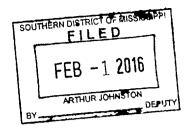
# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF MISSISSIPPI WESTERN DIVISION



Plaintiff,  v.  Complaint For Damages  AND  JOHNSON & JOHNSON; JANSSEN  RESEARCH & DEVELOPMENT, LLC; and  JANSSEN PHARMACEUTICALS, INC.;  Defendants.  Defendants.  1. Strict Liability  2. Product Liability – Failure to  Warn  3. Negligence  4. Breach of Express Warranty  5. Breach of Implied Warranty  6. Fraud  7. Negligent Representation  8. Fraudulent Concealment	WILMA CODY;	)
JOHNSON & JOHNSON; JANSSEN RESEARCH & DEVELOPMENT, LLC; and JANSSEN PHARMACEUTICALS, INC.;  Defendants.  Defendants.  Defendants.  Negligence  AND  DEMAND FOR JURY TRIAL  Strict Liability  2. Product Liability – Failure to  Warn  3. Negligence  4. Breach of Express Warranty  5. Breach of Implied Warranty  6. Fraud  7. Negligent Representation	Plaintiff,	) Case No.: 5:16cv 12 DCB-MTP
RESEARCH & DEVELOPMENT, LLC; and  JANSSEN PHARMACEUTICALS, INC.;  Defendants.  Defendants.  1. Strict Liability  2. Product Liability – Failure to  Warn  3. Negligence  4. Breach of Express Warranty  5. Breach of Implied Warranty  6. Fraud  7. Negligent Representation	v.	,
JANSSEN PHARMACEUTICALS, INC.;  ) 1. Strict Liability  2. Product Liability – Failure to  Warn  3. Negligence  4. Breach of Express Warranty  5. Breach of Implied Warranty  6. Fraud  7. Negligent Representation	JOHNSON & JOHNSON; JANSSEN	) DEMAND FOR JURY TRIAL
<ul> <li>Defendants.</li> <li>Warn</li> <li>3. Negligence</li> <li>4. Breach of Express Warranty</li> <li>5. Breach of Implied Warranty</li> <li>6. Fraud</li> <li>7. Negligent Representation</li> </ul>	RESEARCH & DEVELOPMENT, LLC; and	)
Defendants.  ) Warn ) 3. Negligence ) 4. Breach of Express Warranty ) 5. Breach of Implied Warranty ) 6. Fraud ) 7. Negligent Representation	JANSSEN PHARMACEUTICALS, INC.;	) 1. Strict Liability
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) 6. Fraud ) 7. Negligent Representation		) 4. Breach of Express Warranty
) 7. Negligent Representation		) 5. Breach of Implied Warranty
		) 6. Fraud
) 8. Fraudulent Concealment		) 7. Negligent Representation
		) 8. Fraudulent Concealment

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

#### INTRODUCTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of the pharmaceutical drug Levaquin® (also known as levofloxacin). Levaquin® in any of its forms shall herein be referred to as "Levaquin." Plaintiff maintains that Levaquin is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use.

#### **PARTIES**

- 2. Plaintiff Wilma Cody is a natural person and resident and citizen of Amite County, Mississippi. Plaintiff brings this action for personal injuries sustained by the use of Levaquin. As a direct and proximate result of being prescribed and ingesting Levaquin, Plaintiff developed peripheral neuropathy.
- 3. Defendant Johnson & Johnson is a New Jersey corporation that has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.
- 4. Defendant Johnson & Johnson has transacted and conducted business within the State of Mississippi.
- 5. Defendant Johnson & Johnson has derived substantial revenue from goods and products used in the State of Mississippi.
- 6. Defendant Johnson & Johnson expected or should have expected its acts to have consequences within the State of Mississippi, and derived substantial revenue from interstate commerce.
- 7. Defendant Johnson & Johnson was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.
- 8. Defendant Janssen Research & Development, LLC is a New Jersey limited liability company with its principal place of business in New Jersey.
- 9. Defendant Janssen Research & Development, LLC has transacted and conducted business within the State of Mississippi.
- 10. Defendant Janssen Research & Development, LLC has derived substantial revenue from goods and products used in the State of Mississippi.
- 11. Defendant Janssen Research & Development, LLC expected or should have expected their acts to have consequences within the State of Mississippi, and derived substantial

revenue from interstate commerce.

- 12. At all times material hereto, Defendant Janssen Research & Development, LLC conducted research, development, and testing on Levaquin.
- 13. Defendant Janssen Research & Development, LLC is part of the Defendant Johnson & Johnson's "Family of Companies."
- 14. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation which has its principal place of business in New Jersey.
- 15. Defendant Janssen Pharmaceuticals, Inc. has transacted and conducted business within the State of Mississippi.
- 16. Defendant Janssen Pharmaceuticals, Inc. has derived substantial revenue from goods and products used in the State of Mississippi.
- 17. Defendant Janssen Pharmaceuticals, Inc. expected or should have expected their acts to have consequences within the State of Mississippi, and derived substantial revenue from interstate commerce.
- 18. At all times material hereto, Defendant Janssen Pharmaceuticals, Inc. was the responsible U.S. entity for the design, manufacture, labeling, distribution, marketing, and sale of the drug Levaquin in the United States.
- 19. Defendant Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson.
  - 20. As used herein, "Defendants" includes all named Defendants.
- 21. Defendants are authorized to do business in Mississippi and derive substantial income from doing business in this state.
- 22. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities with Mississippi, thus invoking the benefits and protections of its laws.
- 23. Upon information and belief, 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**

- 24. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000, exclusive of interest and costs, and because Defendants are all either incorporated and have their principal place outside of the state in which the Plaintiffs resides.
  - 25. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.
- 26. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 in that Defendants conduct business here and are subject to personal jurisdiction in this District. Furthermore, Defendants sell, market and/or distribute Levaquin within Mississippi and this District.

#### **FACTUAL ALLEGATIONS**

- 27. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired and are responsible for Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the pharmaceutical drug Levaquin.
- 28. Plaintiff was prescribed Levaquin (500mg) from January 2010 through April 2011. Shortly thereafter, Plaintiff began experiencing symptoms of neuropathy. Plaintiff was subsequently diagnosed with neuropathy.
- 29. Plaintiff's use of Levaquin from 2010 through 2011 caused or substantially contributing to her developing neuropathy.
- 30. Levaquin was approved by the United States Food and Drug Administration (hereinafter "FDA") on December 20, 1996, for use in the United States, and is the brand name for the antibiotic levofloxacin.
- 31. Levaquin is a broad-spectrum fluoroquinolone antibiotic used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria.
- 32. In 2003, after generic versions of Cipro (a competing fluoroquinolone antibiotic) went on the market, Levaquin became the number one prescribed fluoroquinolone in the United

States.

- 33. 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.
- 34. In 2007, Levaquin was ranked 37 of the top 200 drugs that were prescribed in the United States.
  - 35. In 2007, Levaquin was ranked 19th in world sales of prescribed drugs.
- 36. In 2007, Levaquin accounted for 6.5% of Johnson & Johnson's total revenue, generating \$1.6 billion in revenue, an 8% increase over the previous year.
- 37. Defendant Janssen Pharmaceuticals, Inc. indicates on its website that "[i]n a large number of clinical trials, Levaquin has been shown to have a proven safety and efficacy profile for the treatment of many bacterial infections."
- 38. However, the scientific evidence has established a clear association between Levaquin and an increased risk of long-term and sometimes irreversible peripheral neuropathy.
- 39. Defendants knew or should have known that Levaquin is associated with an increased risk of developing irreversible peripheral neuropathy.
- 40. Defendants failed to appropriately and adequately inform and warn Plaintiff and Plaintiff's prescribing physicians of the serious and dangerous risks associated with the use of Levaquin concerning peripheral neuropathy, as well as other severe and personal injuries, which are permanent and/or long-lasting in nature, cause significant physical pain and mental anguish, diminished enjoyment of life, and the need for medical treatment, monitoring and/or medications.
- 41. The warning label for Levaquin during the period from September 2004 through August 2013 misled Plaintiff and her treating physician by incorrectly advising patients and physicians that peripheral neuropathy associated with Levaquin was "rare" and in any case could be avoided by discontinuing the drug upon the onset of certain symptoms. The truth, however, is that the onset of irreversible peripheral neuropathy is often rapid and discontinuation of the drug

will not ensure that the peripheral neuropathy is reversible.

- 42. Though this injury can be significant and debilitating, the language regarding the "rare" risk of peripheral neuropathy was buried at the bottom of a long list of adverse reactions that were included on the Levaquin label; the language was in no way highlighted for the benefit of prescribing physicians and patients.
- 43. Additionally, Defendants failed to disseminate a "Dear Doctor" letter to physicians concerning the label change or the risk of irreversible peripheral neuropathy, and Defendants failed to disclose this serious and dangerous effect when promoting Levaquin to physicians.
- 44. Despite their knowledge that Levaquin was associated with an elevated risk of permanent nerve damage, Defendants' promotional campaign was focused on Levaquin's purported "safety profile."
- 45. As early as 1990, there was evidence of the association of between quinolone drugs and peripheral neuropathy. Dr. Chan, et al. published an article reviewing 27 patients treated with the quinolone Peflox for urinary tract infections. One of the 27 patients developed peripheral neuropathy that resolved four weeks after discontinuation of Peflox. This case represents a positive "de-challenge."
- 46. In 1992, there was evidence of the association between fluoroquinolone antibiotics and peripheral neuropathy. Dr. Aoun from the Infectious Diseases Clinic and Microbiology Laboratory at the Institut Jules Bordet in Belgium, along with others, wrote a letter to the editor of the Lancet raising concerns about a 37-year old patient who developed peripheral neuropathy after taking fluoroquinolones.
- 47. A single well-documented case report can be viewed as a safety signal, particularly if the report describes a positive re-challenge.
- 48. In the pharmaceutical industry, safety signals indicate the need for further investigation.
  - 49. After a signal is identified, it should be further assessed to determine whether it

represents a potential safety risk that should be included in product label.

- 50. Four years later, in 1996, Karin Hedenmalm and Olav Spigset published "Peripheral sensory disturbances related to treatment with fluoroquinolones" based on a review of 37 separate reports of symptoms of peripheral nerve damage, highlighting concerns about numbness, pain, and muscle weakness.
- 51. One of the first studies in the United States that included the post market experience concerning Levaquin and neuropathy was "Peripheral Neuropathy Associated with Fluoroquinolones" written by Jay S. Cohen.
- 52. The Cohen paper was published in December 2001 and revealed that adverse events reported by forty-five patients suggested a possible association between fluoroquinolones and long-term peripheral nervous system damage. The study noted in particular the presence of severe and/or persistent nerve problems. Over one-half of the patients surveyed said their symptoms lasted for more than a year, and eighty percent characterized their symptoms as severe. The Cohen paper recommended further investigation of the association between fluoroquinolones and peripheral neuropathy. The study concluded with the following advisory: "If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is confirmed, physicians need to be informed and warnings might be considered for these drugs' product information."
- 53. In 2002 and 2003 Defendants were put on notice that numerous reports had been submitted to the FDA's Adverse Event Reporting System that identified fluoroquinolone users who had developed disabling peripheral neuropathy that persisted long after the drug had been discontinued.
- 54. A scientific review by the FDA of the adverse events in the FDA Adverse Event database in 2003 concerning Levaquin and other fluoroquinolones revealed numerous reports of long-term peripheral neuropathy.
- 55. In September 2004, an amended Levaquin label concerning peripheral nerve damage was approved by the FDA. The amended label included the following statement in the

#### Warnings section:

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

- 56. Thus, rather than warning patients and physician that the use of Levaquin may result in permanent nerve damage, Defendants instead adopted a warning that misleadingly indicated such damage was rare and in any event could be avoided by simply discontinuing the drug upon the onset of certain symptoms.
- 57. Defendants' failure to adequately warn physicians resulted in (1) patients receiving Levaquin instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which Plaintiff presented to the provider; (2) and physicians failing to warn and instruct consumers about the risk of peripheral nervous system injuries associated with Levaquin.
- 58. The failure of Defendants to include appropriate warnings in the label as published to the medical community also resulted in an absence of adequate warnings in patient information presented directly to consumers, either as part of samples packages or as part of the prescription they received from retail pharmacies.
- 59. Despite Defendants' knowledge and failure to adequately warn Plaintiff and her physicians of the above, Defendants continue to market Levaquin as a first line therapy for common bronchitis, sinusitis and other non-life threatening bacterial infections, conditions for which many other safer antibiotics are available.
- 60. In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that the existing warning regarding peripheral nerve damage was inadequate. On August 15, 2013, an

updated warning was issued in which the risk of rapid onset of irreversible peripheral neuropathy was finally included. The updated warning also removed the statement that nerve damage occurred only in rare cases.

- 61. Notwithstanding this updated 2013 label change, the label for Levaquin remains inadequate and confusing regarding the risk of developing irreversible peripheral neuropathy following the use of Levaquin.
- 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.
- 63. In January of 2014, Ayad Ali published "Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis" which reemphasized the link between fluoroquinolones and peripheral neuropathy and called for increased scrutiny of the risk-benefit of fluoroquinolone prescriptions. The Ali paper also detailed the presence of strong safety signals dating back to at least 2005 regarding the potential for Levaquin and other fluoroquinolones to cause long-term, disabling peripheral neuropathy.
  - 64. 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. 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).

# **EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS**

- 65. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.
- 66. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Levaquin.
- 67. The time, place and substance of the Defendants' alleged fraud is as follows. Before Levaquin was approved by the FDA in 1996, there was evidence in the medical literature of an association of between quinolone drugs and peripheral neuropathy.<sup>2</sup> Following approval, additional information came out in the medical literature (e.g., Cohen) reporting peripheral neuropathy events associated with fluoroquinolones.<sup>3</sup> The Cohen paper reported that in 33% of the reported cases, event onset was within twenty-four hours; for 84% onset was within seven days. Forty-seven percent of cases reported sensory and motor symptoms of peripheral neuropathy. The Cohen paper further reported that symptoms of peripheral neuropathy lasted

<sup>&</sup>lt;sup>1</sup> Etminan M, Brophy JM, Samii A. Oral fluoroquinolone use and risk of peripheral neuropathy: A pharmacoepidemiologic study. Neurology 2014; Epub 2014 Aug 22.

<sup>&</sup>lt;sup>2</sup> See, e.g., Chan, PC et al., Clinical experience with pefloxacin in patient with urinary tract infections, Br. J. Clin. Pract. 1990; Auon, M. et al. Peripheral neuropathy associated with fluoroquinolones. Letter to Editor. Lancet. 1992; Hedenmalm, K. et al. Peripheral sensory disturbances related to treatment of fluoroquinolones. J. Antimicrob. Chemother. 1996;37:831-7.

<sup>3</sup> See, e.g., Cohen, JS. Peripheral neuropathy assocated with fluoroquinolones. Annals of Pharmacotherapy. 2001.

longer than one month in 91% of cases; longer than three months in 71% of cases; and longer than two years in 27% of cases. Defendants were obligated under federal regulations to revise the labeling as soon as there was reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved. 21 C.F.R. 201.57(e). Despite the information from the medical literature noted above, as well as other information available to Defendants in their adverse event reporting system (AERS) and clinical trials, Defendants deliberately failed to update the Levaquin label to reflect the rapid onset of symptoms or the risk of developing permanent peripheral neuropathy. By June 2003, Defendants were communicating with the FDA's Office of Dietary Supplements (ODS) in conjunction with the ODS's scientific review of the labeling for fluoroquinolones, including Levaquin. Through these communications with ODS, Defendants were again made aware that the onset of neuropathic symptoms often occurs shortly after the initiation of fluoroquinolone use, and can be rapidly progressive and irreversible. Thus, despite the above-referenced information Defendants had obtained from the medical literature, the AERS database, the clinical trials, and its communications with ODS, Defendants knew, prior to Plaintiff's use of the drug, that central nervous system-related effects were more common with quinolones that with other antimicrobial classes of drugs and that the onset of events like peripheral neuropathy could be rapid and irreversible. Despite this information, Defendants mislead Plaintiff and his prescribing physician(s) by falsely telling them in the product label that "rare" events of peripheral neuropathy had been "reported in patients receiving quinolones" and in any case could be avoided by discontinuing the drug upon onset of certain symptoms: Patients should "discontinue [Levaquin] if symptoms occur in order to prevent irreversibility." As noted above, this information was misleading and false. Defendants knew by at least the mid-1990s that reports of permanent peripheral neuropathy were not "rare," that the event could occur shortly after initiation of drug therapy, and may be irreversible even after one dose, regardless of whether use of the drug was stopped when symptoms first developed.

68. Defendants similarly mislead Plaintiff through the Levaquin Medication Guide,

which advised that "Levaquin may need to be stopped to prevent permanent nerve damage," when in reality Defendants knew by at least the mid-1990s that peripheral neuropathy may be irreversible even after one dose, regardless of whether use of the drug was stopped.

- 69. The above-referenced misleading statements were contained in the Levaquin label and Medication Guide from 2004 through Plaintiff's use of the drug in 2011. Defendants provided this false information with the intent that it would be relied upon by Plaintiff and her prescribing physician(s), which it was. As a direct result Plaintiff's and her prescribing physician's reliance on this false information, Plaintiff was prescribed Levaquin and she took Levaquin, resulting in her developing permanent neuropathy.
- 70. Plaintiff first learned of a possible connection between the use of Levaquin and permanent peripheral neuropathy on or about August 2015, when she saw a lawyer's television commercial about the risk of developing permanent peripheral neuropathy from the use of fluoroquinolones like Levaquin and called the phone number listed in the commercial.
- manufacturers are held to the standard of experts on their products. And unlike ordinary consumers, prescription drug manufacturers are obligated to keep abreast of scientific knowledge, discoveries, advances and research in the field related to their products, and are presumed to know what is imparted thereby. Thus, ordinary consumers (such as Plaintiff) are not presumed, as are drug manufacturers, to have superior or continuing knowledge of medical and scientific evidence concerning the drugs they take, particularly with respect to drugs they have previously ingested. Thus, prior to contacting a law firm in August 2015, Plaintiff, as an ordinary consumer, had no reason to suspect that her use of Levaquin caused or contributed to her development of permanent peripheral neuropathy. This is particularly true given Defendants' fraudulent concealment of the risk of developing permanent peripheral neuropathy following the use of Levaquin (as noted above). In addition, physical symptoms alone, without knowing or being able to discern the cause, is insufficient to start the statute of limitations clock running. Moreover, Plaintiff was diagnosed with peripheral neuropathy on or about 2014, approximately

three years after she used Levaquin. No physician has ever told Plaintiff that her use of Levaquin caused her permanent peripheral neuropathy, only that the cause was unclear or of unknown etiology. Thus, prior to August 2015, Plaintiff had no reason to be suspicious of Defendants' fraudulent conduct or to have reasonably discovered the fraudulent conduct.

- 72. As a result of Defendants' actions, Plaintiff, and, upon information and belief, Plaintiff's treating physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.
- 73. Therefore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Levaquin. Defendants were under a duty to disclose the true character, quality, and nature of Levaquin because this was non-public information over which Defendants had and continues to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff, medical providers and/or to their facilities. In addition, Defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.
- 74. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, promoting and/or distributing a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendants' representations. Accordingly, Defendants are precluded by the discovery rule and/or the doctrine of fraudulent concealment from relying upon any statute of limitations.
- 75. For each Count hereinafter alleged and averred, the above and following Paragraphs should be considered re-alleged as if fully rewritten.

#### **COUNT I**

# [Strict Liability]

- 76. Levaquin was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Levaquin failed to warn of the dangerous risks posed by Levaquin, including the risk of developing irreversible peripheral neuropathy.
- 77. At all times alleged herein, Levaquin was defective and Defendants knew that Levaquin was to be used by consumers without inspection for defects. Moreover, Plaintiff, her prescribing physicians, and her health care providers neither knew nor had reason to know at the time of Plaintiff's use of Levaquin of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.
- 78. At all times alleged herein, Levaquin was prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.
- 79. The design of Levaquin was defective in that the risks associated with using Levaquin outweighed any benefits of the design. Any benefits associated with the use of Levaquin 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.
  - 80. The defect in design existed when the product left Defendants' possession.
- 81. At the time Levaquin left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting Levaquin.
- 82. As a result of Levaquin's defective condition, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred,

attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

# **COUNT II**

# [Product Liability – Failure to Warn]

- 83. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.
- 84. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Levaquin, and through that conduct have knowingly and intentionally placed Levaquin into the stream of commerce with full knowledge that it reaches consumers such as Plaintiff who ingested it.
- 85. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Levaquin to Plaintiff and to her prescribing physicians. Additionally, Defendants expected the Levaquin that they were selling, distributing, supplying, manufacturing, and/or promoting to reach and Levaquin did in fact reach prescribing physicians and consumers, including Plaintiff and her prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.
- 86. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and ingested by Plaintiff. The defective condition of Levaquin was due in part to the fact that it was not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of its use.
- 87. This defect caused serious injury to Plaintiff, who used Levaquin in its intended and foreseeable manner.
- 88. 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 the product did not

cause users to suffer from unreasonable and dangerous side effects.

- 89. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.
- 90. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Levaquin, namely irreversible peripheral neuropathy.
- 91. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Levaquin caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible peripheral neuropathy from Levaquin use, even though this side effect was known or reasonably scientifically knowable at the time of 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.
- 92. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.
- 93. Defendants, as the manufacturers and/or distributors of the subject product, are held to the level of knowledge of an expert in the field.
- 94. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.
- 95. Had Defendants properly disclosed the risks associated with Levaquin, Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using Levaquin.
- 96. 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 her

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

#### **COUNT III**

# [Negligence]

- 97. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.
- 98. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Levaquin.
- 99. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.
- 100. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:
  - a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Levaquin;
  - b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of Levaquin's dangerous and defective characteristics;
  - c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the subject product;
  - d) In promoting the subject product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause irreversible peripheral neuropathy;
  - e) In representing that the subject product was safe for its intended use

- when, in fact, the product was unsafe for its intended use;
- f) In failing to perform appropriate pre-market testing of the subject product;
- g) In failing to perform appropriate post-market surveillance of the subject product;
- h) In failing to adequately and properly test Levaquin before and after placing it on the market;
- In failing to conduct sufficient testing on Levaquin which, if properly performed, would have shown that Levaquin had the serious side effect of causing irreversible peripheral neuropathy;
- j) In failing to adequately warn Plaintiff and her healthcare providers that the use of Levaquin carried a risk of developing irreversible peripheral neuropathy;
- k) In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of irreversible peripheral neuropathy associated with the use of Levaquin; and
- In failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely irreversible peripheral neuropathy, from Levaquin ingestion as described herein.
- 101. Defendants knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.
- 102. 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, has 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 her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

#### **COUNT IV**

# [Breach of Express Warranty]

- 103. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.
- 104. Before Plaintiff was first prescribed Levaquin and during the period in which he used Levaquin, Defendants expressly warranted that Levaquin was safe.
- 105. Levaquin did not conform to these express representations because Levaquin was not safe and had an increased risk of serious side effects, including irreversible peripheral neuropathy, whether taken individually or in conjunction with other therapies.
- 106. 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 her favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

#### **COUNT V**

# [Breach of Implied Warranty]

- 107. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.
- 108. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold Levaquin, and prior to the time that it was prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff that the subject product was of merchantable quality and safe and fit

for the use for which it was intended.

- 109. Plaintiff, individually and through her prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.
- 110. Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.
- 111. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after he used it.
- 112. Contrary to the implied warranty for the subject product, Levaquin was not of merchantable quality, and it was neither safe nor fit for its intended uses and purposes, as alleged herein.
- 113. 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, has 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 Defendant as alleged herein.

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

### **COUNT VI**

#### [Fraud]

- 114. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.
- 115. Defendants misrepresented to Plaintiff, her prescribing physicians, and the healthcare industry the safety and effectiveness of Levaquin and/or fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the

safety and effectiveness of Levaquin.

- 116. Defendants made misrepresentations and actively concealed adverse information when Defendants knew, or should have known, that Levaquin had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physicians, and the healthcare industry generally. Specifically, Defendants actively concealed from Plaintiff, her prescribing physicians, the health care industry, and the consuming public that:
  - (a) As early as 1996, Defendants and/or their predecessors were in possession of data (e.g., Hedenmalm, et al.) demonstrating that fluoroquinolones, including Levaquin, increase the risk of irreversible peripheral neuropathy but Defendants actively concealed that information by failing to include it in their labeling for Levaquin at the time the drugs were initially approved by the FDA or at any time thereafter until the FDA mandated label change in 2013;
  - (b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Levaquin before and after its product launch;
  - (c) Levaquin was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and
  - (d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Levaquin increases the risk of irreversible peripheral neuropathy.
- 117. These misrepresentations and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.
- 118. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, her

prescribing physicians, and the healthcare industry.

- 119. Defendants made these false representations with the intent or purpose that Plaintiff, her prescribing physicians, and the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiff as well as the general public.
- 120. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, her physicians would not have prescribed and Plaintiff would not have utilized the subject product.
- 121. Plaintiff, her 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 Levaquin 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 Levaquin. 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.
- 122. Defendants had a post-sale duty to warn Plaintiff, her prescribing physicians, and the general public about the potential risks and complications associated with Levaquin in a timely manner.
- 123. Defendants made the representations and actively concealed information about the defects and dangers of Levaquin with the intent and specific desire that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Levaquin as a treatment.
- 124. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested Levaquin and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in her favor for compensatory and punitive damages, together with interest, costs herein incurred,

attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

# **COUNT VII**

# [Negligent Misrepresentation]

- 125. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.
- 126. Defendants negligently and/or recklessly misrepresented to Plaintiff, her prescribing physicians, and the healthcare industry the safety and effectiveness of Levaquin and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Levaquin.
- 127. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that Levaquin had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physician(s) and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, her prescribing physicians, the health care industry, and the consuming public that:
  - (a) As early as 1996, Defendants and/or their predecessors were in possession of data (e.g., Hedenmalm, et al.) demonstrating that fluoroquinolones, including Levaquin, increase the risk of irreversible peripheral neuropathy but Defendants failed to include it in their labeling for Levaquin at the time the drugs were initially approved by the FDA or at any time thereafter until the FDA mandated label change in 2013;
  - (b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Levaquin before and after its product launch;
  - (c) Levaquin was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and

- (d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Levaquin increases the risk of irreversible peripheral neuropathy.
- 128. These negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.
- 129. 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, his prescribing physicians, and the healthcare industry.
- 130. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, her prescribing physicians, and the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiff as well as the general public.
- 131. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, his physicians would not have prescribed and Plaintiff would not have utilized the subject product.
- 132. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Levaquin and relied on the absence of information regarding the dangers of Levaquin which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.
- 133. Defendants had a post-sale duty to warn Plaintiff, her prescribing physicians, and the general public about the potential risks and complications associated with Levaquin in a timely manner.
- 134. Defendants made the representations and actively concealed information about the defects and dangers of Levaquin with the absence of due care such that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence

of information, in selecting Levaquin as a treatment.

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

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

#### **COUNT VIII**

# [Fraudulent Concealment]

- 136. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.
- 137. Defendants committed actual fraud by making material representations that were false, knowing that such material representations were false, and/or with reckless disregard for the truth or falsity of such material representations with the intent that Plaintiff and his prescribing physicians would rely on such material representations.
- 138. Plaintiff and his 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.
- 139. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiff, his 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 his prescribing physicians would rely on Defendants' misrepresentations. Plaintiff and his prescribing physicians did, in fact, act in actual and justifiable reliance on Defendants' representations, and Plaintiff was injured as a result.
  - 140. At all times herein mentioned, Defendants had a duty to Plaintiff, his

prescribing physicians, and the general public to accurately inform them of risks associated with Levaquin because Defendants, as the manufacturer and/or distributor of the subject product, were in a position of superior knowledge and judgment regarding any potential risks associated with Levaquin.

- 141. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Levaquin at issue in this lawsuit, said breach or breaches constituting fraud because of his propensity to deceive others or constitute an injury to public interests or public policy.
- 142. In breaching their duties to Plaintiff, Defendants used their position of trust as the manufacturer and/or distributor of Levaquin to increase sales of the drug at the expense of informing Plaintiff that, by ingesting Levaquin, she was placing herself at a significantly-increased risk of developing irreversible peripheral neuropathy.

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

#### **PUNITIVE DAMAGES**

- 143. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.
- 144. At all times material hereto, Defendants knew or should have known that Levaquin was inherently dangerous with respect to the risk of irreversible peripheral neuropathy.
- 145. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Levaquin.
- 146. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the subject product.
  - 147. At all times material hereto, Defendants knew and recklessly disregarded the

fact that Levaquin causes the chronic illness irreversible peripheral neuropathy.

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

- 149. Defendants knew of the subject product's lack of warnings regarding the risk of irreversible peripheral neuropathy, but they intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and/or sell Levaquin without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Levaquin.
- 150. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable them to weigh the true risks of using Levaquin against its benefits.
- 151. 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. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff' injuries and damages are permanent and will continue into the future.
- 152. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

#### RELIEF REQUESTED

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

(a) For general (non-economic) and special (economic) damages in a sum in

excess of the jurisdictional minimum of this Court;

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

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

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

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

this Court;

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

this Court;

(g) For punitive damages in an amount in excess of any jurisdictional

minimum of this Court and in an amount sufficient to impress upon

Defendants the seriousness of their conduct and to deter similar

conduct in the future;

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

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

By:

**JURY DEMAND** 

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

Dated: January 27, 2016

AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC

Respectfully submitted,

Justin G./Witkin (MSB 100827)

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Pensacola, FL 32502 Phone: (850) 202-1010

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Attorney for Plaintiff

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S 44 (Rev. 12:12)

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 layed rules of court. This form approved by the Judicial Conference of the United States in Sentember 1974 is required for the use of the Clerk of Court for the

purpose of initiating the civil de			the United States in September 1 THIS FORM.)	1974, is required for the use of	the Clerk of Court for the
I. (a) PLAINTIFFS WILMA CODY			DEFENDANTS OHNSON & JOHNSON; JANSSEN RESEARCH & DEVELOPMENT, LC; and JANSSEN PHARMACEUTICALS, INC		
(b) County of Residence of (E.	First Listed Plaintiff <u>F</u> CCEPT IN U.S. PLAINTIFF C	larria de la	County of Residence	of First Listed Defendant (IN U.S. PLAINTIFF CASES O  DEFINATION CASES, USE T  OF LAND INVOLVED.	•
(c) Attorneys (Firm Name, Aylstock, Witkin, Kreis, & 17 East Main St., Ste. 20 PH: 850-202-1010	Overholtz, PLLC	MATHUR 3	Attorneys (If Known)		
II. BASIS OF JURISDI	CTION (Place an "X" in C	ne Box Only)		RINCIPAL PARTIES	(Place an "X" in One Box for Plaintiff
☐ 1 U.S. Government Plaintiff	☐ 3 Federal Question (U.S. Government)	Not a Party)		TF DEF  1	
☐ 2 U.S. Government Defendant	☑ 4 Diversity  (Indicate Citizensh	ip of Parties in Item III)	Citizen of Another State		
			Citizen or Subject of a  Foreign Country	3 🗇 3 Foreign Nation	
IV. NATURE OF SUIT		- *		-	
CONTRACT  ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment	PERSONAL INJURY  ☐ 310 Airplane ☐ 315 Airplane Product ☐ Liability ☐ 320 Assault, Libel &	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 Product Liability  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   3462 Naturalization Application Actions   3463 Other Immigration Actions	BANKRUPTCY  □ 422 Appeal 28 USC 158 □ 423 Withdrawal 28 USC 157  PROPERTY RIGHTS □ 820 Copyrights □ 840 Trademark  SOCIAL SECURITY □ 861 HIA (1395ff) □ 862 Black Lung (923) □ 863 DIWC/DIWW (405(g)) □ 864 SSID Title XVI □ 865 RSI (405(g))  FEDERAL TAX SUITS □ 870 Taxes (U.S. Plaintiff or Defendant) □ 871 IRS—Third Party 26 USC 7609	OTHER STATUTES  375 False Claims Act 400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 850 Securities/Commodities/Exchange 890 Other Statutory Actions 891 Agricultural Acts 893 Environmental Matters 895 Freedom of Information Act 896 Arbitration 899 Administrative Procedure Act Review or Appeal of Agency Decision 950 Constitutionality of State Statutes
VI. CAUSE OF ACTION VII. REQUESTED IN	moved from  and 3  Cite the U.S. Civil St. 28 U.S.C. § 1367  Brief description of citizes  CHECK IF THIS	Appellate Court  itute under which you are f  ituse: inship  IS A CLASS ACTION	(specify aling (Do not cite jurisdictional state) DEMAND \$	cr District Litigation  tutes unless diversity).  CHECK YES only	if demanded in complaint:
COMPLAINT: VIII. RELATED CASI IF ANY	UNDER RULE 2  (See instructions):	JUDGE John Tunheir	75,000.00 m (D. Minn.)	JURY DEMAND	
DATE JACKET TO THE FOR OFFICE USE ONLY		SIGNATURE OF ATTO		DOCKET NOMBER III	
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