IN THE SUPERIOR COURT OF NEW JERSEY
LAW DIVISION, ATLANTIC COUNTY

PLAINTIFF(S)	:	
	:	
v.	:	LEVAQUIN LITIGATION
	:	
JOHNSON & JOHNSON, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C. and ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.	:	Case Code Number 286 (MT)
	:	**MASTER LONG FORM COMPLAINT**

1. Pursuant to the Order of this Court, this Complaint is a Master Complaint filed for all plaintiffs, whether individually or through a personal representative, and if applicable plaintiff's spouse represented, by any plaintiff's counsel, and by operation of such order all allegations pleaded herein are deemed pleaded in any Short Form Complaint hereafter filed.

2. As more particularly pleaded below, each plaintiff maintains that the pharmaceutical drug Levaquin® (hereinafter "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.

PLAINTIFFS

3. Plaintiff(s) and, if applicable, Plaintiff's spouse, was (were) injured as a result of his/her use of Levaquin, and therefore seek, to the extent denoted on Plaintiff's Short Form Complaint, all such compensatory damages, punitive damages, ascertainable economic losses, treble damages, attorney's fees, reimbursement of cost of obtaining Levaquin, reimbursement for all past, present and future health and medical care costs related to Levaquin, per quod and derivative damages.

4. Plaintiff(s) is (are) specifically identified in the Short Form Complaint with Certification in the Levaquin Mass Tort litigation, designated with Case Code No. 286, in accordance with the Case Management Order regarding the Master and Short Form Complaints.

DEFENDANTS

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

6. Defendant JOHNSON & JOHNSON has transacted and conducted business within the State of New Jersey.

7. Defendant JOHNSON & JOHNSON has derived substantial revenue from goods and products used in the State of New Jersey.

8. Defendant JOHNSON & JOHNSON expected or should have expected their acts to have consequences within the State of New Jersey, and derived substantial revenue from interstate commerce.

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

10. Defendant JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C. ("JOHNSON & JOHNSON PRD") 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.

11. Defendant JOHNSON & JOHNSON PRD has transacted and conducted business within the State of New Jersey.

12. Defendant JOHNSON & JOHNSON PRD has derived substantial revenue from goods and products used in the State of New Jersey.

13. Defendant JOHNSON & JOHNSON PRD expected or should have expected their acts to have consequences within the State of New Jersey, and derived substantial revenue from interstate commerce.

14. At all times material hereto, Defendant JOHNSON & JOHNSON PRD was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

15. Defendant JOHNSON & JOHNSON PRD is part of the Defendant JOHNSON & JOHNSON'S "Family of Companies."

16. Defendant ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. (hereinafter "ORTHO-MCNEIL") is a Delaware corporation which has its principal place of business at 1000 Route 202 South, P.O. Box 300, Raritan, New Jersey 08869.

17. Defendant ORTHO-MCNEIL has transacted and conducted business within the State of New Jersey.

18. Defendant ORTHO-MCNEIL has derived substantial revenue from goods and products used in the State of New Jersey.

19. Defendant ORTHO-MCNEIL expected or should have expected their acts to have consequences within the State of New Jersey, and derived substantial revenue from interstate commerce.

20. At all times material hereto, Defendant ORTHO-MCNEIL was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

21. Defendant ORTHO-MCNEIL is a wholly owned subsidiary of Defendant JOHNSON & JOHNSON.

FACTUAL ALLEGATIONS

22. 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.

23. 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.

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

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

26. 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.

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

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

29. 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.

30. Defendant ORTHO-MCNEIL 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."

31. However, pre- and post-label epidemiological studies, adverse event reports from around the world, and early product label indications have established a clear association between Levaquin and an increased risk of tendonitis and tendon rupture, especially of the Achilles tendon. Ruptures have also been reported concerning adductor longus, peroneous brevis, extensor pollicis longus, long head of the biceps and the rotator cuff tendon.

32. Defendants knew or should have known that Levaquin is associated with an increased risk of developing tendonitis and tendon rupture.

33. Defendants also knew or should have known that Levaquin is associated with a far greater risk of developing tendonitis and tendon rupture than any other antibiotic marketed in the United States, including all drugs in the fluoroquinolone class.

34. Defendants failed to appropriately and adequately inform and warn Plaintiff(s), Plaintiff's prescribing physician(s) and the Food and Drug Administration ("FDA") of the serious and dangerous risks associated with the use of Levaquin concerning tendonitis and tendon rupture, as well as other severe and personal injuries, which are or may be permanent and lasting in nature, cause significant physical pain and mental anguish, diminished enjoyment of life, and the need for medical treatment, monitoring and/or medications.

A. LEVAQUIN'S INTRODUCTION TO THE UNITED STATES

35. To understand the pharmacological properties of Levaquin, one need look no further than to Levaquin's older brother, ofloxacin, also manufactured and distributed by Defendants.

36. Both ofloxacin and levofloxacin were created and developed by Daiichi, a Japanese Company who holds the patent on both drugs. Daiichi assigned the patents to Defendants and gave Defendants an exclusive license to manufacture and market both of these fluoroquinolone compounds in the United States in return for royalty fees. Daiichi also licenses levofloxacin to a company named Aventis for manufacture and marketing in European counties. To date, levofloxacin remains one of Daiichi's best selling pharmaceuticals.

37. Ofloxacin entered the Japanese market in September, 1985. Thereafter, in 1991, Defendants introduced ofloxacin in the United States under the brand name Floxin.

38. Even before ofloxacin was marketed in Japan, Daiichi began researching products that could be the successor of ofloxacin. Daiichi wanted to develop a newer fluoroquinolone in order to be more competitive with Cipro and the other fluoroquinolones which could be used both orally and by injection, and would have the same or better characteristics of ofloxacin.

39. After many derivatives of ofloxacin were explored and synthesized, Daiichi isolated what is now known as levofloxacin - a purified version of one optically active form of ofloxacin, more specifically the L-isomer.

40. Levofloxacin was introduced in Japan in 1993, and later was approved by the FDA for use in the United States under the brand name Levaquin in 1996.

41. Floxin and Levaquin were considered to be one and the same by the FDA.

42. Within the New Drug Application ("NDA") for Levaquin, the FDA reviewers stated that:

> [P]re-NDA discussions with the applicant suggested quite strongly that levofloxacin is conceptually identical to ofloxacin. For ofloxacin, the dominant active drug substance is its 1-isomer, which is levofloxacin. Conceptually, this premise should lead to microbiological labeling essentially identical to ofloxacin... the applicant provided various basic studies in support of levofloxacin that had been actually performed using ofloxacin instead of levofloxacin. Particularly, some of the studies on mechanisms of action and the related resistance mechanisms were recapitulated from ofloxacin data rather than being generated anew for levofloxacin....

43. Despite the admitted similarities between Levaquin and Floxin, and Defendants' reliance on studies and data concerning ofloxacin when filing the NDA for Levaquin, Defendants failed to advise the FDA, and thereafter healthcare providers, that the epidemiological studies, published reports, and adverse event reports from around the world had (1) confirmed the association between flouroquinolones and tendon related injuries; (2) that Levaquin's older brother, Floxin, was one of the most tenotoxic flouroquinolones on the market; and (3) that the elderly, and especially those using corticosteroids, were at least three times as likely to suffer a tendon injury while on Levaquin.

44. Despite their knowledge, Defendants chose to only use the label that the FDA had required for all flouroquinolones in the United States. More specifically, in response to a Public Citizen petition, dated August 1, 2006, the FDA required all manufacturers of flouroquinolones to include the following class-related language:

> Ruptures of the shoulder, hand, and Achilles tendons that required surgical repair or resulted in prolonged disability have been reported with [the specific drug name].[The specific drug name] should be discontinued if the patient experiences pain, inflammation, or rupture of a tendon. Patients should rest and refrain from exercise until the diagnosis of tendonitis or tendon rupture has been confidently excluded. Tendon rupture can occur at any time during or after therapy with [the specific drug name].

45. The above-referenced language 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; and there was no indication that age and corticosteroid use tripled the risk of tendon injury while using Levaquin. Moreover, there was no indication on the label that Levaquin had a higher level of tendon toxicity in comparison with other flouroquinolones. Additionally, Defendants failed to disseminate a "Dear Doctor" letter to physicians concerning the label, and Defendants failed to highlight this serious and dangerous effect when promoting Levaquin to physicians.

46. Despite their knowledge that Levaquin and Floxin were associated with an elevated risk of tendon toxicity, Defendants' promotional campaign was focused on Levaquin's purported safety profile.

B. LEVAQUIN'S EARLY POST-MARKET EXPERIENCE

47. One of the first comparative studies that included the post market experience concerning Levaquin was from Italy. The authors analyzed Italian adverse event data from 1999 to 2001 to help determine the relative toxicity of each marketed fluoroquinolone antibiotic.

48. The Italian study was published in 2003 and revealed that: 1) the most frequently reported serious reaction to fluoroquinolones were tendon disorders; 2) levofloxacin was the fluoroquinolone with the highest tendonitis reporting rate; and 3) levofloxacin ranked first for tendonitis reports during the same period in the World Health Organization's adverse event database, with 522 reports of levofloxacin-induced tendon disorders and ruptures.

49. In March, 2002, the Italian Health Ministry issued a "Dear Doctor" letter to inform physicians of the risk of Levaquin tendon rupture.

50. Investigators from France also reported a particularly large amount of tendon disorders soon after levofloxacin was first marketed in that country in September, 2000. By June, 2001, in just nine months, 333 adverse reactions had been reported with tendon disorder being the most frequently reported adverse event. Again, the adverse event data supported the epidemiological evidence finding that tendon injuries were more prominent in the elderly, especially when there had been co-administration of corticosteroids. France's regulatory authority published a Dear Doctor letter to highlight this information to French doctors in 2002.

51. Similarly, the Belgian regulatory authority received 161 reports of levofloxacin-induced tendon injury, including 68 reports of tendon rupture, in the first two years of levofloxacin's introduction in Belgium. Again, the average age of patients with levofloxacin-associated tendinopathy was 69 years old and about half were receiving concomitant corticosteroid treatment. As with other adverse event data, the tendon injuries were reported to occur soon after levofloxacin was ingested. The Belgium authority also noted, similar to Italy, that the number of tendon disorders associated with levofloxacin was much higher than that of the other flouroquinolones. Not surprisingly, ofloxacin had the second highest reports of tendon injury.

52. In response, the Belgium regulatory authority disseminated a "Dear Doctor" letter in 2002 highlighting their concerns to physicians in Belgium about levofloxacin's toxicity and suggesting that levofloxacin is only justified for the treatment of community-acquired pneumonia in patients who are allergic to beta-lactams. The Belgium authority stressed that the elderly and people who used corticosteroids were particularly at risk and encouraged doctors to watch for tendon injury concerning levofloxacin treatment.

53. Daiichi, the inventor of ofloxacin and levofloxacin, also published the results of a 1997 rat study which revealed that levofloxacin and ofloxacin were the most toxic to tendons of all the fluoroquinolones marketed in the United States. The study was designed to not only better understand the pathophysiological mechanism of fluoroquinolone-induced tendon disorders, but also to compare the relative tendon toxicity of ten different fluoroquinolones.

C. DEFENDANTS INADEQUATELY AMEND THE LEVAQUIN LABEL CONCERNING TENDON-RELATED INJURIES

54. In December, 2001, an amended Levaquin label concerning tendon-related injuries was approved by the FDA. The amended label included the following statement: "Post-marketing surveillance reports indicate that this risk may be increased in patients receiving concomitant corticosteroids, especially in the elderly."

55. Through an international database managed by Daiichi, Defendants had access to the post market surveillance data all over the world, and specifically France, Belgium, Italy, and the United Kingdom.

56. By 2002, the adverse event data in all those countries consistently, and unequivocally, revealed that the risk of tendon injury was nearly triple for people over 60 as compared to people under 60. Defendants also had knowledge of at least one epidemiological study confirming that age and fluoroquinolone use further increased the risk of tendon toxicity. Additionally, all available data revealed that Levaquin was more tendon toxic than all other fluoroquinolones.

57. By adding the above referenced statement, Defendants muted their original - albeit inadequate - tendon warning. More specifically, rather than warn physicians and patients that the risk of tendon injury was increased (tripled) in the elderly, and that the risk of tendon injuries possibly increased in those elderly patients using corticosteroids, the amended label

indicates that an elderly person who was not on corticosteroids had no additional risk of a tendon injury. Therefore, the label was inadequate to warn about both the risk factors of age and co-medication with corticosteroids.

58. The amended language in the label concerning tendon-related injury continued to be buried at the bottom of a long list of adverse reactions; the language was in no way highlighted for the benefit of prescribing physicians and patients; and there was no indication that age and corticosteroid use tripled the risk of tendon injury while on Levaquin. Moreover, there was no indication on the label that Levaquin had a higher level of tendon toxicity compared with other flouroquinolones and non-flouroquinolones that were on the market. Additionally, no letter was disseminated to any healthcare practitioners concerning the amended Levaquin label.

D. DEFENDANTS THWART EFFORTS TO HIGHLIGHT LEVAQUIN'S INCREASED RISK OF TENDON INJURY

59. As early as September, 2001, the United Kingdom and other European countries convened before the European Agency for the Evaluation of Medicinal Products (EMEA) to discuss increasing the warning for levofloxacin.

60. The EMEA proposal was that levofloxacin would be singled out as the most toxic fluoroquinolone concerning tendon injury, with a warning that stated that levofloxacin (marketed under the brand name Tavanic) was associated with a greater frequency of tendinopathy and tendon rupture than other fluoroquinolones.

61. Aventis Pharmaceutical was the manufacturer and distributor of levofloxacin in Europe.

62. Under increasing pressure to agree to the proposed changes to the warning label, Aventis conducted two epidemiological studies in Europe regarding the relative tendon toxicity of levofloxacin. The first study used the United Kingdom's General Practitioners Research

Database of medical records from 1997 through 2001, and the second study used Germany's Mediplus database of medical records from 1998 to 2001.

63. Before releasing the results of the two epidemiology studies to the European regulatory authorities, and ostensibly because of the results of the studies, Aventis contracted with Defendants, specifically JOHNSON & JOHNSON PRD, to fund and co-author a study in the United States on tendon rupture and fluoroquinolones.

64. The epidemiology studies conducted by Aventis in Europe concluded that levofloxacin was associated with a higher rate of tendon injury as compared to fluoroquinolones. Ofloxacin, the fluoroquinolone indicted in early epidemiological studies as the most toxic fluoroquinolone concerning tendon injury, came in second.

65. An assessor at the MHRA concluded that the two epidemiological studies had findings "supporting a signal generated by spontaneous reporting with respect to an increased risk of tendinopathy with levofloxacin compared to other fluoroquinolones."

66. Moreover, the assessor remarked "the finding that ofloxacin (the racemate) is associated with an intermediate level of risk makes pharmacological sense, suggesting that the L- rather than the D-isomer of ofloxacin is likely to be responsible for tendon toxicity....given the consistency and plausibility of the findings, a real difference is the most likely explanation."

67. By the time Aventis released the results of their epidemiological studies, the preliminary results of the U.S. study was reportedly only six months away. Accordingly, the European regulatory authorities agreed to wait before requiring an increased warning in the label.

68. Unlike the healthcare databases in Europe, which contain computerized medical records, JOHNSON & JOHNSON PRD used data from the Ingenix Research database which consisted of U.S. health insurance claims data from 1997 to 2001. The study analyzed only

Achilles tendon ruptures and sought to examine whether fluoroquinolone exposure was a risk factor for this injury. It did not assess the relative risk of Levaquin tendon toxicity, as had been requested by the United Kingdom.

69. Under the guise of "data validation" Defendant JOHNSON & JOHNSON PRD created an algorithm that conveniently excluded nearly 70 percent of health claims for elderly persons who suffered Achilles tendon rupture.

70. The results of the U.S. epidemiological study – the study upon which regulatory action hinged in Europe, with ramifications to the U.S. market – revealed for the first time that there was no increased risk of Achilles tendon rupture associated with any fluoroquinolone use. Neither the confounders of age nor corticosteroid use altered these findings.

71. Indeed, when one includes the adverse safety data that was excluded by the manufactured algorithm, the result becomes consistent with the approximately eight other epidemiological studies performed on the topic. See Seeger et al. *Achilles Tendon Rupture and its Associations with Fluoroquinolone Antibiotics and Other Potential Risk Factors in a Managed Care Population*, Pharmacoepidemiology and Drug Safety 2006; 15: 784-792 ("There was a stronger association with flouroquinolone antibiotic exposure among these "ruled-out" cases of ATR ... than among the decision rule confirmed cases. This association was stronger with exposure close to the date of the rupture and was more pronounced among the elderly.")

72. As a result of Defendants' fraudulent and/or negligent misrepresentations concerning the U.S. Study, the Medicines and Healthcare products and Regulatory Agency ("MHRA") and the other European regulatory agencies chose not to revise the levofloxacin label as they had previously recommended.

73. Consistent with Defendants' purposeful conduct to downplay their knowledge concerning Levaquin's known risk of tendon injury, Defendants made no attempts to educate physicians in the United States about Levaquin's relationship with this serious and dangerous effect.

E. DEFENDANTS REPEATEDLY AMEND THE LEVAQUIN LABEL CONCERNING TENDON-RELATED INJURIES, DUE TO INADEQUACIES

74. By September 14, 2004, the Levaquin label was amended to include the words "*Tendon Effects:*" in front of the existing tendon related injury "warning."

75. However, the amended label addressing *"Tendon Effects:"* continued to be buried at the bottom of a long list of adverse reactions, and there was no indication that age and corticosteroid use tripled the risk of tendon injury. Additionally, despite Defendants knowledge, there continued to be no indication on the label that Levaquin had a higher level of tendon toxicity than other flouroquinolones and non-flouroquinolones that were on the market.

76. A further review of the events in the FDA Adverse Event database from 1997 through 2005 concerning Levaquin revealed 1,044 reports of tendon injuries, with 282 reports of tendon rupture. This six-year figure for tendon effects associated with Levaquin far surpassed the ten year history of tendon effects from 1985 through 1995 associated with all pre-Levaquin fluoroquinolones.

77. In 2006, 143 tendon-related injuries were reported to the FDA. In just the first quarter of 2007, 107 tendon-related injuries were reported, where Levaquin was the primary suspect.

78. Levaquin's propensity to cause tendon ruptures did not go unnoticed by the Illinois Attorney General. On May 18, 2005, the Illinois Attorney General submitted a petition

to the FDA requesting that a Black Box Warning be added to the label for flouroquinolones. The Illinois Attorney General suggested that the Black Box Warning was necessary in order to highlight the seriousness of tendon injuries and that the risk is increased in the elderly and in patients on corticosteroids.

79. The Illinois Attorney General also requested that the manufacturer issue a "Dear Doctor" letter to inform the health care providers about this significant hazard to health, as the tendon effects of fluoroquinolones were not well known to practicing physicians.

80. In the Petition, the Attorney General's office demonstrated that said office reviewed the literature and concluded that tendon injuries were not a rare complication of fluoroquinolone use. The Petition also complained that the existing language concerning "*Tendon Effects*" was "buried in lists of potential side effects which are both less frequent and less severe."

81. One year later, in 2006, Public Citizen joined the Illinois Attorney General's petition and urged the FDA to require a Black Box Warning on flouroquinolones concerning the risk of tendonitis and tendon rupture, based on the alarming increase in reports of tendon injuries in connection with flouroquinolones.

82. According to an August 29, 2006 *Associated Press* article, a spokeswoman for the Defendants indicated that the current label was adequate, stating "Levaquin's label already 'clearly states' tendon rupture can occur during or after treatment with the antibiotic."

83. The Public Citizen's Health Research Group countered Defendants' assertion by attacking the adequacy of the purported warning, stating that the "warning is buried in a long list of possible adverse reactions and is far too easy to miss."

84. In June, 2007, pursuant to the FDA's instruction, the Levaquin label was amended again concerning "*Tendon Effects.*" The amended label stated the following:

> Ruptures of the shoulder, hand, Achilles tendon or other tendons that required surgical repair or resulted in prolonged disability have been reported in patients receiving quinolones, including levofloxacin. Post-marketing surveillance reports indicate that this risk ***is*** increased in patients receiving concomitant corticosteroids, especially in the elderly... (*Emphasis added*).

85. The amended language concerning "*Tendon Effects*" continued to be buried at the bottom of a long list of adverse reactions, and there was no indication that age and corticosteroid use tripled the risk of tendon injury. Additionally, despite Defendants' knowledge, there continued to be no indication on the label that Levaquin had a higher level of tendon toxicity than other flouroquinolones and non-flouroquinolones that were on the market.

86. Thereafter, in September, 2007, the Levaquin label was amended again, and the purported warning concerning "Tendon Effects" was moved up several paragraphs from the bottom of the long list of adverse reactions.

87. In May, 2008, the Levaquin label was amended again to include a special tendon risk related language for populations over 65, who are at particular risk for tendon injury.

F. LEVAQUIN'S BLACK BOX WARNING

88. In July, 2008, the FDA instructed all flouroquinolone manufacturers, including Defendants, to add a Black Box Warning to the Levaquin label concerning tendon disorders.

89. The Black Box Warning states the following:

> **WARNING: Fluoroquinolones, including LEVAQUIN®, are associated with an increased risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients usually over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants [See *Warnings and Precautions (5.1)*].**

90. Defendants did not add the Black Box Warning to the Levaquin label until several months after the FDA's instruction.

91. Defendants did not issue a "Dear Doctor" letter concerning the Black Box Warning to physicians until November, 2008 – five months after the FDA mandated the Black Box Warning change.

92. As of today, the Black Box Warning on the Levaquin label fails to adequately warn Plaintiffs and Plaintiffs' prescribing physicians that Levaquin is more toxic to tendons than any other fluoroquinolone and non-flouroquinolone antibiotic available on the U.S. market.

93. Defendants failure to adequately warn physicians resulted in (1) patients receiving Levaquin instead of another acceptable and adequate fluoroquinolone or non-fluoroquinolone antibiotic, sufficient to treat the illness for which plaintiff presented to the provider; (2) physicians failing to warn and instruct consumers about the risk of tendon injuries associated with Levaquin; and (3) physicians prescribing and continuing to prescribe steroid drugs in association with the prescription of Levaquin.

94. The failure of Defendants to include appropriate warnings in the label as published to the medical community 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.

95. 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 and sinusitis infections, and for which many other safer antibiotics are available.

COUNT I
PRODUCT LIABILITY - FAILURE TO WARN (N.J.S.A. 2A:58C-1 *et seq.*)

96. Plaintiff(s) repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

97. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical drug Levaquin.

98. Defendant directly advertised and/or marketed the Levaquin to prescribing physicians and consumers.

99. Defendants had a duty to warn physicians and consumers of the serious and dangerous risks associated with the use of Levaquin, in particular the significant risk to consumers concerning tendonitis, tendon rupture and other tendon related injuries.

100. Levaquin was under the exclusive control of Defendants as aforesaid, and was unaccompanied by appropriate warnings regarding all possible adverse side effects and complications associated with the use of Levaquin, dangerous drug-drug interactions and food-drug interactions, and the comparative severity, duration and the extent of the risk of injury with such use.

101. Defendants failed to timely and reasonably warn physicians and consumers about material facts regarding the safety and efficacy of Levaquin.

102. But for Defendants failure to warn about the known material facts regarding safety and efficacy, Plaintiff would not have used Levaquin.

103. Levaquin was defective due to inadequate post-marketing warnings and/or instructions because, after Defendants knew or should have known of the risk of serious side effects and complications from the use of Levaquin, Defendants failed to provide adequate

warnings to the health care physicians, the FDA and the consuming public, including Plaintiff, and continued to promote Levaquin aggressively.

104. Plaintiff was prescribed and used Levaquin for its intended purpose.

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

106. Plaintiff could not have known that Defendants had designed, developed, and manufactured Levaquin in such a way as to increase the risk of harm or injury to the recipients of Levaquin.

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

108. Plaintiff, individually, and through his/her prescribing physician(s), reasonably relied upon the skill, superior knowledge and judgment of Defendants.

109. Defendants had a continuing duty to warn the Plaintiff and his/her physician(s) of the dangers associated with the subject product.

110. The warnings that were provide by Defendants were not adequate or/or clear, and were ambiguous.

111. Had Plaintiff received adequate warnings regarding the risks of Levaquin, he/she would not have used the drug.

112. Defendants failure to adequately warn physicians resulted in (1) patients receiving Levaquin instead of another acceptable and adequate fluoroquinolone or non-fluoroquinolone antibiotic, sufficient to treat the illness for which plaintiff presented to the provider; (2) physicians failing to warn and instruct consumers about the risk of tendon injuries associated

with Levaquin; and (3) physicians prescribing and continuing to prescribe steroid drugs in association with the prescription of Levaquin.

113. The failure of Defendants to include appropriate warnings in the label as published to the medical community 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.

114. As a direct and proximate result of the conduct of Defendants' as aforesaid, Plaintiff(s) have suffered and will continue to suffer serious and permanent physician and emotional injuries, have expended and will continue to expend large sums of money for medical care and treatment, have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff(s) demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II
PRODUCT LIABILITY – DEFECTIVE DESIGN (N.J.S.A. 2A:58C-1 *et seq.*)

115. Plaintiff(s) repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

116. Defendants are the researchers, developers, manufacturers, distributors, marketers, promoters, suppliers and sellers of Levaquin, which is defective and unreasonably dangerous to consumers.

117. Levaquin is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended and indicated purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. Levaquin is defective in design or formation

because it lacks efficacy and/or poses a greater likelihood of injury than other antibiotic medicines and similar drugs on the market, and is more dangerous than ordinary consumers can reasonably foresee.

118. The defective condition of Levaquin renders it unreasonably dangerous, and Levaquin was in this defective condition at the time it left the hands of the Defendant. Levaquin was expected to and did reach consumers, including Plaintiff(s), without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

119. Plaintiff(s) were unaware of the significant hazards and defects in Levaquin. Levaquin was unreasonably dangerous in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Plaintiff(s) were taking Levaquin, the medication was being utilized in the manner that was intended by Defendants. At the time Plaintiff(s) received and consumed Levaquin, it was represented to be safe and free from latent defects, for use as indicated on the label.

120. Defendants are strictly liable to Plaintiff(s) for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendants because of the design defects.

121. Defendants knew or should have known of the danger associated with the use of Levaquin, as well as the defective nature of Levaquin, but have continued to design, manufacture, sell, distribute, market, promote and/or supply Levaquin so as to maximize sales and profits at the expense of the public health safety, in conscious disregard of the foreseeable harm caused by Levaquin.

122. As a direct and proximate result of the design defect and Defendants' misconduct set forth herein, Plaintiff(s) have suffered and will continue to suffer serious and permanent physical and emotional injuries, have expended and will continue to expend large sums of money for medical care and treatment, have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff(s) demand(s) judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III
PRODUCT LIABILITY – MANUFACTURING DEFECT (N.J.S.A. 2A:58C-1 *et seq.*)

123. Plaintiff(s) repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

124. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

125. At all times material to this action, Levaquin was expected to reach, and did reach, consumers in the State of New Jersey and throughout the United States, including Plaintiff, herein without substantial change in the condition in which it was sold.

126. At all times material to this action, Levaquin was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Levaquin contained manufacturing defects which rendered the product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of Defendants;

c. The subject product was not made in accordance with Defendants' specifications or performance standards;

d. The subject product's manufacturing defects existed before it left the control of Defendants;

127. As a direct and proximate result of the design defect and Defendants' misconduct set forth herein, Plaintiff(s) have suffered and will continue to suffer serious and permanent physical and emotional injuries, have expended and will continue to expend large sums of money for medical care and treatment, have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff(s) demand(s) judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV
BREACH OF EXPRESS WARRANTY

128. Plaintiff(s) repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

129. Defendants through their marketing program, promotional activities, product labeling, package inserts, and other written and verbal assurances expressly warranted to physicians and consumers, including Plaintiff and/or his physician(s), that Levaquin had been shown by scientific study to be safe for its intended use.

130. Plaintiff and/or his physicians reasonably relied upon Defendants' express warranties in respectively purchasing, consuming, and prescribing Levaquin.

131. Defendants breached their express warranties because Levaquin as manufactured and sold by Defendants does not conform to these express representations in that Levaquin has a propensity to cause tendon ruptures, other serious tendon injuries, and bodily harm.

132. By the conduct alleged, Defendants, its agents and employees expressly warranted to Plaintiff and Plaintiff's physicians that the products were merchantable and fit for the purpose intended.

133. As a direct result of Defendants' conduct as aforesaid, Plaintiff has suffered and will continue to suffer serious and permanent physician and emotional injuries, have expended and will continue to expend large sums of money for medical care and treatment, have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff(s) demand(s) judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V
NEGLIGENT MISREPRESENTATION

134. Plaintiff(s) repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

135. Defendants had and continue to have a duty to represent to the medical and healthcare community, to Plaintiff, and to the public in general, that said product Levaquin had been tested and found to be safe and effective for use in treating infections caused by bacteria.

136. Defendants had and continue to have a duty to the medical and healthcare community, to the Plaintiff, and to the public in general to market, manufacture, distribute, and/or sell its drug Levaquin with appropriate and/or adequate information and/or warnings.

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

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

139. Defendants breached their duty to represent the serious side effects of Levaquin to the medical and healthcare community, to Plaintiff herein, and to the public in general.

140. As a result of the negligent misrepresentations of Defendants set forth hereinabove, said Defendants knew and were aware or should have known and been aware that the drug had been insufficiently tested, that it had not been tested, that it lacked adequate warnings, and/or that it created a high risk of unreasonable, dangerous side effects, including but not limited to developing tendonitis and tendon ruptures, and other serious injuries and side of Levaquin specifically.

141. As a direct and proximate result of the conduct of Defendants' as aforesaid, Plaintiff has suffered and will continue to suffer serious and permanent physician and emotional injuries, have expended and will continue to expend large sums of money for medical care and treatment, have suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

WHEREFORE, Plaintiff(s) demand(s) judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
NEW JERSEY CONSUMER FRAUD ACT (N.J.S.A. 56:8-1 *et seq.*)

142. Plaintiff(s) repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

143. In the alternative of all causes of action litigated herein under the Product Liability Act, Plaintiff asserts a claim against Defendants for damages under the New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1 *et seq.*).

144. Prescription drugs such as Levaquin are "merchandise" as that term is defined by N.J.S.A. 56:8-1(c).

145. Defendants are the researchers, developers, designers, testers, manufacturers, inspectors, labelers, distributors, marketers, promoters, sellers and/or otherwise released Levaquin into the stream of commerce.

146. Defendants knew, or should have known, that the use of Levaquin causes serious side effects and complications but failed to warn the public, including Plaintiff, of same.

147. In violation of the Act, Defendants made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiff in product packaging, labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, among other ways, regarding the safety and use of Levaquin. Moreover, Defendants downplayed and/or understated the serious nature of the risks associated with Levaquin in order to increase the sales of Levaquin and secure a greater share of the antibiotic market.

148. Defendants' statements and omissions were undertaken with the intent that the FDA, physicians and consumers, including Plaintiff, would rely on the Defendants' statements and/or omissions.

149. Defendants knew of the growing public acceptance of the misinformation and misrepresentations regarding the safety and efficacy of Levaquin but remained silent because Defendants' appetite for significant future profits far outweighed its concern for the health and safety of the Plaintiff(s).

150. Plaintiff(s)' physician prescribed and/or otherwise provided Plaintiff(s) with Levaquin, and Plaintiff(s) consumed Levaquin, primarily for personal and family reasons and suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts, or practices alleged herein.

151. The aforesaid promotion and release of Levaquin into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentations, and/or the knowing concealment, suppression, or omission of material facts with the intent that others would rely upon such concealment, suppression or omission in connection with the sale or advertisement of such merchandise or services by Defendants, in violation of New Jersey Consumer Fraud Act., N.J.S.A. 56:8-1 *et seq.*

152. Defendants concealed, omitted, or minimized the side effects of Levaquin or provided misinformation about adverse reactions, risks and potential harms from Levaquin and succeeded in persuading consumers to purchase and ingest Levaquin despite the lack of safety and the risk of adverse medical reactions, including tendon ruptures.

153. Defendants' practice of promoting and marketing Levaquin created and reinforced a false impression as to the safety of Levaquin, thereby placing consumers at risk of serious side effects and complications.

154. Levaquin lacked appropriate warnings, and the packaging and labels used by Defendants were misleading, inaccurate, incomplete, and/or untimely.

155. Defendants violated its post-manufacture duty to warn which arose when Levaquin knew, or with reasonable care should have known, that Levaquin was injurious.

156. At the time when consumers purchased and ingested Levaquin, Defendants intended that others would rely upon the concealment, suppression or omission of the risks of ingesting Levaquin.

157. Defendants' actions in connection with manufacturing, distributing, and marketing of Levaquin as set forth herein evidence a lack of good faith, honesty in fact, and observance of fair dealing, so as to constitute unconscionable commercial practices, in violation of the New Jersey Consumer Fraud Act., N.J.S.A. 56:8-1 *et seq.*

158. Defendants acted willfully, knowingly, intentionally, unconscionably and with reckless indifference when committing these acts of consumer fraud.

159. The subject product placed and continues to place all consumers of Levaquin at risk for serious injury and potentially lethal side effects.

160. As a direct and proximate result of the acts of consumer fraud set forth above, Plaintiff(s) have purchased an unsafe product and incurred monetary expense and the risk to themselves and members of their household that they would consume Levaquin and thereby suffer an increased risk of harm as previously set forth herein.

WHEREFORE, Plaintiff(s) demand(s) judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
PUNITIVE DAMAGES UNDER COMMON LAW AND PRODUCTS LIABILITY ACT (N.J.S.A. 2A:58C-1 *et seq.*)

161. Plaintiff(s) repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

162. Plaintiff is entitled to punitive damages because Defendants misrepresented and/or withheld information and materials from the FDA, the medical community and the public at large, including the Plaintiff, concerning the safety profile, and, more specifically the serious side effects and/or complications associated with Levaquin.

163. In respect to the FDA, physicians and consumers, Defendants downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of Levaquin, despite available information that Levaquin was likely to cause serious side effects and/or complications.

164. Defendants' failure to provide the necessary materials and information to the FDA, as well as their failure warn physicians' and consumers of the serious side effects and and/or complications, was reckless and without regard for the public's safety and welfare.

165. Defendants were or should have been in possession of evidence demonstrating that Levaquin causes serious side effects. Nevertheless, Defendants continued to market Levaquin by providing false and misleading information with regard to safety and efficacy.

166. Defendants failed to provide the FDA, physicians and consumers with available materials, information and warnings that would have ultimately dissuaded physicians from

prescribing Levaquin consumers from purchasing and consuming Levaquin, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Levaquin.

WHEREFORE, Plaintiff(s) demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VIII
LOSS OF CONSORTIUM/PER QUOD CLAIM

167. Plaintiff(s) repeat and incorporate by reference all other paragraphs of this Master Complaint as if fully set forth herein.

168. By reason of the foregoing, Plaintiff's (mother, father, child) has (have) necessarily paid and has (have) become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expenses of a similar nature in the future.

169. By reason of the foregoing, Plaintiff's (mother, father, child) has (have) been caused presently and in the future the loss of his/her (wife, husband, child)'s companionship, services, and society.

WHEREFORE, Plaintiff(s) demand(s) judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

RELIEF REQUESTED

WHEREFORE, Plaintiff(s) demand judgment against Defendants as follows:

a. Awarding Plaintiff(s) compensatory damages against Defendants in an amount sufficient to fairly and completely compensate Plaintiff(s) for all damages;

b. Awarding Plaintiff(s) treble damages against Defendants so to fairly and completely compensate Plaintiff(s) for all damages, and to deter similar wrongful conduct in the future;

c. Awarding Plaintiff(s) punitive damages against Defendants in an amount sufficient to punish Defendants for its wrongful conduct and to deter similar wrongful conduct.

d. Awarding Plaintiff(s) costs and disbursements, costs of investigations, attorneys' fees and all such other relive available under New Jersey law;

e. Awarding that the costs of this action be taxed to Defendants; and

f. Awarding such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Demand is hereby made for trial by jury.

Dated: August 6, 2009

Richard D. Meadow/RLN

Richard D. Meadow
THE LANIER LAW FIRM, PLLC
126 East 56th St, 6th Fl.
New York, New York 10022
Telephone (212) 421-2800

-and-

Michael A. London
Rebecca G. Newman
DOUGLAS AND LONDON, P.C.
111 John Street, Suite 1400
New York, New York 10038
Telephone: (212) 566-7500

CERTIFICATION PURSUANT TO R. 4:5-1

Plaintiff upon information and belief is not aware of any pending or contemplated action. Further, upon information and belief, she/he is not aware of any other party who should be joined in this action.

DESIGNATION OF TRIAL COUNSEL

Pursuant to R. 4:25-4, _____, is hereby designated as trial counsel in this matter.

CERTIFICATION OF NOTICE

Pursuant to N.J.S.A. 56:8-20, Plaintiffs are mailing a copy of this Complaint and Jury Demand to the Office of the Attorney General, CN-006, Trenton, New Jersey, within ten (10) days of the filing of this Complaint and Jury Demand.

* The above Certification Pursuant to R. 4:5-1, the Designation of Trial Counsel Pursuant to R. 4-25-4, and the Certification of Notice Pursuant to N.J.S.A. 56:8-20 will each be executed on the individually filed Short Form Complaints.