UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BENN PRYBUTOK, Plaintiff, v. JOHNSON & JOHNSON; JANSSEN RESEARCH & DEVELOPMENT, LLC; and JANSSEN PHARMACEUTICALS, INC; Defendants.	CASE No: _____ **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL** **1. Strict Liability** **2. Product Liability-Failure to Warn** **3. Negligence** **4. Breach of Express Warranty** **5. Breach of Implied Warranty** **6. Fraudulent Misrepresentation** **7. Negligent Misrepresentation** **8. Fraudulent Concealment** **9. Violation of New York Consumer Protection Laws**

COMPLAINT

Plaintiff, by and through counsel, files this Complaint against Defendants Johnson & Johnson, Janssen Research & Development, LLC, and Janssen Pharmaceuticals, Inc., as follows:

INTRODUCTION

1. This case involves the prescription drug Levaquin® (levofloxacin).

2. Defendants Johnson & Johnson, Janssen Research & Development, LLC, and Janssen Pharmaceuticals, Inc., are collectively referred to herein as the "J&J Defendants" or "Defendants."

3. Levaquin is designed, developed, manufactured, tested, packaged, promoted, marketed, advertised, distributed, labeled, and/or sold by the J&J Defendants.

4. Plaintiff maintain that Levaquin is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce to treat infections for which they were not required, and lacked proper warnings and directions as to the dangers associated with their all of their uses.

5. Plaintiff is a resident and citizen of Rydal, Pennsylvania and brings claims for personal and economic injuries sustained by the use of the Levaquin. By reason of the foregoing acts and omissions and as a direct and proximate result of being prescribed and ingesting Levaquin, Plaintiff sustained personal injuries, including an aortic dissection which is lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, physical impairment, expenses for hospitalization and medical treatment, and loss of earnings, among other damages.

6. Defendant Johnson & Johnson ("J&J") is a fictitious name adopted by Johnson & Johnson, a New Jersey corporation that has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

7. J&J, and its "Family of Companies," is involved in the research, development, sales, and marketing of pharmaceutical products, including Levaquin.

8. Upon information and belief, at all relevant times, Defendant J&J was present and doing business in the State of New York, New Jersey, and Pennsylvania.

9. Defendant Janssen Research & Development, LLC ("Janssen R&D" and formerly known as Johnson & Johnson Pharmaceutical Research & Development, LLC) is a New Jersey limited liability corporation with its principal place of business at 920 Route 202 South, P.O.

Box 300, Mail Stop 2628, Raritan, New Jersey 08869. Janssen R&D's sole member is Centocor Research & Development, Inc., a Pennsylvania corporation with its principle place of business at 200 Great Valley Parkway, Malvern, Pennsylvania. A limited liability company is a citizen of any state of which a member of the company is a citizen. *Rolling Greens, MHP, L.P. v. Comcast Sch Holdings, L.L.C.*, 374 F.3d 1020, 1022 (11th Cir. 2004). As Janssen R&D is a Pennsylvania corporation, Janssen R&D is a citizen of Pennsylvania for purposes of determining diversity jurisdiction.

10. At all times material hereto, Janssen R&D conducted research, development, and testing on Levaquin.

11. Janssen R&D is part of the J&J "Family of Companies."

12. Upon information and belief, at all relevant times, Defendant Janssen R&D was present and doing business in the State of New York, New Jersey, and Pennsylvania.

13. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharma" and formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc.) is a Pennsylvania corporation that has its principal place of business at 1000 Route 202 South, P.O. Box 300, Raritan, New Jersey 08869.

14. At all times material hereto, Janssen Pharma was the responsible U.S. entity for the design, manufacture, labeling, distribution, marketing, and sale of the drug Levaquin in the United States.

15. Defendant Janssen Pharma is a wholly owned subsidiary of J&J.

16. Upon information and belief, at all relevant times, Defendant Janssen Pharma was present and doing business in the State of New York, New Jersey, and Pennsylvania.

17. The J&J Defendants are authorized to do business in this district and derive income from doing business in this district.

18. Upon information and belief, the J&J Defendants purposefully availed themselves of the privilege of conducting activities within the this district, thus invoking the benefits and protections of its laws.

19. Upon information and belief, the J&J 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

20. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because Defendants are all either incorporated and/or have their principal place outside of the state in which the Plaintiff resides.

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

22. 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 this District.

ACTUAL ALLEGATIONS

23. At all relevant times, the J&J 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 Levaquin.

24. Plaintiff was prescribed and/or otherwise lawfully obtained Levaquin in May 2007. Thereafter, Plaintiff suffered aortic dissection which required surgical repair.

25. Fluoroquinolones (“FLQs”) are broad-spectrum synthetic antibacterial agents marketed and sold in oral tablet, IV solution, and ophthalmic solution, used to treat lung, sinus,

skin, and urinary tract infections caused by certain germs called bacteria. They are members of the quinolone class of antibiotics.

26. Quinolones are divided into four generations based on their spectrum of antimicrobial activity. The 1st generation, non-fluorinated quinolone antibiotics were developed in the early 1960s and soon revealed themselves as effective against common gram-negative bacteria, but resistance developed rapidly.

27. Twenty years later, in the early 1980s, fluorinated derivatives of the quinolones emerged, revealing a broader, more potent antibiotic, effective against common gram-negative and gram-positive bacteria. These so-called 2nd generation quinolones included Noroxin® (norfloxacin), Cipro, Floxin® (ofloxacin), and pefloxacin (never approved for marketing in the United States).

28. Fluoroquinolones have long been associated with serious side effects. Indeed, many fluoroquinolones have been removed from the United States market due to unacceptable risks of certain adverse events. For example, Omniflox® (temafloxacin) was removed from the market in June 1992 only six months after approval due to low blood sugar, kidney failure, and a rare form of anemia; Trovan® (trovafloxacin) was removed from the market in June 1999 due to severe liver toxicity; Raxar® (grepafloxacin) was removed from the market in October 1999 due to QT-interval prolongation; Zagam® (sparfloxacin) was removed from the market in July 2001 due to QT-interval prolongation; and most recently, Tequin® (gatifloxacin) was removed from the market in May 2006 amid reports of severe blood sugar reactions such as hyperglycemia and hypoglycemia.

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

30. In 2003, after generic versions of Cipro went on the market, one of the J&J Defendants "key strategies" was to "displace ciprofloxacin" as the leading fluoroquinolone on the market. Levaquin subsequently became the number one prescribed fluoroquinolone in the United States. Indeed, by the end of 2004 Levaquin had "surpassed $1 billion in net trade sales."

31. 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.

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

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

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

35. Defendant Janssen Pharma 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."

36. However, the scientific evidence has established a clear association between Levaquin and an increased risk of long-term and sometimes irreversible peripheral neuropathy, no matter whether the FLQs are stopped once symptoms develop.

37. Prior to applying to the FDA for and obtaining approval of their FLQs, Defendants knew or should have known that consumption of FLQs were associated with and/or would cause serious collagen disorders like aortic aneurysms and dissections.

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

39. FDA regulations require that manufacturers monitor and report adverse events ("AEs") associated with their marketed products. 21 C.F.R. § 314.80; 21 C.F.R. § 314.81. Manufacturers are required to review all adverse experience information pertaining to their products obtained from any source, foreign or domestic, including from commercial marketing experience, postmarketing clinical investigations, post-marketing epidemiological/surveillance studies, reports in the scientific literature and unpublished scientific papers. Manufacturers review this information for safety "signals."

40. The FDA has recognized that case reports and case series can play important roles in serving as "safety signals." In fact, the FDA states that a single, well-documented case report can be viewed as a safety signal, particularly if the report describes a positive rechallenge.[1]

41. Indeed, even a single case report may be sufficient to establish a causal relationship between the use of a product and an adverse event.[2]

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[1] *See* U.S. Department of Health and Human Services, Food and Drug Administration, Guidance for Industry: Good Pharmacovigilence Practices and Pharmacoepidemiologic Assessment (2005).

42. In the pharmaceutical industry, including within Defendants' companies, safety signals generally indicate the need for further investigation.[3]

43. After a signal is identified, the J&J Defendants are obligated to father assess the signal to determine whether it represents a potential safety risk that should be included in product labeling.

44. The J&J Defendants claim to "continually collect and monitor information on the safety and effectiveness of all our medicines, and, in cooperation with the U.S. FDA and other health authorities, we incorporate new data into our product labels so doctors and patients can make informed decisions."[4]

45. 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 patients presented to the provider; and (2) physicians failing to warn and instruct consumers about the risk of aortic aneurysm or dissection injuries associated with Levaquin.

46. The failure of Defendants to include appropriate warnings in their products' labels 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.

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[2] *See* Principles & Practice of Public Health Surveillance, at p. 343. Steven M. Teutsch & R. Elliott Churchill, eds. Third Edition, Oxford University Press, 2010.

[3] *See* Guidance for Industry: Good Pharmacovigilence Practices and Pharmacoepidemiologic Assessment (2005)

[4] https://www.washingtonpost.com/nationaVhealth-science/it-pays-to-read-the-warnings-when-you-open-up-a-prescription/2015/08/03/a29e11b4-d70e-11e4-b3f2-607bd612aeac_story.html.

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

48. On November 5, 2015, the FDA held a joint meeting of the Antimicrobial Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to discuss the safety and efficacy of systemic fluoroquinolones in the context of three indications: acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis in those with chronic obstructive pulmonary disease (ABECB-COPD), and uncomplicated urinary tract infections (uUTI). The FDA asked committee members to determine whether the benefits of FLQ therapy in these three indications justifies the associated risks of FLQ use.

49. While fluoroquinolones are currently approved for these three indications, FDA reviewers, along with over 30 open public hearing speakers, voiced the need for stronger labels on these indications due to the modest or absent treatment benefits of the drugs for the three indications, and the serious adverse events associated with their use. These serious adverse events include tendonitis, tendon rupture, central nervous system effects, peripheral neuropathy, myasthenia gravis exacerbation, phototoxicity, hypersensitivity and certain cardiovascular effects (i.e., QT prolongation).

50. In advance of the advisory committee meeting, FDA reviewers released briefing documents that indicated the potential side effects of fluoroquinolone use, including permanent peripheral neuropathy, may outweigh the benefits provided by the medications, as patients often receive the drugs for infections that resolve themselves or can be treated with medications that do not carry the same risks. For instance, an evaluation of placebo-controlled trials in ABS or

mild ABECB-COPD showed that a large proportion of patients randomized to receive placebo recovered and thus the illnesses appeared to be self-limited for many. Moreover, some trials failed to show any differences in outcome measures when comparing the antibacterial drug to placebo.

51. A lengthy review of serious and sometimes permanent adverse events, including permanent peripheral neuropathy, associated with FLQ use followed the discussion of questionable efficacy for the three indications in question. The FDA cited specifically adverse event reporting from patients highlighting a "constellation of symptoms" referred to as "Fluoroquinolone-Associated Disability" (FQAD). Individuals with FQAD were defined by the FDA as patients who were prescribed an oral fluoroquinolone to treat urinary tract infections, bronchitis or sinusitis, and who experienced disabling adverse events, lasting 30 days or longer, in two of the following body systems: neuromuscular, neuropsychiatric, peripheral neuropathy, senses, skin, cardiovascular.

52. After hearing testimony from industry representatives, as well as dozens of individuals who described a wide range of harmful effects on their health and cognitive ability from fluoroquinolone use, the panel voted overwhelmingly that the benefits and risks for systemic fluoroquinolone drugs do not support the current labeled indications for the treatment of ABS (unanimous), ABECB-COPD (18-2, with one abstention), or uncomplicated urinary tract infection (20-1).

53. On May 12, 2016, the FDA issued a safety announcement advising that "the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options." The FDA instructed that patients with these conditions should not

be treated with a fluoroquinolone if alternative treatment options are available. The May 12th announcement also cautioned that a safety review demonstrated that FLQs "are associated with disabling and potentially permanent serious side effects that can occur together." The side effects can involve the tendons, muscles, joints, nerves, and central nervous system.

54. Upon information and belief, on or around May 12, 2016, the FDA issued a safety labeling change notification to the Bayer and J&J Defendants. Among other things, the notification directed Defendants to update their FLQ labels to provide new safety information regarding "serious adverse reactions [that] can occur together and can be disabling and potentially irreversible." The FDA also required a revision to the boxed warning for FLQs to include new warnings regarding peripheral neuropathy and central nervous systems effects.

55. In addition, two epidemiologic studies were published in October and November 2015 linking the use of fluoroquinolones to aortic aneurysms and dissections, each of which are major, life-threatening disorders.

56. The first of these was a study published in the Journal of American Medical Association in October 2015 by *Lee et al.*. The authors' stated objective was to "examine the relationship between fluoroquinolone therapy and the risk of developing aortic aneurysm and dissection."[5] In doing so, the authors noted that "fluoroquinolones have been associated with collagen degradation raising safety concerns related to more serious collagen disorders with the use of these [FLQ] antibiotics." The authors conducted a nested case-control study of 1,477 case patients and 147,000 matched control cases from Taiwan's National Health Insurance Research Database from among 1 million individuals observed from January 2000 through December 2011. After propensity score adjustment, *Lee et al.* confirmed that the current use (defined as

[5] Lee CC, Lee MT, Chen YS et al. Risk of Aortic Dissection and Aortic Aneurysm in Patients Taking Oral Fluoroquinolone. JAMA Intern Med. 2015 Nov 1;175(11):1839-47.

patients having a fluoroquinolone prescription filled within 60 days of the index date) of fluoroquinolones was found to be associated with increased risk for aortic aneurysm or dissection with a statistically significant relative risk of 2.43 (95% CI, 1.83-3.22), representing a 143% increased risk. The authors also found a statistically significant increased risk for past users (defined as those who filled a fluoroquinolone prescription between 61 and 365 days prior to the aortic aneurysm) of fluoroquinolones of 1.48 (95% CI, 1.18-1.86), representing a 48% increased risk.

57. In a study published in November 2015, *Daneman et al.* followed 657,950 patients prospectively in a cohort epidemiological study in order to, among other things, "... test for a potentially lethal association between fluoroquinolones and aortic aneurysms."[6] The 657,950 patients received at least one fluoroquinolone during follow-up, amounting to 22,380,515 days of treatment. The authors found that 18,391 developed aortic aneurysms for a statistically significant adjusted hazard ratio of 2.24 (95% CI, 2.02 – 2.49) or 124% increased risk.

58. In 2008, the FDA requested that a black boxed warning be placed on all fluoroquinolone drugs to warn of the increased risk of tendinitis and Achilles tendon rupture. It is widely accepted in the medical literature that one of the suspected mechanisms of action by which fluoroquinolones induce tendinitis is through collagen degradation.[7] As noted, *Lee et al.* similarly recognizes that fluoroquinolones have been associated with collagen degradation. Type I and type III collagen comprise the majority of collagen in the Achilles tendon, and also

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[6] Daneman N, Lu H, Redelmeier DA. Fluoroquinolones and collagen associated severe adverse events: a longitudinal cohort study. BMJ Open. 2015 Nov 18;5(11):e010077.

[7] *See, e.g.*, Childs, S. G. (2007). Pathogenesis of tendon rupture secondary to fluoroquinolone therapy. Orthop.Nurs., 26, 175-182.

comprise the majority (80% to 90%) of collagen in the aorta. Thus, Defendants knew or should have known that the risk for developing tendinitis-a black boxed risk-may cause or aggravate aortic aneurysm or dissection by a similar mechanism. In fact, the relationship between the duration of fluoroquinolone therapy and risk of aortic aneurysm and dissection in comparison with fluoroquinolone-associated tendon rupture was specifically addressed by Lee *et al.* The authors concluded that "our results demonstrating a higher rate of aortic aneurysm and dissection within 60 days of fluoroquinolone therapy are in concordance with these [fluoroquinolone-associated tendon rupture] findings."

59. The Defendants' failure to investigate or study the potential association between Levaquin and aortic rupture and dissection was not due to lack of awareness. Defendants have for years had in their possession adverse event reports denoting patients who had received levofloxacin and suffered aortic aneurysm ruptures, aortic dissections and/or aortic ruptures following therapy. Despite their internal knowledge surrounding the collagen issue with their FLQ drug, Defendants failed to investigate or initiate any studies or testing regarding aortic aneurysm or dissection in association with FLQ use, much less update their Levaquin label to apprise the medical community or patients of this important safety risk.

TOLLING OF THE STATUTE OF LIMITATIONS

60. Defendants, at all relevant times, knew or should have known of the problems and defects with Levaquin, and the falsity and misleading nature of Defendants' statements, representations and warranties with respect to Levaquin. Defendants concealed and failed to notify Plaintiff and the public of such defects.

61. Any applicable statute of limitation has therefore been tolled by Defendants' knowledge, active concealment and denial of the facts alleged herein, which behavior is ongoing.

COUNT I

[Strict Liability]

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

63. The Levaquin manufactured, marketed, supplied and/or distributed by Defendants was defective at the time of manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying such labels failed to warn of the dangerous risks they posed, including the risk of developing aortic aneurysms and dissections.

64. At all times alleged herein, the Levaquin manufactured, marketed, supplied, and/or distributed by Defendants was defective, and Defendants knew that Levaquin was to be used by consumers without inspection for defects. Moreover, Plaintiff, Plaintiff's prescribing physicians, and Plaintiff's healthcare providers 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.

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

66. The design of Levaquin was defective in that the risks associated with using the drugs as a first-line therapy for infections that did not dictate the use of Levaquin outweighed any benefits of their design. Any benefits associated with the use of Levaquin in such situations were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results but without the increased risk of developing aortic aneurysms and dissections.

67. The defect in design existed when the products left Defendants' possession.

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

69. As a result of the defective condition of Levaquin, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT II

[Product Liability - Failure to Warn]

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

71. 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 such drugs into the stream of commerce with full knowledge that their products reach consumers such as Plaintiff who ingested them.

72. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Levaquin to Plaintiff and to Plaintiff's prescribing physicians. Additionally, Defendants expected the drugs they were selling, distributing, supplying, manufacturing, and/or promoting to reach - and they did in fact reach - prescribing physicians and consumers, including Plaintiff and Plaintiff's prescribing physicians, without any substantial change in the condition from when they were initially distributed by Defendants.

73. At all times herein mentioned, Levaquin was defective and unsafe in manufacture such that they were unreasonably dangerous to the user, and were so at the time they were distributed by Defendants and ingested by Plaintiff. The defective condition of such drugs was due in part to the fact that they were not accompanied by proper warnings regarding the possible

side effect of developing long-term and potentially irreversible aortic aneurysms and dissections as a result of their use.

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

75. 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.

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

77. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Levaquin, namely aortic aneurysms and dissections.

78. 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 aortic aneurysms and dissections from its use, even though this side effect was known or reasonably scientifically knowable at the time of their marketing and 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.

79. Plaintiff could not have discovered any defect in Levaquin through the exercise of reasonable care.

80. Defendants, as the manufacturers and/or distributors of Levaquin, are held to the level of knowledge of experts in the field.

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

82. Had Defendants properly disclosed the risks associated with Levaquin, Plaintiff would have avoided the risk of aortic aneurysms and dissections by not using the drug.

83. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT III

[Negligence]

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

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

86. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled Levaquin.

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

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

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

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

d) In promoting Levaquin in an overly aggressive, deceitful, and fraudulent manner, including as a first-line therapy to treat infections for which they were not required despite evidence as to the drug's defective and dangerous characteristics due to its propensity to cause aortic aneurysms and dissections;

e) In representing that Levaquin was safe for its intended use when, in fact, the products were unsafe for their intended use;

f) In failing to perform appropriate pre-market testing of Levaquin;

g) In failing to perform appropriate post-market surveillance of Levaquin;

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 it had the serious side effect of causing aortic aneurysms and dissections;

j) In failing to adequately warn Plaintiff and Plaintiff's healthcare providers that the use of Levaquin drugs carried a risk of developing aortic

aneurysms and dissections. And the J&J Defendants were also specifically aware that the risk information contained in their FLQ medication guide was not effective in conveying the risks to patients regarding Levaquin. In an internal analysis conducted by the J&J Defendants in 2010, it was noted that "there is a continuing problem that at least half of the patients read only some or none of the [medication] guide." Moreover, of those patients who did read it, there were "low scores" on adequately conveying "information regarding risks."

k) In failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risk of aortic aneurysms and dissections associated with the use of Levaquin; and

l) In failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely aortic aneurysms and dissections from Levaquin ingestion as described herein.

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

89. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to an aortic dissection. Plaintiff has endured pain and suffering, physical impairment, suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully request that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT IV

[Breach of Express Warranty]

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

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

92. Levaquin did not conform to these express representations because Levaquin was not safe and had an increased risk of serious side effects, including aortic aneurysms and dissections, whether taken individually or in conjunction with other therapies.

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

WHEREFORE, Plaintiff respectfully request that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT V

[Breach of Implied Warranty]

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

95. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold Levaquin, and before Levaquin was prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff that Levaquin was of merchantable quality and safe and fit for the use for which it was intended.

96. Plaintiff, individually and through Plaintiff's prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

97. Plaintiff was prescribed, purchased, and used the subject products for its intended purpose.

98. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with Levaquin until after Plaintiff used it.

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

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

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VI

[Fraudulent Misrepresentation]

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

102. Defendants falsely and fraudulently represented to the medical and healthcare community, and/or the Plaintiff, and/or the FDA and the public in general, that said product, Levaquin had been tested and was found to be safe and effective.

103. That representations made by Defendants were, in fact, false.

104. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

105. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community it particular, to recommend, prescribe, dispense and/or purchase said product, Levaquin, all of which evinced a callous, reckless, willful, depraved indifferenced to the health, safety and welfare of the Plaintiff herein.

106. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used Levaquin, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

107. In reliance upon said representations, the Plaintiff was induced to and did use Levaquin, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

108. Said Defendants knew and were aware or should have been aware that Levaquin had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

109. Defendants knew or should have known that Levaquin had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

110. Defendants brought Levaquin to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

111. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, an aortic dissection, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

112. As a result of the foregoing acts and omissions, the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VII

[Negligent Misrepresentation]

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

114. Defendants negligently and/or recklessly misrepresented to Plaintiff, 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.

115. 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 Plaintiff, Plaintiff's physicians and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, Plaintiff's prescribing physicians, the health care industry, and the consuming public that:

a) That Levaquin was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing aortic aneurysms and dissections;

b) The wide range of injuries caused by Levaquin to multiple body systems (e.g., musculoskeletal, neuropsychiatric, peripheral nervous system, senses like vision or hearing, skin, and cardiovascular), including specifically aortic aneurysms and dissections; and

c) That Levaquin should not be used as a first-line therapy for minor or uncomplicated infections.

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

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

118. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, Plaintiff's prescribing physicians,

and the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiff as well as the general public.

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

120. Plaintiff justifiably relied on and/or were 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 Plaintiff's detriment.

121. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's prescribing physicians, and the general public about the potential risks and complications associated with their FLQ drugs in a timely manner.

122. 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.

123. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts as set forth above, Plaintiff ingested Levaquin and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully request that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VIII

[Fraudulent Concealment]

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

125. Defendants are estopped from asserting a statute of limitations defense because they fraudulently concealed their wrongful conduct from the Plaintiff with the intent that Plaintiff and Plaintiff's prescribing physicians would rely on such material representations. First, Defendants had actual knowledge of the defective and dangerous nature of Levaquin. Second, Defendants failed to conduct adequate testing on Levaquin to establish safety and efficacy. Third, Defendants had actual knowledge of their misrepresentations, negligence, breach of warranties, and false, misleading, deceptive, and unconscionable conduct. Yet, Defendants continued to perpetuate their wrongful conduct with the intent and fixed purpose of concealing their wrongs from the Plaintiff and the public at large.

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

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

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

128. Defendants, as the manufacturer and/or distributor of Levaquin, were in a position of superior knowledge and judgment regarding any potential risks associated with their drugs.

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

130. In breaching their duties to Plaintiff, Defendants used their position of trust as the manufacturer and/or distributor of Levaquin to increase sales of the drugs at the expense of informing Plaintiff that, by ingesting these drugs, they were placing themselves at a significantly-increased risk of developing aortic aneurysms and dissections.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT IX

Violation of New York Consumer Protection Laws

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

132. By reason of the conduct as alleged herein, and by inducing Plaintiff and Plaintiff's physicians to use Levaquin through the use of deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices and the concealment and suppression of material facts, including but not limited to fraudulent statements, concealments and misrepresentations identified herein and above, Defendants violated the provisions of NY GEN. BUS. §§ 349, 350.

133. As a direct and proximate result of Defendants' statutory violations, Plaintiff was damaged by Levaquin which would not have occurred had Defendants not used deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices and the concealment and suppression of material facts to induce Plaintiff and Plaintiff's physicians to use this products.

134. By reason of such violations and pursuant to NY GEN. BUS. §§ 349, 350, Plaintiff is entitled to recover all of the monies paid for Levaquin; to be compensated for the cost of the medical care arising out of the use of Levaquin; and to recover any and all consequential damages recoverable under the law including but not limited to both past and future medical expenses, past wage loss, loss of future earning capacity, past and future pain, suffering, disability, and emotional distress. Plaintiff is entitled to seek compensatory damages, attorney's fees, injunctive and equitable relief, and other remedies as determined by the Court pursuant NY GEN. BUS. §§ 349, 350.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff’s favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys’ fees, and all such other and further relief as this Court deems just and proper.

PUNITIVE DAMAGES

135. At all times material hereto, Defendants knew or should have known that Levaquin was inherently dangerous with respect to the risk of collagen disorders like aortic aneurysms and dissections.

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

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

138. At all times material hereto, Defendants knew and recklessly disregarded the fact that Levaquin causes injuries to multiple body systems, including serious collagen disorders like aortic aneurysms and dissections.

139. Notwithstanding the foregoing, Defendants continued to aggressively market Levaquin to consumers, including Plaintiff, without disclosing the aforesaid side effects.

140. Defendants knew of Levaquin's lack of warnings regarding the risk of developing serious collagen disorders like aortic aneurysms and dissections, 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 the Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by Levaquin.

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

142. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, an aortic dissection. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such

expenses in the future. Plaintiff's injuries and damages are prolonged and/or permanent and will continue into the future.

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

RELIEF REQUESTED

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

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

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

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

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

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

f) For consequential damages in excess of the jurisdictional minimum of this Court;

g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

h) For attorneys' fees, expenses, and costs of this action; and

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

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

DATED: September 30, 2016

Respectfully submitted,

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