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CLERK OF THE COURT

DISTRICT COURT

CLARK COUNTY, NEVADA

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ROBERT W. GESKE, JR. and OLIVIA GESKE, Plaintiffs, v. TEDROS KEBEDE; BOEHRINGER INGELHEIM CORPORATION, a Domestic Corporation; BOEHRINGER INGELHEIM INTERNATIONAL GmbH, a Foreign Corporation; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., a Delaware Corporation; DOES I through X; and ROE CORPORATIONS XI through XX, inclusive, Defendants.	A- 12- 670302- C CASE NO: DEPT. NO: **COMPLAINT**

COMES NOW, Plaintiffs, ROBERT W. GESKE, JR. and OLIVIA GESKE, by and through their attorney of record, PATTI S. WISE, ESQ. of the law firm, EDWARD M. BERNSTEIN & ASSOCIATES, and hereby complain and allege as follows:

I.

PARTIES AND JURISDICTION

1. Plaintiff, ROBERT W. GESKE, JR., is, and at all times relevant hereto was, a resident of Clark County, Nevada.

2. Plaintiff, OLIVIA GESKE, is, and at all times relevant hereto was, a resident of Clark County, Nevada and is the spouse of Plaintiff ROBERT W. GESKE, JR.

3. Defendant, TEDROS KEBEDE, at all times mentioned herein and to the best knowledge of Plaintiffs, was and is a resident of Clark County, Nevada and was a drug representative who participated in the marketing, distributing and selling of Pradaxa® utilized by physicians and health care providers in Clark County, Nevada (hereinafter referred to as "Defendant Kebede").

4. Defendant, BOEHRINGER INGELHEIM CORPORATION, is and was at all relevant times herein, a domestic corporation chartered by and existing under and by virtue of the laws of the State of Nevada, and is and was in the business of manufacturing, marketing, distributing, and selling Pradaxa® utilized by physicians and health care providers in Clark County, Nevada.

5. Defendant, BOEHRINGER INGELHEIM INTERNATIONAL GmbH, is and was at all relevant times herein, a foreign corporation with its principal place of business located at Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany and is and was in the business of manufacturing, marketing, distributing, and selling Pradaxa® utilized by physicians and health care providers in Clark County, Nevada.

6. Defendant, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., is and was at all relevant times herein, a corporation chartered by and existing under and by virtue of the laws of the State of Delaware, with its principal place of business in the State of Connecticut and is and was in the business of manufacturing, marketing, distributing, and selling Pradaxa® utilized by physicians and health care providers in Clark County, Nevada.

7. Jurisdiction is conferred pursuant to NRS 14.080 in so far as Defendants

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manufactured, marketed, distributed and/or sold Pradaxa®, which was administered and/or prescribed to Plaintiff in Clark County, Nevada. It is reasonably foreseeable to Defendants, that when its product entered the State of Nevada, that Defendants could be expected to be sued in the state where its products caused the injury.

8. Jurisdiction is appropriate under the Due Process Clause. Upon information and belief Defendants were aware of the national distribution system and as a consequence of that awareness, Defendants indirectly and/or directly served the national market and derived economic benefit therefrom. As such, Defendants could reasonably anticipate being subject to suit in any forum within that market where their product caused injury.

9. The true names and capacities, whether individual, corporate, associate, or otherwise of Defendants, DOES I through X, inclusive, and Defendants, ROE CORPORATIONS XI through XX, inclusive, are unknown to Plaintiffs, and are believed to be drug representatives who detailed and/or marketed Pradaxa® to health care providers who provided care and treatment to Plaintiff, and/or are manufacturers, marketers, distributors and/or sellers of Pradaxa® utilized by physicians and health care providers at the relevant time periods who, therefore, sue said Defendants by such fictitious names but are believed to be agents, servants, and/or employees of Defendant Boehringer. Plaintiffs are informed and believe, and therefore allege, that each of the Defendants designated as a DOE and/or ROE CORPORATION are responsible in some manner for the events and happenings herein referred to, and caused injury and damages proximately thereby to Plaintiffs, as herein alleged; that such DOE Defendants and ROE CORPORATIONS Defendants were the agents, servants, or employees of each other and, in doing the things herein alleged, each was acting within the scope and course of said agency, servitude and employment, with the knowledge, permission and consent of the other Defendants. Plaintiffs will ask leave of

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this Court to amend this Complaint to insert the true names and capacities of said DOES I through X, inclusive and ROE CORPORATIONS XI through XX, inclusive, when the same have been ascertained by Plaintiffs, together with the appropriate charging allegations and to join such Defendants in this action.

10. At all times relevant herein, Defendants, and each of them, were the agents, servants, partners and employees of each and every other Defendant, and were acting within the course and scope of their agency, partnership and employment and, to the extent permitted by law, are jointly and severally liable.

II.

GENERAL FACTUAL ALLEGATIONS

11. On October 19, 2010, Defendant Boehringer's proprietary prescription drug Pradaxa® (dabigatran etexilate mesylate) (herein "Pradaxa®"), was approved for sale in the United States in two dosages: 75mg and 150mg, to be taken twice daily. The lower dosage is available for certain patients as described in the Pradaxa® "prescribing information" prepared and distributed by Defendants.

12. Pradaxa® is an anticoagulant designed to inhibit the body from forming blood clots and to prevent strokes. In the U.S., Pradaxa® is approved solely for use in patients diagnosed with atrial fibrillation (herein "A-Fib") not caused by dysfunction or disease of the cardiac valves. A-Fib is a heart rhythm irregularity in which the atria, the upper chambers of the heart, beat erratically and out of normal syncopation with the ventricles, the lower, larger cardiac chambers. A-Fib is known to cause blood clots to form in the heart. Such clots can then migrate to the brain causing an ischemic stroke or to the lungs in the form of pulmonary emboli. Pradaxa®, with its anticoagulation effects, is designed and indicated to prevent the formation of such blood clots

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during an episode of non-valvular A-Fib.

13. At all relevant times to this action, a specific reversal agent to stop anticoagulation caused by Pradaxa® was not available and therefore serious, uncontrollable and irreversible bleeding could and did result from Defendant Boehringer's intended and recommended use of Pradaxa®.

14. Prior to the availability of Pradaxa® in the United States, warfarin (sold under the brand name of Coumadin®) was the common, conventional medication to inhibit the body from forming blood clots. Unlike Pradaxa®, the anticoagulation caused by warfarin can be quickly and effectively reversed by administration of known and readily available antidotes and neutralizing agents.

15. At all times relevant to this action and originating from Defendant Boehringer's principal places of business located in Connecticut, Defendant Boehringer designed, developed, tested, manufactured, labeled, marketed, advertised, promoted, distributed, and sold Pradaxa® throughout the United States, and Defendants Boehringer and Kebede represented and promoted the advantages and benefits of Pradaxa® to U.S. physicians and the public and instructed physicians regarding recommended uses of Pradaxa® for patients such as Mr. Geske.

16. Defendants Boehringer and Kebede began intensive advertising and marketing campaigns to promote the selection, prescribing and use of Pradaxa® by physicians, including Mr. Geske's physician, Salvador Borromeo, M.D.

17. Though Pradaxa® was not approved for sale in the United States until October 19, 2010, Defendant Boehringer reportedly spent $67 million promoting Pradaxa® during 2010.[1]

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[1] Deborah Weinstein, *Study: Sales Support is Dwindling, Not Dead*, March 14, 2012, Medical Marketing and Media.

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18. During 2011, Defendant Boehringer reportedly undertook 1.5 million Pradaxa "detailing sessions" (marketing/sales visits by Defendants' sales force) with U.S. primary care physicians, internists, group practitioners, cardiologists, and practice nurses, spending $464 million to promote Pradaxa® in the United States.[2]

19. Defendants Boehringer and Kebede undertook regular, extensive and widely disseminated direct-to-consumer advertising campaigns designed to promote the sale of Pradaxa® to patients such as Mr. Geske and to influence such patients to request prescriptions for Pradaxa®.

20. Defendant Boehringer utilized print and television advertising to promote the sale of Pradaxa® to patients such as Mr. Geske and, to influence such patients to request prescriptions for Pradaxa®, hired and used practicing cardiologists in such advertising who regularly urged patients to ask their physicians about Pradaxa®. At no time during such advertisements did such spokesperson-cardiologists verbally disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa® and that such irreversibility could have permanently disabling, life-threatening or fatal consequences.

21. From October 2010 until the end of March 2011, approximately 272,119 prescriptions for Pradaxa® were written in the United States. During that same period, there were 932 Pradaxa®-associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the U.S. Food and Drug Administration including at least 120 deaths and over 500 reports of severe, life-threatening bleeding.

22. From April 2011 until the end of June 2011, there were an additional 856 Pradaxa®-associated "SAE" Medwatch reports filed with the U.S. Food and Drug Administration

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[2] Id.

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including at least 117 deaths and over 510 reports of severe, life-threatening bleeding.

23. During Defendant Boehringer's 2011 fiscal year, worldwide Pradaxa® sales eclipsed the $1 billion threshold achieving what is commonly known in the pharmaceutical industry as "blockbuster" sales status.[3]

24. Defendant Boehringer's original labeling and prescribing information for Pradaxa®:

a. failed to include a "Boxed Warning" about serious bleeding events associated with Pradaxa®;

b. failed to include a "Bolded Warning" about serious bleeding events associated with Pradaxa®;

c. failed to disclose in the "Warnings" Section that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa®;

d. failed to advise prescribing physicians, such as Mr. Geske's physician, to instruct patients that there was no antidote to reverse the anticoagulant effects of Pradaxa®;

e. failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Pradaxa®;

f. failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa®;

g. failed to provide adequate warnings about the true safety risks associated with the use of Pradaxa®; and

h. in their "Medication Guide" intended for distribution to patients taking

[3] Heide Oberhauser-Aslan and Tapan Sharma, *Boehringer Sees Sales Rising Further as 2011 Profits Surge* April 24, 2012 WSJ.com

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Pradaxa®, Defendant Boehringer failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa® and that such irreversibility could have permanently disabling, life-threatening or fatal consequences.

25. In March 2011, Defendant Boehringer modified the U.S. labeling and prescribing information for Pradaxa® adding additional information regarding the use of Pradaxa® by patients taking certain medications. Despite being aware of: (I) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (II) over 900 SAE Medwatch reports filed with the U.S. Food and Drug Administration including at least 120 deaths and over 500 reports of severe, life-threatening bleeding, Defendant Boehringer nonetheless:

a. failed to add a "Boxed Warning" about serious bleeding events associated with Pradaxa®;

b. failed to add a "Bolded Warning" about serious bleeding events associated with Pradaxa®;

c. failed to disclose in the "Warnings" Section that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa®;

d. failed to advise prescribing physicians, such as Mr. Geske's physician, to instruct patients that there was no antidote to reverse the anticoagulant effects of Pradaxa®;

e. failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Pradaxa®;

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f. failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa®;

g. failed to provide adequate warnings about the true safety risks associated with the use of Pradaxa®; and

h. in their "Medication Guide" intended for distribution to patients to whom Pradaxa® has been prescribed, Defendant Boehringer failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa® and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences.

26. On July 1, 2011, Pradaxa® was approved for sale in New Zealand with lower dosing (lowered from 150mg to 110mg twice a day) required for patients over 80 years of age and recommended for patients with moderate renal impairment.

27. On July 25, 2011, the highly respected Archives of Internal Medicine published *The Use of Dabigatran* [Pradaxa®] *in Elderly Patients.* [Vol. 171, No. 14] which concluded that "The risk of major overdosage of...[Pradaxa®] in this [elderly] population is, however, much increased owing to frequent renal function impairment, low body weight, drug interactions that cannot be detected with a routine coagulation test and no antagonist available."

28. On January 21, 2011, Pradaxa® (under the brand name Prazaza®), was approved for sale in Japan, in 75mg and 110mg doses only, to treat non-valvular A-Fib.

29. On August 11, 2011, Japan's pharmaceutical regulatory authority announced that it was requiring a "BOXED WARNING" be added to Pradaxa® (marketed as Prazaza® in Japan) to call attention to reports of severe hemorrhages in patients taking the drug.

30. On September 1, 2011, the New Zealand pharmaceutical regulatory authority issued

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a "Prescriber Update" entitled "Dabigatran – Is there a Bleeding Risk" in which physicians were alerted that Pradaxa® had a higher incidence of gastrointestinal bleeds than warfarin and that there was no reversal agent to neutralize the anticoagulation effects of Pradaxa®. A follow-up report issued in December, 2011 indicated that among 10,000 New Zealanders who had taken Pradaxa®, there were 78 reports of serious bleeding events associated with Pradaxa® including 60 reports of gastrointestinal (13) and rectal (47) bleeding. Among the 78 serious events were 10 patient deaths and 55 hospitalizations. Three months later in March, 2012 the New England Journal of Medicine published 2 letters from physicians in New Zealand addressing bleeding events associated with Pradaxa®. In one letter, physicians wrote that "We are concerned that the potential risks of this medication are not generally appreciated. The serious consequences of a lack of an effective reversal agent should not be underestimated."

31. In November 2011, Defendant Boehringer modified the U.S. labeling and prescribing information for Pradaxa® adding additional information regarding the use of Pradaxa® by patients with kidney disease. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the *Archives of Internal Medicine*; (iii) the addition of a BOXED WARNING" to Pradaxa® in Japan; and, (iv) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®, Defendants nonetheless:

a. failed to add a "Boxed Warning" about serious bleeding events associated with Pradaxa®;

b. failed to add a "Bolded Warning" about serious bleeding events associated with Pradaxa®;

c. failed to disclose in the "Warnings" Section that there is no drug, agent or

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means to reverse the anticoagulation effects of Pradaxa®;

d. failed to advise prescribing physicians, such as Mr. Geske's physician, to instruct patients that there was no antidote to reverse the anticoagulant effects of Pradaxa®;

e. failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Pradaxa®;

f. failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa®;

g. failed to provide adequate warnings about the true safety risks associated with the use of Pradaxa®; and

h. in their "Medication Guide" intended for distribution to patients to whom Pradaxa® has been prescribed, Defendant Boehringer failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa® and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences.

32. On December 7, 2011, the U.S. Food and Drug Administration issued a Drug Safety Communication announcing that it was undertaking a "Drug Safety Review" of Post-Marketing Reports of Serious Bleeding Events with the anticoagulant Pradaxa. The purpose of the FDA's review is to determine if serious bleeding events associated with the use of Pradaxa® are more common than expected based on Defendant Boehringer's data submitted to the FDA.

33. As of December 31, 2011, the U.S. Food and Drug Administration received over 540 reports of deaths of U.S. citizens linked to Pradaxa® which, at that point, had been available in

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the U.S. for approximately 14 months. In addition, there were over 2,300 reports of hemorrhages associated with the use of Pradaxa® including over 900 reports of gastrointestinal hemorrhages and over 300 reports of rectal hemorrhages, suffered by U.S. citizens associated with Pradaxa®.

34. In January 2012, Defendant Boehringer modified the U.S. labeling and prescribing information for Pradaxa®. Despite being aware of: (i) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa®; (ii) the July 25, 2011 article in the *Archives of Internal Medicine*; (iii) the addition of a "BOXED WARNING" to Pradaxa® in Japan; (iv) the questions being raised by physicians in New Zealand about serious bleeding events associated with Pradaxa®; and (v) the Drug Safety Communication published by the FDA in December 2011, Defendant Boehringer nonetheless:

a. failed to add a "Boxed Warning" about serious bleeding events associated with Pradaxa®;

b. failed to add a "Bolded Warning" about serious bleeding events associated with Pradaxa®;

c. failed to advise prescribing physicians, such as Mr. Geske's physician, to instruct patients that there was no antidote to reverse the anticoagulant effects of Pradaxa®;

d. failed to provide adequate warnings about the true safety risks associated with the use of Pradaxa®;

e. failed to investigate, research, study and consider, fully and adequately, patient weight as a variable factor in establishing recommended dosages of Pradaxa®;

f. failed to investigate, research, study and define, fully and adequately, the

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safety profile of Pradaxa®; and

g. in their "Medication Guide" intended for distribution to patients to whom Pradaxa® has been prescribed, Defendant Boehringer failed to disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa® and that if serious bleeding occurs, such irreversibility could have permanently disabling, life-threatening or fatal consequences.

35. In March 2012, in response to a directive from Health Canada, the governmental agency responsible for regulating pharmaceuticals in Canada, Defendant Boehringer's Canadian affiliate issued a "Dear Healthcare Provider" letter in which it advised Canadian healthcare providers of certain risks associated with the use of Pradaxa® (marketed as Pradax® in Canada) in elderly patients and patients with impaired kidney function and prosthetic heart valves. No such similar communication was sent to healthcare providers in the United States.

36. At all times relevant hereto, Defendants Boehringer and Kebede failed to warn emergency room doctors, surgeons and other critical care medical professionals that unlike generally-known measures taken to treat and stabilize bleeding that occurs in the presence of warfarin, there is no effective antidote to reverse the anticoagulation effects of Pradaxa® and therefore no effective means to treat and stabilize patients who experience uncontrolled bleeding while taking Pradaxa®.

37. At all times relevant to this action, the Pradaxa® Medication Guide, prepared and distributed by Defendant Boehringer and distributed by Defendant Kebede, and intended for U.S. patients to whom Pradaxa® has been prescribed, fails to warn and disclose to U.S. patients that there is no antidote to reverse the anticoagulation effects of Pradaxa® and that if serious bleeding occurs, it may be irreversible, permanently disabling and life-threatening.

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38. On or about April 15, 2011, Mr. Geske was prescribed and/or given Pradaxa®. On or about May 9, 2011, Mr. Geske was admitted to Spring Valley Hospital Medical Center with an uncontrollable gastrointestinal bleed, due to his use of Pradaxa®.

39. Had Defendants Boehringer and/or Kebede provided adequate warnings about the true risks posed by the use of Pradaxa®, Mr. Geske would not have used Pradaxa®.

40. Pradaxa® was the legal cause of Mr. Geske's injuries.

III.

STRICT PRODUCT LIABILITY–DANGEROUSLY DEFECTIVE PRODUCT AND FAILURE TO WARN

41. Plaintiffs hereby adopt and incorporate by reference all prior paragraphs as though fully set forth herein.

42. At all times relevant hereto, Defendant Boehringer was in the business of manufacturing, marketing, distributing, and/or selling Pradaxa®.

43. At all times relevant hereto, Defendant Kebede was engaged in the business of distributing, selling and/or marketing Pradaxa®.

44. At the time Pradaxa was prescribed and/or administered to Mr. Geske, Defendants failed to include suitable and adequate warnings concerning Pradaxa®'s safe and proper use and the absence of such warnings rendered the product unreasonably dangerous.

45. Defendants are liable under strict liability as follows:

a. Defendant Boehringer negligently designed and formulated Pradaxa® and its packaging, labeling, prescribing information and patient medication guide which rendered Pradaxa® defective;

b. Defendant Boehringer negligently produced and manufactured Pradaxa®

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and its packaging, labeling, prescribing information and patient medication guide which rendered Pradaxa® defective;

c. Defendants Boehringer and/or Kebede sold the negligently designed and/or manufactured Pradaxa® intending it to be prescribed to patients such as Mr. Geske;

d. Defendant Boehringer and/or Kebede sold the negligently designed and/or manufactured Pradaxa® in such a condition that made it unreasonably dangerous and unsafe for its intended use;

e. Defendants Boehringer and/or Kebede promoted Pradaxa® directly to consumers such as Mr. Geske and failed to provide adequate promotional warnings to Mr. Geske that no antidote existed that would reverse the anticoagulant effect of Pradaxa® in the event Mr. Geske experienced serious uncontrollable bleeding, as he did.

f. Defendants Boehringer and/or Kebede failed to provide adequate warnings to inform users of Pradaxa® such as Mr. Geske, of the risks and dangers associated with their use of Pradaxa® thereby rendering Pradaxa® unreasonably dangerous and unsafe for its intended use;

g. Defendants Boehringer and/or Kebede failed to instruct prescribing physicians, such as Mr. Geske's physician, Dr. Borromeo, to inform and warn patients such as Mr. Geske that no antidote existed that would reverse the anticoagulant effect of Pradaxa® in the event Mr. Geske, as he did, experienced serious uncontrollable bleeding, thereby rendering Pradaxa® unreasonably dangerous and unsafe for its intended use;

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h. Defendant Boehringer failed to adequately research, investigate, study and define the safety profile of Pradaxa® thereby rendering Pradaxa® unreasonably dangerous and unsafe for its intended use;

i. Defendants Boehringer and/or Kebede failed to provide physicians such as Dr. Borromeo and consumers such as Mr. Geske with a description of the true safety profile of Pradaxa®, thereby rendering Pradaxa® unreasonably dangerous and unsafe for its intended use;

j. Defendants Boehringer and/or Kebede misrepresented the true nature of the risks and benefits associated with the use of Pradaxa® thereby rendering Pradaxa® unreasonably dangerous and unsafe for its intended use;

46. Plaintiffs are informed and believe and thereupon allege that the aforementioned conduct of Defendants Boehringer and Kebede was willful, reckless, malicious and in total disregard to the health and safety of the patients or, alternatively, was in conscious and deliberate disregard of known safety procedures, thereby justifying an award of punitive damages.

47. As a direct and proximate of Defendants' wrongful conduct, Mr. Geske has sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages, loss of ability to engage in regular activities of daily living, loss of ability to engage in normal recreational and social activities individually and with Plaintiff Olivia Geske, and other harm which will be proven at trial. As a direct result, Mr. Geske expended money and will continue to expend money for medical bills and expenses.

48. As a direct and proximate result of the conduct of Defendants, Mr. Geske has suffered special damages in an amount in excess of Ten Thousand Dollars ($10,000.00).

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49. As a direct and proximate result of the conduct of Defendants, Mr. Geske has suffered general damages in an amount in excess of Ten Thousand Dollars ($10,000.00).

50. As a direct and proximate result of the conduct of Defendants, Mr. Geske is entitled to punitive damages in an amount in excess of Ten Thousand Dollars ($10,000.00).

51. As a further result of Defendants' conduct, Mr. Geske has had to retain the services of attorneys in this matter, and therefore, seeks reimbursement of attorneys' fees and costs.

IV.

NEGLIGENCE

52. Plaintiffs hereby adopt and incorporate by reference all prior paragraphs as though fully set forth herein.

53. At all relevant times to this action, Defendants, and each of them, owed a duty to the general public and specifically to Mr. Geske to exercise reasonable care in the design, study, development, manufacture, promotion, sale, labeling, marketing and distribution of Pradaxa®.

54. Defendant Boehringer breached its duty and failed to exercise reasonable care in the developing, testing, designing, and manufacturing of Pradaxa® because it was capable of causing serious personal injuries, such as those suffered by Mr. Geske during foreseeable use.

55. Defendants Boehringer and Kebede breached their duty and also failed to exercise reasonable care in the marketing of Pradaxa® because they failed to warn that, as designed, Pradaxa® was capable of causing serious personal injuries, such as those suffered by Mr. Geske during foreseeable use.

56. Defendant Boehringer breached its duty and also failed to exercise ordinary care in the labeling of Pradaxa® and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Pradaxa®.

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Moreover, Defendants Boehringer and Kebede over-promoted the benefits of Pradaxa® for anticoagulation therapy in patients suffering from atrial fibrillation and understated the risk of excessive and/or uncontrollable bleeding.

57. Defendants breached their duty and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Mr. Geske:

a. In disseminating information to Mr. Geske and his physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Mr. Geske;

b. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Pradaxa®;

c. Failing to design and/or manufacture a product that could be used safely due to the lack of a known reversal agent; and

d. In designing, manufacturing, and placing into the stream of commerce a product that was unreasonably dangerous for its reasonably foreseeable use, which Defendants knew or should have known could cause injury to Mr. Geske.

58. Despite the fact that Defendants knew or should have known that Pradaxa® posed a serious risk of bodily harm and death to consumers and/or did not provide any additional benefits, Defendants continued to manufacture and market Pradaxa® for use by consumers.

59. Defendant knew or should have known that consumers, including Mr. Geske, would foreseeably suffer injury and death as a result of Defendants' failure to exercise ordinary care as described above.

60. Defendants' failure to exercise reasonable care in the design, dosing information,

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marketing, warnings, labeling, and/or manufacturing of Pradaxa® was a proximate cause of Mr. Geske's subsequent injuries and damages.

61. As a direct and proximate result of the conduct of Defendants, Mr. Geske has suffered special damages in an amount in excess of Ten Thousand Dollars ($10,000.00).

62. As a direct and proximate result of the conduct of Defendants, Mr. Geske has suffered general damages in an amount in excess of Ten Thousand Dollars ($10,000.00).

63. The acts and conduct of Defendants, and each of them, were willful, wanton, and a conscious disregard of known safety precautions and procedures, entitling Mr. Geske to an award of punitive damages in an amount in excess of Ten Thousand Dollars ($10,000.00).

64. As a further result of Defendants' conduct, Mr. Geske has had to retain the services of attorneys in this matter, and therefore, seeks reimbursement of attorneys' fees and costs.

V.

NEGLIGENT PACKAGING, DISTRIBUTION AND MARKETING

65. Plaintiffs hereby adopt and incorporate by reference all prior paragraphs as though fully set forth herein.

66. Defendants, and each of them, owed a duty to Mr. Geske to distribute, market and package Pradaxa® in a safe manner.

67. As a result of Defendants' negligent packaging, marketing and distribution, Defendants breached their duty to Mr. Geske by failing to protect Mr. Geske from foreseeable harm.

68. As a direct and proximate result of the negligence and carelessness of Defendants, Mr. Geske sustained severe injuries and suffered great pain.

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69. Defendants' conduct demonstrated a conscious disregard that such conduct could or would expose Mr. Geske to harm.

70. As a direct and proximate result of the negligence and carelessness of Defendants, in packaging, marketing and distributing Pradaxa, Mr. Geske has incurred and will continue to incur additional medical expenses in an amount in excess of Ten Thousand Dollars ($10,000.00).

71. The acts and conduct of Defendants, and each of them, were willful, wanton, and a conscious disregard of known safety precautions and procedures, entitling Mr. Geske to an award of punitive damages in an amount in excess of Ten Thousand Dollars ($10,000.00).

72. As a further result of Defendants' conduct, Mr. Geske has had to retain the services of attorneys in this matter, and therefore seek reimbursement of attorneys' fees and costs.

VI.

BREACH OF EXPRESS WARRANTY

73. Plaintiffs hereby adopt and incorporate by reference all prior paragraphs as though fully set forth herein.

74. Defendants expressly warranted, through their direct-to-consumer marketing, label and sales representatives, that Pradaxa® was a safe and effective prescription anticoagulant medication. The safety and efficacy of Pradaxa® constitute a material fact in connection with the marketing, promotion and sale of Pradaxa®.

75. Pradaxa® manufactured and sold by Defendants did not conform to these express representations because it was not safe and effective for its intended use, and instead caused serious injury to consumers when taken in recommended dosages.

76. As a direct and proximate result of Defendants' breach of warranty, Mr. Geske sustained severe injuries and suffered great pain.

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77. As a direct and proximate result of Defendants' breach of warranty, Mr. Geske has incurred and will continue to incur additional medical expenses in an amount in excess of Ten Thousand Dollars ($10,000.00).

78. The acts and conduct of Defendants, and each of them, were willful, wanton, and a conscious disregard of known safety precautions and procedures, entitling Mr. Geske to an award of punitive damages in an amount in excess of Ten Thousand Dollars ($10,000.00).

79. As a further result of Defendants' conduct, Mr. Geske has had to retain the services of attorneys in this matter, and therefore seek reimbursement of attorneys' fees and costs.

VII.

BREACH OF IMPLIED WARRANTY

80. Plaintiffs hereby adopt and incorporate by reference all prior paragraphs as though fully set forth herein.

81. At the time Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and/or otherwise released Pradaxa® into the stream of commerce, Defendants knew of the use for which Pradaxa® was intended and impliedly warranted the product to be of merchantable quality and safe for its intended use and purpose.

82. Mr. Geske relied upon Defendants' skill and judgment as to whether Pradaxa® was of merchantable quality and safe and effective for its intended use and purpose, and reasonably relied upon Defendants' implied warranty as to such matters.

83. Defendants breached their implied warranties of the Pradaxa® product sold to Mr. Geske because this product was not fit for its common, ordinary and intended us, in that the product was unreasonably dangerous when used as directed for its intended purpose as described in

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this Complaint.

84. As a direct, foreseeable and proximate result of Defendants' breaches of implied warranties, Mr. Geske sustained severe injuries and suffered great pain.

85. As a direct and proximate result of Defendants' breach of warranty, Mr. Geske has incurred and will continue to incur additional medical expenses in an amount in excess of Ten Thousand Dollars ($10,000.00).

86. The acts and conduct of Defendants, and each of them, were willful, wanton, and a conscious disregard of known safety precautions and procedures, entitling Mr. Geske to an award of punitive damages in an amount in excess of Ten Thousand Dollars ($10,000.00).

87. As a further result of Defendants' conduct, Mr. Geske has had to retain the services of attorneys in this matter, and therefore seek reimbursement of attorneys' fees and costs.

VIII.

NEGLIGENT MISREPRESENTATION

88. Plaintiffs hereby adopt and incorporate by reference all prior paragraphs as though fully set forth herein.

89. Defendants, in the course of their business profession, knowingly and negligently supplied Mr. Geske and his physicians and the FDA with false information through Defendants' written literature and representations by sales agents, including Defendant Kebede, for guidance in the physicians' and patient's decision to use and/or approve Pradaxa®.

90. Defendants represented that Pradaxa® was just as safe or safe and as effective or more effective than other anticoagulation alternatives and had additional benefits compared to other anticoagulation medications available on the market.

91. Defendants made these representations and actively concealed adverse information

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at a time when the Defendants knew, or should have known, that Pradaxa® had defects, dangers and characteristics that were other than what Defendants had represented to Mr. Geske and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiff and the consuming public, among other things, that:

a. Pradaxa® had statistically significant increases in irreversible bleeds and other side effects which could result in serious, permanent injury or death;

b. Pradaxa® had not been fully or adequately tested;

c. Pradaxa® does not have any known reversal agents;

d. Pradaxa® bleeds cannot be stopped or controlled by any effective medical processes or medical intervention;

e. Failed to warn that it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Pradaxa®; and

f. Pradaxa® was not as safe as blood thinners such as warfarin.

92. Defendants negligently and/or intentionally misrepresented or omitted this information in their product labeling, promotions and advertisements and instead labeled, promoted and advertised their product as safer and more effective than other types of anticoagulation alternatives, and understated the risk of excessive and/or uncontrollable bleeding associated with Pradaxa®.

93. The aforementioned misrepresentations were untrue and misleading.

94. Defendants knew and should have known that these representations were false and made the representations with the intent that Plaintiff and his prescribing physicians would rely on them, leading to the use of Pradaxa®.

95. In willfully supplying the false information, Defendants negligently failed to exercise

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reasonable care in obtaining or communicating information to Mr. Geske, his physicians and the FDA.

96. At the time of Defendants' fraudulent misrepresentations, Mr. Geske and/or his prescribing physicians were unaware of the falsity of the statements being made and believed them to be true. Mr. Geske and/or his prescribing physicians justifiably relied on and/or were induced by the misrepresentations and/or active concealment, and relied on the absence of safety information, which Defendants did suppress, conceal or failed to disclose, to Mr. Geske's detriment.

97. The false information obtained and communicated by Defendants to Mr. Geske, his physicians and the FDA was material and upon which Mr. Geske and the medical community justifiably relied in good faith to their detriment.

98. As a direct and proximate result of the negligent misrepresentations of Defendants, Mr. Geske sustained severe injuries and suffered great pain.

99. As a direct and proximate result of Defendants' negligent misrepresentations, Mr. Geske has incurred and will continue to incur additional medical expenses in an amount in excess of Ten Thousand Dollars ($10,000.00).

100. The acts and conduct of Defendants, and each of them, were willful, wanton, and a conscious disregard of known safety precautions and procedures, entitling Mr. Geske to an award of punitive damages in an amount in excess of Ten Thousand Dollars ($10,000.00).

101. As a further result of Defendants' conduct, Mr. Geske has had to retain the services of attorneys in this matter, and therefore seek reimbursement of attorneys' fees and costs.

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IX.

FRAUD AND INTENTIONAL MISREPRESENTATION

102. Plaintiffs hereby adopt and incorporate by reference all prior paragraphs as though fully set forth herein.

103. Defendants knowingly, willfully and intentionally made material, false, fraudulent, and misleading misrepresentations through their written literature and through their sales representatives, including Defendant Kebede, to Mr. Geske, his physicians and to the public that Pradaxa® was safe for its prescribed use and that Defendants' labeling, marketing and promotion fully and adequately described, informed, and warned of all known risks of the product.

104. Defendants' misrepresentations were in fact false and fraudulent, as Pradaxa® is not safe for its intended use and its labeling, marketing, and promotion did not adequately describe, inform, or warn the medical community and patients of all known risks of the product.

105. Defendants had or should have had actual knowledge and information based upon studies, published reports, and clinical experience that its product Pradaxa® created an unreasonable risk of serious bodily injury and death to consumers, when used by patients as directed by Defendants.

106. Defendants knowingly, willfully, and intentionally concealed the true information regarding the risks of harm created by their product in the product labeling, marketing, and promotion and instead, labeled, promoted and marketed their product as safe for use in order to avoid monetary losses and in order to sustain profits in sales to consumers.

107. When Defendants made these misrepresentations that Pradaxa® was safe and effective for its intended use, Defendants knowingly, willfully, and intentionally concealed and withheld from Mr. Geske, his physicians and the public the true facts known by Defendants that

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Pradaxa® is not safe for its intended and prescribed use and purpose.

108. Defendants had a duty to disclose to Mr. Geske, his physicians and the public that Pradaxa® was not safe in that it can cause serious uncontrollable bleeding events and death, because Defendants had superior knowledge of these facts that were material to Mr. Geske's and his physicians' decision to use Pradaxa®.

109. Mr. Geske and his physicians reasonably and justifiably relied upon Defendants' intentional concealment of the true facts, and reasonably and justifiably relied upon Defendants' misrepresentations to Mr. Geske and his health care providers that Pradaxa® was safe and that Defendants' labeling, marketing and promotion fully and adequately described, warned, and informed all known risks of the product.

110. Had Mr. Geske and his physicians known of Defendants' intentional and fraudulent concealment of the true facts that Pradaxa® was not safe for human use, Mr. Geske's healthcare providers would not have prescribed Pradaxa® to Mr. Geske and he would not have agreed to use Pradaxa® as directed by Defendants.

111. As a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment, Mr. Geske was prescribed and used Pradaxa® as instructed by Defendants and sustained severe injuries and suffered great pain.

112. As a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment, Mr. Geske has incurred and will continue to incur additional medical expenses in an amount in excess of Ten Thousand Dollars ($10,000.00).

113. The acts and conduct of Defendants, and each of them, were willful, wanton, and a conscious disregard of known safety precautions and procedures, entitling Mr. Geske to an award of punitive damages in an amount in excess of Ten Thousand Dollars ($10,000.00).

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114. As a further result of Defendants' conduct, Mr. Geske has had to retain the services of attorneys in this matter, and therefore seek reimbursement of attorneys' fees and costs.

X.

LOSS OF CONSORTIUM

115. Plaintiffs hereby adopt and incorporate by reference all prior paragraphs as though fully set forth herein.

116. Plaintiff OLIVIA GESKE is the spouse of Plaintiff ROBERT W. GESKE, JR. and has been his spouse at all times relevant to this Complaint.

117. As a direct and proximate result of each of the Defendants' negligence, Mrs. Geske has suffered loss of consortium and consequent severe emotional distress all to her damage in excess of Ten Thousand Dollars ($10,000.00).

118. As a further direct and proximate result of Defendants' negligence, Mrs. Geske has had to retain the services of attorneys and therefore seeks reimbursement of attorneys' fees and costs.

XI.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for Judgment against Defendants, and each of them, as follows:

1. For general damages in excess of $10,000.00;
2. For special damages in excess of $10,000.00;
3. For punitive damages in an amount to be determined at trial;
4. For reasonable attorneys' fees;
5. For costs of suit; and
6. For any such further relief this Court deems appropriate.

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XII.

DEMAND FOR JURY TRIAL

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

DATED this 18th day of October, 2012.

EDWARD M. BERNSTEIN & ASSOC.

By: _____

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