UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE: PRADAXA (DABIGATRAN ETEXILATE) PRODUCTS LIABILITY LITIGATION	3:12-MD-02385-DRH-SCW **MDL No. 2385** Judge David R. Herndon
SUZANNE MACKIEWICZ, On behalf of the Estate of MALACHY HIGGINS, Deceased and SUZANNE MACKIEWICZ, Individually, Plaintiff, -against- BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, Defendants.	COMPLAINT AND JURY DEMAND Civil Action No: 13-50167

COMPLAINT

Plaintiff, SUZANNE MACKIEWICZ (hereinafter "Plaintiff"), on behalf of the estate of MALACHY HIGGINS (hereinafter "Plaintiff-decedent"), and SUZANNE MACKIEWICZ, individually (hereinafter collectively referred to as "Plaintiffs"), by her attorneys, **DOUGLAS & LONDON, P.C.** on behalf of themselves individually, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiffs reside.

2. Plaintiff is filing this Complaint as permitted by Case Management Order #7 issued by Judge David R. Herndon of this Court. Plaintiff states that but for that Order permitting direct filing into the Southern District of Illinois, Plaintiffs could have filed in the United States District Court in New York. Therefore, Plaintiffs may respectfully request that at the time of transfer of this action back to the trial court for further proceedings this case be transferred to the District Court of New York as set forth in Case Management Order #7.

3. This Court has personal jurisdiction over Defendants consistent with the United States Constitution and MDL No. 2385 as Plaintiff's claims arise out of Defendants' transaction of business and the tortuous acts within the State of New York, and by virtue of Defendants' substantial, continuous and systematic contacts with the State of New York and the State of Illinois unrelated to Plaintiffs' claims.

NATURE OF THE CASE

4. This action is brought on behalf of Plaintiff-decedent, MALACHY HIGGINS, who used Pradaxa also known as dabigatran etexilate to reduce the risk of stroke and systemic embolism.

5. Defendants, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM INTERNATIONAL GMBH, (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Pradaxa.

6. When warning of safety and risks of Pradaxa, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as "FDA"), to Plaintiff and the public in general, that Pradaxa had been tested and was found to be safe and/or effective for its indicated use.

7. Defendants concealed their knowledge of Pradaxa's defects, from Plaintiff-decedent, the Food and Drug Administration, the public in general and/or the medical community specifically.

8. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiff-decedent, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Pradaxa for use as to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff-decedent herein.

9. Defendants negligently and improperly failed to perform sufficient tests, if any, on humans using Pradaxa during clinical trials, forcing Plaintiff-decedent, and Plaintiff-decedent's physicians, hospitals, and/or the FDA, to rely on safety information that applies to other non-valvular atrial fibrillation treatment, which does not entirely and/or necessarily apply to Pradaxa whatsoever.

10. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including inter alia life threatening bleeding and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and premature death. Plaintiff-decedent herein has sustained certain of the above health consequences due to Plaintiff-decedent's use of Pradaxa.

11. Defendants concealed their knowledge of the defects in their products from the Plaintiff-decedent, and Plaintiff-decedent's physicians, hospitals, pharmacists, the FDA, and the public in general.

12. Consequently, Plaintiffs seeks compensatory damages as a result of Plaintiff-decedent's use of the Pradaxa, which has caused Plaintiff-decedent to suffer from life threatening bleeding and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and premature death.

PARTY PLAINTIFF

13. Plaintiff, SUZANNE MACKIEWICZ, is a citizen of the United States of America, and is a resident of the State of New York.

14. Plaintiff, SUZANNE MACKIEWICZ, is the daughter of Plaintiff-decedent MALACHY HIGGINS.

15. Plaintiff-decedent MALACHY HIGGINS was born on August 15, 1926.

16. Plaintiff-decedent, MALACHY HIGGINS, first began using Pradaxa in or about November 8, 2011, and used Pradaxa up through approximately November 29, 2011.

17. As result of using Defendants' Pradaxa, Plaintiff-decedent MALACHY HIGGINS, was caused to suffer from life threatening bleeding, severe and permanent personal injuries, pain, suffering, and emotional distress and sudden death on January 8, 2012.

18. The injuries and death sustained by Plaintiff-decedent, MALACHY HIGGINS, were caused by Defendants' Pradaxa.

PARTY DEFENDANTS

19. Upon information and belief, Defendant BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. (hereinafter referred to as "BOEHRINGER US") is a Delaware corporation, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. As part of its business, BOEHRINGER US is involved in the research, development, sales and marketing of pharmaceutical products including Pradaxa and dabigatran etexilate.

20. Upon information and belief, Defendant, BOEHRINGER US, has transacted and conducted business in the State of Illinois and the State of New York..

21. Upon information and belief, Defendant, BOEHRINGER US, has derived substantial revenue from goods and products used in the State of Illinois and the State of New York.

22. Upon information and belief, Defendant, BOEHRINGER US, expected or should have expected its acts to have consequence within Illinois and New York, and derived substantial revenue from interstate commerce within the United States and the State of Illinois and the State of New York, more particularly.

23. Upon information and belief, and at all relevant times, Defendant, BOEHRINGER US, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Pradaxa for use which primary purpose is to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

24. Upon information and belief, Defendant BOEHRINGER INGELHEIM INTERNATIONAL GMBH (hereinafter referred to as "BOEHRINGER INTERNATIONAL") is a foreign corporation, having a principal place of business at Boehringer Ingelheim GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.

25. Upon information and belief, Defendant, BOEHRINGER INTERNATIONAL, has transacted and conducted business in the State of Illinois and the State of New York.

26. Upon information and belief, Defendant, BOEHRINGER INTERNATIONAL, has derived substantial revenue from goods and products used in the State of Illinois and the State of New York.

27. Upon information and belief, Defendant, BOEHRINGER INTERNATIONAL, expected or should have expected its acts to have consequence within Illinois and the State of New York, and derived substantial revenue from interstate commerce within the United States and Illinois and the State of New York, more particularly.

28. Upon information and belief, and at all relevant times, Defendant, BOEHRINGER INTERNATIONAL, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Pradaxa for use which primary purpose is to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

FACTUAL BACKGROUND

29. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Pradaxa and dabigatran etexilate to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

30. Defendants received FDA approval for Pradaxa, also known as dabigatran etexilate, on October 19, 2010 for prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

31. Defendants launched Pradaxa in the United States in 2010.

32. Pradaxa is an anticoagulant that acts as a direct thrombin inhibitor, and is available by prescription in oral tablet doses of 75mg and 150mg.

33. Approval of Pradaxa in the US was based on a clinical trial known as the Randomized Evaluation of Long-Term Anticoagulation Therapy study (hereinafter referred to as "RE-LY"). The study's findings showed that while Pradaxa 150mg twice daily reduced the risk of stroke and systemic embolism more effectively than warfarin, there was a similar rate of major hemorrhage. However, "[t]here was a significantly higher rate of major life threatening bleeding with dabigatran at the 150-mg dose than with warfarin." There was also an associated increased risk of acute myocardial infarction as compared with warfarin. (Connolly, S.J., et al. *Dabigatran versus Warfarin in Patients with Atrial Fibrillation*. N.Engl.J.Med. 2009; 361:1139-1151.)

34. Defendants use the results of the RE-LY study to promote Pradaxa, and states on its promotional materials, including its website, that in a clinical trial Pradaxa 150mg was 35% more effective at reducing risk of stroke than warfarin. However, it fails to similarly highlight the increased risk of gastrointestinal bleeding.

35. Defendants market Pradaxa as the first oral anticoagulant treatment alternative to warfarin (Coumadin), a long-established safe treatment for preventing stroke and systemic embolism, in 60 years. Defendants emphasize the supposed benefits of treatment with Pradaxa over warfarin, namely that Pradaxa does not require periodic monitoring with blood tests and does not limit a patient's diet.

36. Importantly, there is no antidote to Pradaxa, unlike warfarin. Therefore, in the event of hemorrhagic complications, there is no available reversal agent. Until the belated date of January 17, 2012, the US label did not contain a warning regarding the lack of antidote, but instead only mentioned this important fact in the overdosage section.

37. Defendants spent significant money in promoting Pradaxa, which included $67,000,000.00 spent during 2010 (although Pradaxa was not approved for sale until October 19, 2010).

38. During 2011, Defendants 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 approximately $464,000,000.00 during this 12 month period to promote Pradaxa in the United States.

39. As part of their marketing of Pradaxa, Defendants widely disseminated direct-to-consumer advertising campaigns that were designed to influence patients, including Plaintiff-decedent, to make inquiries to their prescribing physician about Pradaxa and/or request prescriptions for Pradaxa.

40. In the course of these direct to consumer advertisements, Defendants overstated the efficacy of Pradaxa with respect to preventing stroke and systemic embolism, failed to adequately 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 and fatal consequences.

41. Prior to Plaintiff-decedent's prescription of Pradaxa, Plaintiff-decedent became aware of the promotional materials described herein.

42. Prior to Plaintiff-decedent's prescription of Pradaxa, Plaintiff-decedent's prescribing physician received promotional materials and information from sales representatives of Defendants that Pradaxa was more effective than warfain in reducing strokes in patients with non-valvular atrial fibrillation and was more convenient, without also adequately informing prescribing physicians that there was no reversal agent that could stop or control bleeding in patients taking Pradaxa.

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

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

45. From October 2010 until the end of March 2011, approximately 272,119 prescriptions for Pradaxa were dispensed 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, 293 of which involved gastrointestinal hemorrhage, more than any other drug that is regularly monitored.

46. From April 1 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, which totals more than any other regularly monitored drug. The reports included at least 117 deaths and over 510 reports of severe, life-threatening bleeding.

47. During the Defendants' 2011 fiscal year, worldwide Pradaxa sales eclipsed the $1 billion threshold, achieving what is commonly known in the pharmaceutical industry as "blockbuster" sales status.

48. Since its launch worldwide beginning as early as 2008, international health authorities have conducted investigations and evaluations in order to assess the increased risk of serious side effects, such as life threatening bleeding, associated with the use of Pradaxa.

49. 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.

50. In September 2011, the New Zealand pharmaceutical regulatory authority issued a "Prescriber Update" entitled "Dabigatran – Is there a Bleeding Problem?" 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 detailing reports through November 7, 2011, indicated that among 10,000 New Zealanders who had begun taking Pradaxa through the end of September 2011, there were 295 adverse event reports associated with Pradaxa, including 51 serious bleeding events, and 60 reports of gastrointestinal and rectal bleeding. Among 78 serious reported events, there were 10 patient deaths and 55 hospitalizations. Three months later in March, 2012 the *New England Journal of Medicine* published two letters from physicians in New Zealand addressing bleeding events associated with Pradaxa. In one letter, physicians wrote, "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."

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

52. In August of 2011, the Japan Ministry of Health, Labor and Welfare issued a safety warning regarding potential risk of adverse events with Pradaxa, and 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 treated with Pradaxa (Prazaza®). The announcement reported 81 cases of serious events, including gastrointestinal bleeding, in approximately 64,000 users since the January 2011 release of Pradaxa in Japan. The ministry also requested that Defendants issue letters informing healthcare professionals of the increased risk of major bleeding events and urging physicians to asses a patient's renal function prior to initiating Pradaxa treatment.

53. The Europeans Medicine Agency (hereinafter referred to as "EMA") announced on November 18, 2011 that between March 2008 and November 6, 2011 a total of 256 spontaneous case reports of fatal bleeding events worldwide associated with Pradaxa. EMA associated the increased reporting rate of serious bleeding events with the increased use of Pradaxa following the additional indication of prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation in many regions. Based on these reports, EMA recommended a label change regarding bleeding risk, including suggesting a renal assessment prior to beginning Pradaxa and cautioning the use of Pradaxa in high dosage with elderly and renal impaired patient population. Defendants confirmed in its own statement on November 12, 2011 that nearly 260 reports of fatal bleeding events were linked to Pradaxa usage.

54. The Australian Government Department of Health and Ageing Therapeutic Goods Administration (hereinafter referred to as "TGA") also released a safety advisory on November 3, 2011 regarding the risk of bleeding related to Pradaxa treatment. TGA granted the additional indication in April 2011 for prevention of stroke and other blood clots in people with atrial fibrillation, and commented that "[s]ince more people have started to use Pradaxa the TGA has received an increase in the number of bleeding-related adverse event reports." In December 2011, TGA also stated that "the most common site of serious bleeding for dabigatran is the gastrointestinal tract."

55. In addition, TGA criticized the RE-LY study in is May 2011 Public Assessment Report, stating that its open-label design was "subject to bias" and that "the lack of placebo control makes interpretation of some of these outcomes difficult." Within the same report, TGA also discussed the reanalysis of the RE-LY study performed by Defendants after FDA found inconsistencies in the original data, which resulted in an additional 81 outcome events related to safety and efficacy. In regards to that reanalysis, TGA stated that "it was of concern that such a large number of major bleeds were not initially

identified in the original study and this suggests a significant problem with initial quality control and/or auditing of the study."

56. On March 16, 2012, Health Canada endorsed a label change regarding renal function assessments in patients prior to beginning treatment with Pradaxa, due to the fact that renal impairment is a known risk factor for bleeding with Pradaxa.

57. The National Institute for Health and Clinical Excellence in the United Kingdom also published a statement regarding the approval of Pradaxa, noting that the RE-LY study results submission to the FDA "demonstrated that the greatest benefit of dabigatran was in the lowest quartile of INR control and that, in people with good INR control with warfarin, little or no additional benefit in terms of effectiveness would be gained with dabigatran."

58. Defendants original and in some respects current labeling and prescribing information for Pradaxa:

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

b. failed to advise prescribing physicians, such as the Plaintiff's physician, to instruct patients that there was no agent to reverse the anticoagulant effects of Pradaxa;

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

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

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

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

g. failed to provide adequate instructions on how to intervene and/or stabilize a patient who suffers a bleed while taking Pradaxa;

h. failed to provide adequate warnings regarding the need to assess renal functioning prior to starting a patient on Pradaxa and to continue testing and monitoring of renal functioning periodically while the patient is on Pradaxa;

i. failed to provide adequate warnings and information related to the increased risks of bleeding events associated with aging patient populations of Pradaxa users;

j. failed to provide adequate warnings regarding the increased risk of gastrointestinal bleeds in those taking Pradaxa, especially, in those patients with a prior history of gastrointestinal issues and/or upset;

k. failed to include a "**BOXED WARNING**" about serious bleeding events associated with Pradaxa;

l. failed to include a "**Bolded Warning**" about serious bleeding events associated with Pradaxa; and

m. in their "Medication Guide" intended for distribution to patients to whom Pradaxa has been prescribed, Defendants 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.

59. During March, 2011, Defendants modified the U.S. labeling and prescribing information for Pradaxa, which included additional information regarding the use of Pradaxa in patients taking certain medications. Despite being aware of: (I) serious, and sometimes fatal, irreversible bleeding events associated with the use of Pradaxa; (II) almost 1800 SAE Medwatch reports filed with the U.S. Food and Drug Administration, including at least 237 deaths and over 1,000 reports of severe, life-threatening bleeding, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 26 (a – m).

60. On December 7, 2011, FDA issued a Safety Announcement stating that it would be conducting its own evaluation of post-marketing reports of serious bleeding events in patients taking Pradaxa in order to determine whether such events "are occurring more commonly than would be expected, based on observations in the large [RE-LY] clinical trial that supported the approval of Pradaxa."

61. As of December 31, 2011, the U.S. Food and Drug Administration received over 500 reports of deaths of people in the U.S. linked to Pradaxa which, at that point, had been available in the U.S. for approximately 14 months. In addition, there were over 900 reports of gastrointestinal hemorrhages, over 300 reports of rectal hemorrhages, and over 200 reports of cerebrovascular accidents suffered by U.S. citizens associated with Pradaxa.

62. In January, 2012, the Defendants 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, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 26 (a – m).

63. In April 2012, the Defendants 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; (v) the Drug Safety Communication published by the FDA in December, 2011; and (vi) the "Dear Healthcare Provider" letter Defendants were required to provide in Canada, Defendants nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraphs 26 (a – m).

64. Furthermore, on July 25, 2011, the *Archives of Internal Medicine* published *The Use of Dabigatran* [Pradaxa] *in Elderly Patients*. [Vol 171, No. 14] which concluded that, "[t]he 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."

65. A critique published in the *New England Journal of Medicine* on November 24, 2011 discussed the limitations of Pradaxa in comparison to warfarin therapy, namely "three notable concerns: there is no readily available means for assessing the degree of anticoagulation with dabigatran, there is no readily available reversal strategy, and life-threatening bleeding complications can occur after an injury in patients taking this drug."

66. In addition, the Institute for Safe Medication Practices issued a report on January 12, 2012 declaring that Pradaxa had "generated a strong signal illustrating the substantial bleeding risks of this treatment, with more than 500 reports of fatal, disabling and other severe hemorrhages."

67. Prior to applying for and obtaining approval of Pradaxa, Defendants knew or should have known that consumption of Pradaxa was associated with and/or would cause the induction of life threatening bleeding, and Defendants possessed at least one clinical scientific study, which evidence Defendants knew or should have known was a signal that life threatening bleeding risk needed further testing and studies prior to its introduction to the market.

68. Upon information and belief, despite life threatening bleeding findings in a clinical trial and other clinical evidence, Defendants failed to adequately conduct complete and proper testing of Pradaxa prior to filing their New Drug Application for Pradaxa.

69. Upon information and belief, from the date Defendants received FDA approval to market Pradaxa, Defendants made, distributed, marketed and sold Pradaxa without adequate warning to Plaintiff's prescribing physicians or plaintiff that Pradaxa was associated with and/or could cause life threatening bleeding, presented a risk of life threatening bleeding in patients who used it, and that Defendants had not adequately conducted complete and proper testing and studies of Pradaxa with regard to severe side effects, specifically life threatening bleeding.

70. Upon information and belief, Defendants concealed and failed to completely disclose its knowledge that Pradaxa was associated with or could cause life threatening bleeding as well as its knowledge that they had failed to fully test or study said risk.

71. Upon information and belief, Defendants ignored the association between the use of Pradaxa and the risk of developing life threatening bleeding.

72. Defendants' failure to disclose information that they possessed regarding the failure to adequately test and study Pradaxa for life threatening bleeding risk further rendered warnings for this medication inadequate.

73. By reason of the foregoing acts and omissions, Plaintiffs seek compensatory damages as a result of the Plaintiff-decedent's use of Pradaxa, which caused the Plaintiff-decedent to suffer from life threatening bleeding and sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death.

74. Plaintiffs have endured and continue to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff-decedent has suffered serious and dangerous side effects including, inter alia life threatening bleeding and sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death.

75. By reason of the foregoing, Plaintiffs have been severely and permanently injured, including Plaintiff-decedent's premature death.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

76. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

77. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Pradaxa into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

78. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or

distribution of Pradaxa into interstate commerce in that Defendants knew or should have known that using Pradaxa created a high risk of unreasonable, dangerous side effects, including, life threatening bleeding, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications..

79. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Pradaxa without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing Pradaxa without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not Pradaxa was safe for use; in that Defendants herein knew or should have known that Pradaxa was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling Pradaxa without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Pradaxa;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Pradaxa;

(g) Failing to test Pradaxa and/or failing to adequately, sufficiently and properly test Pradaxa.

(h) Negligently advertising and recommending the use of Pradaxa without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that Pradaxa was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that Pradaxa had equivalent safety and efficacy as other forms of Non-valvular atrial fibrillation treatment;

(k) Negligently designing Pradaxa in a manner which was dangerous to its users;

(l) Negligently manufacturing Pradaxa in a manner which was dangerous to its users;

(m) Negligently producing Pradaxa in a manner which was dangerous to its users;

(n) Negligently assembling Pradaxa in a manner which was dangerous to its users;

(o) Concealing information concerning FDA warnings from the Plaintiff in knowing that Pradaxa was unsafe, dangerous, and/or non-conforming with FDA regulations;

(p) Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Pradaxa compared to other forms of Non-valvular atrial fibrillation treatment.

80. Defendants under-reported, underestimated and downplayed the serious dangers of Pradaxa.

81. Defendants negligently compared the safety risk and/or dangers of Pradaxa with other forms of non-valvular atrial fibrillation treatment.

82. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Pradaxa in that they:

(a) Failed to use due care in designing and manufacturing Pradaxa so as to avoid the aforementioned risks to individuals when Pradaxa was used for non-valvular atrial fibrillation treatment;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Pradaxa;

(c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Pradaxa;

(d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Pradaxa;

(e) Failed to warn Plaintiff-decedent of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Pradaxa;

(g) Failed to warn Plaintiff-decedent, prior to actively encouraging the sale of Pradaxa, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

(h) Were otherwise careless and/or negligent.

83. Despite the fact that Defendants knew or should have known that Pradaxa caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Pradaxa to consumers, including the Plaintiff-decedent.

84. Defendants knew or should have known that consumers such as the Plaintiff-decedent would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

85. Defendants' negligence was the proximate cause of Plaintiff-decedent's injuries, harm and economic loss which Plaintiff suffered and/or will continue to suffer.

86. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, as well as other

severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death.

87. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

88. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY)

89. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

90. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Pradaxa as hereinabove described that was used by the Plaintiff-decedent.

91. That Pradaxa was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

92. At those times, Pradaxa was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff-decedent herein.

93. The Pradaxa, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of

the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Pradaxa.

94. The Pradaxa, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

95. At all times herein mentioned, Pradaxa was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

96. Defendants knew, or should have known that at all times herein mentioned its Pradaxa was in a defective condition, and was and is inherently dangerous and unsafe.

97. At the time of the Plaintiff-decedent's use of Pradaxa, Pradaxa was being used for the purposes and in a manner normally intended, namely to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

98. Defendants with this knowledge voluntarily designed its Pradaxa in a dangerous condition for use by the public, and in particular the Plaintiff-decedent.

99. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

100. Defendants created a product unreasonably dangerous for its normal, intended use.

101. The Pradaxa, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Pradaxa left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

102. The Pradaxa designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Pradaxa was manufactured.

103. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff-decedent in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff-decedent.

104. The Plaintiff-decedent could not by the exercise of reasonable care, have discovered Pradaxa's defects herein mentioned and perceived its danger.

105. The Pradaxa, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, life threatening bleeding and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death and the Defendants failed to adequately warn of said risk.

106. The Pradaxa, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

107. The Pradaxa, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, life threatening bleeding and/or sudden death, as well as other severe and permanent health

consequences from Pradaxa , they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Pradaxa.

108. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Pradaxa.

109. Defendants' defective design, manufacturing defect, and inadequate warnings of Pradaxa were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

110. That said defects in Defendants' drug Pradaxa were a substantial factor in causing Plaintiff's injuries.

111. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death.

112. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

113. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

114. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

115. Defendants expressly warranted that Pradaxa was safe and well accepted by users.

116. Pradaxa does not conform to these express representations because Pradaxa is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff-decedent suffered and/or will continue to suffer life threatening bleeding and sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death

117. Plaintiff-decedent did rely on the express warranties of the Defendants herein.

118. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Pradaxa in recommending, prescribing, and/or dispensing Pradaxa.

119. The Defendants herein breached the aforesaid express warranties, as their drug Pradaxa was defective.

120. Defendants expressly represented to Plaintiff-decedent, his physicians, healthcare providers, and/or the FDA that Pradaxa was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of non-valvular atrial fibrillation treatment, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

121. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Pradaxa was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

122. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, as well as other

severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death.

123. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

124. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

125. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

126. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Pradaxa and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Pradaxa, to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

127. At the time Defendants marketed, sold, and distributed Pradaxa for use by Plaintiff-decedent, Defendants knew of the use for which Pradaxa was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

128. The Defendants impliedly represented and warranted to the users of Pradaxa and their physicians, healthcare providers, and/or the FDA that Pradaxa was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

129. That said representations and warranties aforementioned were false, misleading, and

inaccurate in that Pradaxa was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

130. Plaintiff-decedent, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

131. Plaintiff-decedent and Plaintiff-decedent's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Pradaxa was of merchantable quality and safe and fit for its intended use.

132. Pradaxa was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

133. The Defendants herein breached the aforesaid implied warranties, as their drug Pradaxa was not fit for its intended purposes and uses.

134. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death.

135. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

136. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT MISREPRESENTATION)

137. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

138. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff-decedent, and/or the FDA, and the public in general, that said product, Pradaxa, had been tested and was found to be safe and/or effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

139. That representations made by Defendants were, in fact, false.

140. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

141. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff-decedent, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Pradaxa, for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff-decedent herein.

142. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff-decedent used Pradaxa, the Plaintiff-decedent was unaware of the falsity of said representations and reasonably believed them to be true.

143. In reliance upon said representations, the Plaintiff-decedent was induced to and did use Pradaxa, thereby sustaining severe and permanent personal injuries, including premature death.

144. Said Defendants knew and were aware or should have been aware that Pradaxa had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

145. Defendants knew or should have known that Pradaxa had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

146. Defendants brought Pradaxa to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff-decedent.

147. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death.

148. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

149. By reason of the foregoing, each Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT CONCEALMENT)

150. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

151. At all times during the course of dealing between Defendants and Plaintiff-decedent, and/or Plaintiff-decedent's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Pradaxa for its intended use.

152. Defendants knew or were reckless in not knowing that its representations were false.

153. In representations to Plaintiff-decedent, and/or Plaintiff-decedent's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

(a) that Pradaxa was not as safe as other forms of non-valvular atrial fibrillation treatment;

(b) that the risks of adverse events with Pradaxa were higher than those with other forms of non-valvular atrial fibrillation treatment;

(c) that the risks of adverse events with Pradaxa were not adequately tested and/or known by Defendants;

(d) that Defendants were aware of dangers in Pradaxa, in addition to and above and beyond those associated with other forms of non-valvular atrial fibrillation treatment;

(e) that Pradaxa was defective, and that it caused dangerous side effects, including but not limited to life threatening bleeding, as well as other severe and permanent health consequences, in a much more and significant rate than other forms of non-valvular atrial fibrillation treatment;

(f) that patients needed to be monitored more regularly than normal while using Pradaxa;

(g) that Pradaxa was manufactured negligently;

(h) that Pradaxa was manufactured defectively;

(i) that Pradaxa was manufactured improperly;

(j) that Pradaxa was designed negligently;

(k) that Pradaxa was designed defectively; and

(l) that Pradaxa was designed improperly.

154. Defendants were under a duty to disclose to Plaintiff-decedent, and Plaintiff-decedent's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Pradaxa, including but not limited to the heightened risks of life threatening bleeding and/or sudden death.

155. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Pradaxa, including the Plaintiff-decedent, in particular.

156. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Pradaxa was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff-decedent, and Plaintiff-decedent's physicians, hospitals and healthcare providers into reliance, continued use of Pradaxa, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Pradaxa and/or use the product.

157. Defendants knew that Plaintiff-decedent, and Plaintiff-decedent's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Pradaxa, as set forth herein.

158. Plaintiff-decedent, as well as Plaintiff-decedent's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

159. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death.

160. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

161. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENT MISREPRESENTATION)

162. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

163. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, Pradaxa, had been tested and found to be safe and effective to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

164. The representations made by Defendants were, in fact, false.

165. Defendants failed to exercise ordinary care in the representation of Pradaxa, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendants negligently misrepresented Pradaxa's high risk of unreasonable, dangerous side effects.

166. Defendants breached their duty in representing Pradaxa's serious side effects to the medical and healthcare community, to the Plaintiff-decedent, the FDA and the public in general.

167. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, as well as other

severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death.

168. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

169. By reason of the foregoing, Plaintiff have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUD AND DECEIT)

170. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

171. Defendants conducted research and used Pradaxa as part of their research.

172. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff-decedent, Plaintiff-decedent's doctors, hospitals, healthcare professionals, and/or the FDA that Pradaxa was safe and effective for use as a means to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

173. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff-decedent.

174. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff-decedent, as well as Plaintiff-decedent's respective healthcare providers and/or the FDA.

175. The information distributed to the public, the FDA, and the Plaintiff-decedent by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

176. The information distributed to the public, the FDA, and the Plaintiff-decedent by Defendants intentionally included representations that Defendants' drug Pradaxa was safe and effective for use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

177. The information distributed to the public, the FDA, and the Plaintiff-decedent, by Defendants intentionally included representations that Defendants' drug Pradaxa carried the same risks, hazards, and/or dangers as other forms of non-valvular atrial fibrillation treatment.

178. The information distributed to the public, the FDA, and the Plaintiff-decedent, by Defendants intentionally included false representations that Pradaxa was not injurious to the health and/or safety of its intended users.

179. The information distributed to the public, the FDA, and the Plaintiff-decedent, by Defendants intentionally included false representations that Pradaxa was as potentially injurious to the health and/or safety of its intended as other forms of non-valvular atrial fibrillation treatment.

180. These representations were all false and misleading.

181. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Pradaxa was not safe as a means of non-valvular atrial fibrillation treatment and/or was not as safe as other means of non-valvular atrial fibrillation treatment.

182. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff-decedent, regarding the safety of Pradaxa, specifically but not limited to Pradaxa not having dangerous and serious health and/or safety concerns.

183. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession and the Plaintif-decedent, regarding the safety of Pradaxa, specifically but not limited to Pradaxa being a safe means of treating non-valvular atrial fibrillation.

184. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff-decedent, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff-decedent, to falsely ensure the quality and fitness for use of Pradaxa and induce the public, and/or the Plaintiff-decedent to purchase, request, dispense, prescribe, recommend, and/or continue to use Pradaxa.

185. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff-decedent that Pradaxa was fit and safe for use as treatment for non-valvular atrial fibrillation.

186. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff-decedent that Pradaxa was fit and safe for use as non-valvular atrial fibrillation treatment and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of non-valvular atrial fibrillation treatment.

187. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff-decedent that Pradaxa did not present serious health and/or safety risks.

188. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff-decedent that Pradaxa did not present health and/or safety risks greater than other oral forms of non-valvular atrial fibrillation treatment.

189. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

190. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff-decedent, including his respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff-decedent and/or his respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff-decedent to purchase, use, rely on, request, dispense, recommend, and/or prescribe Pradaxa.

191. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Pradaxa to the public at large, the Plaintiff-decedent in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of non-valvular atrial fibrillation treatment.

192. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Pradaxa by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Pradaxa.

193. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff-decedent, as well as his respective healthcare professionals into a sense of security so that Plaintiff-decedent would rely on the representations and purchase, use and rely on Pradaxa and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

194. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff-decedent, as well as Plaintiff-decedent's respective healthcare professionals would rely upon the information being disseminated.

195. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Pradaxa.

196. That the Plaintiff-decedent and/or his respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of non-valvular atrial fibrillation treatment and were thereby induced to purchase, use and rely on Defendants' drug Pradaxa.

197. That at the time the representations were made, the Plaintiff-decedent and/or his respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Pradaxa.

198. That the Plaintiff-decedent did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff-decedent with reasonable diligence have discovered the true facts.

199. That had the Plaintiff-decedent known the true facts with respect to the dangerous and serious health and/or safety concerns of Pradaxa, Plaintiff-decedent would not have purchased, used and/or relied on Defendants' drug Pradaxa.

200. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff-decedent.

201. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, life threatening bleeding and sudden death, as well as other

severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life and premature death.

202. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

203. By reason of the foregoing, Plaintiffs have been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

NINTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (WRONGFUL DEATH)

204. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

205. As a result of the foregoing, on January 8, 2012 Plaintiff-decedent, MALACHY HIGGINS died from complications proximately related to the Defendant's Pradaxa.

206. Plaintiff-decedent, MALACHY HIGGINS, left heirs, next-of-kin and/or distributes surviving who, by reason of the Plaintiff-decedents's death have suffered a pecuniary loss including, but not limited to support, income, services and guidance of the Plaintiff-decedent, MALACHY HIGGINS, and were all permanently damaged thereby.

207. At all times herein mentioned, the actions of the named Defendants and their agents, servants, and/or employees, were wanton, grossly negligent, reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of the general public and to the decedent in particular.

208. As a result Plaintiff-decedent's estate has been damaged in the sum of TEN MILLION DOLLARS ($10,000,000.00) and punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case will be transferred for trial in accordance with Case Management Order #7 issued by United States District Court Judge David R. Herndon;

2. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff-decedent, health care costs, medical monitoring, together with interest and costs as provided by law;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff-decedent in an amount sufficient to punish Defendants and deter future similar conduct;

4. Awarding all applicable statutory damages of the state whose laws will govern this action;

5. Awarding Plaintiffs reasonable attorneys' fees;

6. Awarding Plaintiffs the costs of these proceedings; and

7. Such other and further relief as this Court deems just and proper.

Dated: New York, New York
April 3, 2013

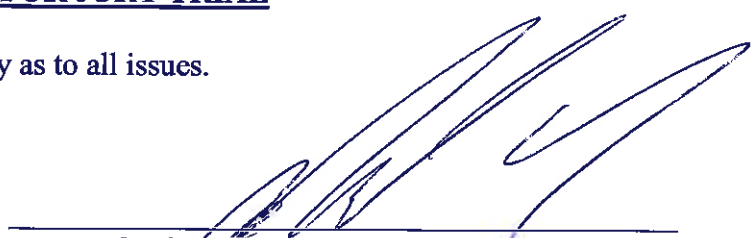
RESPECTFULLY SUBMITTED,

By: _____

MICHAEL A. LONDON (ML-7510)
DOUGLAS & LONDON, P.C.
111 John Street, Suite 1400
New York, New York 10038
Ph: (212) 566-7500
Fax: (212) 566-7501
Email: mlondon@douglasandlondon.com

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues.



MICHAEL A. LONDON (ML-7510)

JS 44 (Rev. 09/11)

CIVIL COVER SHEET

The JS 44 civil coversheet and the information contained herein neither replace nor supplement the filing and service of pleadngs or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States inSeptember 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Suzanne Mackiewicz, on behalf of the Estate of Malachy Higgins, deceased, and Suzanne Mackiewicz, individually

(b) County of Residence of First Listed Plaintiff New York
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Douglas and London, P.C.
111 John Street, Suite 1400, New York, NY 10038
212-566-7500

DEFENDANTS
Boehringer Ingelheim Pharmaceuticals, et al

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff) and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*
☐ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district *(specify)* ☒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
U.S.C. § 1332 (Diversity)
Brief description of cause:
Severe and permanent personal injuries caused by the use of the drug Pradaxa

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND $ 10 million plus cause of action plus punitives
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*: JUDGE David R. Herndon DOCKET NUMBER 13-50167

DATE 04/03/2013
SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

JS 44 Reverse (Rev. 09/11)

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.CP., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdicti on arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing **date**.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.