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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

WINDY GARLAND;

Plaintiff,
v.

JOHNSON & JOHNSON; JOHNSON & JOHNSON
PHARMACEUTICAL RESEARCH &
DEVELOPMENT, L.L.C.; ORTHO-MCNEIL-
JANSSEN PHARMACEUTICALS, INC.;
MCKESSON CORPORATION; and DOES 1-100,
inclusive,

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, by and through the undersigned counsel, hereby brings this Complaint for damages against the Defendants, and alleges the following:

INTRODUCTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution,

1 labeling, and/or sale of the pharmaceutical drug Levaquin® (also known as levofloxacin).
2 Levaquin® in any of its forms shall herein be referred to as “Levaquin.” Plaintiff maintains that
3 Levaquin is defective, dangerous to human health, unfit and unsuitable to be marketed and sold
4 in commerce, and lacked proper warnings and directions as to the dangers associated with its
5 use.

6 **PARTIES**

7 2. Plaintiff Windy Garland is a natural person and at all relevant times a resident
8 and citizen of Campbell County, Tennessee. Plaintiff brings this action for personal injuries
9 sustained by the use of Levaquin. As a direct and proximate result of being prescribed and
10 ingesting Levaquin, Plaintiff developed peripheral neuropathy and/or symptoms of peripheral
11 neuropathy.

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

15 4. Defendant Johnson & Johnson has transacted and conducted business within the
16 State of California.

17 5. Defendant Johnson & Johnson has derived substantial revenue from goods and
18 products used in the State of California.

19 6. Defendant Johnson & Johnson expected or should have expected its acts to have
20 consequences within the State of California, and derived substantial revenue from interstate
21 commerce.

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

25 8. Defendant Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
26 (“Johnson & Johnson PRD”) is a limited liability company organized under the laws of New
27 Jersey, which has its principal place of business at 920 Route 202 South, P.O. Box 300, Mail
28 Stop 2628, Raritan, New Jersey 08869.

1 9. Defendant Johnson & Johnson PRD has transacted and conducted business
2 within the State of California.

3 10. Defendant Johnson & Johnson PRD has derived substantial revenue from goods
4 and products used in the State of California.

5 11. Defendant Johnson & Johnson PRD expected or should have expected their acts
6 to have consequences within the State of California, and derived substantial revenue from
7 interstate commerce.

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

11 13. Defendant Johnson & Johnson PRD is part of the Defendant Johnson &
12 Johnson's "Family of Companies."

13 14. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. (hereinafter "Ortho-
14 McNeil") is a Delaware corporation which has its principal place of business at 1000 Route 202
15 South, P.O. Box 300, Raritan, New Jersey 08869.

16 15. Defendant Ortho-McNeil has transacted and conducted business within the State
17 of California.

18 16. Defendant Ortho-McNeil has derived substantial revenue from goods and
19 products used in the State of California.

20 17. Defendant Ortho-McNeil expected or should have expected their acts to have
21 consequences within the State of New Jersey, and derived substantial revenue from interstate
22 commerce.

23 18. At all times material hereto, Defendant Ortho-McNeil was engaged in the
24 business of designing, developing, manufacturing, testing, packaging, promoting, marketing,
25 distributing, labeling, and/or selling Levaquin.

26 19. Defendant Ortho-McNeil is a wholly owned subsidiary of Defendant Johnson &
27 Johnson.

28 20. Defendant McKesson Corporation (hereinafter "McKesson") is a Delaware

1 corporation with its principal place of business at One Post Street, San Francisco, California
2 94104. At all relevant times, McKesson was in the business of manufacturing, labeling, selling,
3 marketing, packaging, re-packaging and/or distributing Levaquin, including, on information and
4 belief, the Levaquin used by Plaintiff.

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

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

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

20 24. At all times herein mentioned, McKesson conducted regular and sustained
21 business in California by selling and/or distributing its products and services, including
22 Levaquin, in California.

23 25. Plaintiffs are informed and believe, and on this basis alleges that, at all times
24 herein mentioned, DOES 1 through 50, were the officers, employees, servants, agents,
25 contractors, subsidiaries, divisions, and other affiliated individuals or entities, of each other, and
26 were acting within the scope and purpose of such agency or employment, and with the power
27 and authority vested in them as officers, employees, or servants, or ratification, endorsement or
28 approval of the conduct of each other with respect to the events and happenings alleged herein.

1 All Defendants herein named may be referred to collectively as “Defendants.”

2 26. The true names and capacities of Defendants DOES 51 through 100 inclusive are
3 unknown to Plaintiffs, who therefore sue said Defendants by such fictitious names. Plaintiffs
4 are informed and believe and allege thereon that each of the Defendants herein designated as
5 DOE is responsible in some manner for the events and happenings herein referred to and caused
6 the injuries and damages legally thereby as hereinafter alleged.

7 27. As used herein, “Defendants” includes all named Defendants.

8 28. Defendants are authorized to do business in California and derive substantial
9 income from doing business in this state.

10 29. Upon information and belief, Defendants purposefully availed themselves of the
11 privilege of conducting activities with California, thus invoking the benefits and protections of
12 its laws.

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

16 **JURISDICTION AND VENUE**

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

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

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

25 **FACTUAL ALLEGATIONS**

26 34. At all relevant times, Defendants were in the business of and did design, research,
27 manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired and are
28 responsible for Defendants who have designed, researched, manufactured, tested, advertised,

1 promoted, marketed, sold and distributed the pharmaceutical drug Levaquin.

2 35. Plaintiff was prescribed Levaquin in December 2013 and used it as directed.

3 36. McKesson was the largest single distributor of Johnson & Johnson's
4 pharmaceutical products. Plaintiff filled her prescription at a Walgreens Pharmacy.

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

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

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

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

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

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

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

21 44. Defendant Ortho-McNeil indicates on its website that "[i]n a large number of
22 clinical trials, Levaquin has been shown to have a proven safety and efficacy profile for the
23 treatment of many bacterial infections."

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

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

28 47. Defendants failed to appropriately and adequately inform and warn Plaintiff and

1 Plaintiff's prescribing physicians of the serious and dangerous risks associated with the use of
2 Levaquin concerning peripheral neuropathy, as well as other severe and personal injuries, which
3 are permanent and/or long-lasting in nature, cause significant physical pain and mental anguish,
4 diminished enjoyment of life, and the need for medical treatment, monitoring and/or
5 medications.

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

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

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

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

23 52. As early as 1992, there was evidence of the association between fluoroquinolone
24 antibiotics and peripheral neuropathy. Dr. Aoun from the Infectious Diseases Clinic and
25 Microbiology Laboratory at the Institut Jules Bordet in Belgium, along with others, wrote a
26 letter to the editor of the Lancet raising concerns about a 37-year old patient who developed
27 peripheral neuropathy after taking fluoroquinolones.

28 53. Four years later, Karin Hedenmalm and Olav Spigset published "Peripheral

1 sensory disturbances related to treatment with fluoroquinolones” based on a review of 37
2 separate reports of symptoms of peripheral nerve damage, highlighting concerns about
3 numbness, pain, and muscle weakness.

4 54. One of the first studies in the United States that included the post market
5 experience concerning Levaquin and neuropathy was “Peripheral Neuropathy Associated with
6 Fluoroquinolones” written by Jay S. Cohen.

7 55. The Cohen paper was published in December 2001 and revealed that adverse
8 events reported by forty-five patients suggested a possible association between fluoroquinolones
9 and long-term peripheral nervous system damage. The study noted in particular the presence of
10 severe and/or persistent nerve problems. Over one-half of the patients surveyed said their
11 symptoms lasted for more than a year, and eighty percent characterized their symptoms as
12 severe. The Cohen paper recommended further investigation of the association between
13 fluoroquinolones and peripheral neuropathy. The study concluded with the following advisory:
14 “If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is
15 confirmed, physicians need to be informed and warnings might be considered for these drugs’
16 product information.”

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

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

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

27 Peripheral Neuropathy: Rare cases of sensory or sensorimotor axonal
28 polyneuropathy affecting small and/or large axons resulting in paresthesias,

1 hypoesthesias, dysesthesias and weakness have been reported in patients
2 receiving quinolones, including levofloxacin. Levofloxacin should be
3 discontinued if the patient experiences symptoms of neuropathy including pain,
4 burning, tingling, numbness, and/or weakness or other alterations of sensation
5 including light touch, pain, temperature, position sense, and vibratory sensation
6 in order to prevent the development of an irreversible condition.

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

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

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

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

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

1 damage occurred only in rare cases.

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

9 **EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS**

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

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

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

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

27 69. The Plaintiff had no knowledge that Defendants were engaged in the wrongdoing
28 alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, the

1 Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the
2 economics of this fraud should be considered. Defendants had the ability to and did spend
3 enormous amounts of money in furtherance of their purpose of marketing, promoting and/or
4 distributing a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff
5 and medical professionals could not have afforded and could not have possibly conducted
6 studies to determine the nature, extent and identity of related health risks, and were forced to
7 rely on only the Defendants' representations. Accordingly, Defendants are precluded by the
8 discovery rule and/or the doctrine of fraudulent concealment from relying upon any statute of
9 limitations.

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

12 **FIRST CAUSE OF ACTION**

13 **[Strict Liability]**

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

18 72. At all times alleged herein, Levaquin was defective and Defendants knew that
19 Levaquin was to be used by consumers without inspection for defects. Moreover, Plaintiff, her
20 prescribing physicians, and her health care providers neither knew nor had reason to know at the
21 time of Plaintiff's use of Levaquin of the aforementioned defects. Ordinary consumers would
22 not have recognized the potential risks for which Defendants failed to include the appropriate
23 warnings.

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

26 74. The design of Levaquin was defective in that the risks associated with using
27 Levaquin outweighed any benefits of the design. Any benefits associated with the use of
28 Levaquin were either relatively minor or nonexistent and could have been obtained by the use of

1 other, alternative treatments and products that could equally or more effectively reach similar
2 results.

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

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

6 77. As a result of Levaquin's defective condition, Plaintiff suffered the injuries and
7 damages alleged herein.

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

13 **SECOND CAUSE OF ACTION**

14 **[Product Liability – Failure to Warn]**

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

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

20 80. Defendants did in fact sell, distribute, supply, manufacture, and/or promote
21 Levaquin to Plaintiff and to her prescribing physicians. Additionally, Defendants expected the
22 Levaquin that they were selling, distributing, supplying, manufacturing, and/or promoting to
23 reach – and Levaquin did in fact reach – prescribing physicians and consumers, including
24 Plaintiff and her prescribing physicians, without any substantial change in the condition of
25 the product from when it was initially distributed by Defendants.

26 81. At all times herein mentioned, the aforesaid product was defective and unsafe
27 in manufacture such that it was unreasonably dangerous to the user, and was so at the time it
28 was distributed by Defendants and ingested by Plaintiff. The defective condition of Levaquin

1 was due in part to the fact that it was not accompanied by proper warnings regarding the
2 possible side effect of developing long-term and potentially irreversible peripheral neuropathy
3 as a result of its use.

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

6 83. At all times herein mentioned, Defendants had a duty to properly design,
7 manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain
8 supply, provide proper warnings, and take such steps to assure that the product did not
9 cause users to suffer from unreasonable and dangerous side effects.

10 84. Defendants so negligently and recklessly labeled, distributed, and promoted the
11 aforesaid product that it was dangerous and unsafe for the use and purpose for which it was
12 intended.

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

15 86. Defendants were aware of the probable consequences of the aforesaid conduct.
16 Despite the fact that Defendants knew or should have known that Levaquin caused serious
17 injuries, they failed to exercise reasonable care to warn of the dangerous side effect of
18 developing irreversible peripheral neuropathy from Levaquin use, even though this side effect
19 was known or reasonably scientifically knowable at the time of distribution. Defendants
20 willfully and deliberately failed to avoid the consequences associated with their failure to warn,
21 and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.

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

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

26 89. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment
27 of Defendants.

28 90. Had Defendants properly disclosed the risks associated with Levaquin,

1 Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using
2 Levaquin.

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

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

10 **THIRD CAUSE OF ACTION**

11 **[Negligence]**

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

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

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

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

- 21 a) In the design, development, research, manufacture, testing, packaging,
22 promotion, marketing, sale, and/or distribution of Levaquin;
- 23 b) In failing to warn or instruct, and/or adequately warn or adequately
24 instruct, users of the subject product, including Plaintiff herein, of
25 Levaquin's dangerous and defective characteristics;
- 26 c) In the design, development, implementation, administration,
27 supervision, and/or monitoring of clinical trials for the subject product;
- 28 d) In promoting the subject product in an overly aggressive, deceitful, and

1 fraudulent manner, despite evidence as to the product's defective and
 2 dangerous characteristics due to its propensity to cause irreversible
 3 peripheral neuropathy;

4 e) In representing that the subject product was safe for its intended use
 5 when, in fact, the product was unsafe for its intended use;

6 f) In failing to perform appropriate pre-market testing of the subject
 7 product;

8 g) In failing to perform appropriate post-market surveillance of the
 9 subject product;

10 h) In failing to adequately and properly test Levaquin before and after
 11 placing it on the market;

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

15 j) In failing to adequately warn Plaintiff and her healthcare providers that
 16 the use of Levaquin carried a risk of developing irreversible peripheral
 17 neuropathy;

18 k) In failing to provide adequate post-marketing warnings or instructions
 19 after Defendant knew or should have known of the significant risk of
 20 irreversible peripheral neuropathy associated with the use of Levaquin;
 21 and

22 l) In failing to adequately and timely inform Plaintiff and the healthcare
 23 industry of the risk of serious personal injury, namely irreversible
 24 peripheral neuropathy, from Levaquin ingestion as described herein.

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

28 97. As a direct and proximate result of Defendants' carelessness and negligence,

1 Plaintiff suffered severe and permanent physical and emotional injuries, including, but not
 2 limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has
 3 suffered economic loss, including incurring significant expenses for medical care and
 4 treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and
 5 punitive damages from Defendants as alleged herein.

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

10 **FOURTH CAUSE OF ACTION**

11 **[Breach of Express Warranty]**

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

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

15 100. Levaquin did not conform to these express representations because Levaquin was
 16 not safe and had an increased risk of serious side effects, including irreversible peripheral
 17 neuropathy, whether taken individually or in conjunction with other therapies.

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

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

24 **FIFTH CAUSE OF ACTION**

25 **[Breach of Implied Warranty]**

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

27 103. At all times mentioned herein, Defendants manufactured, compounded,
 28 packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or

1 sold Levaquin, and prior to the time that it was prescribed to Plaintiff, Defendants impliedly
2 warranted to Plaintiff that the subject product was of merchantable quality and safe and fit
3 for the use for which it was intended.

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

6 105. Plaintiff was administered, and used the subject product for its intended
7 purpose.

8 106. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not
9 have known about the nature of the risks and side effects associated with the subject product
10 until after she used it.

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

14 108. As a direct and proximate result of Defendants' breach of implied warranty,
15 Plaintiff suffered severe and permanent physical and emotional injuries, including, but not
16 limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has
17 suffered economic loss, including incurring significant expenses for medical care and
18 treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and
19 punitive damages from Defendant as alleged herein.

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

24 **SIXTH CAUSE OF ACTION**

25 **[Fraud]**

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

27 110. Defendants misrepresented to Plaintiff, her prescribing physicians, and the
28 healthcare industry the safety and effectiveness of Levaquin and/or fraudulently, intentionally,

1 and/or negligently concealed material information, including adverse information, regarding the
2 safety and effectiveness of Levaquin.

3 111. Defendants made misrepresentations and actively concealed adverse
4 information when Defendants knew, or should have known, that Levaquin had defects, dangers,
5 and characteristics that were other than what Defendants had represented to Plaintiff, her
6 physicians, and the healthcare industry generally. Specifically, Defendants actively concealed
7 from Plaintiff, her prescribing physicians, the health care industry, and the consuming public
8 that:

- 9 (a) Since at least 1996 Defendant Johnson & Johnson and/or its
10 predecessors were in possession of data demonstrating that Levaquin
11 increases the risk of irreversible peripheral neuropathy;
- 12 (b) There had been insufficient studies by Defendants and/or their
13 predecessors regarding the safety and efficacy of Levaquin before and
14 after its product launch;
- 15 (c) Levaquin was not fully and adequately tested by Defendants and/or their
16 predecessor for the risk of developing irreversible peripheral neuropathy;
17 and
- 18 (d) Testing and studies by other entities as reported in the scientific
19 literature has shown that the use of Levaquin increases the risk of
20 irreversible peripheral neuropathy.

21 112. These misrepresentations and/or active concealment alleged were perpetuated
22 directly and/or indirectly by Defendants.

23 113. Defendants knew or should have known that these representations were false,
24 and they made the representations with the intent or purpose of deceiving Plaintiff, her
25 prescribing physicians, and the healthcare industry.

26 114. Defendants made these false representations with the intent or purpose that
27 Plaintiff, her prescribing physicians, and the healthcare industry would rely on them, leading
28 to the use of Levaquin by Plaintiff as well as the general public.

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

5 116. Plaintiff, her prescribing physicians, and the healthcare industry justifiably relied
6 on and/or were induced by Defendants' misrepresentations and/or active concealment and relied
7 on the absence of information regarding the dangers of Levaquin that Defendants did suppress,
8 conceal, or fail to disclose to Plaintiff's detriment. Plaintiff justifiably relied, directly or
9 indirectly, on Defendants' misrepresentations and/or active concealment regarding the true
10 dangers of Levaquin. Based on the nature of the physician-patient relationship, Defendants had
11 reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or
12 active concealment.

13 117. Defendants had a post-sale duty to warn Plaintiff, her prescribing physicians,
14 and the general public about the potential risks and complications associated with Levaquin
15 in a timely manner.

16 118. Defendants made the representations and actively concealed information about
17 the defects and dangers of Levaquin with the intent and specific desire that Plaintiff's
18 prescribing physicians and the consuming public would rely on such information, or the
19 absence of information, in selecting Levaquin as a treatment.

20 119. As a result of the concealment and/or suppression of the material facts set
21 forth above, Plaintiff ingested Levaquin and suffered injuries as set forth herein.

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

26 **SEVENTH CAUSE OF ACTION**

27 **[Negligent Misrepresentation]**

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

121. 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.

122. 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 physician(s) and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, her prescribing physicians, the health care industry, and the consuming public that:

- (a) Since at least 1996 Defendant Johnson & Johnson and/or its predecessors were in possession of data demonstrating that Levaquin increases the risk of irreversible peripheral neuropathy;
- (b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Levaquin before and after its product launch;
- (c) Levaquin was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and
- (d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Levaquin increases the risk of irreversible peripheral neuropathy.

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

124. 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.

125. Defendants made these false representations without the exercise of due care

1 knowing that it was reasonable and foreseeable that Plaintiff, her prescribing physicians, and
2 the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiff as well
3 as the general public.

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

8 127. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or
9 reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of
10 Levaquin and relied on the absence of information regarding the dangers of Levaquin which
11 Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's
12 detriment.

13 128. Defendants had a post-sale duty to warn Plaintiff, her prescribing physicians,
14 and the general public about the potential risks and complications associated with Levaquin
15 in a timely manner.

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

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

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

27 **EIGHTH CAUSE OF ACTION**

28 **[Fraudulent Concealment]**

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

132. 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.

133. 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.

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

135. 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.

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

137. 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 Levaquin, she was placing herself at a significantly-increased risk of developing irreversible peripheral neuropathy.

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

5
6 **PUNITIVE DAMAGES**

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

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

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

13 141. Defendants' misrepresentations included knowingly withholding material
14 information from the medical community and the public, including Plaintiff, concerning the
15 safety of the subject product.

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

18 143. Notwithstanding the foregoing, Defendants continued to aggressively market the
19 subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side
20 effect.

21 144. Defendants knew of the subject product's lack of warnings regarding the risk
22 of irreversible peripheral neuropathy, but they intentionally concealed and/or recklessly failed
23 to disclose that risk and continued to market, distribute, and/or sell Levaquin without said
24 warnings so as to maximize sales and profits at the expense of the health and safety of the
25 public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable
26 harm caused by Levaquin.

27 145. Defendants' intentional and/or reckless failure to disclose information deprived
28 Plaintiff of necessary information to enable them to weigh the true risks of using Levaquin

1 against its benefits.

2 146. As a direct and proximate result of Defendants' willful, wanton, careless,
3 reckless, conscious, and deliberate disregard for the rights and safety of their consumers,
4 Plaintiff suffered severe and permanent physical and emotional injuries, including, but not
5 limited to, irreversible peripheral neuropathy. Plaintiff have endured pain and suffering, has
6 suffered economic loss, including incurring significant expenses for medical care and treatment,
7 and will continue to incur such expenses in the future. Plaintiff' injuries and damages are
8 permanent and will continue into the future.

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

13 **PRAYER FOR RELIEF**

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

- 15 (a) For general (non-economic) and special (economic) damages in a sum in
16 excess of the jurisdictional minimum of this Court;
- 17 (b) For medical, incidental, and hospital expenses according to proof;
- 18 (c) For pre-judgment and post-judgment interest as provided by law;
- 19 (d) For full refund of all purchase costs Plaintiff paid for Levaquin;
- 20 (e) For compensatory damages in excess of the jurisdictional minimum of
21 this Court;
- 22 (f) For consequential damages in excess of the jurisdictional minimum of
23 this Court;
- 24 (g) For punitive damages in an amount in excess of any jurisdictional
25 minimum of this Court and in an amount sufficient to impress upon
26 Defendants the seriousness of their conduct and to deter similar
27 conduct in the future;
- 28 (h) For attorneys' fees, expenses, and costs of this action; and

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

Dated: December 12, 2014

Respectfully Submitted,

By: /s/ John P. Fiske

John H. Gomez

John P. Fiske

Stephanie S. Poli

Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

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

Dated: December 12, 2014

Respectfully Submitted,

By: /s/ John P. Fiske

John H. Gomez

John P. Fiske

Stephanie S. Poli

Attorneys for Plaintiffs

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. 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.
- VIII. 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.

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