UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

KELLY SEIM; 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. Fraud** **7. Negligent Representation** **8. Fraudulent Concealment**

Plaintiff, Kelly Seim ("Plaintiff"), by and through the undersigned counsel, hereby brings this Complaint for damages against Defendants Johnson & Johnson, Janssen Research & Development, LLC, and Janssen Pharmaceuticals, Inc. and alleges the following:

INTRODUCTION

This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of the pharmaceutical drug Levaquin® (also known as Levofloxacin). Levaquin in its brand form shall herein be referred to as "Levaquin" and in its generic form as "Levofloxacin."

PARTIES

1. Plaintiff Kelly Seim is a natural person and a resident and citizen of Cook County, Illinois. Plaintiff brings this action for personal injuries sustained by the use of

Levofloxacin. As a direct and proximate result of being prescribed and ingesting Levofloxacin, Plaintiff developed irreversible peripheral neuropathy.

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

3. Defendant Johnson & Johnson has transacted and conducted business within the State of Illinois.

4. Defendant Johnson & Johnson has derived substantial revenue from goods and products used in the State of Illinois.

5. Defendant Johnson & Johnson expected or should have expected its acts to have consequences within the State of Illinois, and derived substantial revenue from interstate commerce.

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

7. Defendant Janssen Research & Development, LLC (f/k/a Johnson & Johnson Pharmaceutical Research & Development, LLC) is a limited liability company organized under the laws of the State of New Jersey, with its principle place of business at 920 Route 202 South, P.O. Box 300, Mail Stop 2628, Raritan, New Jersey 08869.

8. The members of Janssen R&D are corporate citizens of Pennsylvania, New Jersey and Deleware for purposes. Accordingly, Janssen R&D is a citizens of Pennsylvania, New Jersey and Deleware for purposes of determining diversity under 28 U.S.C. § 1332.

9. Defendant Janssen Research & Development, LLC has transacted and conducted business within the State of Illinois.

10. Defendant Janssen Research & Development, LLC has derived substantial revenue from goods and products used in the State of Illinois.

11. Defendant Janssen Research & Development, LLC expected or should have

expected their acts to have consequences within the State of Illinois, and derived substantial revenue from interstate commerce.

12. At all times material hereto, Defendant Janssen Research & Development, LLC conducted research, development, and testing on Levaquin.

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

14. Defendant Janssen Pharmaceuticals, Inc. (f/k/a 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.

15. Defendant Janssen Pharmaceuticals, Inc. has transacted and conducted business within the State of Illinois.

16. Defendant Janssen Pharmaceuticals, Inc. has derived substantial revenue from goods and products used in the State of Illinois.

17. Defendant Janssen Pharmaceuticals, Inc. expected or should have expected their acts to have consequences within the State of Illinois, and derived substantial revenue from interstate commerce.

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

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

20. Defendants are authorized to do business in Illinois and derive substantial income from doing business in this state.

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

22. Upon information and belief, the Johnson & Johnson 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

23. 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.

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

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

FACTUAL ALLEGATIONS

26. 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 drugs Levaquin.

27. Plaintiff was prescribed Levofloxacin, manufactured by Teva Pharmaceuticals USA, Inc., on October 25, 2013 and used it as directed. Shortly thereafter, Plaintiff began experiencing symptoms of peripheral neuropathy. Plaintiff was subsequently diagnosed with paresthesia, a form of peripheral nerve damage (hereafter "peripheral neuropathy), and continues to suffer from that condition today.

28. Levaquin is a broad-spectrum antibiotic used to treat certain infections caused by certain germs called bacteria.

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

30. 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.

31. 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), Levaquin® (Levofloxacin), Floxin® (ofloxacin), and pefloxacin (never approved for marketing in the United States).

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

33. Levaquin was approved by the FDA on December 20, 1996, for use in the United States, and is the brand name for the antibiotic levofloxacin.

34. 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.

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

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

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

38. Defendant Janssen Pharmaceuticals, Inc. indicates on its website that "[i]n a large

number of clinical trials, Levaquin has been shown to have a proven safety and efficacy profile for the treatment of many bacterial infections."

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

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

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

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

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

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

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

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

47. As early as 1990, there was evidence of the association of between quinolone drugs and peripheral neuropathy. Dr. Chan, et al. published an article reviewing 27 patients treated with the quinolone Peflox for urinary tract infections. One of the 27 patients developed peripheral neuropathy that resolved four weeks after discontinuation of Peflox. This case represents a positive "de-challenge."

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

49. A single well-documented case report can be viewed as a safety signal, particularly if the report describes a positive re-challenge.

50. In the pharmaceutical industry, safety signals indicate the need for further investigation.

51. After a signal is identified, it should be further assessed to determine whether it represents a potential safety risk that should be included in product label.

52. Four years later, in 1996, Karin Hedenmalm and Olav Spigset published "Peripheral sensory disturbances related to treatment with fluoroquinolones" based on a review of 37 separate reports of symptoms of peripheral nerve damage, highlighting concerns about numbness, pain, and muscle weakness.

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

54. The Cohen paper was published in December 2001 and revealed that adverse

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

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

56. In September 2004, an amended Levaquin label concerning peripheral nerve damage was approved by the FDA. The amended label included the following statement in the Warnings section:

> Peripheral Neuropathy: Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones, including Levofloxacin. Levofloxacin should be discontinued if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation in order to prevent the development of an irreversible condition.

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

drug upon the onset of certain symptoms.

58. 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 Plaintiff presented to her providers; (2) and physicians failing to warn and instruct consumers about the risk of peripheral nervous system injuries associated with Levaquin.

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

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

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

62. Notwithstanding this updated 2013 label change, the label for Levaquin remains inadequate and confusing regarding the risk of developing irreversible peripheral neuropathy following the use of Levaquin.

63. For instance, the Levaquin label currently states under the "Warnings and Precautions" section of the first page as follows: "Peripheral neuropathy: discontinue immediately if symptoms occur in order to *prevent irreversibility* (5.8)." This statement implies to physicians and patients that, if the patient stops using the drug immediately after symptoms

occur, the symptoms are reversible. However, in section 5.8, the label states that "Symptoms [of peripheral neuropathy] may occur soon after initiation of LEVAQUIN® and *may be irreversible*." This later statement conflicts with the earlier statement by implying that no matter whether the patient stops using the drug immediately after experiencing symptoms, the symptoms may be permanent. It is inconsistent to advise physicians and patients in one section of the label that that the symptoms of peripheral neuropathy are reversible if the drug is stopped immediately after symptoms occur, but to advise physicians and patients in another section of the label that symptoms may be irreversible no matter whether they stop taking the medication immediately upon experiencing symptoms.

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

65. An epidemiologic study published in the August 2014 online edition of *Neurology* provided further quantitative support for the association between fluoroquinolone antibiotics and peripheral neuropathy.[1] The study compared 6,226 cases of peripheral neuropathy among men ages 48-80 to 24,904 controls and determined that those on fluoroquinolones were at a statistically significant higher risk of developing peripheral neuropathy (RR = 1.83, 95% CI: 1.49-2.27), with current users having the highest risk of exposure (RR = 2.07, 95% CI: 1:56-2.74).

[1] Etminan M, Brophy JM, Samii A. Oral fluoroquinolone use and risk of peripheral neuropathy: A pharmacoepidemiologic study. Neurology 2014; Epub 2014 Aug 22.

66. In *Dolin v. Smithkline Beecham Corp.*, 62 F.Supp.3d 705, 720-21 (N.D. Ill. 2014), the court held that under Illinois common law, a brand-name manufacturer owes a duty of care to the generic consumer.

67. Thus, the Defendants' duty of care in disseminating product information extends to those patients, such as Plaintiff, who are injured by generic Levofloxacin as a result of prescriptions written in reliance on Defendants' product information for brand-name Levaquin. Defendants knew or should have known that prescribing physicians would rely upon the warnings or product labeling disseminated by the Defendants for brand-name Levaquin in prescribing brand-name or generic Levofloxacin for patients, such as Plaintiff.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

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

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

70. The time, place and substance of the Defendants' alleged fraud is set forth as follows. Before Levaquin was approved by the FDA in 1996, there was evidence in the medical literature of an association of between quinolone drugs and peripheral neuropathy.[2] Following approval, additional information came out in the medical literature (e.g., Cohen) reporting peripheral neuropathy events associated with fluoroquinolones.[3] The Cohen paper reported that in 33% of the reported cases, event onset was within twenty-four hours; for 84% onset was

[2] *See, e.g.*, Chan, PC et al., Clinical experience with pefloxacin in patient with urinary tract infections, Br. J. Clin. Pract. 1990; Auon, M. et al. Peripheral neuropathy associated with fluoroquinolones. Letter to Editor. Lancet. 1992; Hedenmalm, K. et al. Peripheral sensory disturbances related to treatment of fluoroquinolones. J. Antimicrob. Chemother. 1996;37:831-7.
[3] *See, e.g.*, Cohen, JS. Peripheral neuropathy assocated with fluoroquinolones. Annals of Pharmacotherapy. 2001.

within seven days. Forty-seven percent of cases reported sensory and motor symptoms of peripheral neuropathy. The Cohen paper further reported that symptoms of peripheral neuropathy lasted longer than one month in 91% of cases; longer than three months in 71% of cases; and longer than two years in 27% of cases. Defendants were obligated under federal regulations to revise the labeling as soon as there was reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved. 21 C.F.R. 201.57(e). Despite the information from the medical literature noted above, as well as other information available to Defendants in their adverse event reporting system (AERS) and clinical trials, Defendants deliberately failed to update the Levaquin label to reflect the rapid onset of symptoms or the risk of developing *permanent* peripheral neuropathy. By June 2003, Defendants were communicating with the FDA's Office of Dietary Supplements (ODS) in conjunction with the ODS's scientific review of the labeling for fluoroquinolones, including Levaquin. Through these communications with ODS, Defendants were again made aware that the onset of neuropathic symptoms often occurs shortly after the initiation of fluoroquinolone use, and can be rapidly progressive and irreversible. Thus, despite the above-referenced information Defendants had obtained from the medical literature, the AERS database, the clinical trials, and its communications with ODS, Defendants knew, prior to Plaintiff's use of the drug, that central nervous system-related effects were more common with quinolones that with other antimicrobial classes of drugs and that the onset of events like peripheral neuropathy could be rapid and irreversible. Despite this information, Defendants deliberately failed to update the Levaquin label to reflect this important safety information.

71. In failing to update its label, the Defendants intended that that the misinformation contained in the label would be relied upon by Plaintiff and her prescribing physician(s), which it was. As a direct result Plaintiff's and her prescribing physician's reliance on this false information, Plaintiff was prescribed Levaquin and she took Levaquin, resulting in her developing permanent peripheral neuropathy.

72. Plaintiff first learned of a possible connection between the use of Levaquin and

permanent peripheral neuropathy on or about April 14, 2014 after being diagnosed with peripheral neuropathy by her physician.

73. Unlike ordinary consumers of prescription drug products, prescription drug manufacturers are held to the standard of experts on their products. And unlike ordinary consumers, prescription drug manufacturers are obligated to keep abreast of scientific knowledge, discoveries, advances and research in the field related to their products, and are presumed to know what is imparted thereby. Thus, ordinary consumers (such as Plaintiff) are not presumed, as are drug manufacturers, to have superior or continuing knowledge of medical and scientific evidence concerning the drugs they take, particularly with respect to drugs they have previously ingested. Thus, prior to learning of the connection in 2014, Plaintiff, as an ordinary consumer, had no reason to suspect that his use of Levaquin might have caused or contributed to his development of permanent peripheral neuropathy. This is particularly true given Defendants' fraudulent concealment of the risk of developing permanent peripheral neuropathy following the use of Levaquin (as noted above). In addition, physical symptoms alone, without knowing or being able to discern the cause, is insufficient to start the statute of limitations clock running. Plaintiff was diagnosed with the nerve damage complained-of here around April 2014, several months after her last use of used Levaquin. Further, no physician has ever told her that her use of Levaquin is associated with or could have caused her permanent peripheral neuropathy, and she did not otherwise learn of any such connection prior to April 2014. Thus, prior to the April 2014, Plaintiff had no reason to be suspicious of Defendants' fraudulent conduct or to have reasonably discovered the fraudulent conduct.

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

75. Therefore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Levaquin.

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

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

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

COUNT I

[Common Law Negligence]

77. Plaintiffs re-allege all prior paragraphs of the Complaint as if set out here in full.

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

79. Defendants breached their duty of reasonable care to Plaintiffs in that they negligently promoted, marketed, distributed, and/or labeled the drugs.

80. Plaintiffs' 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 Plaintiffs 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 for minor and uncomplicated infections despite evidence as to the drug's defective and dangerous characteristics due to its propensity to cause irreversible peripheral neuropathy;

e) In representing that Levaquin was safe for its intended use when, in fact, it was not safe for its 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 irreversible peripheral neuropathy;

j) In failing to adequately warn Plaintiffs and their healthcare providers that the use of their FLQ drugs carried a risk of developing irreversible peripheral neuropathy;

k) In failing to provide adequate post-marketing warnings or instructions

after Defendants knew or should have known of the significant risk of irreversible peripheral neuropathy associated with the use of Levaquin; and

l) In failing to adequately and timely inform Plaintiffs and the healthcare industry of the risk of serious personal injury, namely irreversible peripheral neuropathy and/or nerve damage, from Levaquin as described herein.

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

82. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff as 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 request that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT II

[Negligent Misrepresentation]

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

84. Defendants negligently and/or recklessly misrepresented to Plaintiff, her 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.

85. Defendants made reckless or negligent misrepresentations and negligently or

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

(a) As early as 1996, Defendants and/or their predecessors were in possession of data (e.g., Hedenmalm, et al.) demonstrating that fluoroquinolones, including Levaquin, increase the risk of irreversible peripheral neuropathy but Defendants failed to include it in their labeling for Levaquin at the time the drugs were initially approved by the FDA or at any time thereafter until the FDA mandated a label change in 2013;

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

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

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

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

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

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

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

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

90. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of 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.

91. Defendants had a post-sale duty to warn Plaintiff, her prescribing physicians, the general public, and generic manufacturers of Levofloxacin about the potential risks and complications associated with Levaquin and Levofloxacin in a timely manner.

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

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

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

COUNT III

[Fraudulent Concealment]

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

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

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

97. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiff, her prescribing physicians, and the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff and her prescribing physicians would rely on Defendants' misrepresentations. Plaintiff and her prescribing physicians did, in fact, act in actual and justifiable reliance on Johnson & Johnson Defendants' representations, and Plaintiff was injured as a result.

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

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

100. 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 drug at the expense of

informing Plaintiff that, by ingesting generic Levofloxacin, she was placing herself at a significantly increased risk of developing irreversible peripheral neuropathy.

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

PUNITIVE DAMAGES

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

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

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

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

105. Defendants knew of the subject product's lack of warnings regarding the risk of irreversible peripheral neuropathy, but Defendants 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 Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Levaquin and Levofloxacin.

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

107. 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, peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

108. 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.

PRAYER FOR RELIEF

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

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

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

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

(d) For full refund of all purchase costs Plaintiff paid for 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 hereby demands a trial by jury on all issues so triable.

DATED this 12 of April, 2016

Respectfully submitted,

By: /s/ E. Samuel Geisler

E. Samuel Geisler, Esq. (ARDC# 6305996)
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JS 44 (Rev. 3/13)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Kelly Seim

(b) County of Residence of First Listed Plaintiff Cook
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

E. Samuel Geisler, Esq., Aylstock, Witkin, Kreis & Overholtz, PLLC, 17 E. Main Street, Ste. 200, Pensacola, FL 32502, (850) 202-1010

DEFENDANTS

JOHNSON & JOHNSON; JANSSEN RESEARCH & DEVELOPMENT, LLC; and JANSSEN PHARMACEUTICALS, INC.

County of Residence of First Listed Defendant Middlesex County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☑ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☑ 1	1	Incorporated *or* Principal Place of Business In This State	4	4
Citizen of Another State	2	2	Incorporated *and* Principal Place of Business In Another State	5	☑ 5
Citizen or Subject of a Foreign Country	3	3	Foreign Nation	6	6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ■ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities Employment
- ☐ 446 Amer. w/Disabilities Other
- ☐ 448 Education

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

(Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)

28 U.S.C. 1332; negligence; fraud; fraudulent concealment; punitive damages

VII. Previous Bankruptcy Matters

(For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.

VIII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75000.00

CHECK YES only if demanded in complaint:

JURY DEMAND: ☑ Yes ☐ No

IX. RELATED CASE(S) IF ANY

(See instructions): JUDGE JOHN R. TUNHEIM DOCKET NUMBER MDL No. 15-2642 (JRT)

X. This case (check one box) ☑ **Is not a refiling of a previously dismissed action** ☐ is a refiling of case number _____ previously dismissed by Judge _____

DATE 4/12/2016

SIGNATURE OF ATTORNEY OF RECORD /s/ E. Samuel Geisler

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; NOTE: federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. Do not cite jurisdictional statutes unless diversity. Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Previous Bankruptcy Matters For nature of suit 422 and 423 enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this court. Use a separate attachment if necessary.

VIII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P. Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

IX. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

X. Refiling Information. Place an "X" in one of the two boxes indicating if the case is or is not a refilling of a previously dismissed action. If it is a refiling of a previously dismissed action, insert the case number and judge.

Date and Attorney Signature. Date and sign the civil cover sheet.