UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

IN RE: PRADAXA (DABIGATRAN ETEXILATE) PRODUCTS LIABILITY LITIGATION	)	SECTION:
Claude R. Knight and Claudia Stevens, individually and as Personal Representatives of the Estate of Betty Erelene Knight, Deceased Plaintiffs	)	JUDGE: MAG. JUDGE:
vs.	)	
Boehringer Ingelheim Pharmaceuticals, Inc. Defendant.	)	Civil Action No.: 3:15-cv-6424 COMPLAINT AND JURY DEMAND

PLAINTIFFS' ORIGINAL COMPLAINT

Comes now Plaintiffs, Claude R. Knight and Claudia Stevens, individually and as Personal Representative of Betty Erelene Knight's Estate by and through their undersigned attorneys, and file this Complaint against Defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI" or "Defendant") for selling, distributing, and manufacturing the defective and unreasonably dangerous drug Pradaxa® (dabigatran etexilate), a prescription medication used as a blood thinner in the United States, which has proximately caused personal injuries to Plaintiffs as further set forth below.

PARTIES

1. Plaintiffs, Claude R. Knight and Claudia Stevens, individually and as Personal Representatives of the Estate of Betty Erelene Knight, ("Plaintiffs") are citizens and residents of West Virginia. Decedent, Betty Erelene Knight ("Decedent" or "Betty Knight") suffered personal injuries as a result of ingesting Pradaxa. At the time of Knight's injury and death, she

resided in West Virginia. As a direct and proximate result of ingesting Pradaxa, Knight suffered severe personal injuries, including gastrointestinal bleeding, acute post-hemorrhagic anemia, and death. Plaintiffs specifically aver that Defendant's Pradaxa was defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the true dangers associated with its use, and that Decedent suffered injury and death as a result of her ingestion of Pradaxa.

2. Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI" or "Defendant") is a Delaware corporation, which has its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Boehringer US has conducted business and derived substantial revenue from within the State of West Virginia, and may be served through its registered agent: The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801.

JURISDICTION AND VENUE

3. Jurisdiction is proper in this court pursuant to 28 USC §1332 for the reason that there is complete diversity of citizenship between Plaintiffs and Defendant and the matter in controversy greatly exceeds the sum of seventy-five thousand dollars ($75,000.00), exclusive of interest and costs. This Court has jurisdiction over the non-resident Defendant because they have done business in the State of West Virginia, have committed a tort in whole or in part in the State of West Virginia, and have continuing contacts with the State of West Virginia.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2), a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred in that Betty Knight ingested Pradaxa and suffered injuries and death as a result in this District, and more specifically the Huntington Division.

GENERAL BACKGROUND

5. Defendant, directly or through their agents, apparent agents, servants or employees, are and at all relevant times have been engaged in the business of formulating, designing, manufacturing, licensing, testing, advertising, marketing, warranting, selling, distributing, and introducing into the stream of commerce a drug compound known as "dabigatran etexilate," which Defendant has sometimes marketed under the brand name "Pradaxa." Regardless of the name under which Defendant marketed, sold, and distributed the drug, all of its forms were and are, for all purposes relevant to Plaintiffs' claims, chemically and pharmacologically identical. Plaintiffs, for purposes of this Complaint, will refer to the drug compound by the common brand name, "Pradaxa."

6. Pradaxa is an oral anticoagulant and is from the class of the direct thrombin inhibitors ("DTI") approved by the Food and Drug Administration ("FDA") in October of 2010, for prevention of stroke in patients with non-valvular atrial fibrillation. The FDA approved two dosages: Pradaxa 75mg and Pradaxa 150mg, to be taken twice daily. Pradaxa is the first new treatment alternative to warfarin (Coumadin) in more than 50 years for patients with non-valvular atrial fibrillation.

7. Defendant's launched Pradaxa in North America in 2010. Defendant designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold Pradaxa as a blood-thinning medicine primarily used to reduce the risk of stroke and blood clots in people with atrial fibrillation not caused by a heart valve problem.

8. According to Defendant's testing and marketing materials, which extol the supposed benefits and virtues of Pradaxa, Pradaxa had fewer drug interactions than warfarin, and the frequent laboratory tests needed to manage warfarin blood levels were not recommended for

patients taking Pradaxa. Moreover, unlike warfarin, which is adjusted for individual patient blood levels on an ongoing basis, Pradaxa was approved in an allegedly easy "one size fits all" dose of 150 mg twice a day. This "one size fits all" characteristic of the drug, while simple for physicians to follow, means that a lower (or personalized) dose is unavailable and patients ingesting Pradaxa are not routinely monitored to see if they are getting too much of the drug's active ingredient, as are patients on other blood thinning medications like warfarin.

9. Moreover, the "RE-LY Clinical Trial" (Randomized Evaluation of Longterm anticoagulant therapy) sponsored by Defendant concluded that vitamin K antagonists such as warfarin are cumbersome to use because of their multiple interactions with food and drugs and because these drugs require frequent laboratory monitoring. The RE-LY Clinical Trial went on to suggest that there is a need for new anticoagulant agents that are effective, safe, and convenient to use (i.e., Defendant's product, Pradaxa). The Defendant's marketing materials suggest that Pradaxa represented a therapeutic simplification and therapeutic progress because it does not require patients to undergo periodic monitoring with blood tests. A fundamental tenet of the RE-LY Clinical Trial was a claim by Defendant that Pradaxa was apparently safe to use as compared to warfarin.

10. What the RE-LY Clinical Trial seemed to prove was quite simple: With Pradaxa there is (1) a higher rate of major GI bleeds (1.6% vs 1.1%) as compared to warfarin; and (2) a similar rate of major bleeds (3.3% vs 3.6%) as compared to warfarin. Additionally, Pradaxa appears to be particularly dangerous when used in older patients, as the label states: "The risk of major bleeds was similar with PRADAXA 150 mg and warfarin across major subgroups defined by baseline characteristics, with the exception of age, where there was a trend towards a higher incidence of major bleeding on PRADAXA (HR 1.2, 95% CI: 1.0 to 1.4) for patients ≥75 years

of age."[1] In spite of this reference regarding age, the label is still wholly inadequate because, among other reasons, this information was not conveyed in the warnings section. In essence, the Defendant has created a new drug, Pradaxa, that is no better than warfarin from a safety perspective, and at best, perhaps slightly easier to use and administer. The idea of this apparently easier-to-use anticoagulant evidently appealed to physicians, who were subject to extreme marketing and promotion by the Defendant, but it ignores patient safety.

11. On February 14, 2011, the American College of Cardiology Foundation and American Heart Association added Pradaxa to their guidelines for management of non-valvular atrial fibrillation with a "Class I" recommendation. The endorsement, along with heavy marketing from the Defendant, caused sales of Pradaxa to skyrocket. By the end of the first quarter of 2011, IMS Health's National Prescription Audit data showed 272,119 dispensed outpatient prescriptions. But, as prescriptions mounted, reports of serious adverse drug events also surged.[2]

12. As part of the marketing of Pradaxa, Defendant widely disseminated direct-to-consumer advertising campaigns that were designed to influence patients, including Betty Knight, to make inquiries to their prescribing physician about Pradaxa and/or request prescriptions for Pradaxa. In the course of these direct to consumer advertisements, Defendant 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.

[1] http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022512s009lbl.pdf
[2] Institute for Safe Medication Practices, QuarterWatch Report, January 12, 2012

13. Prior to Betty Knight's prescription of Pradaxa, Betty Knight became aware of the promotional materials described herein.

14. Prior to Betty Knight's prescription of Pradaxa, Betty Knight's physician received promotional materials and information from sales representatives of Defendant that Pradaxa was more effective than warfarin 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.

15. At all times relevant to this action, The Pradaxa Medication Guide, prepared and distributed by Defendant 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.

16. As a result of the defective nature of Pradaxa, persons who were prescribed and ingested Pradaxa for even a brief period of time, including Decedent herein, was at increased risk for developing life-threatening bleeds. Due to the flawed formulation of Pradaxa (and unlike any of the traditional blood thinners on the market, Pradaxa has a questionable "one size fits all" dose), its levels in the blood are difficult or impossible to assess, and bleeds cannot be stopped since there is no known reversal antidote for this dangerous drug.

17. In November 2011, Defendant confirmed at least 260 fatal bleeding events were reported in patients taking Pradaxa worldwide between March 2008 and October 2011. Moreover, The Institute for Safe Medication Practices, reported that:

> In the first quarter of 2011 [Pradaxa] produced two different kinds of signals of major drug risk: a large volume of total serious reports, and large numbers of reports for a specific adverse event, hemorrhage. Overall [the study] identified 932 serious adverse drug events of all types in which [Pradaxa] was the primary

> suspect drug, including 120 patient deaths, 25 cases of permanent disability, and 543 cases requiring hospitalization. For the quarter, this was a higher total than for any drug [The Institute for Safe Medication Practices] monitor[s] with one exception. In the Standardized MedDRA Query ("SMQ") for Hemorrhage, [Pradaxa™] accounted for 505 cases, more than any other drug. (Warfarin ranked second with 176 cases.) The 932 overall [Pradaxa] cases in the first quarter [of 2011] included 293 cases that were also classified in the narrower gastrointestinal hemorrhage SMQ, more than any other regularly monitored drug. An additional 120 cases contained event terms in the Hemorrhagic stroke SMQ. The strokes are of particular concern because if treatment intended to prevent ischemic strokes then causes hemorrhagic strokes the risk/benefit balance is called into fundamental question. In 65 hemorrhage cases overall, the patients died.[3]

18. 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.

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

20. On December 7, 2011, the FDA initiated an investigation into serious bleeding events associated with Pradaxa stating that the "FDA is working to determine whether the reports of bleeding in patients taking Pradaxa are occurring more commonly than would be expected, based on observations in the large clinical trial that supported the approval of Pradaxa [RE-LY trial]."

21. Defendant concealed their knowledge that Pradaxa can cause life threatening, irreversible bleeds from Betty Knight, other consumers, the general public, and the medical community. Indeed, the Defendant did not warn of the irreversible nature of Pradaxa in the

[3] Institute for Safe Medication Practices, QuarterWatch Report, January 12, 2012

"Warnings and Precautions" section of the products initial warning label. The only warnings provided by Defendant were as follows:

----------WARNINGS AND PRECAUTIONS----------

- Risk of bleeding: PRADAXA can cause serious and sometimes, fatal bleeding. Promptly evaluate signs and symptoms of blood loss. (5.1)
- Temporary discontinuation: Avoid lapses in therapy to minimize stroke (5.2)
- P-gp inducers and inhibitors: avoid co-administration of rifampin with PRADAXA because of the effects of dabigatran exposure (5.3).

22. Specifically, Defendant did not adequately inform consumers and the prescribing medical community about the risks of uncontrollable bleeds associated with Pradaxa™ usage, nor did Defendant warn or otherwise advise on how to intervene and stabilize a patient should a bleed occur. Even in the expanded "Warnings and Precautions" section of the initial label only the following meager and unacceptably inadequate information was given:

5. WARNINGS AND PRECAUTIONS

5.1 Risk of Bleeding

PRADAXA increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Risk factors for bleeding include the use of drugs that increase the risk of bleeding in general (e.g. anti-platelet agents, heparin, fibrinolytic therapy, and chronic use of NSAIDs) and labor and delivery. Promptly evaluate any signs or symptoms of blood loss (e.g., a drop in hemoglobin and/or hematocrit or hypotension). Discontinue PRADAXA in patients with active pathological bleeding.

In the RE-LY (Randomized Evaluation of Long-Term Anticoagulent Therapy) study, a life-threatening bleed (bleeding that met one or more of the following criteria: fatal, symptomatic, intracranial, reduction in hemoglobin of at least 5 grams per deciliter, transfusion of at least 4 units of blood, associated with hypotension requiring the use of intravenous inotropic agents or necessitating surgical intervention) occurred at an annulized rate of 1.5% and 1.8% for PRADAXA 150 mg and warfarin, respectively [*see Adverse Reactions (6.1.)*].

23. In fact, the only section of Defendant original label that references the fact that Pradaxa has no known "reversal agent" is buried in section 10 of the "Full Prescribing

Information" section of the Pradaxa™ label, which discusses "Overdosage" on the medication. The language in section 10 is effectively no warning at all as the "warning" is both inadequate and misplaced, as shown below:

> **10 OVERDOSAGE**
>
> Accidental overdose may lead to hemorrhagic complications. There is no reversal agent for dabigatran. In the event of hemmorhagic complications, initiate appropriate clinical support, discontinue treatment with PRADAXA, and investigate the source of bleeding. Dabigatran is primarily excreted in the urine and shows low plasma protein binding. Therefore, dabigatran can be dialyzed with the removal of about 60% of drug over 2 to 3 hours; however, data supporting this approach are limited. Measurement of PTT or ECT may help guide therapy. [*see Warnings and Precautions (5.1) and Clinical Pharmacology 12.2*].

24. As this demonstrates, Defendant's original 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 Betty Knight'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 the "Medication Guide" intended for distribution to patients to whom Pradaxa has been prescribed, Defendant 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.

25. In March 2011, Defendant 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, Defendant nonetheless failed to provide adequate disclosures or warnings in the label as detailed in Paragraph 24 (a – m) above.

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. 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 "The risk of major over dosage 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."

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

28. On September 1, 2011, the New Zealand pharmaceutical regulatory authority issued 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 and rectal 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 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."

29. In November 2011, Defendant modified the U.S. labeling and prescribing information for Pradaxa adding additional information regarding the use of Pradaxa in 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, Defendant nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 24 (a – m) above.

30. 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 the Defendant's data submitted to the FDA.

31. 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.

32. Finally, in January of 2012, after thousands of Pradaxa users had been killed or injured as a result of their ingestion of Pradaxa, the Defendant belatedly initiated an extremely modest, and wholly inadequate, label change. The only labeling modification Defendant made in January 2012, regarding the irreversible nature of Pradaxa bleeds was made in the "Warnings and Precautions" part of the "Full Prescribing Information" section of the Pradaxa label, buried in small print on the fifth and sixth pages of the label. It reads:

> 5. WARNINGS AND PRECAUTIONS
>
> 5.1 Risk of Bleeding
> PRADAXA increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Discontinue PRADAXA in patients with active pathological bleeding. [*see Dosage and Administration (2.2).]*.

***

Risk factors for bleeding include the use of drugs that increase the risk of bleeding in general (e.g. anti-platelet agents, heparin, fibrinolytic therapy, and chronic use of NSAIDs). PRADAXA's anticoagulant activity and half-life are increased in patients with renal impairment. [*See Clinical Pharmacology (12.2.)*].

A specific reversal agent for dabigatran is not available. Dabigatran can be dialyzed (protein binding is low, the removal of about 60% of drug over 2-3 hours); however, the amount of data supporting such an approach is limited. Activated prothombin complex concentrates (aPCCs, e.g. FEIBA), or recombinant Factor VIIa, or concentrates of coagulation factors II, IX or X may be considered but their use has not be evaluated in clinical trials. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of dabigatran. Consider administration of platelet concentrates in cases where thrombocytopenia is present or long-acting antiplatelet drugs have been used.

33. Importantly, Pradaxa still does not have a "black box" warning letting patients or their prescribing doctors know that Pradaxa can cause sudden and irreversible bleeds. Indeed, the relevant part of the "Warnings and Precautions" section itself essentially the same (with no reference to the irreversible nature of Pradaxa bleeds) on the current Pradaxa label as shown below:

----------WARNINGS AND PRECAUTIONS----------

- Bleeding: PRADAXA can cause serious and fatal bleeding (5.2)
- Bioprosthetic heart valves: PRADAXA use not recommended (5.4)

34. The current warning is simply inadequate. The Defendant has failed and continues to fail in its duties to warn and protect the consuming public, including the Decedent herein. 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 nonetheless

failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 24 (a – m) above.

35. In March 2012, in response to a directive from Health Canada, the governmental agency responsible for regulating pharmaceuticals in Canada, Defendant'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. In April 2012, the Defendant modified the U.S. labeling and prescribing information for Pradaxa. And 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, Defendant nonetheless failed to provide adequate disclosures or warnings in their label as detailed in Paragraph 24 (a – m) above.

37. With the knowledge of the true relationship between use of Pradaxa and irreversible bleeds, rather than taking steps to pull the drug off the market, provide strong warnings, or create an antidote, Defendant promoted and continues to promote Pradaxa as a safe and effective treatment for AF and an alternative to warfarin.

38. While Defendant enjoys great financial success from its blockbuster drug, Pradaxa, they continue to place American citizens at risk of severe bleeds and death. Consumers,

including Betty Knight, who used Pradaxa for treatment of AF and blood thinning, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with Pradaxa therapy.

39. Defendant, through its affirmative misrepresentations and omissions, failed to warn Knight and her physicians of the true and significant risks associated with Pradaxa use.

40. Consumers, including Betty Knight, who have used for treatment of AF and blood thinning, have several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with Pradaxa therapy.

41. As a result of Defendant's actions, Betty Knight and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that she would be exposed to the risks identified in this Complaint. The increased risks and subsequent medical damages associated with Knight's Pradaxa use was the direct and proximate result of Defendant's conduct.

42. Pradaxa was and is a defective product, unreasonably dangerous in light of its nature and intended use. That defect existed when the product left Defendant's control and has been the proximate cause of injuries to Decedent, whose injuries were caused by the use of Pradaxa in its intended or foreseeable manner or in the manner recommended by Defendant.

43. Defendant knew or should have known of the dangerous condition of its product, Pradaxa, but failed to adequately warn or instruct physicians and consumers of the risks, dangers, and proper uses of the drug.

44. Defendant has breached its duty of reasonable care in connection with the design, testing, manufacture, marketing, and/or labeling of Pradaxa.

45. Betty Knight would not have used Pradaxa had Defendant properly disclosed the risks associated with its use.

DECEDENT BETTY KNIGHT'S PRADAXA USE AND INJURIES

46. As a result of Defendant's claims regarding the effectiveness, safety, and benefits of Pradaxa, Betty Knight and her physicians were unaware, and could not have reasonably known or have learned through reasonable diligence that Betty Knight would be exposed to the risk of excessive and /or uncontrollable bleeding and the risk of injuries described herein.

47. Consequently, Betty Knight was prescribed Pradaxa in October 2011 for the treatment of non-valvular atrial fibrillation. Thereafter, Betty Knight experienced uncontrollable bleeding on or about May 20, 2013, causing her to be hospitalized for 20-days. Betty Knight never recovered from the uncontrollable bleeding which was caused and/or worsened by her use of Pradaxa, and she died on September 2, 2013.

48. Before Betty Knight's use of Pradaxa, Defendant knew or should have known that the original labeling of the drug did not adequately warn of the risks associated with using the drug as described above.

49. Before Betty Knight's use of Pradaxa, Defendant knew or should have known of the defective nature of Pradaxa and persons who were prescribed and ingested Pradaxa for even a brief period of time, including Betty Knight, were at increased risk for developing life-threatening bleeds. Defendant, through its affirmative misrepresentations and omissions, concealed from Betty Knight and her physicians the true and significant risks associated with Pradaxa use.

50. Betty Knight was unaware of the increased risk for developing life-threatening injuries as compared to warfarin. Had Betty Knight and/or her healthcare providers known of the

risks and dangers associated with Pradaxa, as well as the lack of additional benefits, and had Defendant provided adequate warnings that there is no agent to reverse the anticoagulation effects of Pradaxa, Betty Knight would not have used Pradaxa.

51. As a direct and proximate result of Betty Knight's using Pradaxa, Plaintiffs have suffered personal injuries, economic and non-economic damages, including pain and suffering and wrongful death as previously described herein.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

52. Defendant failed to disclose a known defect and affirmatively misrepresented that Pradaxa was safe for its intended use. Further, Defendant actively concealed the true risks associated with the use of Pradaxa. Neither Betty Knight nor her prescribing physicians had knowledge that Defendant engaged in the wrongdoing alleged herein. Because of Defendant's concealment of and misrepresentations regarding the true risks associated with Pradaxa, Plaintiffs could not have reasonably discovered Defendant's wrongdoing at any time prior to the commencement of this action.

53. Thus, because Defendant fraudulently concealed the defective nature of Pradaxa and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendant is estopped from relying on any statute of limitations.

54. Additionally, and alternatively, Plaintiffs file this lawsuit within the applicable limitations period of first suspecting that Pradaxa caused the appreciable harm sustained by Betty Knight. Plaintiffs did not have actual or constructive knowledge of facts indicating to a reasonable person that Betty Knight was the victim of a tort. Plaintiffs were unaware of the facts upon which a cause of action rests until less than the applicable limitations period prior to the filing of this action. Plaintiffs' lack of knowledge was not willful, negligent or unreasonable.

CAUSES OF ACTION

COUNT I: Strict Products Liability

55. Plaintiffs incorporates the allegations contained in the foregoing paragraphs as if fully set forth herein.

56. It was the duty of Defendant to manufacture, test, market, advertise, label, distribute, and sell Pradaxa so that it was reasonably safe for its foreseeable use. At the time Pradaxa left the control of Defendant and was sold, it contained one or more conditions which rendered it defective and unreasonably dangerous in light of its nature and intended use. At all times, Pradaxa was used in the manner intended, recommended, or reasonably foreseeable by Defendant.

57. The Pradaxa manufactured and/or supplied by Defendant and to which Decedent was exposed was defective in design, manufacture, and/or formulation in that when it left the hands of Defendant, the foreseeable risks exceeded the benefits associated with the design and/or formulation of this product.

58. The Pradaxa manufactured by Defendant reached Betty Knight without substantial change and was ingested as directed.

59. The Pradaxa marketed, sold, and supplied by Defendant and to which Decedent was exposed was defective in its marketing and labeling in that Defendant knew or should have known of its dangers and risks of irreversible bleeding, but failed to adequately warn or instruct physicians, consumers, and the general public of the nature and extent of those risks.

60. The Pradaxa marketed, sold, and supplied by Defendant and to which Decedent was exposed was defective in its marketing and labeling in that Defendant knew or should have known of its dangers and risks, as well as the means for reducing or eliminating those dangers

and risks, but failed to adequately warn or instruct physicians, consumers, and the general public of those means of reducing or eliminating the risks.

61. Defendant marketed Pradaxa in multiple ways, including but not limited to direct-to-consumer advertisements, which were misleading in that Defendant overstated the safety and efficacy of Pradaxa and understated its risks.

62. The Pradaxa marketed, sold, and supplied by Defendant was defective in marketing in that Defendant represented to the consuming public that the product was safe and had qualities that it, in fact, did not have.

63. The Pradaxa manufactured and/or supplied by Defendant was defective in design and formulation in at least the following respects:

a. When it left the hands of the Defendant, this drug was unreasonably dangerous to an extent beyond that which could reasonably be contemplated by Betty Knight or her physicians;

b. Any benefit of this drug was outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendant intended;

c. The dosages and/or formulation of Pradaxa sold by the Defendant were unreasonably dangerous;

d. There are no patients for whom the benefits of Pradaxa outweighed the risks;

e. The product was not made in accordance with the Defendant's specifications or performance standards;

f. Defendant failed to adequately test this product before placing it into the stream of commerce;

g. There are no patients for whom Pradaxa is a safer and more efficacious drug than other drug products in its class; and/or

h. There were safer alternatives that did not carry the same risks and dangers that Defendant's Pradaxa had.

64. The Pradaxa administered to Betty Knight was defective at the time it was distributed by the Defendant or left its control.

65. The foreseeable risks associated with the design or formulation of the Pradaxa include, but are not limited to, the fact that the design or formulation of Pradaxa is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or did not have the claimed benefits.

66. The defective and unreasonably dangerous design, marketing, and labeling of Pradaxa was a direct, proximate, and producing cause of Betty Knight's injuries and death.

COUNT II: Negligence

67. Plaintiffs incorporates the allegations contained in the foregoing paragraphs as if fully set forth herein.

68. Defendant had a duty to exercise reasonable care in the design, manufacture, testing, sale, labeling and/or distribution of Pradaxa it placed into the stream of commerce, including a duty to assure that the product did not cause unreasonable or unnecessary injury.

69. Defendant breached its duty of care to the Plaintiffs through its negligent acts and omissions. Defendant did not exercise reasonable care in the warning, design, manufacture, sale, testing, labeling and/or distribution into the stream of commerce of Pradaxa in that Defendant knew or should have known that Pradaxa could cause serious adverse events, including irreversible bleeding, but failed to warn that the drug was capable of causing serious personal injuries such as those suffered by Plaintiffs during foreseeable use.

70. Defendant was negligent in the design, manufacture, sale, testing, and/or distribution of Pradaxa in that it: (a) failed to use due care in designing, formulating, developing, testing, and manufacturing Pradaxa so as to avoid or warn against the described risks to consumers who used Pradaxa; (b) placed an unsafe product into the stream of commerce; (c) failed to discover or warn of the dangers associated with the use of Pradaxa despite having actual

and/or constructive knowledge of such dangers; (d) represented to physicians, including but not limited to Decedent's prescribing physicians, that this drug was safe and effective for use when it is not; (e) Defendant over-promoted the benefits of Pradaxa for anticoagulation therapy in patients suffering from atrial fibrillation and understated the risk of excessive, uncontrollable bleeding; (f) failed to remove Pradaxa from the market when Defendant's knew or should have known of the likelihood of serious side effects and injury to its users; and (g) failed to design and/or manufacture a product that could be used safely due to the lack of a known reversal agent.

71. Defendant knew or should have known that consumers, including Betty Knight, could foreseeably suffer injuries as a result of Defendant's failure to exercise ordinary care as described above.

72. As a direct and proximate result of Defendant's negligence, Betty Knight and Plaintiffs suffered the injuries and damages described herein.

COUNT III: Negligent Misrepresentation / Fraud

73. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

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

75. Defendant made these misrepresentations and actively concealed adverse information at a time when the Defendant knew, or should have known, that Pradaxa had defects, dangers, and characteristics that were other than what Defendant had represented to Betty Knight, her physicians, and the health care industry generally. Specifically, Defendant

misrepresented to and/or actively concealed from Betty Knight 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.

76. The aforementioned misrepresentations were untrue and misleading.

77. Defendant negligently and/or intentionally misrepresented or omitted this information in the product labeling, promotions and advertisements, and instead labeled promoted and advertised the 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.

78. Defendant knew or should have known that these representations were false and made the representations with the intent that Betty Knight and/or her prescribing physicians would rely on them, leading to the use of Pradaxa.

79. At the time of Defendant's negligent and fraudulent misrepresentations, Betty Knight and/or her prescribing physicians were unaware of the falsity of the statements being made and believed them to be true. Betty Knight and/or her 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 Defendant did suppress, conceal or failed to disclose, to Decedent's detriment.

80. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendant, Plaintiffs suffered personal injuries, economic and noneconomic damages, including pain and suffering and wrongful death.

COUNT IV: Breach of Express Warranty

81. Plaintiffs incorporate by reference each preceding paragraph as though set forth fully at length herein.

82. Defendant expressly warranted, through their direct-to-consumer marketing, label, and sales representatives, that Pradaxa was a safe and effective prescription blood thinner. The safety and efficacy of Pradaxa constitutes material facts in connection with the marketing, promotion, and sale of Pradaxa.

83. Pradaxa manufactured and sold by Defendant did not conform to these express representations because it caused serious injury to consumers when taken in recommended dosages.

84. As a direct and proximate result of Defendant's breach of warranty, Plaintiffs suffered harm, damages and economic loss.

COUNT V: Breach of Implied Warranty

85. Plaintiffs incorporate by reference each preceding paragraph as though set forth fully at length herein.

86. At the time Defendant researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released Pradaxa into

the stream of commerce, Defendant knew of the use for which Pradaxa was intended and impliedly warranted the product to be of merchantable quality and safe for such use.

87. Defendant breached its implied warranties of merchantability and fitness for a particular purpose when it sold Pradaxa to Betty Knight because Pradaxa was not of merchantable quality nor was it fit for its common, ordinary, and intended use.

88. As a direct, foreseeable and proximate result of Defendant's breaches of implied warranties, Betty Knight suffered grievous bodily injury and death. Plaintiffs have suffered consequential economic and other losses, as described above, when Betty Knight ingested Pradaxa, in reasonable reliance upon the implied warranties.

COUNT VI: Negligence Per Se –
Defendants' Violations of 21 U.S.C. §§ 331(a) & 352

89. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

90. As part of their duty to exercise reasonable care, Defendant was obligated to follow public laws and regulations enacted and promulgated to protect the safety of persons such as Betty Knight, including 21 U.S.C. §§ 331(a) and 352, and other statues and regulations, which make it unlawful to misbrand prescription drug products.

91. The labeling, including package inserts, for Pradaxa failed to conform to the requirements of 21 U.S.C. § 352, including subsections (a), (c), and (t), and the requirements of 21 C.F.R. § 201.100(c)(1), and, therefore, violated 21 U.S.C. § 331(a), which prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

92. Specifically, the product label and package insert for Pradaxa is misbranded within the meaning of 21 U.S.C. § 352(a) and (f) because it was false and misleading and failed to give adequate warnings and directions for use by physicians who prescribe Pradaxa.

93. Pradaxa is misbranded pursuant to 21 U.S.C. § 352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

94. Pradaxa is misbranded pursuant to 21 U.S.C. § 352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

95. Pradaxa is misbranded pursuant to 21 U.S.C. § 352 because it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

96. Because the Defendant had a statutory duty under 21 U.S.C. § 352 (a) and (f) not to misbrand Pradaxa, and because it violated this duty, Defendant is guilty of negligence per se. Pradaxa® is further misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

97. Defendant also violated 21 C.F.R. § 201.57 because it failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug Pradaxa.

98. Defendant violated 21 C.F.R. § 201.57 because the safety considerations regarding Pradaxa are such that the drug should be reserved for certain situations, and the Defendant failed to state such information.

99. Pradaxa is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

100. Pradaxa is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug (i.e., irreversible bleeding).

101. Pradaxa is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling does not state an upper limit dosing beyond which safety and effectiveness have not been established.

102. Pradaxa violates 21 C.F.R. § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

103. Pradaxa violates 21 C.F.R. § 310.303 in that it is not safe and effective for its intended use.

104. Defendant violated 21 C.F.R. §§ 310.305 & 314.80 by failing to report adverse events associated with Pradaxa as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drug experience.

105. Defendant violated 21 C.F.R. §§ 310.305 & 314.80 by failing to conduct an investigation of each adverse event associated with Pradaxa, evaluate the cause of the adverse event, submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA, and keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

106. Defendant violated 21 C.F.R. § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the I5-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated) and/or (d) a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

107. Defendant violated 21 C.F.R. § 312.32 because they failed to review all information relevant to the safety of Pradaxa or otherwise received by Defendant from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

108. Defendant failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as Betty Knight, making Defendant liable to the Plaintiffs, and further, because Defendant violated the above referenced duties required by these statutes and regulations, Defendant is guilty of negligence per se.

109. Defendant's failure to adequately warn about the magnitude of the risk associated with use of Pradaxa constitutes negligence per se. This negligence per se proximately caused injury to the Plaintiffs as described more fully herein.

COUNT VIII: Fraudulent Concealment

110. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

111. At all times during the course of dealings between Defendant and Betty Knight, and/or his healthcare providers, and/or the FDA, Defendant misrepresented the safety of Pradaxa for its intended use.

112. Defendant knew or was reckless in not knowing that its representations were false.

113. In representations to Betty Knight, and/or her healthcare providers, and/or the FDA, Defendant fraudulently concealed and intentionally omitted the following material information:

a. that Pradaxa was not as safe or effective as other forms of anticoagulation medication for atrial fibrillation patients;

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

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

d. that Defendant failed to provide adequate warnings that there was no drug, agent or means to reverse the anticoagulation effects of Pradaxa;

e. that Defendant failed to include an adequate warning about serious bleeding events associated with Pradaxa;

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

g. that Defendant failed to adequately instruct physicians on how to intervene and/or stabilize a patient who suffers a bleed while taking Pradaxa;

h. that it is critical to fully 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. that there is an increased risk of bleeding events associated with aging patient populations of Pradaxa users;

j. that there is an increased risk of gastrointestinal bleeds in those taking Pradaxa, especially, in those patients with a prior history of gastrointestinal issues and/or upset;

k. that Pradaxa was defective, and that it caused dangerous side effects, including but not limited to higher incidence of excessive and/or uncontrollable bleeding;

l. that Pradaxa was manufactured negligently;

m. that Pradaxa was manufactured defectively;

n. that Pradaxa was manufactured improperly;

o. that Pradaxa was designed negligently;

p. that Pradaxa was designed defectively; and

q. that Pradaxa was designed improperly.

114. Defendant was under a duty to disclose to Betty Knight, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Pradaxa, including but not limited to the heightened risks of excessive and/or uncontrollable bleeding.

115. Defendant 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 Betty Knight, in particular.

116. Defendant's concealment and omissions of material facts concerning, inter alia, the safety of Pradaxa was made purposefully, willfully, wantonly, and/or recklessly, to mislead Betty Knight, and her 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. Defendant knew that Betty Knight and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendant's

concealment and omissions, and that these included material omissions of facts surrounding Pradaxa, as set forth herein.

117. Betty Knight and her 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 Defendant.

118. As a result of the foregoing acts and omissions Betty Knight was caused to suffer excessive and/or uncontrollable bleeding, as well as other severe and personal injuries, economic and non-economic damages, physical pain and mental anguish, and death.

COUNT IX: Punitive Damages

119. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

120. At all material times, the Defendant knew or should have known that Pradaxa was inherently dangerous.

121. Despite such knowledge, the Defendant continued to aggressively market Pradaxa to consumers, including Betty Knight, without disclosing its dangerous side effects when there existed safer alternative products such as Warfarin and/or Coumadin.

122. Defendant's conduct was grossly negligent, fraudulent, reckless, willful and/or wanton.

123. Defendant's conduct as described above, including, but not limited to, its failure to adequately test the product, to provide adequate warnings, and its continued manufacture, sale, and marketing or the product when it knew or should have known of the serious health risks created, was intentional, willful wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences in

that Defendant acted only out of self-interest and personal gain. Accordingly, punitive damages should be imposed against Defendant to punish and deter Defendant from repeating or continuing such unlawful conduct.

COUNT X: Wrongful Death and Survivorship

124. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

125. As a direct and proximate result of the acts and omissions of Defendant, Decedent ingested Pradaxa which was causally related to and contributed to the Decedent's death, for which damages may be sought and recovered.

126. As a direct and proximate result of the acts and omissions of Defendant, the Decedent suffered physical injury, pain and suffering, mental anguish, loss of enjoyment of life, loss of association, as well as other special and general damages permitted by law.

127. The Decedent's heirs have likewise suffered harm as the proximate result of Defendant' acts and omissions, including suffering pecuniary loss, including loss of love, guidance, care, comfort, support, affection, and/or society, and death and burial expenses, as well as other special and general damages permitted by law.

128. As such, Plaintiffs, individually, and in their representative capacity, seeks recovery for all damages as allowed by law and as found by the Court to be just compensation.

DAMAGES

129. Plaintiffs incorporates the allegations contained in the foregoing paragraphs as if fully set forth in the following paragraphs.

130. The facts set out above demonstrate that, as a direct and proximate result of Defendant's conduct, Plaintiffs have suffered severe economic and non-economic losses and injuries for which they are entitled to recover damages.

131. Plaintiffs are entitled to recover the following damages, including without limitation the following:

(a) compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, and other non-economic damages in an amount to be determined at trial of this action;

(b) economic damages in the form of medical expenses, out of pocket expenses, and other economic damages in an amount to be determined at trial of this action;

(c) Punitive damages;

(d) Wrongful death damages;

(e) Burial and funeral expenses;

(f) Damage for loss of companionship and society;

(g) Pre-judgment interest;

(h) Post-judgment interest;

(i) Reasonable attorneys' fees;

(j) Costs of these proceedings; and

(k) Such other and further relief as this Court deems just and proper.

JURY DEMAND

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

PRAYER

WHEREFORE, Plaintiffs asks that Defendant Boehringer Ingelheim Pharmaceuticals, Inc. be cited to appear and answer herein. That, upon final trial, Plaintiffs have judgment against

Defendant Boehringer Ingelheim Pharmaceuticals, Inc. and for damages, pre-and post-judgment interest, costs of court, and any other relief to which Plaintiffs may be entitled.

Dated: May 19, 2015

Respectfully submitted,

BY: /s/Harry F. Bell, Jr.

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