and paying veterinarian bills for treatment relating to the neurological adverse reactions in their pets after consuming Bravecto. Plaintiff and the Connecticut Subclass members' injuries were a reasonably foreseeable result from Defendants misrepresentations and omissions relating to Bravecto.

178. Defendant's deceptive acts and practices caused substantial, ascertainable injury to Plaintiffs and Connecticut Subclass members, which they could not reasonably avoid, and which outweighed any benefits to consumers or to competition.

179. Defendant's violations of Connecticut law were done with reckless indifference to the rights of Plaintiffs and the Connecticut Subclass or was with an intentional or wanton violation of those rights.

180. Plaintiffs and the Connecticut Subclass request damages in the amount to be determined at trial, including statutory and common law damages, attorneys' fees, and punitive damages, under Rules 23(b)(2), (b)(3), and (c)(4) of the Federal Rules of Civil Procedure.

<u>COUNT VI</u> Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, et seq. By Plaintiff Gordon on behalf of the Illinois Subclass

181. Plaintiff Gordon ("Plaintiff" for purposes of this Count) realleges and incorporates by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

182. Plaintiff brings this claim on behalf of herself and the Illinois Subclass.

183. Plaintiff Gordon asserts that the Defendant violated Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 et seq. ("ICFA"), which prohibits the use of "unfair and deceptive practices" in the conduct of trade or commerce. The ICFA is to be liberally construed to effectuate that purpose.

184. Plaintiff Gordon and the Illinois Subclass members are consumers as defined in815 ILCS 505/1(c) and (e).

185. Defendant failed to disclose material safety defects that could impact the health and well-being of Plaintiff Gordon's and the Illinois Subclass members' pets, and otherwise only made partial disclosures concerning the safety of Bravecto sufficient to mislead reasonable consumers into believing Bravecto was safe for use.

186. Defendant's misconduct, including the misrepresentations and the omission of material facts, took place in the course of trade or commerce in Illinois, arose out of transactions that occurred in Illinois, and/or harmed individuals located in Illinois.

187. Defendant uniformly misrepresented Bravecto as a "safe" flea and tick treatment, omitted material information regarding risk of neurological adverse reactions, and/or was otherwise engaged in deceptive, common business practices. Defendant represented that Bravecto was a safe flea and tick treatment without disclosing the risk of any serious adverse reactions.

188. By undertaking the conduct at issue herein, Defendant has engaged in unfair or deceptive acts prohibited by the ICFA.

189. If not for the Defendant's deceptive and unfair acts, including Defendant's omission of material information regarding risks of neurological adverse reactions, as alleged herein, Plaintiff Gordon and the Illinois Subclass members would not have purchased the Products or would have paid significantly less for them.

190. Defendant, at all relevant times, knew or should have known that Plaintiff Gordon and the Illinois Subclass members did not know and could not have reasonably discovered its deceptive and unfair acts, including Defendant's omission of material information regarding risks of neurological adverse reactions, prior to their purchases of the Bravecto.

191. As discussed above, the statute of limitations has been tolled due to Defendant's deceptive conduct.

192. As a direct and proximate result of Defendant's violations of the ICFA, Plaintiff Gordon and the Illinois Subclass members sustained damages in an amount to be proven at trial.

193. In addition, Defendant's conduct showed malice, motive, and the reckless disregard of the truth such that on account of Defendant's conduct, Plaintiff Gordon and the Illinois Subclass members seek statutory and actual damages, punitive damages, injunctive relief, attorneys' fees and costs, and all other relief allowed under the ICFA.

<u>COUNT VII</u> Illinois Uniform Deceptive Trade Practices Act 815 ILCS 510/1, et seq. By Plaintiff Gordon on behalf of the Illinois Subclass

194. Plaintiff Gordon ("Plaintiff" for purposes of this Count) realleges and incorporates by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

195. Plaintiff brings this claim on behalf of herself and the Illinois Subclass.

196. Defendant is a "person" as defined by 815 ILCS \$\$ 510/1(5).

197. Defendant engaged in deceptive trade practices in the conduct of its business, in violation of 815 ILCS §§ 510/2(a), including knowingly manufacturing, advertising, and selling Bravecto products with uniform defects that endanger the health and well-being of pets, omitting details of the defect from consumers and otherwise denying that Bravecto caused any of Plaintiff Gordon's or other Illinois Subclass members' pets' neurological or health issues, and misrepresenting Bravecto by only making partial disclosures that showed a reckless indifference or disregard for the health of Plaintiff Gordon's and Illinois Subclass members' pets.

198. Defendant's representations and omissions were material because they were likely to deceive—and did deceive—reasonable consumers.

199. The above unfair and deceptive practices and acts by Defendant were immoral, unethical, oppressive, and unscrupulous. These acts caused substantial injury to Plaintiff Gordon and Illinois Subclass members that they could not reasonably avoid; this substantial injury outweighed any benefits to consumers or to competition.

200. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiff Gordon and Illinois Subclass members have suffered and will continue to suffer injury,

ascertainable losses of money or property, and monetary and non-monetary damages, including from not receiving the benefit of their bargain in purchasing Bravecto.

201. Plaintiff Gordon and Illinois Subclass members are entitled to such injunctive relief to ensure that Defendant fully discloses the material safety risks of Bravecto to its customers—including Plaintiff Gordon and the Illinois Subclass.

202. Plaintiff Gordon and Illinois Subclass members seek all relief allowed by law, including injunctive relief and reasonable attorney's fees.

<u>COUNT VIII</u> New York General Business Law, N.Y. Gen. Bus. Law §§ 349, et seq. By Plaintiff Tucker on behalf of the New York Subclass

203. Plaintiff Tucker ("Plaintiff" for purposes of this Count) realleges and incorporates by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

204. Plaintiff brings this claim on behalf of herself and the New York Subclass.

205. Defendant engaged in deceptive acts or practices in the conduct of its business, trade, and commerce or furnishing of services, in violation of N.Y. Gen. Bus. Law § 349, as described herein.

206. Defendant's representations and omissions directed to Plaintiffs and consumers and their veterinarians were material because they were likely to deceive reasonable consumers.

207. Defendant recklessly disregarded Plaintiff and other New York Subclass members' rights. Defendant's knowledge of the true health and safety risks of Bravecto put Defendant on notice that Bravecto was less safe than advertised and represented.

208. Defendant elected to omit details of material safety defects from its customers details which only it knew about and which Plaintiff and New York Subclass members had no

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reason to know about. These omissions showed reckless disregard for the health and safety of Plaintiff's and New York Subclass members' pets. Additionally, Defendant only made partial disclosures through its misrepresentations, which did not inform consumers about the dangers Bravecto posed to their pets.

209. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiff and New York Subclass members have suffered and will continue to suffer injury, ascertainable losses of money or property, and monetary and non-monetary damage, including from not receiving the benefit of their bargain in purchasing Bravecto, and increased time and expense in treating any damage that Bravecto caused.

210. Defendant's deceptive and unlawful acts and practices complained of herein affected the public interest and consumers at large, including the many New Yorkers who purchased and/or used Bravecto for their pets.

211. The above deceptive and unlawful practices and acts by Defendant caused substantial injury to Plaintiff and New York Subclass members that they could not reasonably avoid.

212. Plaintiff and New York Subclass members seek all monetary and non-monetary relief allowed by law, including actual damages and statutory damages of \$50 (whichever is greater), treble damages, declaratory relief, and attorney's fees and costs.

<u>COUNT IX</u> Texas Trade Deceptive Practices–Consumer Protection Act, Texas Bus. & Com. Code §§ 17.41, et seq. By Plaintiff Reeves on behalf of the Texas Subclass

213. Plaintiff Reeves ("Plaintiff" for purposes of this Count) realleges and incorporates by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

214. Plaintiff brings this claim on behalf of herself and the Texas Subclass.

215. Defendant is a "person" as defined by Tex. Bus. & Com. Code § 17.45(3).

216. Plaintiff and the Texas Subclass members are "consumers" as defined by Tex.Bus. & Com. Code § 17.45(4).

217. Defendant advertised, ordered or sold goods or services in Texas and engaged in trade or commerce directly or indirectly affecting the people of Texas, as defined by Tex. Bus. & Com. Code § 17.45(6).

218. Defendant engaged in false, misleading or deceptive acts and practices, in violation of Tex. Bus. & Com. Code § 17.46(b), including omitting that the Bravecto products had material safety risks that could impact the health and well-being of Plaintiff's and Texas Subclass members' pets, and failing to make adequate disclosures to allow consumers to understand the nature the safety defects pose to their pets.

219. Defendant's representations and omissions were material because they were likely to deceive reasonable consumers.

220. Defendant's representations and omissions were uniform; Defendant engaged in a concerted effort to ensure that Plaintiff and Texas Subclass members did not associate their product with adverse health events, and it routinely and uniformly denied claims submitted by consumers whose pets were impacted by Bravecto. Defendant's misrepresentations were also uniform

because they contained no disclosures relating to the serious health and safety defects of Bravecto, thus not allowing a consumer to make an informed decision when purchasing the product.

221. Had Defendant disclosed to Plaintiff and the Texas Subclass members that it misrepresented Bravecto, omitted material information regarding defects (including health and safety risks as alleged herein), and was otherwise engaged in deceptive, common business practices, Defendant would have been unable to continue in business and would have been forced to disclose the truth and uniform defects in Bravecto. Instead, Defendant omitted or minimized the known safety risks of Bravecto. Plaintiff and Texas Subclass Members acted reasonably in relying on Defendant's misrepresentations and omissions, the truth of which they could not have discovered. Defendant's misrepresentations and omissions were a substantial factor in Plaintiff and the Texas Subclass Members decision to purchase Bravecto at the price they did. Had they known the truth about Bravecto, they may not have purchased it or paid the price they did for it.

222. Defendant's duty to disclose the true safety risks of Bravecto arose from its possession of exclusive knowledge regarding the defects in Bravecto and its incomplete representations about Bravecto.

223. Defendant engaged in unconscionable actions or courses of conduct, in violation of Tex. Bus. & Com. Code Ann. § 17.50(a)(3). Defendant engaged in acts or practices which, to consumers' detriment, took advantage of consumers' lack of knowledge, ability, experience or capacity to a grossly unfair degree.

224. Consumers, including Plaintiff and Texas Subclass members, lacked knowledge about the business practices, omissions, and misrepresentations because this information was known exclusively by Defendant.

225. Defendant took advantage of consumers' lack of knowledge, ability, experience, or capacity to a grossly unfair degree, with reckless disregard of the unfairness that would result. The unfairness resulting from Defendant's conduct is noticeable, flagrant, complete, and unmitigated.

226. Defendant recklessly disregarded Plaintiff and the Texas Subclass members' rights. Defendant's knowledge of Bravecto's true safety risks put Defendant on notice that Bravecto was less safe than advertised.

227. As a direct and proximate result of Defendant's deceptive acts and practices, Plaintiff and Texas Subclass members have suffered and will continue to suffer injury, ascertainable losses of money or property, and monetary and non-monetary damages, including from not receiving the benefit of their bargain in purchasing Bravecto, and increased time and expense in treating any damages caused by Bravecto. If Defendant had not misrepresented or omitted the information about the health risks from Bravecto, Plaintiff and the Texas Subclass would not have suffered the injuries they did.

228. Defendant received notice pursuant to Tex. Bus. & Com. Code Ann. § 17.505 concerning its wrongful conduct as alleged herein by Plaintiff and the Texas Subclass members.

229. However, sending pre-suit notice pursuant to tex. Bus. & Com. Code Ann. § 17.505 is an exercise in futility for Plaintiff, as Defendant has already been informed of the allegedly unfair and unlawful conduct as described herein as of the date of the initial Complaint in this action, and has yet to offer any remedy in accordance with similar consumer protection statutes.

230. Plaintiff and the Texas Subclass seek all monetary and non-monetary relief allowed by law, including economic damages, damages for mental anguish, treble damages for

each act committed intentionally or knowingly, court costs, reasonable and necessary attorneys' fees, injunctive and declaratory relief, and any other relief which the court deems proper.

<u>COUNT X</u> Florida Deceptive and Unfair Trade Practices Act By Plaintiffs Ippolito and Mastric on behalf of the Florida Subclass

231. Plaintiffs Ippolito and Mastric ("Plaintiffs" for purposes of this Count) reallege and incorporates by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

232. Plaintiffs bring this claim on behalf of themselves and the Florida Subclass against Defendant.

233. Plaintiffs are "consumers" within the meaning of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. § 501.203(7).

234. Defendant is engaged in "trade or commerce" within the meaning of Fla. Stat. § 501.203(8).

235. FDUTPA prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce. . ." Fla. Stat. § 501.204(1). Defendant participated in unfair and deceptive trade practices that violated the FDUTPA as described herein.

236. In the course of their business, Defendant failed to disclose and actively concealed the dangers and risks posed by Bravecto as described herein and otherwise engaged in activities with a tendency or capacity to deceive.

237. Defendant also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, or misrepresentations or concealment, suppression, or omission of any material fact, likely to deceive a consumer acting reasonably under the circumstances in connection with their purchase of Bravecto.

238. Defendant knew about the dangers Bravecto posed, but elected not to inform consumers, downplay safety issues, and deny that its products was the cause of any adverse effects. Defendants misrepresented Bravecto as a safe and effective flea and tick product without the risk of any serious adverse reactions and failed to disclose and warn consumers about the dangers and risks posed by Bravecto.

239. By failing to disclose the risks of neurological adverse events, by misrepresenting Bravecto as safe without the risk of any serious adverse reactions, Defendant engaged in unfair or deceptive business practices in violation of the FDUTPA. Defendant's deceptive conduct is compounded by its continued representation that Bravecto is safe downplaying health risks as well as its failure to take remedial action.

240. Defendant's unfair or deceptive acts or practices, including these misrepresentations, concealments, omissions, and suppressions of material facts, had a tendency or capacity to mislead and create a false impression in consumers, and were likely to and did in fact deceive reasonable consumers, including Plaintiffs and the Florida Subclass about the true safety and reliability of Bravecto, and the true value of Bravecto Products.

241. Defendant knew or should have known that its conduct violated the FDUTPA.

242. As alleged above, Defendant made material statements about the safety and lack of serious adverse reactions risk of Bravecto that were either false or misleading.

243. Defendant made these misrepresentations and omissions in written advertising materials, packaging and labeling, displays in veterinarians' offices, online advertisements and on its website and in television commercials directed to Plaintiffs and other members of the Florida Subclass at the time of purchases.

244. Defendant failed to disclose the risk of serious neurological adverse reactions to their pets from Bravecto. Defendant possessed exclusive knowledge of these risks posed by Bravecto and, yet, made incomplete representations about them and instead touted the safety of Bravecto, while purposefully withholding material facts from Plaintiffs and the Florida Subclass that contradicted these representations.

245. Plaintiffs and the Florida Subclass suffered ascertainable loss caused by Defendant's misrepresentations and failure to disclose material information. Had they been aware of the truth about Bravecto and the risk to their pets, Plaintiffs and the Florida Subclass would not have purchased Bravecto or paid as much as they did for it. Plaintiffs and the Florida Subclass did not receive the benefit of their bargain as a result of Defendant's misconduct.

246. Plaintiffs and the Florida Subclass risk irreparable injury as a result of Defendant's acts and omissions in violation of the FDUTPA, and these violations present a continuing risk to Plaintiffs, the Florida Subclass, and the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

247. As a direct and proximate result of Defendant's violations of the FDUTPA, Plaintiffs and the Florida Subclass have suffered injury-in-fact and/or actual damage.

248. Plaintiffs and the Florida Subclass are entitled to recover their actual damages under Fla. Stat. § 501.211(2) and attorneys' fees under Fla. Stat. § 501.2105(1).

249. Plaintiffs and the Florida Subclass also seek an order enjoining Defendants' unfair, unlawful, and/or deceptive practices, and awarding declaratory relief, attorneys' fees, and any other just and proper relief available under the FDUTPA.

<u>COUNT XI</u> Strict Liability, Failure to Warn By All Plaintiffs on behalf of the State Subclass

250. Plaintiffs Palmieri, Gordon, Ippolito, Mastric, Moraski, Reeves, and Tucker ("Plaintiffs" for purposes of this Count) reallege and incorporate by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

251. Plaintiffs bring this claim, if necessary and in the alternative, on behalf of themselves and the State Subclasses based upon the laws of the states in which Bravecto was used and purchased by Plaintiffs and Subclass members. Issues regarding choice of law principles may be briefed after discovery.

252. At all times relevant hereto, Defendant was the manufacturer of Bravecto, and marketed the product directly to consumers for purchase.

253. Bravecto was designed, produced, created, made, manufactured, distributed, and sold and placed into the stream of commerce by Defendant.

254. At the time Defendant sold Bravecto, the warnings and instructions were inadequate and defective. As described herein and below, there was an unreasonable risk that Bravecto would not perform safely and effectively for the purposes for which it was intended. Defendant failed to design and manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

255. Bravecto was expected to and did reach the ultimate users, including Plaintiffs and State Subclass members.

256. Plaintiffs and State Subclass members were unaware of the safety risks associated with Bravecto, because Defendant concealed them.

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257. Defendant's Bravecto product posed a foreseeable risk of danger when used for its intended purpose. As demonstrated above, when Plaintiffs used Bravecto for its intended purpose, the product severely injured—and in some instances killed—their pets.

258. Defendant failed to warn consumers that Bravecto posed health and safety risks, including those that it now specifically mentions to consumers after the FDA disclosed risks of similar safety issues with similar products.

259. Defendant failed to provide any warning or instruction to Plaintiffs and Class members of the harm that the defects could cause and the defects were present in Bravecto products when they left Defendant's control.

260. Bravecto was unsafe for normal or reasonably anticipated use.

261. Plaintiffs and State Subclass members used Bravecto in the manner for which it was intended and/or in a reasonably foreseeable manner.

262. Plaintiffs and State Subclass members could not, through the exercise of reasonable care, have discovered the defects or perceived the dangers associated with Bravecto.

263. As a direct and proximate cause of the safety defects, Plaintiffs experienced injury: their pets were harmed and some died.

264. As a further direct and proximate result of Defendant's Bravecto defect, as described above, Plaintiffs and State Subclass members incurred medical and other related to expenses, and in some instances may continue to incur such expenses related to additional treatments, medications, and therapies to treat the health issues caused by taking Bravecto.

265. As a direct and proximate result of Defendant's actions and the defects present in Bravecto, Plaintiffs and State Subclass members were damaged in amounts to be proven at trial.

<u>COUNT XII</u> Unjust Enrichment By All Plaintiffs on behalf of the State Subclasses

266. Plaintiffs Palmieri, Gordon, Ippolito, Mastric, Moraski, Reeves, and Tucker ("Plaintiffs" for purposes of this Count) reallege and incorporate by reference the preceding paragraphs 1 through 110 as if set forth fully herein.

267. To the extent necessary, Plaintiffs bring this claim on behalf of themselves and the State Subclass in the alternative to their warranty claims based upon the laws of the states in which Bravecto was used and purchased by Plaintiffs and Subclass members. Issues regarding choice of law principles may be briefed after discovery.

268. Defendant received and retained a benefit from the Plaintiffs and inequity has resulted.

269. Defendant did this in two ways: by selling a product that was unsafe, and by retaining the profits to unused products that can no longer be used.

270. Defendant benefitted through its unjust conduct, by selling Bravecto to consumers, who can no longer use the product without fearing that they will seriously endanger their pets.

271. Defendant also benefitted by selling Bravecto products that were unsafe, so they were unable to be used as directed.

272. Defendant has not offered a recall to consumers for unused dosages of Bravecto products, nor as Defendant offered adequate compensation to consumers whose pets took the Bravecto product.

273. It is inequitable for Defendant to retain these benefits when Plaintiffs and State Subclass members can no longer use the Bravecto product without endangering their pets.

274. Plaintiffs and class members do not have an adequate remedy at law.

275. As a result of Defendant's conduct, the amount of its unjust enrichment should be

disgorged, in an amount to be proven at trial.

VIII. <u>REOUEST FOR RELIEF</u>

WHEREFORE, Plaintiffs, individually and on behalf of all other Class members,

respectfully requests that the Court enter judgment in their favor and against Defendant as follows:

- a. Certifying the Class and Subclasses as requested herein, either injunctive relief classes, monetary relief classes, or classes certifying particular issues for trial, designating Plaintiffs as Class Representatives, and appointing the undersigned counsel as Class Counsel;
- b. Declaring that Defendant is financially responsible for notifying the Class members of the pendency of this suit;
- c. Awarding actual (*e.g.*, compensatory and consequential) and/or statutory damages (including exemplary or punitive damages) to the maximum extent allowed in an amount to be proven at trial;
- d. Requiring restitution and disgorgement of all profits and unjust enrichment Defendant obtained from Plaintiffs and the other Class members as a result of Defendant's unlawful, unfair, and/or fraudulent business practices;
- e. Awarding injunctive relief as permitted by law or equity, including enjoining Defendant from continuing the unlawful practices as set forth herein, and ordering Defendant to engage in a corrective advertising campaign;
- f. Awarding injunctive relief as permitted by law or equity to prevent Defendant from manufacturing such flea and tick medication or treatments that contain the same risks as described herein, or not including adequate warnings;
- g. Awarding Plaintiffs their reasonable attorneys' fees, costs, and expenses;
- h. Awarding pre- and post-judgment interest on any amounts awarded; and
- i. Awarding such other and further relief as may be just and proper.

IX. JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

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July 1, 2020

Respectfully submitted,

/s/ Mark A. DiCello MARK A. DICELLO N.J. Bar No. 306102019 madicello@dicellolevitt.com **DICELLO LEVITT GUTZLER LLC** Western Reserve Law Building 7556 Mentor Avenue Mentor, Ohio 44060 Telephone: (440) 953-8888

ADAM J. LEVITT (*admitted pro hac vice*) alevitt@dicellolevitt.com AMY E. KELLER (*admitted pro hac vice*) akeller@dicellolevitt.com ADAM PROM (*admitted pro hac vice*) aprom@dicellolevitt.com **DICELLO LEVITT GUTZLER LLC** Ten North Dearborn Street, Sixth Floor Chicago, Illinois 60602 Telephone: (312) 214-7900

JESSICA J. SLEATER (*admitted pro hac vice*) jessica@andersensleater.com **ANDERSEN SLEATER SIANNI LLC** 1250 Broadway, 27th Floor New York, New York 10001 Telephone: (646) 599-9848

RALPH N. SIANNI (*admitted pro hac vice*) rsianni@andersensleater.com **ANDERSEN SLEATER SIANNI LLC** 2 Mill Road, Suite 202 Wilmington, Delaware 19806 Telephone: (302) 510-8528

MELISSA S. WEINER mweiner@pswlaw.com **PEARSON, SIMON & WARSHAW, LLP** 800 LaSalle Avenue, Suite 2150 Minneapolis, Minnesota 55402 Telephone: (612) 389-0600 Case 2:19-cv-22024-JXN-AME Document 49 Filed 07/01/21 Page 75 of 76 PageID: 1122

HASSAN A. ZAVAREEI hzavareei@tzlegal.com **TYCKO & ZAVAREEI LLP** 1828 L Street NW, Suite 1000 Washington, D.C. 20036 Telephone: (202) 973-0900

Counsel for Plaintiffs and the Proposed Classes

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was filed using this Court/s CM/ECF service,

which will send notice of such filing to all counsel of record this 1st day of July 2021.

<u>/s/ Mark A. DiCello</u> Mark A. DiCello