IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Zelda Ellis,	)	Civil Action No.:
	)	
Plaintiff,	)	Judge:
	)	
v.	)	
	)	
Johnson & Johnson, Janssen Research & Development, LLC, and Janssen Pharmaceuticals, Inc.,	)	**COMPLAINT WITH JURY DEMAND**
	)	
	)	
	)	
Defendants.	)	

Plaintiff, by and through counsel, file this Complaint against Defendants Johnson & Johnson, Janssen Research & Development, LLC, Janssen Pharmaceuticals, Inc. (collectively referred to as the "J&J Defendants" or "Defendants") as follows:

INTRODUCTION

1. This case involves the prescription drug Levaquin® (levofloxacin) (collectively referred to hereafter as "FLQs").

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

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

PARTIES

4. Plaintiff Zelda Ellis is a resident of California. By reason of the foregoing acts and omissions and as a direct and proximate result of being prescribed and ingesting Defendants' FLQs, Plaintiff sustained personal injuries, including irreversible peripheral neuropathy which is lasting in

nature, physical pain and mental anguish, including diminished enjoyment of life, physical impairment, expenses for hospitalization and medical treatment, and economic and other damages.

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

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

7. Defendant Janssen Research & Development, LLC ("Janssen R&D" and formerly known as Johnson & Johnson Pharmaceutical Research & Development, LLC) is a limited liability company organized under the laws of the State of New Jersey, with its principal place of business at 920 Route 202 South, P.O. Box 300, Mail Stop 2628, Raritan, New Jersey 08869.

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

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

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

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

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

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

14. Defendants are authorized to do business in the United States and derive income from doing business in the United States and this District.

15. Upon information and belief, Defendants purposefully availed themselves of the

privilege of conducting activities within the United States and this District, thus invoking the benefits and protections of its laws.

16. Upon information and belief, the J&J Defendants did act together to design, sell, advertise, manufacture and/or distribute Levaquin with full knowledge of its dangerous and defective nature.

JURISDICTION AND VENUE

17. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and Defendants.

18. Defendants have significant contacts in this District e such that they are subject to the personal jurisdiction of the court.

19. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in this District. Pursuant to 28 U.S.C. § 1391(a), venue is proper in this district.

FACTUAL ALLEGATIONS

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

21. Plaintiff was prescribed and took brand-name Levaquin as directed by her physician. Thereafter, Plaintiff developed symptoms of irreversible peripheral neuropathy, and/or a worsening of those symptoms, including pain, burning, tingling, numbness, weakness, alterations of sensation.

22. FLQs are broad-spectrum synthetic antibacterial agents marketed and sold in oral tablet, IV solution, and ophthalmic solution, used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria. They are members of the quinolone class of antibiotics.

23. Quinolones are divided into four generations based on their spectrum of

antimicrobial activity. The 1st generation, non-fluorinated quinolone antibiotics were developed in the early 1960s and soon revealed themselves as effective against common gram-negative bacteria, but resistance developed rapidly.

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

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

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

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

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

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

United States.

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

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

32. Defendant Janssen Pharma indicates on its website that "[i]n a large number of clinical trials, Levaquin has been shown to have a proven safety and efficacy profile for the treatment of many bacterial infections."

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

34. Prior to applying to the FDA for and obtaining approval of their FLQs, Defendants knew or should have known that consumption of FLQs were associated with and/or would cause chronic and/or permanent peripheral neuropathy.

35. By 1988, Defendants knew or should have known that the use of FLQs was associated with "peripheral paraesthesia" (a form of peripheral nerve damage) and required further investigation and study.

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

37. The warning labels for Levaquin September 2004 through August 2013 misled and deceived Plaintiff and Plaintiff's treating physicians by incorrectly advising them that peripheral neuropathy associated with FLQs was "rare" and in any case could be avoided by discontinuing the drug upon the onset of certain symptoms. The truth, however, is that the onset of irreversible peripheral neuropathy is often rapid and discontinuation of the drug will not ensure that the

peripheral neuropathy is reversible. Defendants misled patients and physicians by omitting any mention of the possibility that FLQ use could result in irreversible peripheral neuropathy.

38. Further, though this injury can be severe and debilitating, the language regarding the "rare" risk of peripheral neuropathy was buried at the bottom of a long list of adverse reactions that were included on the Defendants' FLQ labels; the language was in no way highlighted for the benefit of prescribing physicians and patients.

39. Additionally, upon information and belief, following the 2004 label change Defendants did not issue any "Dear Doctor" or "Dear Healthcare Professional" letters in the United States that were specific to Levaquin and the risk of developing irreversible peripheral neuropathy. Further, Defendants failed to disclose the serious and dangerous side effect of irreversible peripheral neuropathy when promoting Levaquin to physicians.

40. Despite their knowledge that their FLQ drugs were associated with an elevated risk of prolonged and/or permanent peripheral neuropathy, Defendants' promotional campaign was focused on the purported "safety profile" of their FLQs.

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

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

43. Indeed, even a single case report may be sufficient to establish a *causal* relationship

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

between the use of a product and an adverse event.[2]

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

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

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

47. Despite these representations, as early as 1988 there was evidence in the medical literature of peripheral nerve damage associated with FLQ therapy (ciprofloxacin), representing a safety "signal" that Defendants ignored in violation of the federal regulations.[5] Specifically, in a report from a Swedish Study Group, Karlman et al. reviewed 40 patients treated with ciprofloxacin for acute or chronic osteomyelitis (38) and acute arthritis (2). The authors identified 9 patients with adverse experiences. Of these 9 adverse experiences, the authors reported one case of "peripheral paraesthesia" which they found was "probably related" to ciprofloxacin treatment.[6]

48. Thereafter, a 1990 study by Chan et al. reviewed 27 patients treated with the fluoroquinolone Peflox for urinary tract infections.[7] One patient developed peripheral neuropathy

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[2] *See* Principles & Practice of Public Health Surveillance, at p. 343. Steven M. Teutsch & R. Elliott Churchill, eds. Third Edition, Oxford University Press, 2010.
[3] *See* Guidance for Industry: Good Pharmacovigilence Practices and Pharmacoepidemiologic Assessment (2005).
[4] https://www.washingtonpost.com/national/health-science/it-pays-to-read-the-warnings-when-you-open-up-a-prescription/2015/08/03/a29e11b4-d70e-11e4-b3f2-607bd612aeac_story.html.
[5] *See* 21 C.F.R. 201.57(e) (product label must be revised as soon as there was reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved).
[6] *See* Karlman, K. et al. (Report from a Swedish Study Group). Therapy of acute and chronic gram-negative osteomyelitis with ciprofloxacin. *J Antimicrob Chemother* 1988 Aug;22(2):221-8.
[7] Chan, PC et al., Clinical experience with pefloxacin in patient with urinary tract infections, *Br. J. Clin. Pract.* 1990.

that resolved 4 weeks after discontinuation, generating an incidence rate of 3.7%. The authors concluded that "[i]ts [i.e. peripheral neuropathy's] relation to the use of pefloxacin was *indisputable*, since it recurred on re-introduction of the drug." (emphasis added). Reviewers at the FDA's Office of Surveillance and Epidemiology (OSE) concluded in an April 17, 2013 pharmacovigilence review that this case represents a positive dechallenge.

49. Then, in 1992, Aoun et al. published a case report titled "Peripheral neuropathy associated with fluoroquinolones."[8] Specifically, the authors reported an association between the use of pefloxacin, ofloxacin and ciprofloxacin and peripheral neuropathy in a 37 year old patient. The case report was notable for numerous positive dechallenges and rechallenges of the fluoroquinolones in the patient, resulting in reviewers at FDA's OSE to characterize the quality of the evidence reported as a "strong case." Indeed, the J&J Defendants have acknowledged in other causality assessments that a "positive rechallenge makes causality of levofloxacin highly probable."

50. In 1996, Hedenmalm et al. reported the results from a review of 37 patients treated with fluoroquinolones.[9] Of those, 81% experienced paresthesia, 51% experienced numbness, 27% experienced pain, and 11% experienced muscle weakness. The highest incidence of reported symptoms occurred during the first weeks of treatment. The duration of symptoms in the cases where information was provided varied from a few hours to over a year. According to reviewers at FDA's OSE, the quality of evidence from at least 20 of the 37 cases seemed to be "strong with both a good temporal relationship and a positive dechallenge."

51. One of the first large scale studies in the United States that included the post market experience concerning fluoroquinolones and neuropathy was "Peripheral Neuropathy Associated with Fluoroquinolones" written by Jay S. Cohen. The Cohen paper was published in December

[8] Auon, M. et al. Peripheral neuropathy associated with fluoroquinolones. Letter to Editor. *Lancet*. 1992.
[9] Hedenmalm, K. et al. Peripheral sensory disturbances related to treatment of fluoroquinolones. *J. Antimicrob. Chemother*. 1996;37:831-7.

2001 and revealed that adverse events reported by 45 patients suggested a possible association between fluoroquinolones and long-term peripheral nervous system damage. The study noted in particular the presence of severe and/or persistent nerve problems. Over one-half of the patients surveyed said their symptoms lasted for more than a year, and eighty percent characterized their symptoms as severe. The Cohen paper recommended further investigation of the association between fluoroquinolones and peripheral neuropathy. The study concluded with the following advisory: "If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is confirmed, physicians need to be informed and warnings might be considered for these drugs' product information."

52. Beyond the numerous safety signals generated by internal postmarketing review and the medical literature, Defendants were also put on notice of an association between fluoroquinolone use and peripheral neuropathy by the FDA, in 2001 and again in 2003.

53. In 2001, the Division of Drug Risk Evaluation within the Office of Drug Safety uncovered 35 reports of quinolone-associated peripheral neuropathy and 46 cases of potentially prolonged paresthesia collected by the FDA's Adverse Event Reporting System ("AERS") for the quinolone class (including reports for ciprofloxacin, ofloxacin, and levofloxacin). Twenty-eight of these cases lasted over one month, with some patients still experiencing symptoms two years after fluoroquinolone use.

54. In 2003, FDA's Office of Drug Safety conducted an additional post-marketing safety review of the AEs reported in the FDA's AERS for those who had been treated with ciprofloxacin (Cipro), ofloxacin (Floxin), and/or levofloxacin (Levaquin). The AERS contained 108 unduplicated cases reported as peripheral neuropathy, or events suggestive of peripheral neuropathy, lasting at least one month in patients who had been treated with ciprofloxacin, ofloxacin and/or levofloxacin. As noted in the FDA's Office of Drug Safety review report dated June 10, 2003, the cases were temporally associated with fluoroquinolones, with a median time to onset of a few days. Gender distribution was approximately equal. The report further stated that these cases provided an indication that the fluoroquinolones could have been responsible for the

prolonged peripheral neuropathies. As a result of its review, the Office of Drug Safety recommended that "peripheral neuropathy" be added to the labeling for ciprofloxacin and levofloxacin as it had been for ofloxacin.

55. In September 2004, Defendants amended the labeling Levaquin (levofloxacin). The amended label contained the following statement in the Warnings section:

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

56. In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that Defendants' existing warnings regarding peripheral neuropathy were inadequate. On August 15, 2013, an updated warning and accompanying safety communication was issued in which the risk of rapid onset of irreversible peripheral neuropathy was finally included in the labels for all fluoroquinolones, including Levaquin. The updated warning also removed the statement that peripheral neuropathy occurred only in "rare" cases:

> Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving fluoroquinolones, including [drug name]. Symptoms may occur soon after initiation of [drug name] and may be irreversible. [Drug name] should be discontinued immediately if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation.

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

58. For instance, the Levaquin label currently states under the "Warnings and Precautions" section of the first page as follows: "Peripheral neuropathy: discontinue immediately

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

59. Additionally, Defendants' updated label does not disclose the serious, progressive and disabling nature of FLQ-induced irreversible peripheral neuropathy.

60. Upon information and belief, Defendants failed to provide adequate information to the medical community about the frequency with which AEs indicative of peripheral neuropathy were being reported. Prior to the August 2013 label change, Defendants knew or should have known that FLQ-associated neuropathies could be rapid, permanent, and disabling, and that such injuries were not, as they had been stating, "rare." For instance, from September 2004 through August 2013, the FLQ labels stated that "Rare cases of polyneuropathy affecting small and/or large axons resulting in *paresthesias*, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones" (emphasis added). The pre-2013 FLQ labels further represented that "the most common adverse drug reactions (≥3%) are nausea, headache, diarrhea, insomnia, constipation, and dizziness."

61. Even though the J&J Defendants represented, through their labeling, to patients and the medical community that central nervous system AEs such as *paresthesias* were "rare" and were not a common adverse drug reaction, J&J knew the opposite to be true.[10] As early as the mid-

[10] "Paraesthesia" is an abnormal sensation, typically tingling or prickling ("pins and needles"), burning, or numbness, caused primarily by damage to peripheral nerves.

1990s, the J&J Defendants knew from their own postmarketing experience that the "most frequently reported" central nervous system AEs in the United States from December 1996 through August 1999 were "dizziness, *paraesthesia* and headache" (emphasis added). The J&J Defendants knew that the same was true outside the United States, but for an even longer reporting period. The J&J Defendants knew from non-U.S. postmarketing experience that "most frequently reported" central nervous system AEs outside the United States from December 1993 through August 1999 were "dizziness, *paraesthesia* and headache" (emphasis added). Yet the J&J Defendants deliberately avoided listing "paraesthesia" in their marketing statements and product labels as one of the most common adverse drug reactions. Upon information and belief, the trend of symptoms indicative of peripheral neuropathy (including pain, burning, tingling, numbness, weakness, and/or alterations of sensation) continued to be one of the most frequently reported central nervous system AEs for all Defendants from the 1990s through the labeling change in August 2013.

62. Defendants' failure to adequately warn physicians resulted in: (1) patients receiving FLQs instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which patients presented to the provider; and (2) physicians failing to warn and instruct consumers about the risk of long-term peripheral nervous system injuries associated with FLQs.

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

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

65. In January of 2014, Ayad Ali published "Peripheral neuropathy and Guillain-Barré

syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis," which reemphasized the link between fluoroquinolones and peripheral neuropathy and called for increased scrutiny of the risk-benefit of fluoroquinolone prescriptions.

66. An epidemiologic study published in the August 2014 online edition of *Neurology* provided further quantitative support for the association between fluoroquinolone antibiotics and peripheral neuropathy.[11] The study compared 6,226 cases of peripheral neuropathy among men ages 48-80 to 24,904 controls and determined that those on fluoroquinolones were at a statistically significant higher risk of developing peripheral neuropathy (RR = 1.83, 95% CI: 1.49-2.27), with current users having the highest risk of exposure (RR = 2.07, 95% CI: 1:56-2.74).

67. Notably, long before the publications from Ali et al. and Etminan et al., the J&J Defendants acknowledged that a causal relationship existed regarding FLQs and peripheral neuropathy. Specifically, following the FDA's October 2003 request for a label change regarding FLQs and peripheral neuropathy, the J&J Defendants conducted an internal evaluation of the proposed labeling change. This evaluation led them to conclude in an internal document dated December 2003 that there were case reports "across the quinolone class" of signs and symptoms "consistent with peripheral neuropathy." This assessment further concluded that "onset may be rapid" and "[r]eports were consistent with a causal association for both levofloxacin and oxfloxacin. Some reports include positive dechallenge and/or rechallenge." The report further acknowledged that symptoms of peripheral neuropathy "can occur in setting of other signs and symptoms (allergy, musculoskeletal, and CNS)."

68. On November 5, 2015, the FDA held a joint meeting of the Antimicrobial Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to discuss the safety and efficacy of systemic fluoroquinolones in the context of three indications: acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis in those with chronic obstructive pulmonary disease (ABECB-COPD), and uncomplicated urinary tract infections

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

(uUTI). The FDA asked committee members to determine whether the benefits of FLQ therapy in these three indications justifies the associated risks of FLQ use.

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

70. In advance of the advisory committee meeting, FDA reviewers released briefing documents that indicated the potential side effects of fluoroquinolone use, including permanent peripheral neuropathy, may outweigh the benefits provided by the medications, as patients often receive the drugs for infections that resolve themselves or can be treated with medications that do not carry the same risks. For instance, an evaluation of placebo-controlled trials in ABS or mild ABECB-COPD showed that a large proportion of patients randomized to receive placebo recovered and thus the illnesses appeared to be self-limited for many. Moreover, some trials failed to show any differences in outcome measures when comparing the antibacterial drug to placebo.

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

72. After hearing testimony from industry representatives, as well as dozens of individuals who described a wide range of harmful effects on their health and cognitive ability

from fluoroquinolone use, the panel voted overwhelmingly that the benefits and risks for systemic fluoroquinolone drugs do not support the current labeled indications for the treatment of ABS (unanimous), ABECB-COPD (18-2, with one abstention), or uncomplicated urinary tract infection (20-1).

73. On May 12, 2016, the FDA issued a safety announcement advising that "the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options." The FDA instructed that patients with these conditions should not be treated with a fluoroquinolone if alternative treatment options are available. The May 12th announcement also cautioned that a safety review demonstrated that FLQs "are associated with disabling and potentially permanent serious side effects that can occur together." The side effects can involve the tendons, muscles, joints, nerves, and central nervous system.

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

75. At the FDA's joint advisory committee meeting in November 2015, Dr. Susan Nicholson, Vice-President of safety, surveillance, and risk management for the Johnson & Johnson Family of Companies, testified on behalf of Janssen Pharma and the other industry partners. Dr. Nicholson was asked the following question by the FDA subcommittee concerning quinolones and their causal relationship to tendon ruptures, severe arrhythmia, *and neuropathy*:

> Q: Dr. Winterstein [FDA]: So for the tendon piece, I think there is a fairly good body of literature now that looks at collagen tissue. And to me, that seems to be also a plausible mechanism for neuropathy. So I guess my question is, number one, when does it have to be a unified mechanism or what exactly did that refer to? And then number two, *does the sponsor*

> *disagree*, number one, that quinolones cause tendon ruptures, that quinolones cause severe arrhythmia, and then number three, *that quinolones cause neuropathy*? . . . So I'm just trying to get my arms around what the issue is here. *But it seems like we agree that there is a causal association with these three outcomes that we are discussing. Yes*?

A: Dr. Nicholson: *Yes. We do agree*.

APPLICATION OF THE STATUTE OF LIMITATIONS

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

77. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Defendants' FLQ drugs, including the actual incidence of FLQ-induced peripheral neuropathy, the serious, progressive and disabling nature of FLQ-induced peripheral neuropathy, the rapid onset of FLQ-induced peripheral neuropathy, and the irreversibility of FLQ-induced peripheral neuropathy.

78. The time, place and substance of the Defendants' alleged fraud is set forth as follows. Between 1995 and 2002, FLQs became the most commonly prescribed class of antibiotics to adults in the United States.[12] The explosive increase in FLQ prescriptions was a direct result of Defendants' deliberate decision to reframe FLQs from a "big gun" antibiotic that should be reserved for serious infections to a "first choice" antibacterial that is appropriate for a wide range of mild infections.

79. As the J&J Defendants explained in their 2003 Levaquin brand plan: "In late 2000 through mid 2001, after extensive market research and segmentation analysis, the LEVAQUIN brand team made the decision to reposition LEVAQUIN from a 'big gun' anti-infective used in serious/recalcitrant infections, to a product that is effective in fighting more common infections

[12] *See* Linder, JA. et al. Fluoroquinolone prescribing in the United States: 1995 to 2002. *Am J Med.* 2005 Mar;118(3):259-68 ("Fluoroquinolone prescribing increased threefold in outpatient clinics and emergency departments in the United States from 1995 to 2002. Fluoroquinolones became the most commonly prescribed class of antibiotics to adults in 2002.").

where growth potential was the greatest, such as bronchitis and sinusitis. A new message, based on the research and segmentation analysis was implemented beginning in August of 2001." In 2004 the J&J Defendants were still strategizing on ways to prevent Levaquin "from being pigeon-holed into the more severely ill patient."

80. One key obstacle to Defendants' re-branding scheme was their awareness of the nature and extent of peripheral neuropathy that could result from taking FLQs. Defendants had long been on notice that FLQs were associated with serious nerve injuries. For example, by the mid-1990s the J&J Defendants knew from their own postmarketing experience that the most frequently reported adverse events concerned the central nervous system ("CNS"). The most common CNS adverse events were "dizziness, paraesthesia and headache." Paraesthesia (or paresthesia) is a medical term that refers to a burning or prickling sensation that is usually felt in the hands, arms, legs, or feet. Paresthesia is considered a hallmark of peripheral neuropathy but is believed to be more commonly reported in clinical trials and adverse event reports due to the lack of an immediate confirmation of the diagnosis of neuropathy. Indeed, since 2004 Defendants have admitted that FLQ-associated peripheral neuropathy results in "paresthesias, hypoesthesias, dysesthesias and weakness." Thus, reports of paresthesia, hypoesthesia, dysesthesia and weakness are consistent with a person who is suffering from peripheral neuropathy, even though that person may not yet have been formally diagnosed.

81. For more than a decade, Defendants have known that paresthesia and other symptoms associated with peripheral neuropathy were among the most common side effects of FLQs.

82. In the fall of 2003, members of the Janssen pharmacovigilance team were engaged in evaluating the "neuropathy question". Their evaluation included a review of neuropathy adverse events. Notably, a frequency tabulation of adverse events for Levaquin through May 31, 2003 demonstrated that there were numerous reports of symptoms of peripheral neuropathy, including paraesthesia, hypoesthesia, and weakness. The total number of such reports during this period was 421. During the same period there were 246 reports of headaches, 377 reports of insomnia, 421

reports of dizziness, and 489 reports of nausea. Thus, the reports of neuropathy-associated symptoms exceeded the number of reports of headaches and insomnia and were comparable to the frequency of dizziness and nausea.

83. A review of adverse events performed by the J&J Defendants in early 2006 shows very similar results. In the tabulation of adverse event frequency, there were at least 640 reports of peripheral neuropathy or symptoms indicative of peripheral neuropathy. Compare this with 351 cases of headache, 529 cases of diarrhea, 577 cases of insomnia, 633 cases of dizziness and 716 cases of nausea.

84. Given their close association with peripheral neuropathy, the frequent occurrence of paraesthesia, hypoesthesia and other neuropathy symptoms among FLQ users posed a significant hurdle to Defendants' stated goal of expanding the use of FLQs for mild infections. If practitioners were adequately warned about the risk of serious peripheral neuropathy, they would be much more hesitant to prescribe FLQs for the type of routine infections that Defendants were targeting through their marketing strategies. So Defendants elected to conceal the true nature of the risk.

85. In order to continue to trumpet the allegedly "excellent" safety profile of FLQs, Defendants had little choice but to omit any discussion of the significant risk of paraesthesia, hypoesthesia, dysesthesia and weakness (with their implication for the risk of peripheral neuropathy), and instead focus on what would be perceived as more mild and acceptable side effects, such as headaches or nausea.

86. Beginning in at the late 1990s, Defendants aggressively marketed FLQs while at the same time concealing, through misrepresentations or omissions, the risk of peripheral neuropathy. They did this by focusing on the incidence of relatively benign side effects, such as headaches or dizziness, while concealing the equally common but far more serious symptoms of peripheral neuropathy.

87. The J&J Defendants instituted a marketing campaign that was designed to promote Levaquin's "excellent" safety profile by disclosing the occurrence of only mild symptoms while

concealing the presence of more serious and more frequent symptoms of peripheral neuropathy. In doing so, the J&J Defendants misled physicians regarding the true risks of Levaquin.

88. A 2001 advertisement promoting Levaquin as a first choice for bronchitis and sinusitis points out Levaquin's "unmatched safety profile" and mentions the following adverse events: nausea, diarrhea, insomnia, dizziness and "other side effects." Similarly, in a 2002 Levaquin advertisement promoting Levaquin as the first choice for acute bacterial exacerbation of chronic bronchitis, Defendants point out Levaquin's proven safety profile and highlight the following adverse events: nausea, diarrhea, insomnia and dizziness.

89. Defendants' sales forces promoted FLQs to physicians through "details" or sales calls to physicians' offices. On these sales calls, sales representatives – often using a sales aid and/or sales script developed by Defendants' marketing teams – "detail" the physician on various uses of Defendants' products. For example, one 2004 Levaquin detail script began by explaining that the purpose of the call was to discuss "the use of LEVAQUIN in the treatment of acute maxillary sinusitis." The script continued by pointing out the safety profile of Levaquin, noting a "very low incidence of both GI and CNS adverse events, including a much lower rate of diarrhea compared with Augmentin." This statement was false and misleading and constituted blatant concealment of the product's actual risk profile because the J&J Defendants were aware that CNS adverse events occurred frequently among FLQ patients. Additionally, the comparison with Augmentin was especially misleading because it suggested that the safety of FLQs was superior to Augmentin, even though Augmentin carries much less severe side effects then FLQs. The J&J Defendants concealed the superiority of Augmentin from physicians.

90. In a 2004 sales aid, J&J's sales representatives were being trained to effectively convince physicians and other medical personnel to prescribe Levaquin over other FLQs by emphasizing the drug's safety profile. In one script, these sales representatives were given these "catchy phrases" to use: "Levaquin is 'tried and true' in 300 million patients over the past 10 years. Bottomline, doctor, you know what you're getting when you prescribe Levaquin. No surprises! If safety issues were going to crop up, you'd know it by now, unlike the newer

quinolones, which are unproven in a limited patient population." Another sales technique was to recklessly compare Levaquin to candy: "M&M bags of candy – Doctor, when you think of Levaquin, think of M&Ms. Levaquin is mild on the belly and mean on the bugs."

91. In a 2007 sales aid, the J&J Defendants pointed to Levaquin's safety profile and noted that the most common adverse drug reactions in US clinical trials were nausea, headache, diarrhea, insomnia, constipation and dizziness while concealing the most serious side effects they knew to exist.

92. In a November 2007 advertisement promoting Levaquin as the first choice for acute maxillary sinusitis, the J&J Defendants trumped Levaquin's "excellent safety" profile, citing the following adverse events: nausea, diarrhea, insomnia, and dizziness. Defendants again concealed Levaquin's true risk profile.

93. The J&J Defendants made similar representations in their promotional "patient brochures" aimed at patients and physicians. For example, in one "patient brochure" from 2010 the "intended audience" was "Healthcare Professionals and Patients." The "objective" of the brochure was for the brochure to be "left behind" in the "HCP [Healthcare Professional's] waiting and exam room that *capture the attention* of bacterial RTI patients and highlight the coupon." This brochure, whose theme was "A Step Ahead," states that "LEVAQUIN has been shown to be a safe and effective way to treat certain bacterial infections such as ABS [acute bacterial sinusitis] ABECD [acute bacterial exacerbation of chronic bronchitis]." This brochure further represents that "The most common side effects include dizziness, headache, constipation, nausea, and diarrhea."

94. Plaintiff's treating physicians would have received some form of these marketing materials, and with them the repeated misrepresentations and concealment regarding FLQs' safety profile and the concealment of the risk of irreversible peripheral neuropathy and associated symptoms.

95. Despite the claims in their marketing materials, Defendants were aware that paraesthesia and other symptoms indicative of peripheral neuropathy had occurred frequently in FLQ patients. Defendants' marketing materials deliberately omitted any mention of neuropathy-

type symptoms in their laundry list of side effects, even though the neuropathy symptoms occurred with similar, if not greater, frequency than the headaches, constipation, nausea, diarrhea, insomnia and dizziness they repeatedly mentioned.

96. Failing to disclose the high incidence of neuropathy and neuropathy-associated symptoms was not the only way in which Defendants concealed the true risk of FLQ-induced peripheral neuropathy. Defendants also misrepresented the extent of the injury. They did this in at least three ways. First, they concealed the true risk of irreversible peripheral neuropathy. Second, they concealed the fact that the irreversible peripheral neuropathy caused by FLQs is often the result of a rapid onset of symptoms – in other words, a patient could suffer permanent nerve injuries after taking as few as one or two FLQ pills. Third, Defendants misrepresented the severity of the injury and failed to disclose that it can be serious and disabling.

97. Defendants knew at least by the mid-1990s that FLQs were capable of inducing prolonged, irreversible peripheral neuropathy. This knowledge came from the numerous adverse event reports Defendants received during this period. Defendants concealed these reports from the medical community. Just a few examples of these reports are included below:

- In a 1994 report from Japan, a patient was started on levofloxacin on July 7 at noon. That evening the patient developed numbness. Levofloxacin was discontinued on July 12. The patient had a nerve biopsy suggestive of axonal neuropathy. In an addendum about this patient's progress several months later (December 6, 2004), it was noted of the patient that "Walking by herself was impossible (she was confined to a wheelchair most of the day)." In performing a causality assessment, the J&J Defendants concluded that "Paraesthesia may occur under quinolones." They also agreed with the reporting physician that toxic neuropathy is also suspected.
- An adverse event report from May 1997 documented a patient/physician who took Levaquin and developed peripheral neuropathy. The reporter determined the patient's peripheral neuropathy was "Very Likely/Certain" caused by Levaquin. After conducting a causality assessment, the J&J Defendants concluded it was "probable" the

patient's peripheral neuropathy was caused by Levaquin. J&J received updated reports on this patient on several occasions in 1998 and 1999 and retained its causality determination of "probable" while also indicating the patient's peripheral neuropathy never resolved.

- A 1998 report documented that a Levaquin patient had developed neuropathy that left the patient "unable to work and housebound." The neuropathy had not resolved even months after the patient discontinued the Levaquin.
- A report from August 2000 detailed a patient that started suffering from polyneuropathy with burning sensations in the feet and legs on the second day of Levaquin therapy. The patient did not recover.
- The J&J Defendants received another report in 2000 of a patient who had taken four days of Levaquin and suffered from demyelinating polyneuropathy that had not resolved at the time of the report, approximately 3 months later.
- The J&J Defendants received multiple reports in 2001 that confirmed the rapid and long-term danger posed by Levaquin. For example, a report received in May of 2001 detailed a patient that was prescribed Levaquin to treat sinusitis and that within 6-hours of the first dose began experiencing paraesthesia of the hands and feet, forcing him to discontinue treatment after three days. Several months later the patient was again prescribed Levaquin and he suffered a second adverse event. The patient had not recovered as of the last report. In September 2001 another report was received by the J&J Defendants describing a patient who was given Levaquin and by the tenth day of treatment developed polyneuropathy. The reporter assessed the causal relationship between this event and Levaquin as "highly probable".
- A 2003 report noted that a patient's disabling neuropathy had still not resolved almost two years after the Levaquin was discontinued.

98. Many of the foregoing reports highlight the rapid onset of peripheral neuropathy. In addition, numerous other early adverse event reports reviewed by Defendants provided ample

indication of the rapid onset of permanent nerve damage – information not provided to the medical community. Examples include:

- A July 2002 report of a 48 year old female was treated with Levaquin and within three days she experienced neuropathy.
- A July 2004 report described a 23-year old female patient who began treatment with Levaquin at noon and by that evening she was experiencing numbness. A subsequent nerve biopsy indicated axonal neuropathy. The adverse event report indicated that the patient suffered from numbness, pain, and twinges and muscle weakness in her extremities.

99. The potential for rapid onset of neuropathy symptoms was also apparent in the Levaquin clinical trials. In a Phase I study conducted in 1999, one of the study subjects developed paresthesia after taking just a single dose, and this adverse event was considered to be "probably related" to study medication by the study investigator.

100. Defendants were also aware of, and concealed, the fact that, while many patients experience a rapid onset of symptoms, other patients suffered injuries after a delay in onset even though they only took the FLQ for a week or two. One such example is a patient that reported taking Levaquin for 14 days at which point he discontinued therapy due to tendinitis. After discontinuation of the drug, he later experienced peripheral neuropathy presenting with numbness in his hands and feet, and his symptoms were persistent at the time of the report. Id.

101. Defendants also concealed the severity of the permanent peripheral neuropathy caused by FLQs. In numerous adverse event reports, Defendants learned of the serious and disabling nature of the irreversible peripheral neuropathy that can result from FLQ use. In addition to those previously mentioned, a 2002 report described a 46-year old man who developed symptoms after starting Levaquin treatment and eighteen months after stopping treatment still needed a cane to ambulate.

102. In 2003 the J&J Defendants conducted an in-depth review of post-marketing adverse event reports to determine whether a warning regarding the risk of peripheral neuropathy

was merited. This review identified "numerous cases [of peripheral neuropathy] without apparent alternative explanations which could represent causality associated with the use of levofloxacin." The review noted the potential for rapid onset and concluded that the reports were "consistent with causal association for both levofloxacin and ofloxacin."

103. In connection with a 2004 review of peripheral neuropathy adverse event reports from the previous twelve-month period, the J&J Defendants identified at least five separate reports. Upon reviewing these reports, the J&J Defendants learned that none of the five reports indicated the neuropathy had resolved. Thus, in 100% of the reported cases, the J&J Defendants did not have any reason to believe that the neuropathy was reversible. Similarly, the review of these five cases revealed that the date of symptom onset ranged from 1 to 5 days after starting Levaquin, which highlighted yet again the problem of rapid onset. Yet the J&J Defendants revealed none of this to the medical community or prospective patients.

104. In 2006 the J&J Defendants again confirmed they were fully aware of the true risk of their product. In a report by the Senior Director and Vice-President of Janssen R&D's Benefit Risk Management team, a detailed review of 263 reported cases of peripheral neuropathy led to the conclusion that the onset of symptoms "appeared to be rapid in some cases" and that "there was evidence of longer-term sequelae."

105. The aforementioned internal reports and analyses underscore the extent to which Defendants were on notice that their FLQs could cause rapid onset of a permanent and severe peripheral neuropathy. But the disclosure of a permanent, disabling nerve injury that could occur after taking one or two doses of their FLQs would undercut and disrupt Defendants' marketing strategy. So instead of disclosing the risk of such an injury, Defendants chose to conceal it.

106. In order to appreciate the significance of Defendants' concealment, including both omissions and misrepresentations, regarding the extent and nature of the risk of FLQ-induced irreversible peripheral neuropathy, it is important to understand the prevailing wisdom among medical professionals regarding the nature of drug-induced peripheral neuropathy. Physicians are generally taught that the various forms of drug-induced peripheral neuropathy have two traits in

common. First, they develop only after prolonged use of the offending drug, in the range of several weeks to months.[13] Second, they are transient in nature, and resolve after the drug is discontinued.[14] While there are instances where a drug-induced neuropathy may fail to resolve and become a permanent condition, doctors are typically led to believe that this would only occur when the patient had been taking the drug for an extended period of time.

107. Thus, Defendants' failure to disclose the unique characteristics of FLQ-induced peripheral neuropathy—including rapid onset, irreversibility, and severity—meant that Plaintiff's treating physicians, when tasked with determining the cause of Plaintiff's peripheral neuropathy, would not "rule in" FLQs as a potential cause and thus FLQ use was excluded from their differential diagnosis. After all, these physicians would have assumed that the rapid onset of Plaintiffs' symptoms, combined with their persistence even after discontinuation of FLQ treatment, eliminated FLQs as a possible cause. Simply put, Plaintiff's treating physicians believed that drug-induced irreversible peripheral neuropathy does not occur in these situations, and prior to August 2013, they would have had no reason to believe any differently for FLQ-induced peripheral neuropathy. As noted herein, however, the current label for Levaquin remains misleading regarding the risk of developing irreversible peripheral neuropathy.

108. Defendants fraudulently concealed from physicians, patients, and the medical community that the development of peripheral neuropathy could be permanent. Defendants failed to disclose this important safety risk to patients or the medical community.

109. It was not until September 2004 that Defendants provided any kind of warning to

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[13] *See*, *e.g.*, Ropper A. et al., Principles of Neurology – Tenth Edition, p. 1336, McGraw-Hill Education (2014) (most drug-induced neuropathies occur "after large cumulative doses of the drug have been given (e.g., in cancer chemotherapy) or after prolonged administration"); Benichou C., Adverse Drug Reactions: A Practical Guide to Diagnosis and Management, pp. 105-109, J. Wiley & Sons (1994) ("Most drug-induced polyneuropathies are subacute having an onset of a few weeks or months.").

[14] *See* Vilholm O.J. et al. Drug-Induced Peripheral Neuropathy. *Basic & Clinical Pharmacology & Toxicology* 2014 Aug; 115(2):185-192 ("Drug-induced peripheral neuropathy can begin weeks to months after initiation of treatment with a particular drug and reach a peak at, or after, the end of treatment. In most cases, the pain and paraesthesia completely resolve after cessation of treatment.").

Plaintiff or Plaintiff's physicians regarding the risk of peripheral neuropathy. It was at this point in time that Defendants warned that "rare" cases of "polyneuropathy . . . resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones." This warning failed to disclose the true risk of irreversible peripheral neuropathy, the possibility of rapid onset, or the serious and disabling nature of the injury. By underscoring the "rare" incidence of neuropathy among FLQ users, Defendants reinforced the misleading statements in their marketing materials that the most frequent symptoms were minor reactions such as headaches and diarrhea.

110. Thereafter, from September 2004 through May 2016 for Levaquin, Defendants, through their product labeling, continued to mislead physicians, patients, and the medical community by representing that patients experiencing symptoms of peripheral neuropathy should discontinue treatment "in order to prevent the development of an irreversible condition." By including this language, Defendants misled patients and their physicians into believing that permanent peripheral neuropathy could be avoided by simply discontinuing the drug upon the onset of symptoms. This was false. Defendants knew that cases of peripheral neuropathy associated with FLQ use could be permanent, regardless of when the patient stopped taking the drug.

111. This is evidenced by Defendants' own internal documents. For instance, in August 2004 the J&J Defendants updated their Company Core Data Sheet ("CCDS")[15] to include the risk of developing "irreversible" peripheral neuropathy. Specifically, the J&J Defendants updated their CCDS to provide as follows:

> Very rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysethesias, and weakness have been reported in patients receiving

[15] According to J&J's internal documents, "[i]nformation in [the] CDS is 'in principle' supposed to be core medical information to be implemented in every local labeling." Thus, there should not be a discrepancy between the CCDS and Defendants' drug labels.

> quinolones, including levofloxacin. Levofloxacin should be discontinued if the patient experiences any of the above symptoms. *Peripheral neuropathy associated with quinolone use may be an irreversible condition* (emphasis added).

112. At the same time, the J&J Defendants concealed the irreversible nature of this condition from the medical community in the United States by representing in their FLQ labeling that patients experiencing symptoms of neuropathy should discontinue treatment "in order to *prevent* the development of an irreversible condition." Nothing else was said about the risk of irreversible peripheral neuropathy.

113. The J&J Defendants were aware of the inconsistency in risk conveyed in their internal CCDS (not for public dissemination) and the US label (for public dissemination). Indeed, by March 2005, just a few months after the US label change regarding peripheral neuropathy, the J&J Defendants held a meeting to discuss "apparent difference between CCDS and USPI [United States Product Insert] re last two sentences of CCDS" concerning the irreversibility of the condition. However, upon information and belief, the medical community was never advised by the J&J Defendants that the risk conveyed in the USPI was not scientifically justified based on their own internal "core medical information" regarding the drug's risk for developing irreversible peripheral neuropathy. It was not until almost a decade later—after the expiration of their patent on Levaquin—that the true irreversible nature of the condition was included in the USPI. Even still, the FLQ labeling in the USPI remains deficient and confusing.

114. Defendants had a duty to disclose all facts about the risks associated with use of the medication. However, Defendants failed to disclose in their FLQ labels that the onset of peripheral neuropathy is often rapid, that discontinuation of the drug will not ensure that the peripheral neuropathy is reversible, or that neuropathy symptoms were among the most common side effects (and certainly were not rare).

115. Further, upon information and belief, Defendants intentionally misrepresented the number of reported cases of peripheral neuropathies by improperly excluding certain forms of

peripheral neuropathy from the total number of cases counted towards the condition. In this way they concealed the true risk profile of their product. This allowed Defendants to falsely represent to the medical community and patients in the labeling that reported cases of peripheral neuropathy were "rare," thereby vastly minimizing the risk.

116. For example, in the fall of 2004 the J&J Defendants reported that they received only 5 adverse drug reaction ("ADR") reports of peripheral neuropathy during the period from October 2003 to September 2004. However, the J&J Defendants were in fact aware of many other reports of peripheral neuropathy during this same time period that they excluded from their count of peripheral neuropathy cases. These include:

- AER NSADSS2002023094: a report of "peripheral neuropathy"
- AER NSADSS2003014295: a report of "polyneuropathy" (Defendants use the terms "polyneuropathy" and "peripheral neuropathy" interchangeably)
- AER NSADSS2003024330: a report of "neuropathy peripheral"
- AER NSADSS2003017842: a report of "neuropathy" in which the symptoms include tingling in the limbs and numbness in the fingers and toes
- AER NSADSS2002039226: a report of "neuropathy" in which the symptoms included tingling in the foot and legs
- AER NSADSS2002043399: a report of "neuropathy" in which there were symptoms reported in the arms and legs
- AER JP-JNJFOC-20030901883: a report of "neuropathy" in which the patient reported tingling and numbness in her feet and fingers

117. In a summary of adverse event reports generated in 2002, the J&J Defendants repeatedly altered the original reporting terms so that numerous reports of peripheral neuropathy were ignored. Examples include the following adverse event reports:

- AER NSADSS2001008976: a report of "burning neuropathy" was changed to "paraesthesia"
- AER NSADSS2001016934: a report of "polyneuropathy" was changed to "neuropathy"

- AER NSADSS2001021557: a report of "peripheral neuropathy" was changed to "paraesthesia"
- AER PRIUSA1999003597: a report of "polyneuropathy" was changed to "neuropathy"
- AER PRIUSA2000001269: a report of "axonal demyelinating polyneuropathy" was changed to "neuropathy"
- AER PRIUSA2000001431: a report of "polyneuropathy" was changed to "neuropathy"
- AER PRIUSA2000002025: a report of "polyneuropathy" was changed to "neuropathy"

118. Another way in which the J&J Defendants concealed the incidence of peripheral neuropathy was by manipulating the terms that were used to search for reports of peripheral neuropathy. The J&J Defendants were aware that by choosing only a narrow group of search terms, they could ensure that the number of peripheral neuropathy adverse events they must report would be reduced by almost 80%.

119. Defendants were obligated under federal regulations to revise the labeling as soon as there was reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved. 21 C.F.R. 201.57(e). Despite the information known to Defendants discussed above, Defendants deliberately failed to update their FLQ labels to reflect the rapid onset of symptoms or the risk of developing *permanent* peripheral neuropathy or the severity of nerve damage or the higher incidence of neuropathy symptoms. Defendants knew, prior to Plaintiff's use of the FLQ drugs, that central nervous system-related effects were one of the most common adverse effects of quinolones and that the onset of events like peripheral neuropathy could be rapid and irreversible. Despite this information, Defendants deliberately failed to update their FLQ labels, marketing materials, or educational and promotional documents and statements to reflect this important safety information or to modify their marketing materials and mantras.

120. In failing to update their labels and marketing materials, Defendants intended that that the misinformation contained in the label would be relied upon by Plaintiff and Plaintiff's prescribing physicians, which it was. As a direct result of Plaintiff and Plaintiff's prescribing physician's reliance on the false information contained within the FLQ labels, Plaintiff was

prescribed and took Defendants' FLQs and developed permanent peripheral neuropathy.

121. The nature of Plaintiff's injuries and the relationship of such injuries to FLQs were inherently undiscoverable prior to the full dissemination of the FDA disclosure of risk information that began in August 2013 and continued through further warnings in May 2016.

122. Accordingly, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through reasonable care and diligence should have known, of their claims against Defendants, and in any event such tolling should continue until at least the date of FDA's disclosure of risk information in August 2013, and arguably through May 2016.

COUNT I

[Strict Liability]

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

124. The FLQ drugs manufactured, marketed, supplied and/or distributed by Defendants were defective at the time of manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying such labels failed to warn of the dangerous risks they posed, including the risk of developing irreversible peripheral neuropathy.

125. At all times alleged herein, the FLQs manufactured, marketed, supplied, and/or distributed by Defendants were defective, and Defendants knew that their FLQ drugs were to be used by consumers without inspection for defects. Moreover, Plaintiff, Plaintiff's prescribing physicians, and Plaintiff's healthcare providers neither knew nor had reason to know at the time of Plaintiffs' use of the drugs of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

126. At all times alleged herein, the Defendants' FLQs were prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

127. The design of Defendants' FLQ drugs were defective in that the risks associated with using the drugs as a first-line therapy for infections that did not dictate the use of an FLQ outweighed any benefits of their design. Any benefits associated with the use of the FLQs in such

situations were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results but without the increased risk of developing irreversible peripheral neuropathy.

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

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

130. As a result of the defective condition of Defendants' FLQs, Plaintiff suffered the injuries and damages alleged herein.

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

COUNT II

[Product Liability – Failure to Warn]

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

132. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting their FLQ drugs and, through that conduct, have knowingly and intentionally placed such drugs into the stream of commerce with full knowledge that their products reach consumers such as Plaintiff who ingested them.

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

134. At all times herein mentioned, Defendants' FLQ drugs were defective and unsafe in manufacture such that they was unreasonably dangerous to the user, and were so at the time they were distributed by Defendants and ingested by Plaintiff. The defective condition of

such drugs was due in part to the fact that they were not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of their use.

135. This defect caused serious injuries to Plaintiff, who used Defendants' FLQs in their intended and foreseeable manner.

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

137. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid products that they were dangerous and unsafe for the use and purpose for which they were intended.

138. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with their FLQ products, namely irreversible peripheral neuropathy.

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

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

141. Defendants, as the manufacturers and/or distributors of the FLQ products, are held to the level of knowledge of experts in the field.

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

143. Had Defendants properly disclosed the risks associated with their FLQ drugs, Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using the drugs.

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

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

COUNT III

[Negligence]

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

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

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

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

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

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

c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for Defendants' FLQ drugs;

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

e) In representing that Defendants' FLQ drugs were safe for their intended use when, in fact, the products were unsafe for their intended use;

f) In failing to perform appropriate pre-market testing of Defendants' FLQ drugs;

g) In failing to perform appropriate post-market surveillance of Defendants' FLQ drugs;

h) In failing to adequately and properly test Defendants' FLQ drugs before and after placing them on the market;

i) In failing to conduct sufficient testing on Defendants' FLQ drugs which, if properly performed, would have shown that it had the serious side effect of causing irreversible peripheral neuropathy;

j) In failing to adequately warn Plaintiff and Plaintiff's healthcare providers that the use of Defendants' FLQ drugs carried a risk of developing irreversible peripheral neuropathy. In fact, prior to August 2013, Defendants were aware that their FLQ labels did not warn about irreversible peripheral neuropathy. And the J&J Defendants were also specifically aware that the risk information contained in their FLQ medication guide was not effective in conveying the risks to patients regarding Levaquin. In an internal analysis conducted by the J&J Defendants in 2010, it was noted that that "there is a continuing problem that at least half of the patients read only some or none of the [medication] guide." Moreover, of those patients who did read it, there were "low scores" on adequately conveying "information

regarding risks."

k) In failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risk of irreversible peripheral neuropathy associated with the use of their FLQ drugs; and

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

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

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

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

COUNT IV

[Breach of Express Warranty]

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

152. Before Plaintiff was first prescribed Defendants' FLQ drugs and during the period in which they used the drugs, Defendants expressly warranted that their FLQ drugs were safe.

153. Defendants' FLQs did not conform to these express representations because their drugs were not safe and had an increased risk of serious side effects, including irreversible

peripheral neuropathy, whether taken individually or in conjunction with other therapies.

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

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

COUNT V

[Breach of Implied Warranty]

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

156. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold FLQ drugs (including Levaquin), and before such drugs were prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff that these drugs were of merchantable quality and safe and fit for the use for which they were intended.

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

158. Plaintiff was prescribed, purchased, and used the subject products for their intended purpose.

159. 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 products until after they used them.

160. Contrary to the implied warranty for the subject products, Defendants' FLQs are not of merchantable quality, and they were neither safe nor fit for their intended uses and purposes, as alleged herein.

161. 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 has endured pain and suffering, suffered economic

loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

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

COUNT VI

[Fraud]

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

163. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell their FLQ drugs, owed a duty to provide accurate and complete information regarding these drugs.

164. Defendants' advertising, marketing and educational programs, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of FLQ drugs were safe for human use, had no unacceptable side effects, and would not interfere with daily life.

165. Defendants did not properly study nor report accurately the results of their studies in terms of risks and benefits of its FLQ drugs. For instance, Defendants failed to investigate or initiate any studies or testing following the safety signal generated by Karlman, et al. in 1988, wherein the study determined that an adverse event of peripheral paresthesia was "probably related" to ciprofloxacin treatment.

166. Defendants purposefully concealed, failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of their FLQs. For instance, the J&J Defendants hired physicians, scientists, and medical communications companies (including DesignWrite, LLC) to write inaccurate and misleading scientific articles for the purpose of creating confusion so as to pollute existing scientific and medical knowledge pertaining to the risk of developing permanent peripheral neuropathy with FLQ use. The J&J Defendants then used and

relied on these inaccurate and fraudulently prepared scientific papers to defend and justify the marketing, promotions, and labeling of its FLQ drugs. At all times, Defendants knew that what they were publishing or having published was inaccurate and that this information would mislead the members of the medical and scientific communities who were studying, or more importantly, prescribing FLQ drugs.

167. Defendants, through the publication of medical literature, deceived potential users and prescribers of FLQ drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying the known adverse and serious health effects, including permanent peripheral neuropathy.

168. Defendants similarly used promotional practices to deceive potential users and prescribers of FLQ drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying the known adverse and serious health effects, including permanent peripheral neuropathy. These promotional practices include the J&J Defendants issuing fake "Confidence Court Summons" to hospitals commanding them to appear before the "Confidence Court to answer charges of aiding and abetting results the second or third time, with inconvenience to patients and physicians." The alleged "charges" of wrongdoing included claims that "Levaquin should not be considered the physician's first choice for Bronchitis/Sinusitis" and "that Levaquin should not be considered the workhorse quinolone in the hospital."

169. Defendants also falsely and deceptively kept relevant information from potential FLQ users and minimized prescriber concerns regarding the safety and efficacy of FLQs. For instance, despite learning as early as 1988 (Karlman, et al.) that there was reasonable evidence of an association of a serious hazard with its FLQs, Defendants intentionally withheld this information from physicians and patients until September 2004, when the FLQ labeling was finally changed to reflect any risk of developing neuropathy. Even then, however, Defendants sought to minimize the frequency and permanency of these serious events by indicating that they were "rare" and in any event reversible. Defendants knew these labeling statements were false and misleading, because they knew as early as the 1990s that central nervous system-related effects were more

common with quinolones than with other antimicrobial classes of drugs and that the onset of events like peripheral neuropathy could be rapid and irreversible. Moreover, as noted above, J&J specifically knew that the label's claim that peripheral neuropathy was "rare" was completely false because they learned in the 1990s through their own postmarketing review that "paraesthesia" (a peripheral nerve injury) was one of the three "most frequently reported AEs" in the U.S. *and* abroad. Defendants continued, through August 2013, to misrepresent in their product labels that cases of neuropathy were "rare."

170. Defendants also continued, through August 2013, to intentionally misrepresent that irreversible neuropathy could be avoided by simply discontinuing the drug upon the onset of symptoms. More specifically, until the August 2013 label change, Defendants' FLQ labels specifically stated that the drugs should be "discontinued if the patient experiences symptoms of neuropathy . . . in order to prevent the development of an irreversible condition." This statement is misleading because it implies that permanent peripheral neuropathy could be avoided by simply discontinuing the drug upon the onset of symptoms, which, as noted above, is false. Moreover, as noted herein, the current label for Levaquin remains misleading regarding the risk of developing irreversible peripheral neuropathy following the use of Levaquin.

171. The scientific and medical communities were misled as to the true nature of the risk and benefits of the Defendants' FLQ drugs in particular and in general as to the treatment needs and options for patients in need of antibiotic therapy. It was not until the FLQ label change in August 2013 regarding the rapid onset and potentially permanent nature of neuropathies that the truth began to be generally available in the scientific community. Even then, however, physicians had been so conditioned by the false science published and/or funded for years by Defendants that it was difficult for many of those physicians to accept the truth about the risks and lack of benefits associated with these FLQ drugs. This realization, that FLQ drugs have for years been overprescribed, which is supported by independent studies,[16] has once again prompted the FDA to

[16] *See* Lautenbach E, Larosa LA, Kasbekar N, Peng HP, Maniglia RJ, Fishman NO. Fluoroquinolone utilization in the emergency departments of academic medical centers: prevalence

take action. In November 2015, a FDA subcommittee advisory panel was convened wherein panel members noted that FLQ drugs are overprescribed for common infections when other treatments would work as well with less risk. The advisory panel called on the FDA to strengthen labeling warnings and clarify when FLQ drugs should—and should not—be used.

172. The misconceptions as to the true risks and benefits of Defendants' FLQ drugs were pervasive throughout the medical and scientific communities due to the marketing methods employed by Defendants that included the following:

(a) The publication of fraudulent scientific papers in scientific and medical literature;

(b) Providing false and misleading information to doctors during sales and detailing calls at the doctors' offices or at medical or scientific conferences and meetings;

(c) Funding and sponsoring physicians, consultants and/or Key Opinion Leaders to disseminate false and misleading scientific and medical information through medical journals and publications;

(d) Funding third-party companies (including DesignWrite, LLC) to disseminate false and misleading scientific and medical information through its publications and its members to physicians and patients;

(e) Funding continuing medical education to disseminate false and misleading information to doctors;

(f) Paying specialists in the field to meet with prescribing doctors for the purpose of disseminating false and misleading information about the risks and benefits of the FLQ drugs;

(g) Disseminating direct to consumers advertising to drive patients to their doctors' offices to ask for their FLQ drugs based on false and misleading

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of risk factors for inappropriate use. *Arch Intern Med*. 2003;163(5):601–605.

information regarding the risks and benefits of the drugs.

173. In particular, Defendants falsely and deceptively misrepresented material facts regarding the safety and effectiveness of FLQ drugs and fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of their products, including by concealing the following information:

(a) That there was evidence of peripheral paraesthesia associated with FLQ therapy as early as 1988;

(b) That there was evidence demonstrating that FLQs increase the risk of irreversible peripheral neuropathy as early as 1996;

(c) That the J&J Defendants in particular knew in the mid-1990s that cases of paraesthesia were one of the three "most frequently reported AEs" related to the central nervous system.

(d) That the FLQ drugs were not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy;

(e) The severity, frequency, rapid onset, and potentially disabling nature of peripheral neuropathy caused by the FLQ drugs;

(f) The wide range of injuries caused by FLQ drugs to multiple body systems (e.g., musculoskeletal, neuropsychiatric, peripheral nervous system, senses like vision or hearing, skin, and cardiovascular); and

(g) That FLQs should not be used as a first-line therapy to treat infections for which they are not required.

174. The misrepresentations and/or active concealments were perpetuated directly and/or indirectly by Defendants. Moreover, as a result of these efforts it was accepted by the medical and scientific communities that these FLQ drugs had a certain risk benefit profile that was shown to be completely false by independent studies, case series, J&J's own postmarketing experience, and individual AE reports (including those contained in the FDA AERS).

175. Defendants were in possession of evidence demonstrating that the FLQ drugs caused serious and sometimes debilitating side effects, including permanent peripheral neuropathies. Nevertheless, Defendants continued to market such products by providing false and misleading information with regard to its safety and efficacy to Plaintiff and Plaintiff's treating physicians.

176. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, their prescribing physicians, and the healthcare industry generally.

177. Defendants made these false representations with the intent or purpose that Plaintiff, their prescribing physicians, and the healthcare industry would rely on them, leading to the widespread use of FLQs by Plaintiff as well as the general public.

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

179. Plaintiff, its prescribing physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of FLQs that Defendants did suppress, conceal, or fail to disclose to Plaintiff's detriment. Plaintiff justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true dangers of FLQs. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or active concealment.

180. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested the Defendants' FLQ drugs and suffered injuries as set forth herein.

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

COUNT VII

[Negligent Misrepresentation]

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

182. Defendants negligently and/or recklessly misrepresented to Plaintiff, its prescribing physicians, and the healthcare industry the safety and effectiveness of FLQs and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by FLQ drugs.

183. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that FLQs had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physicians and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, Plaintiff's prescribing physicians, the health care industry, and the consuming public that:

(a) That there was evidence (e.g., Karlman, et al.) of peripheral paraesthesia associated with FLQ therapy (ciprofloxacin) as early as 1988;

(b) That there was evidence (e.g., Hedenmalm, et al.) demonstrating that FLQs increase the risk of irreversible peripheral neuropathy as early as 1996;

(c) That the J&J Defendants in particular knew in the mid-1990s that cases of paraesthesia were one of the three "most frequently reported AEs" related to the central nervous system.

(d) That the FLQ drugs were not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy;

(e) The severity, frequency, rapid onset, and potentially disabling nature of peripheral neuropathy caused by the FLQ drugs;

(f) The wide range of injuries caused by FLQ drugs to multiple body systems (e.g., musculoskeletal, neuropsychiatric, peripheral nervous system, senses

like vision or hearing, skin, and cardiovascular); and

(g) That FLQs should not be used as a first-line therapy for minor or uncomplicated infections.

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

185. 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, their prescribing physicians, and the healthcare industry.

186. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, their prescribing physicians, and the healthcare industry would rely on them, leading to the use of FLQs by Plaintiff as well as the general public.

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

188. Plaintiff justifiably relied on and/or were induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Defendants' FLQ drugs and relied on the absence of information regarding the dangers of these drugs which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

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

190. Defendants made the representations and actively concealed information about the defects and dangers of their FLQ drugs with the absence of due care such that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence

of information, in selecting these FLQs as a treatment.

191. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts as set forth above, Plaintiff ingested Defendants' FLQ drugs and suffered injuries as set forth herein.

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

COUNT VIII

[Fraudulent Concealment]

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

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

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

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

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

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

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

198. In breaching their duties to Plaintiff, Defendants used their position of trust as the manufacturer and/or distributor of FLQ drugs to increase sales of the drugs at the expense of informing Plaintiff that, by ingesting these drugs, they were placing themselves at a significantly-increased risk of developing irreversible peripheral neuropathy and/or injuries to multiple other body systems (e.g., musculoskeletal, neuropsychiatric, senses like vision or hearing, skin, and cardiovascular).

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

COUNT IX

[Violation of Consumer Protection Laws/Consumer Fraud Laws]

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

200. Plaintiff pleads this Count in the broadest sense available under the law, to include pleading same pursuant to all substantive law that applies to this case, as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

201. Plaintiff used Defendants' FLQ drugs and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

202. Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

(a) Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

203. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of their FLQ drugs.

204. Defendants violated consumer protection laws of various states.

205. Defendants uniformly communicated the purported benefits of their FLQ drugs while failing to disclose the serious and dangerous side effects related to the use of FLQs and of the true state of FLQs' safety, efficacy, and usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers, such as Plaintiff, in the marketing and advertising campaign described herein.

206. Defendants' conduct in connection with their FLQ drugs were also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of FLQs.

207. As a result of these violations of consumer protection laws, Plaintiff has incurred and will incur serious physical injury (including in some cases death), pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

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

PUNITIVE DAMAGES

208. At all times material hereto, Defendants knew or should have known that their FLQ drugs were inherently dangerous with respect to the risk of irreversible peripheral neuropathy.

209. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of their FLQ drugs.

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

211. At all times material hereto, Defendants knew and recklessly disregarded the fact that their FLQ drugs cause the chronic disease of irreversible peripheral neuropathy and/or injuries to multiple other body systems.

212. Notwithstanding the foregoing, Defendants continued to aggressively market their FLQ drugs to consumers, including Plaintiff herein, without disclosing the aforesaid side effect.

213. Defendants knew of their FLQ drug's lack of warnings regarding the risk of developing irreversible peripheral neuropathy and/or injuries to multiple other body systems, but they intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and/or sell their FLQ drugs without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by their FLQ drugs.

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

215. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy and/or injuries to multiple other body systems. Plaintiff has endured pain and suffering, have suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff's injuries and damages are prolonged and/or permanent and will continue into the future.

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

RELIEF REQUESTED

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

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

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

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

(d) For full refund of all purchase costs Plaintiff paid for Defendants' FLQ drugs;

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

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

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

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

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

JURY DEMAND

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

DATED: December 22, 2016

Respectfully submitted,

/s/ Derek T. Braslow
Derek T. Braslow
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Counsel for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

ZELDA ELLIS	:	CIVIL ACTION
v.	:	
JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC. and JANSSEN RESEARCH & DEVELOPMENT, L.L.C.,	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security -- Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

12/22/16	/s/ Derek T. Braslow	Zelda Ellis
Date	**Attorney-at-law**	**Attorney for**
610-941-4204	610-941-4245	dbraslow@pbmattorneys.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

JS 44 (Rev. 07/16)

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
Zelda Ellis

DEFENDANTS
JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC. and JANSSEN RESEARCH & DEVELOPMENT, L.L.C.,

(b) County of Residence of First Listed Plaintiff Los Angeles, CA
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Middlesex Cty, NJ
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Pogust Braslow Millrood, LLC
Eight Tower Bridge
161 Washington St., Ste 940
Conshohocken PA 19428
Phone: 610- 941-4204

Attorneys *(If Known)*

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

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

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

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

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

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

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

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

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

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

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

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

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
Brief description of cause:
Prescription Medication Levaquin

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.
DEMAND $
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*:
JUDGE John R. Tunheim DOCKET NUMBER MDL 2642 (0:15-md-2642)

DATE 12/22/16

SIGNATURE OF ATTORNEY OF RECORD
/s/ Derek T. Braslow

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 617 Kew St. #1, Inglewood, CA 90302

Address of Defendant: One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933

Place of Accident, Incident or Transaction: California

(*Use Reverse Side For Additional Space*)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☒

Does this case involve multidistrict litigation possibilities? Yes☒ No☐

RELATED CASE, IF ANY: MDL No. 2642; IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION

Case Number: _____ Judge _____ Date Terminated: _____

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☒ No☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases:*

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases
    (Please specify) _____

B. *Diversity Jurisdiction Cases:*

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☒ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases
    (Please specify) _____

ARBITRATION CERTIFICATION

(*Check Appropriate Category*)

I, Derek T. Braslow, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 12/22/16 /S/ Derek T. Braslow 78994

Attorney-at-Law Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 12/22/16 /S/ Derek T. Braslow 78994

Attorney-at-Law Attorney I.D.#

CIV. 609 (5/2012)