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7 UNITED STATES DISTRICT COURT
8 NORTHERN DISTRICT OF CALIFORNIA
9 SAN FRANCISCO DIVISION

10 KARYN JOY GROSSMAN;

11 Plaintiff,

12 v.

13 JOHNSON & JOHNSON; JOHNSON & JOHNSON
14 PHARMACEUTICAL RESEARCH &
15 DEVELOPMENT, L.L.C.; ORTHO-MCNEIL-
16 JANSSEN PHARMACEUTICALS, INC.; and
MCKESSON CORPORATION;

17 Defendants.

Case No.: 3:14-cv-03557

**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**

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

20 **INTRODUCTION**

21
22 1. This is an action for damages suffered by Plaintiff as a direct and proximate
23 result of Defendants' negligent and wrongful conduct in connection with the design,
24 development, manufacture, testing, packaging, promoting, marketing, advertising, distribution,
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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 Karyn Joy Grossman is a natural person and at all relevant times a
8 resident and citizen of Baltimore County, Maryland. Plaintiff brings this action for personal
9 injuries 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
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1 Stop 2628, Raritan, New Jersey 08869.

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

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

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

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

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

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

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

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

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

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

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

2 20. Defendant McKesson Corporation (hereinafter “McKesson”) is a Delaware
3 corporation with its principal place of business at One Post Street, San Francisco, California
4 94104. At all relevant times, McKesson was in the business of manufacturing, labeling, selling,
5 marketing, packaging, re-packaging and/or distributing Levaquin, including, on information and
6 belief, the Levaquin used by Plaintiff.

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

12 22. At all times herein mentioned, McKesson was the largest single distributor of
13 Johnson & Johnson’s pharmaceutical products.

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

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

25 25. As used herein, “Defendants” includes all named Defendants.

26 26. Defendants are authorized to do business in California and derive substantial
27 income from doing business in this state.

1 27. Upon information and belief, Defendants purposefully availed themselves of the
2 privilege of conducting activities with California, thus invoking the benefits and protections of
3 its laws.

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

7 **JURISDICTION AND VENUE**

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

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

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

16 **FACTUAL ALLEGATIONS**

17 32. At all relevant times, Defendants were in the business of and did design, research,
18 manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired and are
19 responsible for Defendants who have designed, researched, manufactured, tested, advertised,
20 promoted, marketed, sold and distributed the pharmaceutical drug Levaquin.

21 33. Plaintiff was prescribed Levaquin and used it as directed.

22 34. Upon information and belief, McKesson distributed the Levaquin that Plaintiff
23 ingested. Plaintiff filled her Levaquin prescription at a Rite Aid Pharmacy at a time when
24 McKesson had a distribution agreement with Rite Aid Corp. Rite Aid Corp. is the second
25 largest customer of McKesson.

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

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

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

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

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

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

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

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

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

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

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

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

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

11 48. Additionally, Defendants failed to disseminate a “Dear Doctor” letter to
12 physicians concerning the label change or the risk of irreversible peripheral neuropathy, and
13 Defendants failed to disclose this serious and dangerous effect when promoting Levaquin to
14 physicians.

15 49. Despite their knowledge that Levaquin was associated with an elevated risk of
16 permanent nerve damage, Defendants’ promotional campaign was focused on Levaquin’s
17 purported “safety profile.”

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

23 51. Four years later, Karin Hedenmalm and Olav Spigset published “Peripheral
24 sensory disturbances related to treatment with fluoroquinolones” based on a review of 37
25 separate reports of symptoms of peripheral nerve damage, highlighting concerns about
26 numbness, pain, and muscle weakness.

27 52. One of the first studies in the United States that included the post market
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1 experience concerning Levaquin and neuropathy was “Peripheral Neuropathy Associated with
2 Fluoroquinolones” written by Jay S. Cohen.

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

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

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

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

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

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

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

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

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

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

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

7 **EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS**

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

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

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

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

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

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

11 **FIRST CAUSE OF ACTION**

12 **[Strict Liability]**

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

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

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

25 72. The design of Levaquin was defective in that the risks associated with using
26 Levaquin outweighed any benefits of the design. Any benefits associated with the use of
27 Levaquin were either relatively minor or nonexistent and could have been obtained by the use of
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1 other, alternative treatments and products that could equally or more effectively reach similar
2 results.

3 73. The defect in design existed when the product left Defendants’ possession.

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

6 75. 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 76. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

16 77. 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 78. 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 79. 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
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1 was distributed by Defendants and ingested by Plaintiff. The defective condition of Levaquin
2 was due in part to the fact that it was not accompanied by proper warnings regarding the
3 possible side effect of developing long-term and potentially irreversible peripheral neuropathy
4 as a result of its use.

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

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

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

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

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

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

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

27 87. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment
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1 of Defendants.

2 88. Had Defendants properly disclosed the risks associated with Levaquin,
3 Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using
4 Levaquin.

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

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 just
11 and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

12 **THIRD CAUSE OF ACTION**

13 **[Negligence]**

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

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

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

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

- 23 a) In the design, development, research, manufacture, testing, packaging,
24 promotion, marketing, sale, and/or distribution of Levaquin;
25 b) In failing to warn or instruct, and/or adequately warn or adequately
26 instruct, users of the subject product, including Plaintiff herein, of
27 Levaquin's dangerous and defective characteristics;

- 1 c) In the design, development, implementation, administration,
2 supervision, and/or monitoring of clinical trials for the subject product;
- 3 d) In promoting the subject product in an overly aggressive, deceitful, and
4 fraudulent manner, despite evidence as to the product's defective and
5 dangerous characteristics due to its propensity to cause irreversible
6 peripheral neuropathy;
- 7 e) In representing that the subject product was safe for its intended use
8 when, in fact, the product was unsafe for its intended use;
- 9 f) In failing to perform appropriate pre-market testing of the subject
10 product;
- 11 g) In failing to perform appropriate post-market surveillance of the
12 subject product;
- 13 h) In failing to adequately and properly test Levaquin before and after
14 placing it on the market;
- 15 i) In failing to conduct sufficient testing on Levaquin which, if properly
16 performed, would have shown that Levaquin had the serious side effect
17 of causing irreversible peripheral neuropathy;
- 18 j) In failing to adequately warn Plaintiff and her healthcare providers that
19 the use of Levaquin carried a risk of developing irreversible peripheral
20 neuropathy;
- 21 k) In failing to provide adequate post-marketing warnings or instructions
22 after Defendant knew or should have known of the significant risk of
23 irreversible peripheral neuropathy associated with the use of Levaquin;
24 and
- 25 l) In failing to adequately and timely inform Plaintiff and the healthcare
26 industry of the risk of serious personal injury, namely irreversible
27 peripheral neuropathy, from Levaquin ingestion as described herein.

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

4 95. As a direct and proximate result of Defendants' carelessness and negligence,
5 Plaintiff suffered severe and permanent physical and emotional injuries, including, but not
6 limited to, irreversible peripheral neuropathy. Plaintiff have endured pain and suffering, have
7 suffered economic loss, including incurring significant expenses for medical care and
8 treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and
9 punitive damages from Defendants as alleged herein.

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

14 **FOURTH CAUSE OF ACTION**

15 **[Breach of Express Warranty]**

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

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

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

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

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

FIFTH CAUSE OF ACTION

[Breach of Implied Warranty]

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

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

102. Plaintiff, individually and through her prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

103. Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

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

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

106. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff have 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 ham actual and punitive damages from Defendant as alleged 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

1 and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

2 **SIXTH CAUSE OF ACTION**

3 **[Fraud]**

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

5 108. Defendants misrepresented to Plaintiff, her prescribing physicians, and the
6 healthcare industry the safety and effectiveness of Levaquin and/or fraudulently, intentionally,
7 and/or negligently concealed material information, including adverse information, regarding the
8 safety and effectiveness of Levaquin.

9 109. Defendants made misrepresentations and actively concealed adverse
10 information when Defendants knew, or should have known, that Levaquin had defects, dangers,
11 and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's
12 physicians, and the healthcare industry generally. Specifically, Defendants actively concealed
13 from Plaintiff, her prescribing physicians, the health care industry, and the consuming public
14 that:

15 (a) Since at least 1996 Defendant Johnson & Johnson and/or its
16 predecessors were in possession of data demonstrating that Levaquin
17 increases the risk of irreversible peripheral neuropathy;

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

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

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

27 110. These misrepresentations and/or active concealment alleged were perpetuated
28

1 directly and/or indirectly by Defendants.

2 111. Defendants knew or should have known that these representations were false,
3 and they made the representations with the intent or purpose of deceiving Plaintiff, her
4 prescribing physicians, and the healthcare industry.

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

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

12 114. Plaintiff, her prescribing physicians, and the healthcare industry justifiably relied
13 on and/or were induced by Defendants' misrepresentations and/or active concealment and relied
14 on the absence of information regarding the dangers of Levaquin that Defendants did suppress,
15 conceal, or fail to disclose to Plaintiff's detriment. Plaintiff justifiably relied, directly or
16 indirectly, on Defendants' misrepresentations and/or active concealment regarding the true
17 dangers of Levaquin. Based on the nature of the physician-patient relationship, Defendants had
18 reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or
19 active concealment.

20 115. Defendants had a post-sale duty to warn Plaintiff, her prescribing physicians,
21 and the general public about the potential risks and complications associated with Levaquin
22 in a timely manner.

23 116. Defendants made the representations and actively concealed information about
24 the defects and dangers of Levaquin with the intent and specific desire that Plaintiff's
25 prescribing physicians and the consuming public would rely on such information, or the
26 absence of information, in selecting Levaquin as a treatment.

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

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

6 **SEVENTH CAUSE OF ACTION**

7 **[Negligent Misrepresentation]**

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

9 119. Defendants negligently and/or recklessly misrepresented to Plaintiff, her
10 prescribing physicians, and the healthcare industry the safety and effectiveness of Levaquin
11 and/or recklessly and/or negligently concealed material information, including adverse
12 information, regarding the safety, effectiveness, and dangers posed by Levaquin.

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

- 19 (a) Since at least 1996 Defendant Johnson & Johnson and/or its
20 predecessors were in possession of data demonstrating that Levaquin
21 increases the risk of irreversible peripheral neuropathy;
- 22 (b) There had been insufficient studies by Defendants and/or their
23 predecessors regarding the safety and efficacy of Levaquin before and
24 after its product launch;
- 25 (c) Levaquin was not fully and adequately tested by Defendants and/or their
26 predecessor for the risk of developing irreversible peripheral neuropathy;
27 and

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

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

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

9 123. Defendants made these false representations without the exercise of due care
10 knowing that it was reasonable and foreseeable that Plaintiff, her prescribing physicians, and
11 the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiff as well
12 as the general public.

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

17 125. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or
18 reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of
19 Levaquin and relied on the absence of information regarding the dangers of Levaquin which
20 Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's
21 detriment.

22 126. Defendants had a post-sale duty to warn Plaintiff, her prescribing physicians,
23 and the general public about the potential risks and complications associated with Levaquin
24 in a timely manner.

25 127. Defendants made the representations and actively concealed information about
26 the defects and dangers of Levaquin with the absence of due care such that Plaintiff's
27 prescribing physicians and the consuming public would rely on such information, or the
28

1 absence of information, in selecting Levaquin as a treatment.

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

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

9 **EIGHTH CAUSE OF ACTION**

10 **[Fraudulent Concealment]**

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

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

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

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

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

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

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

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

16
17 **PUNITIVE DAMAGES**

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

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

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

24 139. Defendants' misrepresentations included knowingly withholding material
25 information from the medical community and the public, including Plaintiff, concerning the
26 safety of the subject product.

27 140. At all times material hereto, Defendants knew and recklessly disregarded the
28

1 fact that Levaquin causes the chronic illness irreversible peripheral neuropathy.

2 141. Notwithstanding the foregoing, Defendants continued to aggressively market the
3 subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side
4 effect.

5 142. Defendants knew of the subject product’s lack of warnings regarding the risk
6 of irreversible peripheral neuropathy, but they intentionally concealed and/or recklessly failed
7 to disclose that risk and continued to market, distribute, and/or sell Levaquin without said
8 warnings so as to maximize sales and profits at the expense of the health and safety of the
9 public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable
10 harm caused by Levaquin.

11 143. Defendants’ intentional and/or reckless failure to disclose information deprived
12 Plaintiff of necessary information to enable them to weigh the true risks of using Levaquin
13 against its benefits.

14 144. As a direct and proximate result of Defendants’ willful, wanton, careless,
15 reckless, conscious, and deliberate disregard for the rights and safety of their consumers,
16 Plaintiff suffered severe and permanent physical and emotional injuries, including, but not
17 limited to, irreversible peripheral neuropathy. Plaintiff have endured pain and suffering, has
18 suffered economic loss, including incurring significant expenses for medical care and treatment,
19 and will continue to incur such expenses in the future. Plaintiff’ injuries and damages are
20 permanent and will continue into the future.

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

25 **PRAYER FOR RELIEF**

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

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

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

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

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

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

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

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

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

14 (i) For such further relief as this Court deems necessary, just, and proper.
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DATED: August 6, 2014

BARON & BUDD, P.C.

By: /s/ Thomas Sims
Thomas Sims
Russell Budd
3102 Oak Lawn Ave, Ste. 1100
Dallas, Texas 75219
Tel: (214) 521-3605/Fax: (214) 520-1181
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

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

DATED: August 6, 2014

BARON & BUDD, P.C.

By: /s/ Thomas Sims
Thomas Sims
Russell Budd
3102 Oak Lawn Ave, Ste. 1100
Dallas, Texas 75219
Tel: (214) 521-3605/Fax: (214) 520-1181
Attorneys for Plaintiff

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

Karyn Joy Grossman

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

(c) Attorneys (Firm Name, Address, and Telephone Number) Thomas Sims, Baron & Budd, P. C., 3102 Oak Lawn Avenue, Suite 1100, Dallas, Texas 75219, (214) 521-3605

DEFENDANTS

Johnson & Johnson; Johnson & Johnson Pharmaceutical Research & Development, L.L.C.; Ortho-Mcneil-Janssen Pharmaceuticals, Inc.; and Mckesson Corporation

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)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation

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

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Personal Injury, Real Estate, etc.

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, 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. 1332(a)

Brief description of cause: Personal injury from plaintiff's use of pharmaceutical product manufactured or distributed by defendants.

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ 75,001.00 CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE 08/06/2014 SIGNATURE OF ATTORNEY OF RECORD /s/ Thomas Sims

IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

- (Place an "X" in One Box Only) SAN FRANCISCO/OAKLAND, SAN JOSE, EUREKA