UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION

FRANK A. MOORE,	)	
	)	
Plaintiff,	)	
	)	**Docket No.**
	)	
v.	)	
	)	**COMPLAINT AND**
TAKEDA PHARMACEUTICALS USA, INC; TAKEDA PHARMACEUTICALS AMERICA, INC; TAKEDA DEVELOPMENT CENTER AMERICAS, INC; TAKEDA PHARMECUETICALS INTERNATIONAL, INC; TAKEDA PHARMACEUTICAL COMPANY LIMITED,	)	**DEMAND FOR JURY TRIAL**
	)	
Defendants.	)	

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, by his attorneys, **CRUMLEY ROBERTS LLP** and **ZONIES LAW LLC**, allege as follows:

SUBJECT MATTER JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as Plaintiff is a citizen of North Carolina, which is different from the states where the Defendants are incorporated and have their principal places of business. Plaintiff is a citizen of the United States of America, and a resident of the City of Rutherfordton, in Rutherford County, in the State of North Carolina.

2. Venue is proper within this District pursuant to 28 U.S.C. § 1391 because it is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c).

NATURE OF CASE

3. This is an action for personal injury action on behalf of Plaintiff, Frank A. Moore, against Defendants who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling proton pump inhibitor ("PPI"s) prescription and over-the-counter medications such as Prevacid, herein collectively referred to as PPIs.

4. Plaintiff, Frank A. Moore used Prevacid which caused him to suffer from Renal Insufficiency and Renal Failure in late 2015.

PARTY DEFENDANTS AND PERSONAL JURISDICTION

5. Defendant TAKEDA PHARMACEUTICALS USA, INC. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

6. Defendant TAKEDA PHARMACEUTICALS AMERICA, INC. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

7. Defendant TAKEDA DEVELOPMENT CENTER AMERICAS, INC. is an Illinois corporation which has its principal place of business at 208 South LaSalle Street, Chicago, IL 60604.

8. Defendant TAKEDA PHARMACUETICALS INTERNATIONAL, INC. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

9. Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chrome, Chuo-ku, Osaka 540-8645.

10. On information and belief, TAKEDA PHARMACEUTICALS USA INC is either the direct or indirect owner of substantially all the stock or other ownership interests of TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC., TAKEDA PHARMACEUTICALS INTERNATIONAL, INC., and TAKEDA PHARMACEUTICAL COMPANY LIMITE.

11. In doing the acts alleged herein, said Takeda Defendants (including TAKEDA PHARMACEUTICALS USA INC, TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC., TAKEDA PHARMACEUTICALS INTERNATIONAL, INC., and TAKEDA PHARMACEUTICAL COMPANY LIMITED) were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence, and ratification of each other (hereinafter TAKEDA PHARMACEUTICALS USA INC, TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC., TAKEDA PHARMACEUTICALS INTERNATIONAL, INC., and TAKEDA PHARMACEUTICAL COMPANY LIMITED are collectively referred to as “TAKEDA”).

12. On information and belief, Defendants have transacted and conducted business in the State of North Carolina, and/or contracted to supply goods and services within the State of North Carolina, and these causes of action have arisen from the same.

13. On information and belief, at all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States of America and the State of North Carolina.

14. On information and belief, at all relevant times, Defendants derived and derive substantial revenue from goods and products used in the State of North Carolina and from interstate commerce.

15. On information and belief, at all relevant times, Defendants committed tortious acts within the State of North Carolina causing injury within the State of North Carolina, out of which act(s) these causes of action arise.

SUMMARY OF THE CASE

16. As a result of the defective nature of PPIs, persons who ingested this product, including Plaintiff, have suffered and may continue to suffer from kidney injuries including acute interstitial nephritis ("AIN"), acute kidney injuries ("AKI"), chronic kidney disease ("CKD") and renal failure, also known as end-stage renal disease ("ESRD").

17. Defendants concealed and continue to conceal their knowledge of PPIs' unreasonably dangerous risks from Plaintiff, his physicians, other consumers, and the medical community. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the magnified risk of kidney injuries related to the use of PPIs.

18. As a result of Defendants' actions and inactions, Plaintiff was injured due to his ingestion of PPIs, which caused and will continue to cause Plaintiff's injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

FACTUAL ALLEGATIONS

19. Over 60 million Americans experience heartburn, a major symptom of Gastrointestinal GERD, at least once a month and some studies have suggested more than 15 million Americans experience heartburn on a daily basis.

20. About 21 million Americans used one or more prescription PPIs in 2009 accounting for nearly 20% of the drugs' global sales and earning an estimated $11 billion annually.

21. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

22. PPIs are one of the most commercially successful groups of medication in the United States. Upon information and belief, between the period of 2008 and 2013, prescription PPIs had a sale of over $50 billion with approximately 240 million units dispensed.

23. Defendants, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed, promoted, and sold PPIs.

24. In October of 1992, three years after the FDA's initial PPI approval, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article associating PPI usage with kidney injuries in The American Journal of Medicine, followed by years of reports from national adverse drug registries describing this association.

25. In 2006, researchers at the Yale School of Medicine conducted a case series published in the International Society of Nephrology's Kidney International finding that PPI use, by way of AIN, left most patients "with some level of chronic kidney disease."

26. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a petition with the FDA to add black box warnings and other safety information concerning several risks associated with PPIs including AIN.

27. According to the petition, at the time of its filing there was "no detailed risk information on any PPI for this adverse effect."

28. On October 31, 2014, more than three years after Public Citizen's petition, the FDA responded by requiring consistent labeling regarding risk of AIN on all prescription PPIs.

29. The FDA noted "that the prescription PPI labeling should be consistent with regard to this risk" and that "there is reasonable evidence of a causal association."

30. In December of 2014, the labels of prescription PPIs were updated to read:

> *Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [Brand] if acute interstitial nephritis develops.*

31. The FDA did **not** require the consistent labeling regarding risk of AIN on over-the-counter PPIs.

32. In January of 2016, a study published in the Journal of the American Medical Association found that PPI use was independently associated with a 20 – 50% higher risk of CKD.

33. In February of 2016, a study published in the Journal of the American Society of Nephrology found that "exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD."

34. To date, over-the-counter PPIs lack detailed risk information for AIN.

35. To date, prescription and over-the-counter PPIs lack detailed risk information for CKD.

36. Parietal cells in the stomach lining secrete gastric juices containing hydrochloric acid to catalyze the digestion of proteins.

37. Excess acid secretion results in the formation of most ulcers in the gastroesophageal system and symptoms of heartburn and acid reflux.

38. PPIs irreversibly block the acidic hydrogen/potassium ATPase enzyme system (H+/K+ ATPase) of the gastric parietal cells, thereby halting the production of most hydrochloric acid.

39. In spite of their commercial success and global popularity, up to 70% of PPIs may be used inappropriately for indications or durations that were never tested or approved.

40. As a result of the defective nature of PPIs, even if used as directed by a physician or healthcare professional, persons who ingested PPIs have been exposed to significant risks stemming from unindicated and/or long-term usage.

41. From these findings, PPIs and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate acute interstitial nephritis ("AIN"), a sudden kidney inflammation that can result in mild to severe problems.

42. PPI-induced AIN is difficult to diagnose with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea, and weakness.

43. In April 2016, a study published in the Journal of Nephrology suggested that the development of and failure to treat AIN could lead to chronic kidney disease and end-stage renal disease, which requires dialysis or kidney transplant to manage.

44. CKD describes a slow and progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

45. Prompt diagnosis and rapid withdrawal of the offending agent are key in order to preserve kidney function. While AIN can be treated completely, once it has progressed to CKD it is incurable and can only be managed, which, combined with the lack of numerous early-onset symptoms, highlights the need for screening of at-risk individuals.

46. Consumers, including the Plaintiff, who have used PPIs for the treatment of increased gastric acid, have and had several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with PPI therapy.

47. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with PPI use.

48. Defendants concealed and continue to conceal their knowledge that PPIs can cause kidney injuries from Plaintiff, other consumers, and the medical community. Specifically, Defendants have failed to adequately inform consumers and the prescribing medical community

against the serious risks associated with PPIs and have completely failed to warn against the risk of CKD and ESRD.

49. As a result of Defendants' actions and inactions, Plaintiff was injured due to his ingestion of PPIs, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

50. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

51. As a direct result of ingesting PPIs, Plaintiff has been permanently and severely injured, having suffered serious consequences from PPI use. Plaintiff requires and will in the future require ongoing medical care and treatment.

52. Plaintiff, as a direct and proximate result of PPI use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living related expenses due to his new lifestyle.

53. Plaintiff would not have used PPIs had Defendants properly disclosed the risks associated with long-term use.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

54. The running of any statute of limitation has been tolled by reason of the Defendants' conduct. The Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with PPIs.

55. As a result of the Defendants' actions, Plaintiff and 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.

56. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPIs. The Defendants were under a duty to disclose the true character, quality and nature of PPIs because this was non-public information that the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers, and/or to their health facilities.

57. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting 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 Defendants' representations.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

58. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

59. Defendants had a duty to Plaintiff to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, labeling, supplying, promoting, packaging, sale and/or distribution of PPI's into the stream of commerce, including a duty to assure that PPI's would not cause users to suffer unreasonable, dangerous side effects such as kidney injuries.

60. Defendants failed to exercise ordinary care and/or were reckless in designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of PPIs into interstate commerce in that Defendants knew or should have known that using PPIs caused a risk of unreasonable, dangerous side effects, including kidney injuries.

61. Despite the fact that Defendants knew or should have known that PPIs were associated with and/or caused kidney injuries, Defendants continued to market, manufacture, distribute and/or sell PPIs to consumers, including the Plaintiff.

62. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

63. Defendants' negligence and/or recklessness were the proximate cause of Plaintiff's injuries, harm and economic loss which he suffered and/or will continue to suffer.

64. As a result of Defendants' negligence and/or recklessness the Plaintiff was caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff's kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above.

65. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiff is informed, believes, and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

66. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

SECOND CAUSE OF ACTION
AS AGAINST DEFENDANTS
(FAILURE TO WARN)

67. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

68. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced PPIs into the stream of commerce, and in the course of same, directly advertised or marketed PPIs to consumers or persons responsible for consumers, and therefore, had a duty to both the Plaintiff directly and Plaintiff's physician to warn of risks associated with the use of the Product.

69. Defendants had a duty to warn of adverse drug reactions, which they know or have reason to know can be caused by the use of PPIs and/or are associated with the use of PPIs.

70. The PPIs manufactured and/or supplied by the Defendants were defective due to inadequate post-marketing warnings and/or instructions because, after the Defendants knew or should have known of the risks of kidney injuries from PPI use, they failed to provide adequate warnings to consumers of the product, including Plaintiff and Plaintiff's physicians, and continued to aggressively promote PPIs.

71. Due to the inadequate warning regarding kidney injuries, PPIs were in a defective condition and unreasonably dangerous at the time that it left the control of the Defendants.

72. Defendants' failure to adequately warn Plaintiff and Plaintiff's prescribing physicians of renal insufficiency and renal failure risks prevented Plaintiff's prescribing physicians and Plaintiff from correctly and fully evaluating the risks and benefits of PPIs.

73. Had Plaintiff been adequately warned of the potential life-threatening side effects of the Defendants' PPI, Plaintiff would not have purchased or taken the PPI and could have chosen to request other treatments or prescription medications.

74. Upon information and belief, had Plaintiff's prescribing physicians been adequately warned of the potential life-threatening side effects of the Defendants' PPI, Plaintiff's prescribing physicians would have discussed the risks of kidney injuries and PPIs with the Plaintiff and/or would not have prescribed it.

75. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages.

76. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(DEFECTIVE DESIGN)

77. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

78. PPIs were expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

79. At all times relevant, PPIs were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff.

80. PPIs as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation in that when they left the hands of the manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of PPIs.

81. PPIs as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, because they were unreasonably dangerous and/or more dangerous than the ordinary consumer would expect when they left the hands of Defendants' manufacturers and suppliers.

82. At all times herein mentioned, the PPIs were in a defective condition and were unsafe, and Defendants knew and had reason to know that the product was defective and inherently unsafe, especially when PPIs were used in a form and manner instructed and provided by Defendants.

83. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, common, intended use.

84. At the time of Plaintiff's use of PPIs, they were being used for their intended purpose, and in a manner that was normally intended.

85. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed a defective product that caused an unreasonable risk to the health of consumers, and to Plaintiff in particular, and Defendants are therefore liable for the injuries and damages sustained by Plaintiff.

86. At the time Defendants' product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of their product. This was demonstrated by the existence of other treatments that had a more established safety profile and a considerably lower risk profile.

87. Plaintiff could not, by the reasonable exercise of care, have discovered PPIs defects and perceived their danger.

88. The defects in Defendants' product were substantial and contributing factors in causing Plaintiff's injuries.

89. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages.

90. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

91. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

92. Defendants expressly warranted that PPIs were safe for their intended use and as otherwise described in this complaint. PPIs did not conform to these express representations, including, but not limited to, the representation that they were safe and the representation that they did not have high and/or unacceptable levels of side effects like kidney injuries.

93. The express warranties represented by the Defendants were a part of the basis for Plaintiff's use of PPIs and Plaintiff relied on these warranties in deciding to use PPIs.

94. At the time of the making of the express warranties, the Defendants had knowledge of the purpose for which the PPIs were to be used, and warranted same to be in all respects safe, effective and proper for such purpose.

95. PPIs do not conform to these express representations because PPIs are not safe or effective and may produce serious side effects, including kidney injuries, degrading Plaintiff's health.

96. As a result of the foregoing breach of express warranty the Plaintiff was caused to suffer Renal Insufficiency and Renal Failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff's kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences and sequela.

97. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to his use of Defendants' PPI drug.

98. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

99. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

FIFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTY
FOR A PARTICULAR PURPOSE)

100. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

101. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold PPIs.

102. The Defendants impliedly represented and warranted to the users of PPIs that PPIs were safe and fit for the particular purpose for which said product was to be used.

103. These representations and warranties aforementioned were false, misleading, and inaccurate in that PPIs were unsafe, and degraded Plaintiff's health.

104. Plaintiff relied on the implied warranty of fitness for a particular use and purpose.

105. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether PPIs were safe and fit for their intended use.

106. PPIs were injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

107. Defendants breached the aforesaid implied warranty, as their PPIs were not fit for their intended purposes and uses.

108. As a result of the foregoing breach of warranty, the Plaintiff was caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff's kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences

109. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

110. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY)

111. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

112. Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold PPIs.

113. Defendants marketed, sold and distributed PPIs and knew and promoted the use for which PPIs were being used by Plaintiff and impliedly warranted to Plaintiff that PPIs were of merchantable quality and fit for the ordinary purpose for which they were intended.

114. These representations and warranties aforementioned were false, misleading, and inaccurate in that PPIs were unsafe, and degraded Plaintiff's health.

115. Plaintiff reasonably relied on the skill, expertise and judgment of the Defendants and their representations as to the fact that PPIs were of merchantable quality.

116. The PPIs manufactured and supplied by the Defendants were not of merchantable quality, as warranted by the Defendants in that the drug had dangerous and life threatening side effects and were thus not fit for the ordinary purpose for which they were intended.

117. As a direct and proximate result of the foregoing, Plaintiff was caused bodily injury, pain and suffering and economic loss.

118. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future kidney injuries, reasonable fear of future kidney function

decline, any and all life complications caused by Plaintiff's kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

119. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

120. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (VIOLATION OF THE NORTH CAROLINA UNFAIR & DECEPTIVE TRADE PRACTICES ACT (N.C. Gen. Stat. § 75-1.1))

121. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

122. Defendants have intentionally and wrongfully disseminated deceptive, inaccurate, false and misleading material information as to the safety of PPIs to Plaintiff's physicians, Plaintiff, and other consumers.

123. Defendants knew or reasonably should have known that PPIs carried the risk of serious adverse effects, including but not limited to Renal Insufficiency and Renal Failure, to its intended users, including Plaintiff.

124. Defendants failed to disclose material facts in the conduct of trade or commerce in that they did not disclose the risk of serious adverse effects to the intended users of PPIs.

125. Reasonable consumers, including Plaintiff, were injured by Defendants' unfair and deceptive acts.

126. By reason of the foregoing, Plaintiffs were caused bodily injury, pain, suffering and economic loss.

127. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered actual damages and requests an award of damages against Defendants, as authorized by North Carolina General Statute § 75-1.1, et seq. Plaintiff is entitled to statutory damages, costs and reasonable attorney's fees, plus disgorgement of any profits Defendants earned as a result of their violation of the law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Awarding Plaintiff's attorney's fees;

3. Awarding Plaintiff the costs of these proceedings; and

4. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, Frank Moore, hereby demands trial by jury as to all issues and claims so triable.

Date: November 7, 2016

Respectfully submitted,

CRUMLEY ROBERTS, LLP

/s/ Brian L. Kinsley
Brian L. Kinsley
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JS 44 (Rev. 11/15)

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
Frank A. Moore

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
CRUMLEY ROBERTS, LLP
2400 Freeman Mill Rd
Greensboro, NC 27406 (336) 333-9899

DEFENDANTS
TAKEDA PHARMACEUTICALS USA, INC; TAKEDA PHARMACEUTICALS AMERICA, INC; TAKEDA DEVELOPMENT CENTER AMERICAS, INC; TAKEDA PHARMACEUTICAL COMPAN

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

Attorneys *(If Known)*

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

- ❒ 1 U.S. Government Plaintiff
- ❒ 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

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332 (a)(1)
Brief description of cause:
Products liability litigation

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 _____ DOCKET NUMBER _____

DATE 11/07/2016
SIGNATURE OF ATTORNEY OF RECORD /s/ Brian L. Kinsley

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

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

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

V. Origin. Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

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

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

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

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