

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
GREENVILLE DIVISION**

**NEAL AND SHERRY HALEY,
JAMES AND LEE ANN SCHOFFNER,
DARLA MAHALITC, AND CLAYTON DAVIS,
on behalf of themselves and
others similarly situated**

PLAINTIFFS

V. Civil Action No. 4:09cv094-P-S

**MERIAL, LIMITED, MERIAL, LLC,
and MERIAL, INC.,**

DEFENDANTS

AMENDED CLASS ACTION COMPLAINT

JURY TRIAL REQUESTED

The above named Plaintiffs assert the causes of action to be hereafter stated against the Defendants named above, and in support thereof, state as follows:

Parties

1. Plaintiffs are all adult resident citizens of the State of Mississippi, who bring this action on behalf of themselves and all others similarly situated as members of the proposed Plaintiff Class to be hereinafter defined.

2. Defendant, Merial, Limited is a company limited by shares registered in England and Wales (registered number 3332751) with a registered office at P.O. Box 327, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow Essex CM1950A, England, and domesticated in Delaware, USA as Merial LLC. Merial, Limited may be served by serving its domesticated agent, Merial LLC.

3. Defendant Merial, LLC is a Delaware Corporation. Process may be served upon its Registered Agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

4. Defendant Merial, Inc. is a Georgia Corporation with its principal place of business in Duluth, Georgia. Merial, Inc. may be served with process through its Registered Agent, CT Corporation Systems, 1201 Peachtree Street, NE, Atlanta, Georgia 30361.

Jurisdiction

5. Plaintiffs invoke jurisdiction pursuant to 28 U.S.C. §1332 (d)(2), which provides federal district courts with original jurisdiction over civil actions in which the matter in controversy exceeds \$5,000,000.00, exclusive of interests and costs, and is a class action in which any member of a class of plaintiffs is a citizen of a state different from any Defendants. Further, this Court has jurisdiction of this matter pursuant to 28 U.S.C. §1331 in that the Plaintiffs' cause of action arises under the Constitution, laws or treaties of the United States, including the Racketeering Influence and Corrupt Organizations Act (RICO) 18 USC §1961 et seq., and therefore brings to the Court's attention a Federal question. Furthermore, the United States District Court has the authority to exercise jurisdiction over any state claims which may be raised herein.

6. Venue is proper in this Court pursuant to 28 U.S.C § 1391 (b) and (c), and 18 U.S.C. §1965(a) in that the Defendant Merial, Limited transacts its affairs in the Northern District of Mississippi, and because a substantial part of the alleged improper conduct took place in this district.

Factual Background

7. All Defendants associated/named Merial (hereafter referred to collectively as “Merial”), are in the business of producing products throughout the world related to animal health. Specifically, Merial manufactures the product known as “HeartGard Plus,” which Merial aggressively markets as a “heartworm preventative.”

8. HeartGard Plus is a beef flavored chewable tablet for dogs which includes the active ingredients ivermectin and pyrantel. The Food and Drug Administration (hereinafter “FDA”) has approved the drug for use in dogs to help prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month after infection and for the treatment and control of ascarids (*Toxocara canis*, *Toxocaris leonine*) and hookworms (*Ancylosotoma caninum*, *Uncinaria stenocephala*, *Ancylostoma braziliense*). It is intended to be given to dogs monthly.

9. Apparently as early as 2002, and perhaps before that, Merial began marketing HeartGard Plus claiming that it was “100% effective against heartworms”. In addition it made numerous other claims of 100% effectiveness as a heartworm preventative. These claims of 100% effectiveness were made by Merial in spite of the fact that it possessed actual knowledge that they were false. The initial studies conducted for the FDA in connection with the licensing of the drug showed a rate of effectiveness of less than 100%. In addition, soon after the widespread use of HeartGard Plus, the lack of effectiveness became clear as a result of numerous post approval adverse drug events, or ADEs.

10. As a result, the FDA, pursuant to its duties and responsibilities under the Federal Food Drug and Cosmetic Act, 21 USC §352(a) and 21 USC § 321(n) (hereinafter

the “Act”) reviewed several promotional materials published by Merial¹ and found as a fact that the claims of 100% effectiveness were false and misleading, causing the drugs to be misbranded under the Act.

11. In a letter dated January 2, 2002, the FDA wrote Rosalind S. Dunn, Director of Regulatory Affairs with Merial, pointing out, among other things, the problems with the claims of 100% effectiveness with respect to HeartGard Plus, and requesting that Merial stop these improper and false promotions. A copy of the letter is attached hereto as Exhibit 1.²

12. Several months later, in October of 2002, the FDA wrote another letter to Ms. Dunn with Merial pointing out the improper and unbalanced nature of the claims of effectiveness of the drug HeartGard Plus. A copy of that letter is attached hereto as Exhibit 2.

13. Instead of complying with the request of the FDA, Merial continued and even strengthened its deceptive advertising. By way of example, attached as Exhibit 3 is the front and back of a promotional placard created by Merial and supplied to the veterinarians free of charge for display in the veterinarians’ offices. This placard was to be displayed in the offices attached to a plastic model of a worm-infested dog’s heart, and was to be displayed in the veterinarians’ offices so as to be seen by dog owners. Clearly visible on the placard and in bold type it states, “HEARTGARD Plus Provides

¹ The false claims were not limited to just HeartGard Plus. They also included HeartGard Chewables for dogs, HeartGard tablets for Dogs and HeartGard Chewables for Cats.

² For the sake of efficiency, Plaintiffs have not physically attached the exhibits to the Amended Complaint, as they are exactly the same as the exhibits to the original Complaint. Accordingly, please see the exhibits attached to Document 1 referred to herein.

100% Protection Against Heartworm Disease.” At the bottom of the placard is an indication that it was created in 2003. It remains visible in many veterinarian offices to this day, and Merial has not instructed the veterinarians to remove it.

14. In January of 2004 Merial’s advertising schemes again came under scrutiny by the FDA as being false and misleading. This time the claims were for IVOMEC Pour-On for Cattle. While the drugs were different, the active ingredient was the same for both IVOMEC and HeartGard Plus (ivermectine). Again, demonstrating a consistent scheme to defraud, Merial claimed “100%” efficacy for the drug. The FDA wrote another letter to Merial warning them yet again about the false and misleading claims of 100% efficacy for the drug. A copy of that letter is attached hereto as Exhibit 4.

15. Merial continued to thumb its nose at the FDA, and to the American consumer by continuing its fraudulent claims of 100% effectiveness. In yet another letter from the FDA to Merial dated August 24, 2005 (a copy of which the Plaintiffs do not have)³ the FDA again requested Merial to stop claiming 100% effectiveness for HeartGard and for HeartGard Plus. This time the FDA noted that the request to stop this deceptive and false advertising was based on the post-approval adverse drug event (ADE) reports of lack of effectiveness of the drug.

16. In response to this request, Merial apparently wrote a letter dated September 30, 2005, and a letter dated May 5, 2006 in which it agreed to “immediately discontinue promotion and advertising 100% effectiveness for [its] heartworm prevention products.” (See comments in the August 14, 2006 Warning letter attached hereto as Exhibit 5)

³ See a discussion of this August 24, 2005 letter and Merial’s response to it in the August 14, 2006 Warning Letter attached hereto as Exhibit 5.

17. Those promises to the FDA were apparently hollow. On August 14, 2006 the FDA issued an official “Warning Letter” directed to Liubov Skibo, Director, Regulatory Affairs at Merial, in which the FDA recited the historical false claims that had been made by Merial concerning its heartworm preventative medicines and the numerous attempts that had been made by the FDA to force Merial to stop making these false and misleading claims. This letter stated in part:

“Given the lack of effectiveness (heartworm prevention) ADEs reported for your products, the promotion of ‘100% effectiveness for prevention of heartworm disease’ is false or misleading and causes your product to be misbranded within the meaning of section 502(a) [21USC 3529a0] of the Act.”

18. In addition, the Warning Letter threatened severe regulatory action, including seizure or injunction unless Merial took the following action:

(a) immediately cease the dissemination of violative promotional materials for HeartGard and HeartGard Plus;

(b) correct the promotional materials on its website concerning HeartGard and HeartGard Plus and other materials that may contain similar information;

(c) with respect to future promotional materials, they should adequately address the claims of heartworm prevention, without overstating the effectiveness, to reflect the reported adverse drug events associated with the products; and

(d) “[b]ecause the violations described above are serious, further we request that your submission include a comprehensive plan of action to disseminate a truthful, non-misleading, and complete corrective message about the issue discussed in this letter to the audience(s) that received the violative promotional materials.”

A copy of the Warning Letter dated August 14, 2006 is attached hereto as Exhibit 5.

19. In yet another Warning Letter (at least the sixth such letter of which Plaintiffs' counsel is aware) dated October 12, 2006 addressed to George Luntz with Native Remedies, 2061 NW 2nd Ave #106, Boca Raton, Fl. 33431, the FDA noted additional websites which were apparently being maintained by Merial which continued to overstate the drug's efficacy. (A copy of the October 12, 2006 letter is attached hereto as Exhibit 6)

20. Apparently Merial amended some of its promotional material to remove the words, "100%". However, it took no other action of which counsel for the Plaintiffs are aware to correct the impression of 100% effectiveness previously given to the consumer or to the veterinarians or other pet care professionals. Specifically, Merial sent out no letters or other correspondence to the veterinarians or other pet care professionals that its previous claims of 100% effectiveness were false, nor did Merial give any instructions to the veterinarians or other pet care professionals to destroy or to remove the fraudulent representations such as the placard referred to above, or other pamphlets that had been previously furnished to the pet care community.

21. Likewise, Merial continues to benefit from fraudulent advertisement on the internet that either it has placed there, or that others who sell Merial's products have placed there with Merial's knowledge. A clear example is the information which appears daily on an internet site known as, "heartgardplus-for-dogs.com. Attached hereto as Exhibits 7(a) through 7(d) are printouts of the information which appears on those websites for the following dates: July 21, 2009 (Exhibit 7(a)); August 7, 2009 (Exhibit 7(b)); August 10, 2009 (Exhibit 7(c)); and August 17, 2009 (Exhibit 7(d)). The information on the website is identical for each date. Each of the above advertisements

constitutes interstate wire transmissions which make the false and fraudulent claim that, “[t]he fact is that HeartGard is 100% effective.”

22. In addition to the claims on its own website, Merial supplied other persons with information to advertise and promote Merial’s products on the internet by making false and fraudulent claims of 100% effectiveness. By way of example are the claims of 100% effectiveness of the drug by vet.com (Exhibit 8); nextag.com (Exhibit 9); smarter.com (Exhibit 10); fabuloussavings.com (180opedmeds) (Exhibit 11); pricegrabber.com (Exhibit 12); petproductsontheweb.com (Exhibit 13); bizrate.com (Exhibit 14); vetmedicines.com (Exhibit 15) dogspetsmeds.com (Exhibit 16); allivet.com (Exhibit 17); petcarechoice.com (Exhibit 18); shopping.com (Exhibit 19); and many, many more. Each of the representations on the above specified websites constitute interstate wire transmissions which make false or fraudulent claims of HeartGard Plus’ effectiveness.

**False and Fraudulent Claims
That Use Of HeartGard Plus Will
Prevent Transmission of Roundworm and
Hookworm Diseases From Dogs to Humans**

23. In addition to the false and fraudulent claims specified in the previous paragraphs, Merial also engaged in a particularly egregious practice of employing fraudulent scare tactics to encourage sales of its drug, HeartGard Plus. In these advertisements and promotional materials Merial implied that use of HeartGard Plus could prevent the transmission of certain diseases from dogs to humans. These diseases include certain diseases caused by roundworms (damage to internal organs, pneumonia, and blindness) and diseases caused by hookworms (a horrible skin disease called, “creeping eruption” and severe stomach aches and nausea). In one of the pamphlets

furnished to veterinarians and other pet care professionals Merial included photographs of a blind child, and a putrid, puss-filled human foot. Below these horrific photographs is the statement:

“Help reduce the risk of exposing other pets - and your family - to roundworms and hookworms by giving your dog HEARTGARD Plus every month. HEARTGARD Plus treats and controls roundworms and hookworms that may affect people.”

A copy of the pamphlet is attached hereto as Exhibit 20.

24. In response to this line of false advertising the FDA issued yet another Warning Letter to Merial. In a letter dated June 21, 2007, again addressed to Liubov Skibo, Director, Regulatory Affairs Merial Limited, 3239 Satellite Boulevard, Duluth, Ga., the FDA again chided Merial for its unsubstantiated claims of effectiveness (this time with respect to roundworm and hookworm prevention) and also noted the overall impression left by the material that use of HeartGard Plus would prevent the transmission of certain parasitic diseases. The FDA again demanded that Merial “immediately cease the dissemination of violative advertisements for HeartGard Plus,” and warned that future advertisements and promotional materials should adequately address the claims for the prevention of heartworm and other intestinal parasites, without overstating the effectiveness. (See Exhibit 21 attached hereto.)

25. In spite of the FDA’s warnings, Merial continues to furnish veterinarians and other pet care professionals with these false promotional materials and they remain on display in veterinarians offices for consumers to review to this day.

**Plaintiffs' Reliance On False and Fraudulent
Representations to Veterinarians, Other
Pet Care Professionals
And the American Consumer**

26. Named plaintiffs, Neal and Sherry Haley have two dogs, Mack and Buddy. Mack is a Chocolate Labrador Retriever that the Haleys have had for many years. Mack was on another heartworm preventative medication known as Interceptor. On October 17, 2005, Mack contracted heartworms and required treatment. Following this experience Neal and Sherry Haley consulted with their veterinarian concerning a change of medication for Mack so that he would not have to again endure the suffering of the treatment for heartworm infection. The veterinarian recommended that they change Mack's medication to HeartGard Plus, since it was guaranteed to be 100% effective. Neal Haley reviewed some of the promotional material present in the veterinarian's office, and comforted by the claims of 100% efficacy, agreed to place Mack on a regimen of monthly doses of HeartGard Plus. This occurred in February of 2006. Neal agreed to this change of medication even though the HeartGard Plus was more expensive than the previous medication. Mack was subsequently tested for heartworms in August of 2006, and tested negative.

27. Later, in August of 2007, the Haleys acquired a second dog. This dog was a Rat Terrier whom they named Buddy. Their veterinarian tested Buddy for heartworms and he tested negative. Again, in reliance upon the claims of 100% efficacy of HeartGard Plus, they also started Buddy on a monthly regimen of HeartGard Plus.

28. Neal Haley administered the doses of HeartGard Plus to both Mack and Buddy in full and complete compliance with the instructions from Merial. Nevertheless, Buddy contracted heartworms and tested positive in August of 2008 while on

HeartGard Plus. Mack contracted heartworms and tested positive in February of 2009 while on HeartGard Plus.

29. Named plaintiff Darla Mahalitic has three dogs. Her oldest dog is a Yellow Lab named Stoner. Stoner is nine years old. She has a Chocolate Lab named Mocha who is seven years old. She also has a Bloodhound named Browser. Browser is five years old.

30. Darla, who worked for a veterinarian for several years, had all three of her dogs on a heartworm preventative known as Interceptor. During the time her dogs were on Interceptor they did not contract heartworms. However, Darla learned in discussions with her veterinarian that some dogs in the area had recently tested positive for heartworms while on Interceptor. Accordingly, after consultations with her veterinarian and after reviewing the promotional material claiming 100% effectiveness, she decided sometime in 2006 to switch her dogs over to HeartGard Plus.

31. Darla administered the doses of HeartGard Plus to all three dogs in full complete compliance with the manufacturer's instructions. Nevertheless, Stoner tested positive for heartworms on October 3, 2007; Mocha tested positive for heartworms on January 9, 2008; and Browser tested positive for heartworms on May 6, 2008. At the time that all three dogs contracted heartworm disease they were on a strict regimen of HeartGard Plus.

32. James and Lee Ann Shoffner have had many dogs through the years. One of their dogs is named Chico. Chico is a black lab mix and is approximately five years old. Chico was placed on HeartGard Plus at the recommendation of the Shoffner's veterinarian on September 27, 2004. The Shoffners also have golden retriever mix

named Katy Mae. Katy Mae is approximately three and one-half years old. Katy Mae was placed on HeartGard Plus on July 8, 2005.

33. While the Shoffners initially purchased HeartGard Plus from their veterinarians, they soon discovered that they could acquire it cheaper from online sources. In reliance upon the online sources' guarantees of 100% effectiveness, they began acquiring their HeartGard Plus from those online sources.

34. The Shoffners maintained both Chico and Katy Mae on a strict regimen of HeartGard Plus in complete compliance with the manufacturer's instructions. Nonetheless, both Chico and Katy Mae have contracted heartworms.

35. Named Plaintiff Clayton Davis has three dogs. They go by the names Duke, Haus, and Jazz. Jazz was born in December of 2003. Both Duke and Haus were born in April of 2005. All three dogs were placed on a strict regimen of HeartGard Plus from the time they were several months old.

36. In June of 2006 Duke tested positive for heartworms. He was thereafter treated, and then placed on a twice monthly regimen of Interceptor and HeartGard Plus. In other words Duke would be given one of the drugs on the first of the month and the other drug would be administered on the fifteenth of the month.

37. Haus and Jazz both tested positive for heartworms in May of 2007. Following this positive test both Haus and Jazz were treated for heartworm infection, and then placed on a twice monthly regimen of HeartGard Plus and Interceptor, just like Duke.

38. Regardless of the fact that all three dogs, Duke, Haus and Jazz, had been placed on a monthly regimen of both HeartGard Plus and Interceptor, all three dogs

once more contracted heartworms. All three dogs have now been treated again for heartworm infestation, and now have been placed on a regimen of ProHeart 6.

39. In reliance upon the veterinarian's recommendations, and the assurances that had been made directly to him through the advertisements claiming excessive effectiveness and also indirectly through the recommendations from his veterinarian who had received promotional material from Merial making unsubstantiated claims of excessive effectiveness, Clayton Davis chose to place his dogs on HeartGard Plus. All dogs remained on a strict regimen of HeartGard Plus in accordance with the manufacturer's directions and nonetheless they contracted heartworms.

CAUSES OF ACTION

Count I.

RICO Violations

40. Defendants' wrongful and fraudulent acts violated the Federal Racketeer Influenced and Corrupt Organizations (RICO) Act, Title 18, U.S.C. §§1961-1968 in that they committed two or more predicate acts within ten years of each other, which constitutes a pattern of racketeering activity through which the Defendant, as a culpable person either invested in, maintained an interest in, or participated in an entity which qualified as an enterprise which affects interstate commerce.

The Enterprise Under 18 U.S.C. §1962(a)

41. The enterprise, for the purpose of the allegations concerning the violations of 18 U.S.C. §1962 (a) consisted either of the defendant Merial Limited itself, or, alternatively consisted of a group of persons including Merial Limited and the other Merial corporate entities and Liubov Skibo and various other directors and officers of

Merial who were associated in fact for the purpose of receiving and reinvesting income directly or indirectly from its pattern of racketeering activity.

The Enterprise Under 18 U.S.C. §1862(b)

42. With respect to the allegations concerning the violations of 18 U.S.C. §1962 (b) the Enterprise consisted either of the defendant Merial Limited itself or, alternatively, consisted of a group of persons including Merial Limited and the other Merial corporate entities and Liubov Skibo and various other unknown officers and directors of Merial and 3CI who were associated in fact for the purpose of acquiring and maintaining an interest in or controlling the heartworm preventative market in the United States of America.

The Enterprise Under 18 U.S.C. §1962(c)

43. With respect to the allegations concerning violations of 18 U.S.C. §1962 (c) the enterprise consisted of an association in fact of Merial Limited, its sister companies, Liubov Skibo and various other unknown officers and directors of Merial, and the online distributors of Merial products, vet.com, nextag.com, smarter.com, fabuloussavings.com, 1800petmeds.com, pricegrabber.com, petproductsontheweb.com, bizrate.com, vetmedicines.com, dogspetmeds.com, allivet.com, petcarechoice.com, and shopping.com, for the purpose of conducting or participating in the conduct of an enterprise's affairs through a pattern of racketeering activity.

Culpable Persons

44. All of the culpable persons conspired for the common purpose of engaging in a course of conduct designed to defraud thousands, if not hundreds of thousands of veterinarians and other pet care professionals, as well as millions of American dog

owners, including the Plaintiffs.

45. The Enterprise and the other culpable persons 1) shared a common purpose of misleading the American veterinarian community and the American dog owners with false and fraudulent claims of overstated effectiveness; 2) functioned over a period of years as a continuing unit; and 3) had and maintained an ascertainable structure separate and distinct from the pattern of racketeering activity. The pattern of racketeering activity that the Enterprise was engaged in was the promotion of its heartworm preventive drug, HeartGard Plus, through a consistent pattern of providing false and fraudulent promotional material to hundreds of thousands of veterinarians by use of the mails (mail fraud) and through providing false and fraudulent advertising and promotional material to millions of American consumers by way of the internet which occurred in interstate commerce (wire fraud). The common purpose of the enterprise was to make sure that HeartGard Plus became, “the #1 choice of veterinarians for heartworm disease prevention,”⁴ and to capture the lion’s share of internet sales of heartworm preventatives to consumers.

Prohibited Activities (Predicate Acts)

46. The specific predicate acts (criminal violations) committed by the Defendants were their acts in advertising and promoting the sale of HeartGard Plus through the use of the mails in furtherance of a scheme to defraud veterinarians, other pet care professionals, and the American consumer in violation of 18 U.S.C. § 1341, and through the use of the internet in furtherance of a scheme to defraud veterinarians,

⁴ Merial’s scheme to use fraudulent promotions to attain dominant market share apparently worked as reflected in their promotional material stating that HeartGard Plus was the number one choice of veterinarians.

other pet care professionals and the American consumer in violation of 18 U.S.C. §1343.

47. Upon information and belief, defendant Merial utilized the postal service to disseminate this false and misleading information to the veterinarians throughout the United States for display. These acts by defendant Merial are clear evidence of two or more predicate offenses in that they violated federal mail fraud statutes (18 USC §1341) these multiple predicate acts clearly demonstrate a pattern of racketeering activity. What's more, the fact that these activities have continued more or less uninterrupted even though defendant Merial has been repeatedly warned by the United States Food and Drug Administration that such acts constituted false or misleading advertising clearly demonstrate that they amount to or pose a threat of continued criminal activity.

48. Each and every "click" on the various websites mentioned in this Complaint constitutes a separate, independent predicate act. Defendant Merial, with actual knowledge that its HeartGard products were being advertised in a false or misleading manner and were also misbranded pursuant to the FDA, continued to allow veterinarians and online distributors of its products to represent to the public at large and to their individual customers that the product was "100% effective."

49. The dates of the commission of these criminal acts and the specific actions which constitute violations of those sections were set forth in detail in the previous enumerated paragraphs, which include:

a) Actions taken to mail advertisements and other promotional material such as the placard marked as Exhibit 3 and to veterinarians and other pet care professionals falsely representing that, "HeartGard Plus provides 100% protection against heartworm disease". These actions are specified in greater detail in paragraph 13.

b) Use of the mail and the internet in furtherance of a scheme to defraud which gave rise to the issuance of the FDA's Warning Letter dated August 14, 2006 addressed to Luibov Skibo, and attached hereto as Exhibit 5. The particular websites and the false and fraudulent representations made therein are specified in detail in the August 14 2006 Warning Letter, and in the previous letters specified in the August 14, 2006 letter, as specified in greater detail in paragraphs 14 through 19.

c) Use of the internet in furtherance of a scheme to defraud by knowingly placing false and misleading advertisements and promotional material on its own websites and by permitting allowing others to place false and misleading advertisements on their websites in order to promote sales of its heartworm preventive drug, HeartGard Plus. These actions, and the false content of the advertisements, the dates of the advertisements, the location of the websites, and the sponsors of those websites are specified in greater detail in paragraphs 21 through 22, and are reflected in Exhibits 7(a) through 19.

d) Failure to take appropriate action to immediately cease dissemination of the false and misleading promotional materials as demanded by the FDA, and failure to take appropriate action to stop others from falsely promoting HeartGard as 100% effective. These actions allowed the impression to remain with veterinarians and the consuming public that HeartGard Plus was 100% effective. These actions, as specified in greater detail in paragraphs 10 through 22 constitute the use of wire and mail in furtherance of a scheme to defraud which affects interstate commerce in violation of 18 U.S.C. §§ 1341 and 1343.

e) It is believed that with the aid of discovery numerous other criminal

violations in the form of wire fraud and mail fraud will come to light.

Pattern of Racketeering Activity

50. The above listed multiple predicate acts were committed within ten years of each other and were committed since the passage of RICO. In addition, they were committed with the common purpose of promoting sales of HeartGard Plus through the dissemination of false and misleading advertisements and promotional material.

Violation of 18 U.S.C. §1962 (a)

51. Defendant Merial's acts were in violation of subsection (a) of Title 18 U.S.C. §1962 (a) in that it invested in and received income directly or indirectly from its pattern of racketeering activity (the dissemination of false and misleading advertising and promotional material in furtherance of a scheme to defraud regarding HeartGard Plus by use of the mail and wire, both of which affected interstate commerce) in violation of 18 U.S.C. §§1341 and 1343. The violations of these and other state and federal statutes were committed for the purpose of obtaining financial gain. Furthermore, Merial participated as a principal within the meaning of Section 2, Title 18 U.S.C. to use or invest, directly or indirectly, any part of the income, or proceeds of such income in acquiring an interest in, or the establishment or operation of any enterprise which is engaged in or affects interstate commerce.

Violation of 18 U.S.C. §1962(b)

52. The Defendants violated subsection (b) of Title 18 U.S.C. §1962 in that they acquired or maintained an interest in or controlled an enterprise through a pattern of racketeering activity.

Violation of 18 U.S.C. §1962(c)

53. Defendants' acts are in violation of 18 U.S.C. §1962 (c) in that they were engaging in conducting or participating in the conduct of an enterprise's affairs through a pattern of racketeering activity.

Violation of 18 U.S.C. §1962(d)

54. Defendants violated 18 U.S.C. §1962(d) in that they conspired with each other and with others to violate subsections (a) (b) or (c) of Title 18 U.S.C. §1962.

Private Right of Action

55. Plaintiffs have been and continues to be injured in their business or property by virtue of the above listed violations of 18 U.S.C. §1962, and as such possess and hereby prosecute a private right of action under the RICO Act.

Count II.

Unjust Enrichment

56. Defendants have been unjustly enriched at the expense of the Plaintiffs by falsely promoting sales of its drug HeartGard Plus, and by knowingly permitting others to falsely promote the effectiveness of the drug. These wrongful actions have misled the veterinarian community and the American consumer. As a result of Defendants' wrongful conduct, these ill-gotten gains should be disgorged from the Defendants and awarded to the Plaintiffs.

Count III.

Injunctive Relief

57. The defendant Merial has been warned numerous times by the FDA to cease and desist its false and misleading advertisements and promotional efforts, and

has been warned to make sure that all future promotional materials adequately express the claims of heartworm prevention without overstating the effectiveness. Merial has steadfastly refused to do so. Accordingly, plaintiffs are entitled to a permanent injunction against Merial requiring it to comply with the previous mandates of the Food and Drug Administration with respect to non-deceptive advertising of its product, HeartGard Plus.

CLASS ALLEGATIONS

58. Plaintiffs bring this action on behalf of themselves and all others similarly situated, as members of the proposed Plaintiff Class (the Class), as to be hereinafter defined. Plaintiffs maintain that it is appropriate to maintain this action under Rule 23(a), 23(b)(2) and 23(b)(3), F.R.Civ.P.

59. This action should be maintained as a class action with respect to particular issues, the class should be divided into subclasses and each subclass treated as a class, and the provisions of 23(c)(4) and 23(c)(5) should be construed and applied accordingly.

60. The proposed “Drug Purchase” class should be certified under 23(b)(3) and defined as follows:

All individuals who purchased HeartGard or HeartGard Plus from and after September 1, 2005, until the date upon which Merial ceases making, or causing to be made, false claims regarding 100% efficacy, and false claims regarding transmission of zoonotic diseases to humans, excluding any members who have taken bankruptcy.

61. The proposed “drug class” subclass should be certified under 23(b)(3) and defined as follows:

All members of the “Drug Purchase” class whose dog or dogs experienced a failure of the drug to perform as advertised.

62. Specifically excluded from this Class are: (1) Any entity in which the Defendants have a controlling interest, and the officers, directors, affiliates, legal representatives, heirs, successors, subsidiaries, and/or assigns of any such individual or entity; (2) Any judge or judicial officer with responsibility of the management or resolution of this litigation, and members of the judicial officers’ immediate family.

63. The members of these two subclasses for whose benefit this action is brought are so numerous that joinder of all class members is impracticable. The exact number of the class is unknown to the Plaintiff. However, the number of these persons is reasonably believed to be in excess of 1,000, and can be determined from records maintained by Defendants and/or Defendants’ agents. There are questions of law or fact common to the class. The claims of the representative Plaintiffs are typical of all members of the Class, and lead Plaintiffs have no interest of which they are aware which is adverse or antagonistic to the interests of the Class, and will adequately represent the class.

64. Lead Plaintiffs and counsel will fairly and adequately protect the interests of the Class. They are committed to the vigorous prosecution of this action and have retained competent counsel experienced in complex litigation of this nature. The claims of the lead Plaintiffs are typical and arise from the same products/deficiencies which give rise to the claims of all other class members.

65. This Class Action is proper for certification. The entire Class should be certified under Rule 23(b)(2) in that the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or

corresponding declaratory relief is appropriate respecting the class as a whole. In addition, the entire class should be certified pursuant to Rule 23(b)(3) in that:

- a. Questions of law or fact common to the class members predominate over any question affecting only individual members; and
- b. A class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

The claims of the putative class in this regard are of the same products/deficiencies, and rest on the same grounds, applying more or less equally to all of the members of the Class.

66. Class Action is superior to other available methods for the fair and efficient adjudication of the claims asserted herein. Because damages suffered by individual Class Members may be relatively small, the expense and burden of individual litigation make it impracticable for the Class to seek redress individually for the wrongs they have suffered. Members of the Class do not have a particular interest in individually controlling the prosecution of separate actions. Plaintiffs envision no difficulty in the management of this case as a Class Action. Absent a Class Action, Defendants will likely suffer no redress for the fraud, failures of the drug, and other allegations set forth in this Complaint.

67. There are questions of law and fact which are common to the members of the Class, and which predominate over questions affecting individual members. Common questions of law and fact include, but are not limited to, the following:

- (a) Did Merial knowingly make false representations to veterinarians and the American consumer with respect to the efficacy of HeartGard Plus?

(b) Did Merial use the mail service in furtherance of a scheme to defraud and/or did Merial utilize the internet in furtherance of a scheme to defraud?

(c) Did the false representations damage the plaintiffs?

(d) Did members of the class experience a failure of the drug to perform as advertised?

PLAINTIFFS' PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiffs and members of the Class pray for the following:

1. That upon motion duly made as required by Rule 23, F.R.Civ.P., this Court certify this action pursuant to F.R.Civ.P. 23(b)(2) and 23(b)(3) as a Class Action on behalf of the Plaintiffs and all similarly situated.

2. Actual damages sufficient to compensate the plaintiffs for each of the alleged categories of damages as set forth above, including, but not limited to, the prices paid by the plaintiffs to purchase HeartGard and HeartGard Plus since the inception of the false advertisements and false promotional materials; costs incurred by the plaintiffs resulting from the failures of HeartGard and HeartGard Plus, and the amounts by which the defendant Merial has been unjustly enriched at the plaintiffs' expense by false and fraudulent advertising and promotional claims of excessive efficacy. According to Merial's website, approximately two billion doses of HeartGard products have been dispensed over the past twenty years. This equates to one hundred million doses per year. If the ill gotten gains equate to only \$1.00 per dose over the past seven years (the time period covered by the class), this equates to actual damages of approximately Seven Hundred Million Dollars.

