IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

CATHERINE FARMER and TIMOTHY FARMER, Plaintiffs, v. JOHNSON & JOHNSON; JANSSEN RESEARCH & DEVELOPMENT, LLC; JANSSEN PHARMACEUTICALS, INC.; and MCKESSON CORPORATION; Defendants.	Case No.: **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL**

COMES NOW the Plaintiffs, Catherine Farmer and Timothy Farmer, by and through their undersigned attorneys, and for their causes of action, hereby sue Defendants, Johnson & Johnson, Janssen Research & Development, LLC, Janssen Pharmaceuticals, Inc. and McKesson Corporation, and allege as follows:

PREAMBLE

1. This is an action for damages suffered by Plaintiffs 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 Levaquin® (also known as levofloxacin). Levaquin® in any of its forms shall herein be referred to as "Levaquin."

2. Plaintiffs maintain that Levaquin 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.

3. Ms. Farmer's injuries, like those striking thousands of similarly situated victims across the country, were avoidable.

PARTIES

4. Plaintiff Catherine Farmer is a natural person residing in Plano, Texas and is a citizen and resident of the United States and of Collin County, Texas.

5. Plaintiff Timothy Farmer is a natural person residing in Plano, Texas and is a citizen and resident of the United States and of Collin County, Texas.

6. Plaintiffs bring this action for personal injuries sustained by the use of Levaquin. As a direct and proximate result of being prescribed and ingesting Levaquin, Plaintiff Catherine Farmer developed peripheral neuropathy and/or symptoms of peripheral neuropathy.

7. Defendant Johnson & Johnson is a New Jersey corporation that has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

8. Defendant Johnson & Johnson has transacted and conducted business within the Middle District of Pennsylvania.

9. Defendant Johnson & Johnson has derived substantial revenue from goods and products used in the Middle District of Pennsylvania.

10. Defendant Johnson & Johnson expected or should have expected its acts to have consequences within the Middle District of Pennsylvania, and derived substantial revenue from interstate commerce.

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

12. Defendant Janssen Research & Development, LLC is a limited liability company organized under the laws of New Jersey, which has its principal place of business at 920 Route 202 South, P.O. Box 300, Mail Stop 2628, Raritan, New Jersey 08869.

13. Defendant Janssen Research & Development, LLC has transacted and conducted business within the Middle District of Pennsylvania.

14. Defendant Janssen Research & Development, LLC has derived substantial revenue from goods and products used in the Middle District of Pennsylvania.

15. Defendant Janssen Research & Development, LLC expected or should have expected their acts to have consequences within the Middle District of Pennsylvania, and derived substantial revenue from interstate commerce.

16. At all times material hereto, Defendant Janssen Research & Development, LLC was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

17. Defendant Janssen Research & Development, LLC is part of the Defendant Johnson & Johnson's "Family of Companies."

18. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation which has its principal place of business at 1000 Route 202 South, P.O. Box 300, Raritan, New Jersey 08869.

19. Defendant Janssen Pharmaceuticals, Inc. has transacted and conducted business within the Middle District of Pennsylvania.

20. Defendant Janssen Pharmaceuticals, Inc. has derived substantial revenue from goods and products used in the Middle District of Pennsylvania.

21. Defendant Janssen Pharmaceuticals, Inc. expected or should have expected their acts to have consequences within the Middle District of Pennsylvania, and derived substantial revenue from interstate commerce.

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

23. Defendant Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson.

24. Defendant McKesson Corporation (hereinafter "McKesson") is a Delaware corporation with its principal place of business at One Post Street, San Francisco, California

94104. At all relevant times, McKesson was in the business of manufacturing, labeling, selling, marketing, packaging, re-packaging and/or distributing Levaquin, including, on information and belief, the Levaquin used by Plaintiff Catherine Farmer.

25. McKesson touts itself as, among other things: (1) the largest pharmaceutical distributor in North America distributing one-third of the medications used daily in North America, (2) the nation's leading health care information technology company, and (3) a provider of "decision support" software to help physicians determine the best possible clinical diagnosis and treatment plans for patients.

26. At all times herein mentioned, McKesson was the largest single distributor of Johnson & Johnson's pharmaceutical products.

27. At all times herein mentioned, McKesson provided research services to pharmaceutical companies such as Johnson & Johnson. For example, on its website, McKesson offered "bio-pharmaceutical manufacturers an unsurpassed suite of services to accelerate the approval and successful commercialization of specialty pharmaceuticals across the product life cycle." Through its Risk Evaluation and Mitigation Strategies (REMS) Services, McKesson provided pharmaceutical manufacturers like Johnson & Johnson with a wide range of risk-based services, including consultation on FDA submissions, strategic program designs, data management, and assistance with drug launch.

28. At all times herein mentioned, McKesson conducted regular and sustained business in the Middle District of Pennsylvania by selling and/or distributing its products and services, including Levaquin, in the Middle District of Pennsylvania.

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

30. Defendants are authorized to do business in The Middle District of Pennsylvania and derive substantial income from doing business in this state.

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

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

JURISDICTION AND VENUE

33. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendant. Defendants are all either incorporated and/or have their principal place outside of the state in which the Plaintiffs resides.

34. The amount in controversy between Plaintiffs and Defendants exceeds $75,000, exclusive of interest and cost.

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

36. 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 Levaquin within the Middle District of Pennsylvania and this District.

FACTUAL ALLEGATIONS

A. Case General Facts

37. 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 Levaquin.

38. Plaintiffs was prescribed Levaquin and used it as directed.

39. Upon information and belief, McKesson distributed the Levaquin that Plaintiffs ingested. Plaintiffs ingested Levaquin in pill form and was also administered an IV of Levaquin in Plano, Texas. Within weeks of her ingestion of the drug, she began to experience tingling, numbness, pain, weakness, dizziness and headaches. These symptoms, among others, continue to persist to the present.

40. Upon information and belief, McKesson distributed the Levaquin that Plaintiffs ingested.

41. Levaquin was approved by the United States Food and Drug Administration (hereinafter "FDA") on December 20, 1996, for use in the United States, and is the brand name for the antibiotic levofloxacin.

42. Levaquin is a broad-spectrum fluoroquinolone antibiotic used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria.

43. In 2003, after generic versions of Cipro (a competing fluoroquinolone antibiotic) went on the market, Levaquin became the number one prescribed fluoroquinolone in the United States.

44. In 2006, after generic versions of Zithromax, a highly popular macrolide antibiotic, went on the market, Levaquin became the number one prescribed antibiotic in the world.

45. In 2007, Levaquin was ranked 37 of the top 200 drugs that were prescribed in the United States.

46. In 2007, Levaquin was ranked 19th in world sales of prescribed drugs.

47. In 2007, Levaquin accounted for 6.5% of Johnson & Johnson's total revenue, generating $1.6 billion in revenue, an 8% increase over the previous year.

48. Defendant Janssen Pharmaceuticals, Inc. indicates on its website that "[i]n a large number of clinical trials, Levaquin has been shown to have a proven safety and efficacy profile for the treatment of many bacterial infections."

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

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

51. Defendants failed to appropriately and adequately inform and warn Plaintiffs and Plaintiffs's prescribing physicians of the serious and dangerous risks associated with the use of

Levaquin 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.

52. The warning label for Levaquin during the period from September 2004 through August 2013 misled Plaintiffs and her treating physician by incorrectly advising patients and physicians that peripheral neuropathy associated with Levaquin was "rare" and in any case could be avoided by discontinuing the drug upon the onset of certain symptoms. The truth, however, is that the onset of irreversible peripheral neuropathy is often rapid and discontinuation of the drug will not ensure that the peripheral neuropathy is reversible.

53. 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 Levaquin label; the language was in no way highlighted for the benefit of prescribing physicians and patients.

54. 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 Levaquin to physicians.

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

56. 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.

57. 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.

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

59. 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."

60. 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.

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

62. In September 2004, an amended Levaquin label concerning peripheral nerve damage was approved by the FDA. 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, including levofloxacin. Levofloxacin should be discontinued if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation in order to prevent the development of an irreversible condition.

63. Thus, rather than warning patients and physician that the use of Levaquin may result in permanent nerve damage, Defendants instead adopted a warning that misleadingly indicated such damage was rare and in any event could be avoided by simply discontinuing the drug upon the onset of certain symptoms.

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

65. 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.

66. Despite Defendants' knowledge and failure to adequately warn Plaintiffs and physicians of the above, Defendants continue to market Levaquin 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.

67. 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.

68. Notwithstanding this updated 2013 label change, the Levaquin label remains inadequate and confusing regarding the risk of developing irreversible peripheral neuropathy. For instance, the Levaquin label currently states under the "Warnings and Precautions" section of the first page as follows: "Peripheral neuropathy: discontinue immediately if symptoms occur in order to *prevent irreversibility* (5.8)." This statement implies to physicians and patients that, if the patient stops using the drug immediately after symptoms occur, the symptoms are reversible. However, in section 5.8, the label states that "Symptoms [of peripheral neuropathy] may occur soon after initiation of LEVAQUIN® and *may be irreversible*." This later statement conflicts with the earlier statement by implying that no matter whether the patient stops using the drug immediately after experiencing symptoms, the symptoms may be permanent. It is inconsistent to advise physicians and patients in one section of the label that that the symptoms of peripheral neuropathy are reversible if the drug is stopped immediately after symptoms occur, but to advise physicians and patients in another section of the label that symptoms may be irreversible no matter whether they stop taking the medication immediately upon experiencing symptoms.

69. In January of 2014, Ayad Ali published "Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis" which reemphasized 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 Levaquin and other fluoroquinolones to cause long-term, disabling peripheral neuropathy.

B. <u>Case Specific Facts</u>

70. On or about April 19, 2006, Plaintiffs was prescribed Levaquin in pill form by her doctor. Plaintiffs was prescribed Levaquin for a sinus infection and used it as directed.

71. On or about May, 2006, Plaintiffs was administered Levaquin via an IV while hospitalized for open heart surgery.

72. On or about May 12, 2006, Plaintiffs was again prescribed a seven day course of 500 mg of Levaquin in pill form upon her discharge from the hospital for open heart surgery.

Plaintiffs was prescribed Levaquin as a post-surgical measure. Plaintiffs used the prescription as instructed.

73. Shortly after being administered the IV Levaquin and subsequent prescription in pill form, Ms. Farmer experienced constant pain, tingling and numbness in her arms and legs, as well as dizziness and headaches.

74. Ms. Farmer's adverse symptoms continued to progress and worsen, and by the year 2008 she was on disability and unable to work.

75. In addition to the burning in her arms and legs and the all-over sensitivity to touch, Ms. Farmer currently experiences tingling in her scalp as if it is on fire. She also currently experiences facial numbness and burning.

76. As a result of the diagnosis, for the rest of her life, Ms. Farmer must take medication to help her live with the symptoms of neuropathy. There is no cure for her neuropathy, so the medication she takes is only meant to help her live with the symptoms.

77. Despite regularly taking medication, Ms. Farmer continues to suffer from pain, tingling, and numbness sensations all over her body. She has dizziness, trouble with balance, memory impairment, and immediate cognitive impairment.

78. Had Defendants properly disclosed the risks associated with Levaquin, Ms. Farmer would have avoided the risk of neuropathy by not using Levaquin at all, and would not have suffered the injuries set forth with particularity herein.

79. As alleged herein, as a direct and proximate result of Defendants' negligent conduct, and the unreasonably dangerous and defective characteristics of the drug Levaquin, Ms. Farmer suffered severe and permanent physical and emotional injuries, including, but not limited to neuropathy. Plaintiffs have further incurred losses and damages including pain and suffering, emotional distress, mental anguish, loss of enjoyment of life; loss of consortium; suffered economic loss, including loss of income and incurring significant expenses for medical care and treatment.

80. Plaintiffs will continue to incur such losses, damages and expenses in the future.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

81. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

82. 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 Plaintiffs and Plaintiff's treating physicians the true risks associated with Levaquin.

83. As a result of Defendants' actions, Plaintiffs 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.

84. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Levaquin. Defendants were under a duty to disclose the true character, quality, and nature of Levaquin 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 Plaintiffs, 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.

85. The Plaintiffs had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, the Plaintiffs 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. Plaintiffs 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.

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

COUNT 1

Negligence

87. Plaintiffs incorporate all paragraphs of this Complaint as if set forth herein.

88. At all times material hereto, Defendants had a duty to exercise reasonable care, and to comply with existing standards of care, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Levaquin.

89. Defendants breached their duty of reasonable care to Plaintiffs, Plaintiff's prescribing physician, and Plaintiff's healthcare providers, and failed to comply with existing standards of care, in that they negligently promoted, marketed, distributed, and/or labeled Levaquin, and were otherwise negligent:

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

b. In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiffs herein, of Levaquin'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 Levaquin before and after placing it on the market;

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

j. In failing to adequately warn Plaintiffs, Plaintiff's prescribing physician and nurse practitioner, and plaintiff's healthcare providers that the use of Levaquin 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 Levaquin; and

l. In failing to adequately and timely inform Plaintiffs, Plaintiff's prescribing physician, Plaintiff's healthcare providers, and the healthcare industry of the risk of serious personal injury, namely irreversible peripheral neuropathy, from Levaquin ingestion as described herein.

90. Plaintiff's injuries and damages as alleged herein were and are the direct and proximate result of Defendants' failure to comport with their obligations of due care.

91. Defendants' actions were a substantial factor in bringing about the injuries and damages suffered by Plaintiffs.

92. Had Defendants exercised ordinary care, and complied with the then existing standards of care, Plaintiffs would not have been injured.

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

94. As a direct and proximate result of Defendants' carelessness and negligence, their failure to exercise reasonable care and their deviation from accepted standards of care, Plaintiff Catherine Farmer suffered and will continue to suffer severe and permanent physical and emotional injuries, including, but not limited to peripheral neuropathy. Plaintiffs have endured and will continue to endure pain, suffering, and loss of enjoyment of life; and has suffered and will continue to suffer economic loss, including incurring significant expenses for medical care and treatment. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this court enter judgment against Defendants in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues herein contained be tried by a jury.

COUNT II

Negligent Failure to Warn

95. Plaintiffs incorporate all paragraphs of this Complaint as if set forth herein.

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

97. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Levaquin to Plaintiff and to her prescribing physicians, healthcare providers, and the healthcare industry. Additionally, Defendants expected the Levaquin that they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and Levaquin did in fact reach – prescribing physicians and consumers, including Plaintiff and her prescribing physicians and

healthcare providers, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

98. 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 Levaquin 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.

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

100. 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.

101. 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.

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

103. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Levaquin caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible peripheral neuropathy from Levaquin 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.

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

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

106. Plaintiffs reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

107. Had Defendants properly disclosed the risks associated with Levaquin, Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using Levaquin and Plaintiff's physician would have avoided the risk of irreversible peripheral neuropathy by not prescribing Levaquin.

108. 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 Plaintiffs to sustain injuries as herein alleged. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this court enter judgment against Defendants in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT III

Negligent Design Defect

109. Plaintiffs incorporate all paragraphs of this Complaint as if set forth herein.

110. 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 Levaquin did not cause users to suffer from unreasonable and dangerous side effects.

111. At all times herein mentioned, the aforesaid product was defective and unsafe in design and 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.

112. Levaquin was defective at the time of its design, manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Levaquin failed to warn of the dangerous risks posed by Levaquin, including the risk of developing irreversible peripheral neuropathy.

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

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

115. The design of Levaquin was defective in that the risks associated with using Levaquin outweighed any benefits of the design. Any benefits associated with the use of Levaquin 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.

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

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

118. As a result of Levaquin's defective condition, Plaintiffs suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiffs respectfully request that this court enter judgment against Defendants in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT IV

Negligent Misrepresentation

119. Plaintiffs incorporate all paragraphs of this Complaint as if set forth herein.

120. At all times herein mentioned, Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Levaquin, and through that conduct have knowingly and intentionally placed Levaquin into the stream of commerce with full knowledge that it reaches consumers such as Ms. Farmer who ingested it.

121. Defendants, in the course of their business, negligently and/or recklessly misrepresented to Plaintiffs, Plaintiff's prescribing physicians, and the healthcare industry the safety and effectiveness of Levaquin and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Levaquin.

122. Defendants made representations that Levaquin was safe and effective to Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry when it marketed its product to them but failed to provide any warning that Levaquin caused long-term, potentially irreversible peripheral neuropathy.

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

(a) Since at least 1996 Defendant Johnson & Johnson and/or its predecessors were in possession of data demonstrating that Levaquin 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 Levaquin before and after its product launch;

(c) Levaquin 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 Levaquin increases the risk of irreversible peripheral neuropathy.

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

125. Defendants knew or should have known under the circumstances and through the exercise of due care, that those representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry.

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

127. At all times herein mentioned, neither Plaintiffs nor Plaintiff's physicians, or Plaintiff's healthcare providers 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, Plaintiff's prescribing physicians would not have prescribed Levaquin and Plaintiff would not have utilized the subject product.

128. Plaintiffs, Plaintiff's prescribing physicians, and Plaintiff's healthcare providers justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Levaquin and relied on the

absence of information regarding the dangers of Levaquin which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiffs' detriment.

129. Defendants had a pecuniary interest in making these statements about Levaquin to Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry as Defendants stood to lose a significant amount in sales and revenue if consumers and medical providers discovered there were safety issues with Levaquin.

130. Defendants had a post-sale duty to warn Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers and the general public about the potential risks and complications associated with Levaquin in a timely manner.

131. Defendants made the representations and actively concealed information about the defects and dangers of Levaquin 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 Levaquin as a treatment.

132. The false information supplied by Defendants to Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry was that Levaquin was safe, effective, and would not harm or adversely affect patients' health, including Plaintiffs, when used as directed.

133. The representations and false information communicated by Defendants to Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry were material and Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry justifiably relied on the misrepresentations and concealments.

134. As a direct and proximate result of Defendants negligent or reckless conduct, Plaintiff ingested Levaquin and suffered and will continue to suffer severe and permanent physical and emotional injuries, including, but not limited to irreversible peripheral neuropathy. Plaintiffs have endured and will continue to endure pain, suffering, and loss of enjoyment of life; and has suffered and will continue to suffer economic loss, including incurring significant

expenses for medical care and treatment. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this court enter judgment against Defendants in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT V

Breach of Express Warranty

135. Plaintiffs incorporate all paragraphs of this Complaint as if set forth herein.

136. Before Plaintiff was first prescribed Levaquin and during the period in which Plaintiff used Levaquin, Defendants expressly warranted that Levaquin was safe.

137. Plaintiffs either directly or indirectly through Plaintiff's prescribing physicians did in fact see and hear these representations and justifiably relied on these representations that Levaquin was safe and effective for the treatment of her sinus infections and post-surgical health.

138. Levaquin did not conform to these express representations because Levaquin 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.

139. As a direct and proximate result of this wrongful conduct, Plaintiffs were injured as described above.

WHEREFORE, Plaintiffs respectfully request that this court enter judgment against Defendants in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT VI

Fraud

140. Plaintiffs incorporate all paragraphs of this Complaint as if set forth herein.

141. Defendants misrepresented to Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry that Levaquin was safe and

effective. Defendants fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of Levaquin.

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

(a) Since at least 1996 Defendant Johnson & Johnson and/or its predecessors were in possession of data demonstrating that Levaquin 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 Levaquin before and after its product launch;

(c) Levaquin 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 Levaquin increases the risk of irreversible peripheral neuropathy.

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

144. Defendants knew and/or showed reckless disregard for the truth and should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry.

145. Defendants made these false representations with the intent or purpose that Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiff as well as the general public.

146. At all times herein mentioned, neither Plaintiffs nor Plaintiff's prescribing 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, Plaintiff's prescribing physicians would not have prescribed and Plaintiff would not have utilized the subject product.

147. Plaintiffs relied on and/or was induced by Defendant's representations and/or active concealment and relied on the absence of safety information which Defendant did suppress, conceal, or fail to disclose in purchasing and using Levaquin.

148. Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, 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 Levaquin that Defendants did suppress, conceal, or fail to disclose to Plaintiffs' detriment. Plaintiffs justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true dangers of Levaquin. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiffs would indirectly rely on Defendants' misrepresentations and/or active concealment.

149. Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry, justifiably relied on Defendants representations that Levaquin was safe and effective as it is reasonable that Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the healthcare industry would rely on the statements of Defendants whether Levaquin was safe because as the manufacturer of Levaquin, they are held to the level of knowledge of an expert in the field.

150. Defendants had a post-sale duty to warn Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the general public about the potential risks and complications associated with Levaquin in a timely manner.

151. Defendants made the representations and actively concealed information about the defects and dangers of Levaquin 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 Levaquin as a treatment.

152. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested Levaquin and suffered severe and permanent physical and emotional injures, as set forth herein.

WHEREFORE, Plaintiffs respectfully request that this court enter judgment against Defendants in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT VII

Constructive Fraud/Fraudulent Concealment

153. Plaintiffs incorporate all paragraphs of this Complaint as if set forth herein.

154. 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 Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, the healthcare industry, and the consuming public would rely on such material representations.

155. Plaintiffs, Plaintiff's prescribing physicians, and Plaintiff's healthcare providers were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material representations, and Plaintiffs were injured as a direct and proximate result.

156. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiffs, Plaintiff's healthcare providers, and the general public of the inaccuracy of

said misrepresentations. Defendants' omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiffs and Plaintiff's prescribing physicians would rely on Defendants' misrepresentations. Plaintiffs, Plaintiff's prescribing physicians, and Plaintiff's healthcare providers did, in fact, act in actual and justifiable reliance on Defendants' representations, and Plaintiffs were injured as a result.

157. At all times herein mentioned, Defendants had a duty to Plaintiffs, Plaintiff's prescribing physicians, Plaintiff's healthcare providers, and the general public to accurately inform them of risks associated with Levaquin 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 Levaquin.

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

159. In breaching their duties to Plaintiffs, Defendants used their position of trust as the manufacturer and/or distributor of Levaquin to increase sales of the drug at the expense of informing Plaintiff that, by ingesting Levaquin, she was placing herself at a significantly-increased risk of developing irreversible peripheral neuropathy.

WHEREFORE, Plaintiffs respectfully request that this court enter judgment against Defendants in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT VIII

Loss of Consortium

158. Plaintiffs incorporate all paragraphs of the complaint as if set forth herein.

159. At all relevant times stated herein, Plaintiff, Timothy Farmer, was and is the husband and spouse of Plaintiff, Catherine Farmer.

160. Before Catherine Farmer suffered the above-characterized permanent injuries as a result of taking Avelox and Levaquin, she and her husband enjoyed a marital relationship characterized by mutual support and shared activities, including both social and recreational activities and other marital activities.

161. As a proximate result of Defendants' tortious conduct, Catherine Farmer has suffered significant permanent injury to her person that substantially changed her lifestyle and has rendered her unable to perform the types of activities that she previously performed.

162. As a direct and proximate result of the injuries sustained by Catherine Farmer, as set forth above, Timothy Farmer has suffered loss of consortium, including but not limited to mental anguish and the past, present, and future loss of his wife's association, companionship, company, society, cooperation, comfort, assistance, affection, moral support, sexual relations, aid and assistance, services and solace.

163. As a result of the injuries sustained by Catherine Farmer, as set forth above, Plaintiffs Catherine Farmer and Timothy Farmer, sustained damages to their marital relationship and Timothy Farmer did suffer and continues to suffer loss of consortium.

PUNITIVE DAMAGES

160. Plaintiffs incorporate all paragraphs of this Complaint as if set forth herein.

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

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

163. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs and Plaintiff's prescribing physicians, concerning the safety of the subject product. Defendants' conduct was outrageous so as to be malicious, willful, wanton, or oppressive and shows a reckless indifference to the interests of others.

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

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

166. Defendants knew of the 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 Levaquin without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs herein, in conscious and/or negligent disregard of the foreseeable harm caused by Levaquin.

167. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using Levaquin against its benefits and this willful and wanton conduct created an unreasonable risk of physical harm to Plaintiffs and other users of the product.

168. As a direct and proximate result of Defendants' outrageous, malicious, willful, wanton, oppressive conduct so as to show a reckless indifference to the interests of others, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiffs 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. Plaintiffs' injuries and damages are permanent and will continue into the future.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray 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 Levaquin;

(e) For compensatory and general 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, treble damages, expenses, and costs of this action; and

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

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and as to all issues so triable.

DATED: July 28, 2015

Respectfully Submitted,

CHIMICLES & TIKELLIS LLP

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Pro Hac Vice Admission to be sought for:
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