UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

AIMEE KING;	)	
	)	**Civil Action No.: _____**
Plaintiff,	)	
	)	
v.	)	**COMPLAINT**
	)	
BAYER CORPORATION; BAYER HEALTHCARE PHARMACEUTICALS, INC.; and MERCK & CO., INC.;	)	**JURY TRIAL DEMAND**
	)	
Defendants.	)	
	)	

NOW COMES Plaintiff, Aimee King ("Plaintiff"), by and through the undersigned counsel, and hereby brings this Complaint for damages against Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., and Merck & Co., Inc., and alleges the following:

INTRODUCTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of the pharmaceutical drug Avelox® (hereinafter, "Avelox"), also known as moxifloxacin.

2. Plaintiff maintains that Avelox is negligently and unreasonably defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use, all in violation of the North Carolina Products Liability Act, N.C. Gen. Stat. § 99B-1 *et seq*., and North Carolina common law.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because

Defendants are all either incorporated and have their principal place outside of the state in which the Plaintiff resides.

4. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

5. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, in that Defendants conduct business here and are subject to personal jurisdiction in this District. Furthermore, Defendants sell, market and/or distribute Avelox within North Carolina and this District.

PARTIES

6. Plaintiff, Aimee King, is a natural person and a resident and citizen of Union County, North Carolina. Plaintiff brings this action for personal injuries sustained by the use of Avelox. As a direct and proximate result of being prescribed and ingesting Avelox, Plaintiff developed permanent peripheral neuropathy and/or symptoms of peripheral neuropathy.

7. Defendant Bayer Corporation ("Bayer Corp.") is an Indiana corporation that has its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

8. Defendant Bayer Corp. has transacted and conducted business within the State of North Carolina.

9. Defendant Bayer Corp. has derived substantial revenue from goods and products used in the State of North Carolina.

10. Defendant Bayer Corp. expected or should have expected its acts to have consequences within the State of North Carolina, and derived substantial revenue from interstate commerce.

11. Defendant Bayer Corp. was engaged in the business of designing, developing, manufacturing, testing, packaging, marketing, distributing, labeling, and/or selling Avelox.

12. Defendant Bayer Healthcare Pharmaceuticals, Inc. ("Bayer Healthcare") is a Delaware corporation that has its principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045.

13. In January 2008, Bayer Pharmaceuticals Corporation was merged into Defendant Bayer Healthcare.

14. Defendant Bayer Healthcare has transacted and conducted business within the State of North Carolina.

15. Defendant Bayer Healthcare has derived substantial revenue from goods and products used in the State of North Carolina.

16. Defendant Bayer Healthcare expected, or should have expected, its acts to have consequences within the State of North Carolina, and derived substantial revenue from interstate commerce.

17. Defendant Bayer Healthcare was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avelox.

18. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation that has its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

19. Defendant Merck has transacted and conducted business within the State of North Carolina.

20. Defendant Merck has derived substantial revenue from goods and products used in the State of North Carolina.

21. Defendant Merck expected, or should have expected, their acts to have consequences within the State of North Carolina, and derived substantial revenue from interstate commerce.

22. At all times material hereto, Defendant Merck was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avelox.

23. As used herein, "Defendants" includes all named Defendants.

24. Defendants are authorized to do business in North Carolina and derive substantial income from doing business in this State.

25. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities with the State of North Carolina, thus invoking the benefits

and protections of its laws.

26. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture, promote and/or distribute Avelox, with full knowledge of its unreasonably dangerous and defective nature.

FACTUAL ALLEGATIONS

27. At all relevant times, Defendants were in the business of, and did, design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired and are responsible for Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the pharmaceutical drug Avelox.

28. Plaintiff was prescribed Avelox and used it as directed.

29. Avelox is a broad-spectrum synthetic antibacterial agent marketed and sold in oral tablet, IV solution, and ophthalmic solution, used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria.

30. Avelox is a member of the quinolone class of antibiotics. Quinolones are divided into four generations based on their spectrum of antimicrobial activity.

31. The first-generation, non-fluorinated quinolone antibiotics were developed in the early 1960s and soon revealed themselves as effective against common gram-negative bacteria, but resistance developed rapidly.

32. Twenty years later, in the early 1980s, fluorinated derivatives of the quinolones emerged, revealing a broader, more potent antibiotic, effective against common gram-negative and gram-positive bacteria. These so-called second-generation quinolones included Noroxin® (norfloxacin), Cipro® (ciprofloxacin), Floxin® (ofloxacin), and pefloxacin (never approved for marketing in the United States).

33. Fluoroquinolones have long been associated with serious side effects. Indeed, many fluoroquinolones have been removed from the United States market due to intolerable adverse events. For example, Omniflox® (temafloxacin) was removed from the market in June 1992 only six months after approval due to low blood sugar, kidney failure, and a rare form of

anemia; Trovan® (trovafloxacin) was removed from the market in June 1999 due to severe liver toxicity; Raxar® (grepafloxacin) was removed from the market in October 1999 due to QT-interval prolongation; Zagam® (sparfloxacin) was removed from the market in July 2001 due to QT-interval prolongation; and most recently, Tequin® (gatifloxacin) was removed from the market in May 2006 amid reports of severe blood sugar reactions such as hyperglycemia and hypoglycemia.

34. Avelox was approved by the United States Food and Drug Administration (hereinafter, the "FDA") on December 10, 1999 for use in the United States, and is the brand name for the antibiotic moxifloxacin.

35. With the patent for Cipro® (Defendants' other blockbuster fluoroquinolone) set to expire in 2003, Defendants set out to develop and effectively market Avelox in order to be more competitive with third- and fourth-generation fluoroquinolones, including Levaquin®. Avelox quickly became Defendants' heir apparent and successor to Cipro®.

36. Similar to Cipro®, Avelox® has proven to be a blockbuster drug for Bayer. In 2007 alone, Avelox® generated international sales of $697.3 million dollars.

37. Defendant Bayer Healthcare has indicated on its website that Avelox is "safe and effective" and "has a well-characterized safety profile, which has been studied in over 14,000 patients in clinical trials and 92,000 patients in post marketing surveillance studies."

38. However, the scientific evidence has established a clear association between Avelox and an increased risk of long-term and sometimes irreversible peripheral neuropathy.

39. Defendants knew or should have known that Avelox is associated with an increased risk of developing irreversible peripheral neuropathy.

40. Defendants failed to appropriately and adequately inform and warn Plaintiff and Plaintiff's prescribing physicians of the serious and dangerous risks associated with the use of Avelox concerning peripheral neuropathy, as well as other severe and personal injuries, which are permanent and/or long-lasting in nature, cause significant physical pain and mental anguish, diminished enjoyment of life, and the need for medical treatment, monitoring and/or

medications.

41. The warning label for Avelox during the period from September 2004 through August 2013 misled Plaintiff and her treating physician by incorrectly advising patients and physicians that peripheral neuropathy associated with Avelox was "rare" and failing to mention the possibility that it could result in irreversible nerve damage.

42. Though this injury can be significant and debilitating, the language regarding the "rare" risk of peripheral neuropathy was buried at the bottom of a long list of adverse reactions that were included on the Avelox label; the language was in no way highlighted for the benefit of prescribing physicians and patients.

43. Additionally, Defendants failed to disseminate a "Dear Doctor" letter to physicians concerning the label change or the risk of irreversible peripheral neuropathy, and Defendants failed to disclose this serious and dangerous effect when promoting Avelox to physicians.

44. Despite their knowledge that Avelox was associated with an elevated risk of permanent nerve damage, Defendants' promotional campaign was focused on Avelox's purported "safety profile."

45. As early as 1992, there was evidence of the association between fluoroquinolone antibiotics and peripheral neuropathy. Dr. Aoun from the Infectious Diseases Clinic and Microbiology Laboratory at the Institut Jules Bordet in Belgium, along with others, wrote a letter to the editor of the Lancet raising concerns about a 37-year old patient who developed peripheral neuropathy after taking fluoroquinolones.

46. Four years later, Karin Hedenmalm and Olav Spigset published "Peripheral sensory disturbances related to treatment with fluoroquinolones" based on a review of 37 separate reports of symptoms of peripheral nerve damage, highlighting concerns about numbness, pain, and muscle weakness.

47. One of the first studies in the United States that included the post market experience concerning fluoroquinolones and neuropathy was "Peripheral Neuropathy Associated

with Fluoroquinolones" written by Jay S. Cohen.

48. The Cohen paper was published in December 2001 and revealed that adverse events reported by forty-five patients suggested a possible association between fluoroquinolones and long-term peripheral nervous system damage. The study noted in particular the presence of severe and/or persistent nerve problems. Over one-half of the patients surveyed said their symptoms lasted for more than a year, and eighty percent characterized their symptoms as severe. The Cohen paper recommended further investigation of the association between fluoroquinolones and peripheral neuropathy. The study concluded with the following advisory: "If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is confirmed, physicians need to be informed and warnings might be considered for these drugs' product information."

49. In 2002 and 2003, Defendants were put on notice that numerous reports had been submitted to the FDA's Adverse Event Reporting System that identified fluoroquinolone users who had developed disabling peripheral neuropathy that persisted long after the drug had been discontinued.

50. A scientific review by the FDA of the adverse events in the FDA Adverse Event database in 2003 concerning Avelox and other fluoroquinolones revealed numerous reports of long-term peripheral neuropathy.

51. In September 2004, the FDA approved an amended Avelox label concerning peripheral nerve damage. The amended Avelox label included the following statement in the Warnings section:

> **Peripheral Neuropathy:** Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones.

52. Thus, rather than warning patients and physician that the use of Avelox may result in permanent nerve damage, Defendants instead adopted a warning that misleadingly indicated such damage was rare and failed to make any mention of the risk of permanent nerve damage.

53. Defendants' failure to adequately warn physicians resulted in (1) patients receiving Avelox instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which patients presented to the provider; and (2) physicians failing to warn and instruct consumers about the risk of long-term peripheral nervous system injuries associated with Avelox.

54. The failure of Defendants to include appropriate and adequate warnings in the label as published to the medical community also resulted in an absence of adequate warnings in patient information presented directly to consumers, either as part of samples packages or as part of the prescription they received from retail pharmacies.

55. Despite Defendants' knowledge and negligent failure to adequately warn Plaintiff and physicians of the above, Defendants continue to market Avelox as a first-line therapy for common bronchitis, sinusitis and other non-life threatening bacterial infections, conditions for which many other safer antibiotics are available.

56. In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that the existing warnings regarding peripheral nerve damage were inadequate. On August 15, 2013, an updated warning was issued in which the risk of rapid onset of irreversible peripheral neuropathy was finally included. The updated warning also removed the statement that nerve damage occurred only in rare cases.

57. In January of 2014, Ayad Ali published "Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis" which re-emphasized the link between fluoroquinolones and peripheral neuropathy and called for increased scrutiny of the risk-benefit of fluoroquinolone prescriptions. The Ali paper also detailed the presence of strong safety signals dating back to at least 2005 regarding the potential for Avelox and other fluoroquinolones to cause long-term, disabling peripheral neuropathy.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

58. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

59. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Avelox.

60. As a result of Defendants' actions, Plaintiff and, upon information and belief, Plaintiff's treating physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

61. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Avelox. Defendants were under a duty to disclose the true character, quality, and nature of Avelox because this was non-public information over which Defendants had and continues to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff, medical providers and/or to their facilities. In addition, Defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

62. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, promoting and/or distributing a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendants' representations. Accordingly, Defendants are precluded by the

discovery rule and/or the doctrine of fraudulent concealment from relying upon any statute of limitations.

FIRST CAUSE OF ACTION

[NC Products Liability Act]

63. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

64. Plaintiff is a claimant and Defendants are each a manufacturer or seller within the ambit of the North Carolina Products Liability Act, N.C. Gen. Stat. § 99B-1.

65. Defendants are jointly and severally liable for acting negligently and unreasonably in failing to provide an adequate warning under N.C. Gen. Stat. § 99B-5. Pursuant to that statute, Defendants acted unreasonably in failing to provide adequate warnings or instructions, and the failure to provide adequate warnings or instructions was a proximate cause of the harm for which damages are sought.

66. Furthermore, under N.C. Gen. Stat. § 99B-5, at the time the product left the control of the Defendants, the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the Defendants knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant.

67. In the alternative, after the product left the control of the Defendants, the Defendants became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

68. Further, under N.C. Gen. Stat. § 99B-6, Defendants are liable for the inadequate design or formulation of the product at issue herein in that at the time of its manufacture they acted unreasonably in designing or formulating the product, this conduct was a proximate cause of the harm for which damages are sought, and in addition, at the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical,

feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.

69. Furthermore, at the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

70. The Avelox manufactured and/or supplied by Defendants was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Avelox failed to warn of the dangerous risks posed by Avelox, including the risk of developing irreversible peripheral neuropathy.

71. At all times alleged herein, Avelox was defective, and Defendants knew that Avelox was to be used by consumers without inspection for defects. Moreover, Plaintiff, her prescribing physicians, and her health care providers neither knew nor had reason to know at the time of Plaintiff's use of Avelox of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

72. At all times alleged herein, Avelox was prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

73. The design of Avelox was defective in that the risks associated with using Avelox outweighed any benefits of the design. Any benefits associated with the use of Avelox were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results but without the increased risk of developing irreversible peripheral neuropathy.

74. The defect in design existed when the product left Defendants' possession.

75. At the time Avelox left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting Avelox.

76. As a result of Avelox's defective condition and the Defendants' negligent conduct leading to the failure to adequately warn and adequately design and formulate the product in question, Plaintiff suffered the injuries and damages alleged herein and has been damaged in excess of $75,000.

SECOND CAUSE OF ACTION

[Product Liability – Common Law Failure to Warn]

77. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

78. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Avelox, and, through that conduct, have knowingly and intentionally placed Avelox into the stream of commerce with full knowledge that it reaches consumers such as Plaintiff who ingested it.

79. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Avelox to Plaintiff and to her prescribing physicians. Additionally, Defendants expected the Avelox that they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and Avelox did in fact reach – prescribing physicians and consumers, including Plaintiff and her prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

80. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and ingested by Plaintiff. The defective condition of Avelox was due in part to the fact that it was not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of its use.

81. This defect caused serious injury to Plaintiff, who used Avelox in its intended and foreseeable manner.

82. At all times herein mentioned, Defendants had a duty to properly design,

manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

83. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

84. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Avelox, namely irreversible peripheral neuropathy.

85. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Avelox caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible peripheral neuropathy from Avelox use, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.

86. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

87. Defendants, as the manufacturers and/or distributors of the subject product, are held to the level of knowledge of an expert in the field.

88. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

89. Had Defendants properly disclosed the risks associated with Avelox, Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using Avelox.

90. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged and has been damaged in excess of $75,000.

THIRD CAUSE OF ACTION

[Negligence]

91. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

92. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Avelox.

93. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

94. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Avelox;

b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of Avelox's dangerous and defective characteristics;

c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the subject product;

d) In promoting the subject product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause irreversible peripheral neuropathy;

e) In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;

f) In failing to perform appropriate pre-market testing of the subject product;

g) In failing to perform appropriate post-market surveillance of the subject

product;

h) In failing to adequately and properly test Avelox before and after placing it on the market;

i) In failing to conduct sufficient testing on Avelox which, if properly performed, would have shown that Avelox had the serious side effect of causing irreversible peripheral neuropathy;

j) In failing to adequately warn Plaintiff and her healthcare providers that the use of Avelox carried a risk of developing irreversible peripheral neuropathy;

k) In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of irreversible peripheral neuropathy associated with the use of Avelox; and

l) In failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely irreversible peripheral neuropathy, from Avelox ingestion as described herein.

95. Defendants knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

96. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein and has been damaged in excess of $75,000.

FOURTH CAUSE OF ACTION

[Breach of Express Warranty]

97. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

98. Before Plaintiff was first prescribed Avelox and during the period in which she used Avelox, Defendants expressly warranted that Avelox was safe by express warranty within the meaning of N.C. Gen. Stat. § 25-2-313.

99. Avelox did not conform to these express representations because Avelox was not safe and had an increased risk of serious side effects, including irreversible peripheral neuropathy, whether taken individually or in conjunction with other therapies.

100. As a direct and proximate result of this wrongful conduct, Plaintiff was injured as described above and has been damaged in excess of $75,000.

FIFTH CAUSE OF ACTION

[Breach of Implied Warranty]

101. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

102. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold Avelox, and prior to the time that it was prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff that the subject product was of merchantable quality and safe and fit for the use for which it was intended in accordance with N.C. Gen. Stat. § 25-2-314.

103. Plaintiff, individually and through her prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

104. Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

105. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until

after she used it.

106. Contrary to the implied warranty for the subject product, Avelox was not of merchantable quality, and it was neither safe nor fit for its intended uses and purposes, as alleged herein.

107. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein in excess of $75,000.

SIXTH CAUSE OF ACTION

[Fraud]

108. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

109. Defendants made misrepresentations to Plaintiff, her prescribing physicians, and the healthcare industry regarding the safety and effectiveness of Avelox and/or fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of Avelox.

110. Defendants made misrepresentations and actively concealed adverse information when Defendants knew, or should have known, that Avelox had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physicians, and the healthcare industry generally. Specifically, Defendants actively concealed from Plaintiff, her prescribing physicians, the health care industry, and the consuming public that:

(a) Since at least 1996 Defendant Bayer and/or its predecessors were in possession of data demonstrating that Avelox increases the risk of irreversible peripheral neuropathy;

(b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Avelox before and after its product launch;

(c) Avelox was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and

(d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Avelox increases the risk of irreversible peripheral neuropathy.

111. The misrepresentations and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

112. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, her prescribing physicians, and the healthcare industry.

113. Defendants made these false representations with the intent or purpose that Plaintiff, her prescribing physicians, and the healthcare industry would rely on them, leading to the use of Avelox by Plaintiff as well as the general public.

114. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, her physicians would not have prescribed and Plaintiff would not have taken the subject product.

115. Plaintiff, her prescribing physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of Avelox that Defendants did suppress, conceal, or fail to disclose to Plaintiff's detriment. Plaintiff justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true dangers of Avelox. Based on the nature of the physician-patient relationship, Defendants had

reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or active concealment.

116. Defendants had a post-sale duty to warn Plaintiff, her prescribing physicians, and the general public about the potential risks and complications associated with Avelox in a timely manner.

117. Defendants made the representations and actively concealed information about the defects and dangers of Avelox with the intent and specific desire that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Avelox as a treatment.

118. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested Avelox and suffered injuries as set forth herein and has been damaged in excess of $75,000.

SEVENTH CAUSE OF ACTION

[Negligent Misrepresentation]

119. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

120. Defendants negligently and/or recklessly misrepresented to Plaintiff, her prescribing physicians, and the healthcare industry the safety and effectiveness of Avelox and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Avelox.

121. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that Avelox had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physician(s) and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, her prescribing physicians, the health care industry, and the consuming public that:

(a) Since at least 1996, Defendants and/or their predecessors were in

possession of data demonstrating that Avelox increases the risk of irreversible peripheral neuropathy;

(b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Avelox before and after its product launch;

(c) Avelox was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and

(d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Avelox increases the risk of irreversible peripheral neuropathy.

122. These negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

123. Defendants should have known through the exercise of due care that these representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiff, her prescribing physicians, and the healthcare industry.

124. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, her prescribing physicians, and the healthcare industry would rely on them, leading to the use of Avelox by Plaintiff as well as the general public.

125. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, her physicians would not have prescribed and Plaintiff would not have taken the subject product.

126. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Avelox and relied on the absence of information regarding the dangers of Avelox which Defendants

negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

127. Defendants had a post-sale duty to warn Plaintiff, her prescribing physicians, and the general public about the potential risks and complications associated with Avelox in a timely manner.

128. Defendants made the representations and actively concealed information about the defects and dangers of Avelox with the absence of due care such that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Avelox as a treatment.

129. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts as set forth above, Plaintiff ingested Avelox and suffered injuries as set forth herein and has been damaged in excess of $75,000.

EIGHTH CAUSE OF ACTION

[Fraudulent Concealment]

130. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

131. Defendants committed actual fraud by making material representations that were false, knowing that such material representations were false, and/or with reckless disregard for the truth or falsity of such material representations with the intent that Plaintiff and her prescribing physicians would rely on such material representations.

132. Plaintiff and her prescribing physicians were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material misrepresentations, and Plaintiff was injured as a direct and proximate result.

133. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiff, her prescribing physicians, and the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff and her prescribing physicians would rely on Defendants' misrepresentations. Plaintiff

and her prescribing physicians did, in fact, act in actual and justifiable reliance on Defendants' representations, and Plaintiff was injured as a result.

134. At all times herein mentioned, Defendants had a duty to Plaintiff, her prescribing physicians, and the general public to accurately inform them of risks associated with Avelox because Defendants, as the manufacturer and/or distributor of the subject product, were in a position of superior knowledge and judgment regarding any potential risks associated with Avelox.

135. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Avelox at issue in this lawsuit, said breach or breaches constituting fraud because of its propensity to deceive others or constitute an injury to public interests or public policy.

136. In breaching their duties to Plaintiff, Defendants used their position of trust as the manufacturer and/or distributor of Avelox to increase sales of the drug at the expense of informing Plaintiff that, by ingesting Avelox, she was placing herself at a significantly-increased risk of developing irreversible peripheral neuropathy and has been damaged in excess of $75,000.

NINTH CAUSE OF ACTION

[Punitive Damages, N.C. Gen. Stat. § 1D-1, *et seq*.]

137. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

138. At all times material hereto, Defendants knew or should have known that Avelox was inherently dangerous with respect to the risk of irreversible peripheral neuropathy.

139. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Avelox.

140. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the subject product.

141. At all times material hereto, Defendants knew and recklessly disregarded the fact that Avelox causes the chronic illness irreversible peripheral neuropathy.

142. Notwithstanding the foregoing, Defendants continued to aggressively market the subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side effect.

143. Defendants knew of their subject product's lack of warnings regarding the risk of irreversible peripheral neuropathy, but they intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and/or sell Avelox without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Avelox.

144. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using Avelox against its benefits.

145. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

146. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

147. Defendants are liable for punitive damages in accordance with N.C. Gen. Stat. § 1D-1 *et seq.* in that the conduct of the Defendants, as set forth in above, was willful, wanton,

malicious, and in reckless disregard for the rights and interests of the Plaintiff.

148. The conduct of the Defendants, as referenced above, justifies an award of punitive damages in that pursuant to N.C. Gen. Stat. § 1D-15(a), Defendants are liable for compensatory damages and have committed one or more aggravating factors justifying an award of punitive damages, including without limitation, acts of egregious, reckless, willful and wanton conduct.

149. As a direct and proximate result of its acts and omissions herein, Defendants are liable for punitive damages in excess of $75,000.

JURY TRIAL DEMAND

150. Plaintiff requests a trial by jury of all claims and causes of action herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

(a) For general and special damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For full refund of all purchase costs Plaintiff paid for Avelox;

(e) For compensatory and consequential damages in excess of the jurisdictional minimum of this Court;

(f) For punitive damages as allowable by law;

(g) For attorneys' fees, expenses, and/or costs of this action to the extent allowable by law; and

(h) For such further relief as this Court deems necessary, just, and proper.

Dated: May 1, 2015

Respectfully submitted,

s/Mona Lisa Wallace
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