

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

STEPHANIE HELLER;

Plaintiff,

v.

BAYER HEALTHCARE PHARMACEUTICALS,
INC.; and MERCK & CO., INC.;

Defendants.

Case No.: 1:14-cv-01953

Plaintiff, Stephanie Heller (“Plaintiff”) by and through the undersigned counsel, hereby brings this Complaint for damages against the Defendants, and alleges the following:

NATURE OF THE CASE

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 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.

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 the District of Columbia.

PARTIES

6. Plaintiff Stephanie Heller is a natural person and at all relevant times a resident and citizen of the District of Columbia. 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 peripheral neuropathy and/or symptoms of peripheral neuropathy.

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

8. Defendant Bayer has transacted and conducted business within the District of Columbia.

9. Defendant Bayer has derived substantial revenue from goods and products used in the District of Columbia.

10. Defendant Bayer expected, or should have expected, its acts to have consequences within the District of Columbia, and derived substantial revenue from interstate commerce.

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

12. Defendant Merck & Co., Inc. (“Merck”) is New Jersey corporation which has its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

13. Defendant Merck has transacted and conducted business within the District of Columbia.

14. Defendant Merck has derived substantial revenue from goods and products used in the District of Columbia.

15. Defendant Merck expected, or should have expected, their acts to have consequences within the District of Columbia, and derived substantial revenue from interstate commerce.

16. 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.

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

18. Defendants are authorized to do business in the District of Columbia and derive substantial income from doing business in this state.

19. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities with the District of Columbia, thus invoking the benefits and protections of its laws.

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

GENERAL FACTUAL ALLEGATIONS

21. 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.

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

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

24. Avelox is a broad spectrum synthetic antibacterial agent manufactured by Bayer

and marketed and sold in the United States in oral tablet, IV solution, and ophthalmic solution under the brand name Avelox by Bayer and Bayer's marketing partner, Defendant Merck.

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

26. The 1st 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.

27. 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 2nd generation quinolones included Noroxin® (norfloxacin), Cipro® (ciprofloxacin), Floxin® (ofloxacin), and pefloxacin (never approved for marketing in the United States).

28. 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.

29. Bayer submitted a New Drug Application ("NDA") for Avelox on December 9, 1998.

30. With the patent for Cipro® (Bayer's other blockbuster fluoroquinolone) set to expire in 2003, Defendants set out to develop and effectively market Avelox in order to be more competitive with 3rd and 4th generation fluoroquinolones, including Levaquin®. Avelox

quickly became Bayer's heir apparent and successor to Cipro®.

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

32. Defendant Bayer 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.”

33. However, the scientific evidence has established a clear association between Avelox and an increased risk of irreversible peripheral neuropathy.

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

35. 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.

36. 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.

37. 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.

38. 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.

39. 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."

40. 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.

41. 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.

42. One of the first studies in the United States that included the post market experience concerning Avelox and neuropathy was "Peripheral Neuropathy Associated with Fluoroquinolones" written by Jay S. Cohen.

43. 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."

44. 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.

45. 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.

46. In September 2004, the FDA approved an amended Avelox label concerning peripheral nerve damage. The amended 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.

47. 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.

48. 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 Plaintiff presented to the provider; (2) and physicians failing to warn and instruct consumers about the risk of long-term peripheral nervous system injuries associated with Avelox.

49. The failure of Defendants to include appropriate 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.

50. Despite Defendants' knowledge and 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.

51. In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that the existing warning regarding peripheral nerve damage was 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.

52. 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.

SPECIFIC FACTUAL ALLEGATIONS

53. In April of 2013, Plaintiff Stephanie Heller was prescribed a 10-day course of Avelox. After taking 4 days of that course, Stephanie was concerned about the impact that Avelox was having on her wellbeing.

54. Stephanie returned to the doctor and reported her initial symptoms. After hearing of Stephanie’s symptoms, her doctor instructed her to discontinue taking the Avelox.

55. The following day, Stephanie began suffering from severe pain and cramping throughout her legs, making it difficult to stand or walk.

56. Within a few days, Stephanie suffered from extreme weakness and pain throughout her body, and her wrists and ankles became extremely weak and she began to suffer from incessant tingling and vibrating that did not ease or subside. Stephanie had extreme

difficulty carrying on any of her normal functions such as walking, standing, sleeping, or driving.

57. Stephanie was diagnosed with peripheral neuropathy.

58. To date, Stephanie continues to suffer from the symptoms of her peripheral neuropathy, including joint weakness, severe cramping, difficulty standing, walking, sleeping, driving, tightness throughout her limbs, and tingling that does not go away.

59. As a direct and proximate cause of her Avelox-induced side effects, Plaintiff has suffered significant pain and suffering, and her quality of life has been severely diminished.

60. For each Count hereinafter alleged and averred, the above and following Paragraphs should be considered re-alleged as if fully rewritten.

FIRST CAUSE OF ACTION

[Strict Liability]

61. Avelox 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.

62. 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.

63. 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.

64. 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.

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

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

67. As a result of Avelox's defective condition, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demand that the issues herein contained be tried by a jury.

SECOND CAUSE OF ACTION

[Product Liability – Failure to Warn]

68. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

69. 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.

70. 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.

71. 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.

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

73. 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.

74. 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.

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

76. 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.

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

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

79. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment

of Defendants.

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

81. 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.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

THIRD CAUSE OF ACTION

[Negligence]

82. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

83. 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.

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

85. 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.

86. 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.

87. 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 have endured pain and suffering, have 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.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

FOURTH CAUSE OF ACTION

[Breach of Express Warranty]

88. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

89. Before Plaintiff was first prescribed Avelox and during the period in which she used Avelox, Defendants expressly warranted that Avelox was safe.

90. 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.

91. As a direct and proximate result of this wrongful conduct, Plaintiff was injured as described above.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

FIFTH CAUSE OF ACTION

[Breach of Implied Warranty]

92. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

93. 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.

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

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

96. 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.

97. 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.

98. 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 have 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 ham actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

SIXTH CAUSE OF ACTION

[Fraud]

99. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

100. Defendants misrepresented to Plaintiff, her prescribing physicians, and the healthcare industry 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.

101. 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.

102. These misrepresentations and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

103. 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.

104. 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.

105. 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 utilized the subject product.

106. 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.

107. 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.

108. 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.

109. 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.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her

favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

SEVENTH CAUSE OF ACTION

[Negligent Misrepresentation]

110. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

111. 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.

112. 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 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.

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

114. 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.

115. 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.

116. 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 utilized the subject product.

117. 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.

118. 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.

119. 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.

120. As a result of the negligent or reckless concealment and/or the negligent or

reckless failure to provide materials facts set forth above, Plaintiff ingested Avelox and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

EIGHTH CAUSE OF ACTION

[Fraudulent Concealment]

121. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

122. 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.

123. 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.

124. 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.

125. 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.

126. 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 her propensity to deceive others or constitute an injury to public interests or public policy.

127. 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.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

NINTH CAUSE OF ACTION

[VIOLATION OF UNFAIR AND DECEPTIVE TRADE PRACTICES ACTS]

128. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

129. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of Avelox.

130. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Avelox, and would not have incurred related medical costs. Specifically, Plaintiff, her physician, and medical staff were misled by the deceptive conduct described herein.

131. Defendants' deceptive, unconscionable, and/or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statute listed below.

132. Defendants engaged in wrongful conduct while at the same time obtaining, under

false pretenses, sums of money from Plaintiff for Avelox that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

133. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representation in violation of D.C. Code § 28-3901 et seq.

134. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create a demand for and sell Avelox. Each aspect of Defendants' conduct combined to artificially bolster sales of Avelox.

135. The medical community relied upon Defendants' misrepresentations and omissions in determining to use Avelox.

136. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages.

137. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff was damaged by paying in whole or in part for Avelox.

138. As a direct and proximate result of Defendants' violations of the District of Columbia's unfair trade practice acts, Plaintiff has sustained economic losses and other damages for which he is entitled to statutory and compensatory damages, and declaratory relief, in an amount to be proven at trial.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

TENTH COUNT

[NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS]

139. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

140. Defendants carelessly and negligently manufactured, marketed, and sold Avelox to

Plaintiff, carelessly and negligently concealed these defects from Plaintiff, and carelessly and negligently misrepresented the quality and safety of Avelox. Defendants should have realized that such conduct involved an unreasonable risk of causing emotional distress to reasonable persons, that might, in turn, result in illness or bodily harm.

141. Defendants owed a duty to treating physicians and Plaintiff to accurately and truthfully represent the risks of Avelox. Defendants breached that duty by misrepresenting and/or failing to adequately warn of the risks of Avelox – effects of which Defendants knew or in the exercise of diligence should have known – to the treating physicians and Plaintiff.

142. As a direct and proximate result of Defendants' wrongful conduct and breach of duty, Plaintiff has sustained and will continue to sustain severe emotional distress either due to physical injury or a rational fear of physical injury and is entitled to recovery of damages in an amount to be proven at trial. Defendants are liable to Plaintiff jointly and/or severally for all general, special and equitable relief to which Plaintiff is entitled by law in an amount to be proven at trial.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

PRAYER FOR RELIEF

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

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


- (f) For consequential damages in excess of the jurisdictional minimum of this Court;
- (g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;
- (h) For attorneys' fees, expenses, and costs of this action; and
- (i) For such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

DATED: November 19, 2014

NIDEL LAW, P.L.L.C.

By: 
Christopher T. Nidel, Esq. Bar # 497059
NIDEL LAW, P.L.L.C.
1615 New Hampshire Ave., N.W.
Washington, D.C. 20009
Phone: (202) 558-2030

<input type="checkbox"/> G. Habeas Corpus/ 2255 <input type="checkbox"/> 530 Habeas Corpus-General <input type="checkbox"/> 510 Motion/Vacate Sentence	<input type="checkbox"/> H. Employment Discrimination <input type="checkbox"/> 442 Civil Rights-Employment (criteria: race, gender/sex, national origin, discrimination, disability age, religion, retaliation) *(If pro se, select this deck)*	<input type="checkbox"/> I. FOIA/PRIVACY ACT <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	<input type="checkbox"/> J. Student Loan <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (excluding veterans)
<input type="checkbox"/> K. Labor/ERISA (non-employment) <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Labor Railway Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="checkbox"/> L. Other Civil Rights (non-employment) <input type="checkbox"/> 441 Voting (if not Voting Rights Act) <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 445 American w/Disabilities-Employment <input type="checkbox"/> 446 Americans w/Disabilities-Other	<input type="checkbox"/> M. Contract <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholder's Suits <input type="checkbox"/> 190 Other Contracts <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<input type="checkbox"/> N. Three-Judge Court <input type="checkbox"/> 441 Civil Rights-Voting (if Voting Rights Act)

V. ORIGIN

1 Original Proceeding
 2 Removed from State Court
 3 Remanded from Appellate Court
 4 Reinstated or Reopened
 5 Transferred from another district (specify)
 6 Multi district Litigation
 7 Appeal to District Judge from Mag. Judge

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)
 Product liability case for state common law and statutory causes of action brought under diversity jurisdiction under 28 U.S.C. § 1332(a)

VII. REQUESTED IN COMPLAINT CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND \$** >75,000 **JURY DEMAND:** YES NO

VIII. RELATED CASE(S) IF ANY (See instruction) YES NO If yes, please complete related case form.

DATE 11/19/2014 **SIGNATURE OF ATTORNEY OF RECORD** 

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
 Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the Cover Sheet.

- I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff is resident of Washington, D.C.; 88888 if plaintiff is resident of the United States but not of Washington, D.C., and 99999 if plaintiff is outside the United States.
- III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.
- IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of case.
- VI. CAUSE OF ACTION: Cite the US Civil Statute under which you are filing and write a brief statement of the primary cause.
- VIII. RELATED CASES, IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.