IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

WAYNE SAMUELS, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA LP, MERCK & CO. INC. D/B/A MERCK, SHARP & DOHME CORPORATION, PFIZER, INC., TAKEDA PHARMACEUTICALS USA, INC., TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC. F/K/A TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC., TAKEDA PHARMACEUTICAL COMPANY LIMITED, Defendants.	Civil Action No.: Judge: Magistrate Judge: JURY TRIAL DEMANDED

COMPLAINT

COMES NOW, Plaintiff, Wayne Samuels, by and through the undersigned counsel, and brings this Complaint against the above named defendants (collectively, "Defendants"), and further alleges, upon information and belief, except that information based upon personal knowledge, as follows:

I. INTRODUCTION

1. This is a personal injury action against Defendants, and their affiliates, subsidiaries, alter-egos, and/or joint venturers, who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling drugs belonging to the class of pharmaceuticals known as proton pump inhibitors ("PPIs").

2. As used herein, the terms "PPIs" or "PPI Products" include, but is not limited to Prilosec, Prilosec OTC, Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Protonix and Dexilant.

3. PPIs are used to suppress the production of acid in order to reduce the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers, as well as to treat gastroesophageal reflux disease ("GERD") and certain pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

4. PPIs can cause extremely serious and dangerous kidney injuries, including acute kidney injury (AKI), acute interstitial nephritis (AIN), chronic kidney disease (CKD), and end-stage renal disease (ESRD), which is also known as "renal failure" or "kidney failure," as well as life-threatening complications thereof and even death. Hereinafter, any of the foregoing conditions may be referred to as a "kidney injury," and all may collectively be referred to as "kidney injuries."

5. Plaintiff in this case, Wayne Samuels, ingested PPI Products in the manner intended and as directed by Defendants and/or Plaintiff's physicians.

6. As a direct and proximate result of Plaintiff's use of PPIs, Plaintiff suffered and will continue to suffer injuries and damages.

II. JURISDICTION AND VENUE

7. This Court has diversity jurisdiction over the claims in this Complaint because the aggregate amount in controversy exceeds the sum of $75,000.00 and is between citizens of different states. 28 U.S.C. § 1332(a)(1).

8. Venue is proper within this District under 28 U.S.C. § 1391 because injuries sustained by the Plaintiff, as described herein, occurred in this District.

III. DEFENDANT PARTIES

9. Defendant AstraZeneca Pharmaceuticals LP is and, at all times relevant to this action, has been a Delaware limited partnership having a principal place of business at 1800 Concord Pike, Wilmington, DE 19850.

10. Defendant AstraZeneca Pharmaceuticals LP is and, at all times relevant to this action, has been a wholly owned subsidiary of AstraZeneca PLC and is comprised of four partners, AstraZeneca AB, Zeneca Inc., Astra US Holdings Corporation and Astra USA LLC.

11. Defendant AstraZeneca LP is and, at all times relevant to this action, has been a Delaware limited partnership having a principal place of business at 1800 Concord Pike, Wilmington, DE 19850. Defendant AstraZeneca LP is and, at all times relevant to this action, has been a wholly owned subsidiary of AstraZeneca PLC.

12. Defendant AstraZeneca LP is comprised of a sole partner, Defendant AstraZeneca Pharmaceuticals LP.

13. Defendant AstraZeneca Pharmaceuticals LP and Defendant AstraZeneca LP are referred to collectively herein as the "AstraZeneca Defendants."

14. Each of the AstraZeneca Defendants was the agent and employee of the other AstraZeneca Defendants and, in doing the things alleged, was acting within the course and scope

of such agency and employment and with the other AstraZeneca Defendants' actual and implied permission, consent, authorization and approval.

15. The AstraZeneca Defendants, in collaboration amongst themselves, designed, tested, researched and developed the prescription and non-prescription over-the-counter Prilosec (omeprazole) and Nexium (esomeprazole) products.

16. As a part of their business and at all relevant times, the AstraZeneca Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of both prescription and over-the-counter Prilosec and Nexium products.

17. In 1982, the AstraZeneca Defendants entered a joint venture with Defendant Merck to design and develop the first proton pump inhibitor.

18. The result of this joint-venture was the development of omeprazole, which was ultimately marketed and sold under the brand name Prilosec.

19. In September 1989, the FDA approved Prilosec for healing of erosive esophagitis, maintenance of healing erosive esophagitis and treatment of GERD.

20. The AstraZeneca Defendants hold and have held the patent for the drug Prilosec which, by the year 2000, was the most widely prescribed drug in the world.

21. In an agreement reached in 1997, the AstraZeneca Defendants licensed to the Procter & Gamble Defendants the exclusive rights to market the over-the-counter version of Prilosec, known as Prilosec OTC, which was launched in September 2003.

22. According to the agreement between the Procter & Gamble Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants supply Prilosec OTC and the Procter & Gamble Defendants market and sell Prilosec OTC.

23. In 2006, the FDA approved New Drug Application ("NDA") 22056 to allow the AstraZeneca Defendants the right to market and sell prescription Prilosec to children aged two and younger for the treatment of GERD.

24. Defendant AstraZeneca Pharmaceuticals LP is the holder of approved NDA 019810 for Prilosec Delayed-Release Capsule Pellets and 022056 for Prilosec Delayed-Release Oral Suspension.

25. Defendant AstraZeneca LP is the holder of NDAs 019810/S-1 – S-102 for Prilosec Delayed Release Capsules, 022056/S-1-S-019 for Prilosec delayed release oral suspension and 021229/S-1-S-029 for Prilosec OTC delayed release tablets.

26. The AstraZeneca Defendants manufacture and market each of these Prilosec formulations in the United States.

27. In anticipation of the expiration of the patent for prescription Prilosec, the AstraZeneca Defendants launched an internal program called Operation Shark Fin for the purpose of developing a second PPI Product in order to capitalize on the market for PPI Products. The result of Operation Shark Fin was the development of Nexium (esomeprazole).

28. In December 1999, Defendant AstraZeneca Pharmaceuticals LP submitted its first NDA for a Nexium product, NDA 021153, to the FDA for approval to market Nexium in the United States.

29. In December 2000, the FDA simultaneously approved Nexium, NDA 021153, and Nexium Delayed Release, NDA 021154, for healing of erosive esophagitis, maintenance of healing erosive esophagitis, treatment of symptomatic GERD and H. pylori eradication to reduce the risk of duodenal ulcer recurrence (as part of a triple therapy with amoxicillin and clarithromycin).

30. Defendant AstraZeneca Pharmaceuticals LP is also the holder of approved NDAs 021957 and 022010 for Nexium Delayed-Release Oral Suspension, and NDAs 022101 and 021689 for Nexium Injection Solution.

31. The AstraZeneca Defendants manufacture and market each of the aforementioned Nexium formulations in the United States.

32. In 2003, the AstraZeneca Defendants spent $260 million alone in promoting and marketing Nexium products to American consumers, the largest amount spent on marketing a single brand of pharmaceutical to that date.

33. In an agreement reached in 2012, the AstraZeneca Defendants licensed to the Pfizer Defendants the exclusive right to market an over-the-counter version of Nexium, known as Nexium 24HR, which was launched in 2014.

34. According to the agreement between the Pfizer Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants receive royalty payments from the Pfizer Defendants on product launches and sales.

35. The AstraZeneca Defendants have transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

36. The AstraZeneca Defendants have derived substantial revenue from PPI Products used in each of the States and Territories of the United States. For example, in 2003 alone, sales of Nexium in the United States was $2.7 billion and world-wide was $3.9 billion.

37. The AstraZeneca Defendants have expected or should have expected their acts to have consequences within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPIs.

38. Defendant Merck & Co. Inc. d/b/a Merck, Sharp & Dohme Corporation (hereinafter "Defendant Merck") is and, all times relevant to this action, has been a New Jersey corporation having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

39. In 1982, Defendant Merck entered into an agreement with the AstraZeneca Defendants, under the terms of which Defendant Merck developed and marketed the AstraZeneca Defendants' products, including Nexium and Prilosec products, under a royalty-bearing license.

40. In 1993, Merck's total sales of the AstraZeneca Defendants' products reached a level that triggered the first step in the establishment of a joint venture business (the "Joint Venture") in which Defendant Merck and the AstraZeneca Defendants each owned a 50% share. This Joint Venture, formed in 1994, was called Astra Merck Inc. and was responsible for the sale of Prilosec and other of the AstraZeneca Defendants' products.

41. Defendant Pfizer Inc. is and, all times relevant to this action, has been a Delaware corporation having a principal place of business at 235 East 42nd Street, New York, NY 10017.

42. As a part of their business and at all relevant times, Defendant Pfizer Inc. has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of the drugs Protonix (pantoprazole) and Nexium 24HR.

43. In or about 2012, Defendant Pfizer Inc. entered into a marketing agreement with the AstraZeneca Defendants whereby Defendant Pfizer Inc. acquired the rights to market Nexium 24HR products.

44. On or about March 28, 2014, Defendant Pfizer Inc., in collaboration with and pursuant to its marketing agreement with the AstraZeneca Defendants, was granted FDA approval to market Nexium 24HR products.

45. Defendant Pfizer Inc. makes Nexium 24HR available for purchase in the United States in and around 2014 and continues to manufacture and market Nexium 24HR in the United States.

46. Defendant Pfizer Inc. manufactures and markets Protonix in the United States.

47. Defendant Pfizer Inc. has transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

48. Defendant Pfizer Inc. has derived substantial revenue from PPI Products in each of the States and Territories of the United States.

49. Defendant Pfizer Inc. has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

50. Defendant Takeda Pharmaceuticals USA, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

51. Defendant Takeda Pharmaceuticals America, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

52. Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. is and, at all times relevant to this action, has been an

Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

53. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

54. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been the parent/holding company of Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

55. Defendant Takeda Pharmaceutical Company Limited, at all times relevant to this action, has exercised and exercises dominion and control over Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

56. Defendant Takeda Pharmaceuticals USA, Inc., Defendant Takeda Pharmaceuticals America, Inc., Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Defendant Takeda Pharmaceutical Company Limited are referred to collectively herein as the "Takeda Defendants."

57. Each of the Takeda Defendants was the agent and employee of the other Takeda Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other Takeda Defendants' actual and implied permission, consent, authorization and approval.

58. As a part of their business and at all relevant times, the Takeda Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion,

marketing, sale and distribution of Dexilant (dexlansoprazole), Prevacid, Prevacid24HR and Protonix products.

59. The Takeda Defendants, in collaboration amongst themselves, designed and developed the Dexilant, Prevacid, Prevacid 24HR and Protonix products.

60. Defendant Takeda Pharmaceuticals USA, Inc. is the holder of approved NDAs 022287 and 208056 for Dexilant, and NDAs 020406, 021428 and 021281 for Prevacid.

61. The Takeda Defendants manufacture and market each of these prescription Prevacid formulations in the United States.

62. The Takeda Defendants manufacture and market each of these Prevacid 24HR formulations in the United States.

63. Takeda Defendants manufacture and market each of these Dexilant formulations in the United States.

64. The Takeda Defendants manufacture and market each of these Protonix formulations in the United States.

65. The Takeda Defendants have transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

66. The Takeda Defendants have derived substantial revenue from PPI Products in each of the States and Territories of the United States.

67. The Takeda Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

68. In doing the acts alleged herein, said Defendants 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.

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

70. 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 New Hampshire.

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

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

IV. PLAINTIFF

Plaintiff incorporates all preceding and succeeding paragraphs in this complaint as if fully set forth at length herein, and further allege as follows:

73. Plaintiff Wayne Samuels, an adult whose principal place of residence is in Pelham, New Hampshire brings this action due to injuries he has sustained as a direct and proximate result of his use of Defendants' PPI Products and subsequent CKD diagnosis.

74. Upon information and belief, Plaintiff ingested PPIs between approximately early 1990s and 2016. During this time, Plaintiff resided in the States of New Hampshire and Massachusetts.

75. Before purchasing PPIs, Plaintiff and Plaintiff's doctors were exposed to the advertising and marketing of Defendants. Plaintiff relied on the representations and warranties from Defendants made therein in making the decision to purchase PPIs, believing they would be safe and effective for their advertised use and relying on the expertise of Defendants.

76. Upon information and belief, at no time did Plaintiff take more than the recommended dosing regimen contained in the packaging and labeling of PPIs.

77. After taking the recommended dosing of and as a result of the PPI Products manufactured by one of the Defendants herein named, Plaintiff suffered serious kidney injuries which required hospitalization and extensive treatment.

78. As a result of the defective nature of PPIs, persons who ingested this product, including Plaintiff, have suffered and may continue to suffer from serious kidney injuries.

79. Defendants concealed and continue to conceal their knowledge of PPIs' unreasonably dangerous risks from Plaintiff, Plaintiff's 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.

80. As a result of Defendants' actions and inactions, and due to Plaintiff's ingestion of PPIs, Plaintiff sustained, and will continue to sustain, permanent and lasting physical, emotional and psychological injuries, as well as severe permanent physical impairment and/or severe disfigurement.

81. Specifically, on or about 2010, Plaintiff was caused to suffer CKD, a serious kidney injury, which required, and will continue to require, hospitalization, extensive treatment, and ongoing health monitoring.

82. As a result of the foregoing injuries, Plaintiff sustained damages, which include but are not limited to past and future medical expenses, lost time, emotional distress, special and/or consequential damages, loss of enjoyment of life and pain and suffering.

83. Plaintiff accordingly seeks damages associated with these injuries as alleged herein.

V. FACTUAL ALLEGATIONS

84. PPI Products are indicated for the treatment of the following conditions: GERD; dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

85. PPI Products work by inhibiting the secretion of stomach acid. They shut down acid production of the active acid pumps in the stomach, thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

86. PPI Products are one of the most commercially successful groups of medication in the history of pharmaceutical sales in the United States. 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.

87. As of 2009, approximately 21 million Americans used one or more prescription PPI Products, accounting for nearly 20% of the drugs' global sales and earning an estimated $11 billion annually.

88. Between the period of 2008 and 2013, prescription PPI Products had sales of over $50 billion with approximately 240 million units dispensed.

89. According to the 2011–2012 National Health and Nutritional Examination Survey, 7.8% of US adults had used prescription PPI Products within the last 30 days.

A. PPI Products Cause Severe Kidney Injuries

90. As early as October of 1992, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article reporting PPI usage associated with kidney injury in The American Journal of Medicine.

91. Since 1992, there have been numerous adverse case reports and scientific studies published in medical journals and reported by physicians and scientists, as well as adverse reports from national adverse drug registries, which document an association between use of PPI Products and the occurrence of kidney injuries such as AIN, AKI, CKD and ESRD.

(i) <u>PPI-Induced Acute Interstitial Nephritis (AIN)</u>

92. The current warning contained on prescription PPI Products regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left untreated, AIN can lead to CKD, Renal Failure, Dialysis, Kidney Transplant and/or death.

93. Defendants have also failed to adequately inform physicians, and other healthcare providers such as pharmacists, and consumers regarding the risk of AIN and the use of over-the counter PPI Products.

94. PPI Products 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 AIN, a sudden kidney inflammation that can result in mild to severe problems.

95. PPI-induced AIN can be 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.

96. Use of PPI Products may lead to subclinical AIN according to multiple studies, including but not limited to:

a. Lazarus B, Chen Y, Wilson FP, *et al.*, *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*. 176 JAMA INTERNAL MED. 238 (2016); and

b. DG Moledina & MA Perazella, *Proton Pump Inhibitors and CKD*, 27 J. AM. SOC. NEPHROL. 2926 (2016).

97. AIN's slow presentation can cause significant damage over time without those affected exhibiting acute symptoms.

98. Where AIN is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AIN can lead to CKD and ESRD requiring the patient to undergo permanent dialysis, kidney transplant or, in some cases, death.

99. While AIN can be treated, once AIN has progressed to CKD it is incurable and can only be managed.

(ii) PPI-Induced Acute Kidney Injury (AKI)

100. AKI is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly.

101. Studies indicate that those using PPI Products are at a more than 2.5 times greater risk than the general population to suffer AKI.

102. Studies also indicate that those who develop AIN are at a significant risk of AKI, even though they may not obviously exhibit kidney dysfunction.

103. Currently, the product labeling for PPI Products, both prescription and over-the counter, does not contain any warning regarding the increased risk of AKI.

104. Where AKI is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AKI can lead to CKD and ESRD.

(iii) PPI-Induced Chronic Kidney Disease (CKD)

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

106. In February 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."

107. In April 2016, a study published in the Journal of Nephrology suggested that the development of and failure to treat AIN could lead to CKD and ESRD, which requires dialysis or kidney transplant to manage. Analyses of the study were adjusted for age, sex, race, baseline eGFR, cigarette smoking, BMI, systolic blood pressure, diabetes, a history of cardiovascular disease, antihypertensive medication use, anticoagulant medication use, statin, aspirin and NSAID use. Across all groups, "each of these sensitivity analyses showed a consistent association between PPI use and a higher risk of CKD."

108. CKD is often a slow 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.

109. PPI Products have also been shown to cause CKD independent of, and in the absence of, an intervening AKI or AIN event, even where the AKI or AIN is subclinical. For example, the results of a 2017 epidemiologic study "showed a significant association between PPI use and chronic renal outcomes including incident CKD, CKD progression, and ESRD in the absence of intervening AKI." Yan Xie et al., *Long-Term Kidney Outcomes among Users of Proton Pump Inhibitors without Intervening Acute Kidney Injury*, 91 KIDNEY INT'L 1482 (2017).

110. To date, the labeling for Defendants' PPI Products lack adequate risk information about CKD.

B. PPI Products Caused Rebound Acid Hypersensitivity, Worsening GERD and Acid Reflux, Creating Dependency

111. Users of PPI Products experience worse GERD or acid reflux upon ceasing PPI Product use, evidencing that PPI Products can lead to physical dependency and/or the worsening of symptoms upon removal of the PPI therapy.

112. The worsening of GERD or acid reflux after withdrawal of PPI Products has been characterized by scientists as "rebound acid hypersecretion" and is characterized by an increase in acid secretion with the withdrawal of the PPI Products.

113. This phenomenon was first identified during preclinical animal studies on rats treated with omeprazole/Prilosec.

114. Because PPI Products work by preventing the acidification of the stomach's contents by blocking the proton pumps of the stomach, the body may react by compensating with increased production of gastrin, a hormone that stimulates secretion of gastric acid.

Consequently, when users discontinue treatment with PPI Products, their bodies' acid production increases beyond their pre-PPI treatment levels.

115. The increase in acid production after discontinuation of PPI Products caused and will continue to cause Plaintiff significant harm and a dependency on PPI Products.

116. After Plaintiff's discontinuation of PPI Products, increased acid production to a level above that which existed before treatment with PPI Products was initiated has caused and will cause Plaintiff to treat GERD as a more severe condition than that which existed when PPI Products were initiated.

117. Several studies have shown that treatment with PPI Products induces acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment is withdrawn in healthy individuals who have never before experienced heartburn or related symptoms.

118. Due to rebound hypersecretion, patients are unable, in many instances, to cease use of PPI Products, despite choosing and wanting to do so after learning of the risks of using PPI Products, including kidney injuries.

119. To date, the labeling for the Defendants' respective PPI Products contains no information regarding rebound acid hypersecretion or information that would assist healthcare providers and/or patients who suffer from this after ceasing to use PPI Products.

C. Safer Alternatives to PPIs

120. Despite the fact that PPI Products lead to an increased risk of such severe injuries as outlined herein, several safer alternatives have been and are available, including but not limited to:

a. The use of over-the-counter calcium carbonate tablets that have been available since the 1930s, such as Maalox and Tums; and/or

b. The use of histamine H2-receptor antagonists (also known as "H2 Blockers") that were developed in the late 1960s. H2 Blockers act to prevent the production of stomach acid, work more quickly than PPI Products and are prescribed for the same indications as PPI Products. Examples of H2 Blockers include Zantac, Pepcid and Tagamet. H2 Blockers are not associated with an increased risk of kidney injuries.

121. In spite of their commercial success and global popularity, up to 70% of PPI Products may be used inappropriately for indications or durations that were never tested or approved. D. Marks, Time to Halt the Overprescribing of Proton Pump Inhibitors, THE PHARMACEUTICAL JOURNAL (Aug. 8, 2016).

122. Consumers, including Plaintiff, who have used Defendants' PPI Products for the treatment of increased gastric acid have and had several alternative safer treatments available and have not been adequately warned about the significant risks and lack of benefits associated with use of PPI Products.

D. Injuries Resulting from PPI Products

123. The use of PPI Products for time periods longer than those tested or approved is a direct consequence of Defendants' (1) failure to adequately and specifically warn patients and healthcare providers as to the appropriate length of usage; (2) failure to provide adequate, clear and accurate marketing materials regarding appropriate usage of PPI Products and the appropriate and approved indications; and (3) engaging in off-label promotion of their respective PPI Products for indications that were not approved.

124. As a result of the defective nature of Defendants' PPI Products, persons who ingested Defendants' PPI Products have been exposed to significant risks stemming from

unindicated and/or long-term usage, even when used as directed and/or prescribed by a physician or healthcare professional.

125. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from severe kidney injuries including, but not limited to, AIN, AKI, CKD and ESRD.

126. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from a worsening of acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment with Defendants' PPI Products was withdrawn and have developed and suffered from a physical dependence on PPI treatment.

E. Defendants Actively Concealed the Dangers Associated with Use of PPI Products

127. Defendants, through their affirmative misrepresentations and/or omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with the use of Defendants' PPI Products.

128. Defendants concealed and continue to conceal from Plaintiff, other consumers and/or the medical community that Defendants' PPI Products can cause kidney injuries.

129. Specifically, Defendants failed to adequately inform Plaintiff, other consumers and/or the medical community about the serious risks associated with Defendants' PPI Products, and Defendants completely failed to warn against the risk of AKI, CKD and ESRD, and Defendants still fail to warn of these risks, even to this day. Defendants have concealed and continue to conceal and have failed to adequately inform Plaintiff, other consumers, Plaintiff's physicians and/or others within the medical community that over-the-counter PPI Products are associated with AIN, and fail to warn and inform regarding the risk of AIN developing into CKD and ESRD.

130. Defendants concealed and continue to conceal that Defendants' PPI Products can cause consumers to become physically dependent on PPI treatment. Specifically, Defendants have failed to inform consumers and/or healthcare providers that a patient's symptoms may worsen after the withdrawal of PPI Products.

131. As a result of Defendants' actions, Plaintiff and/or Plaintiff's healthcare providers 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.

132. Plaintiff would not have used Defendants' PPI Products had Defendants properly disclosed the risks associated with long-term use.

133. Defendants had an obligation to comply with the law in the manufacture, design and sale of Defendants' respective PPI Products.

134. Materials, including advertisements, press releases, website publications and other communications regarding Defendants' PPI Products, are part of the labeling of the Defendants' respective PPI Products, and Defendants could have altered the same without FDA approval.

135. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPI Products and failed to warn about the risks of AIN, acute kidney failure, CKD and other kidney injuries.

136. Defendants' marketing campaigns and advertising to consumers failed to adequately instruct consumers regarding the appropriate duration for using their respective over the-counter PPI Products.

137. Defendants knew or should have known of the risks of AIN, AKI, CKD and ESRD based on the data available to them or that could have been generated by them, including,

but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, preclinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

138. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AIN.

139. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AKI.

140. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of CKD.

141. At all times, Defendants could have implemented changes to the labeling of their respective PPI Products regarding the risks of AIN, AKI, CKD and ESRD.

(i) Defendants' Violations of Federal Law

142. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*

143. With respect to Defendants' PPI Products, Defendants have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading;

b. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because words, statements or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

c. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because their labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;

d. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;

e. Defendants' PPI Products do not contain adequate directions for use pursuant to 21 CFR § 201.5, because of, among other reasons, omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;

f. Defendants violated 21 CFR § 201.56 because the labeling of their respective prescription PPI Products were and are not informative and accurate;

g. Defendants' prescription PPI Products are misbranded pursuant to 21 CFR § 201.56 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading;

h. Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for monitoring of patients who took their respective prescription PPI Products;

i. Defendants' prescription PPI products are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;

j. Defendants' over-the-counter PPI Products are mislabeled pursuant to 21 CFR §201.66 because they were and are not informative and accurate;

k. Defendants' over-the-counter PPI Products are misbranded pursuant to 21 CFR § 201.66 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false or misleading;

l. Defendants' PPI Products violate 21 CFR § 210.1 because the process by which they were manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meet the quality and purity characteristic that they purport or are represented to possess;

m. Defendants' PPI Products violate 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications;

n. Defendants' PPI Products violate 21 CFR § 211.165 because the test methods Defendants employed are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;

o. Defendants' PPI Products violate 21 CFR § 211.165 in that they fail to meet established standards or specifications and any other relevant quality control criteria;

p. Defendants' PPI Products violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the PPI Products were not followed;

q. Defendants' PPI Products violate 21 CFR § 310.303 in that they are not safe and effective for their intended use;

r. Defendants violated 21 CFR § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;

s. Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with their respective PPI Products as soon as possible or at least within 15 days of the initial receipt of the adverse drugs experience report;

t. Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with their respective PPI Products, and evaluating the cause of the adverse event;

u. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;

v. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences;

w. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as "15-day Alert report," or "15- day Alert report follow-up";

x. Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Defendant's PPI Products or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor;

y. Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated); and

z. Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

144. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff.

VI. ESTOPPEL FROM PLEADING AND TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts in this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

145. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including but not limited to equitable tolling, class action tolling, delayed discovery, discovery rule and fraudulent concealment.

146. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew or, through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

147. Plaintiff is not an expert in the field of nephrology, epidemiology, or pharmaceutical regulation.

148. As a result of Defendant's actions and inactions, and Plaintiff's lack of relevant training and expertise, Plaintiff and Plaintiff's prescribing 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 these risks were the direct and proximate result of the Defendant's acts and omissions.

149. Despite diligent investigation by Plaintiff into the cause of Plaintiff's injuries, the nature of Plaintiff's injuries and damages and their relationship to PPIs was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate

application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

150. The running of the statute of limitations in this case is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and/or the consuming public of the true risks associated with PPIs. As a result of the Defendants' fraudulent concealment, Plaintiff and/or Plaintiff's physicians were unaware, and could not have known 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 the wrongful acts and omissions of the Defendants.

151. 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 nonpublic information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, Plaintiff's medical providers and/or to their health facilities.

152. 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/or 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, instead, were forced to rely on Defendants' representations.

153. Defendants were and continue to be in possession of information and data that show the risk and dangers that PPI causes, which is not otherwise in the possession or available to Plaintiff and/or Plaintiff's physicians.

154. At the time of Plaintiff's injuries, Plaintiff and/or Plaintiff's physicians were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because Plaintiff and Plaintiff's physicians reasonably relied on Defendants' representations that PPIs do not cause kidney injuries.

155. At no time prior to Plaintiff's eventual discovery of wrongdoing did any of Plaintiff's doctors ever inform, advise, suggest or otherwise imply that Plaintiff's PPI use was a potential contributing cause of Plaintiff's kidney injuries.

156. Plaintiff reasonably relied on the skill and judgment of Plaintiff's doctors and had no reason to further investigate, inquire into or suspect that PPIs caused Plaintiff's conditions.

157. Plaintiff exercised reasonable diligence in an attempt to discover the cause of the kidney injuries. Plaintiff relied on the physicians to advise them of any known complications. Plaintiff had no reason to believe the injuries were the result of any wrongdoing, whether intentional and/or negligent, until the discovery dates suggested below and are therefore relying on the benefit of the discovery rule.

158. Plaintiff had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at the time of injury.

159. At the time of Plaintiff's injuries, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries caused by

PPI use or have any discussions with Plaintiff's doctors that there was an association between their kidney injuries and PPI use.

VIII. CAUSES OF ACTION

COUNT I

STRICT LIABILITY – DESIGN DEFECT

Plaintiff incorporates by reference each and every preceding and succeeding paragraph of this Complaint as if fully set forth in this cause of action and further alleges as follows:

160. At all relevant and material times, the Defendants designed, manufactured, packaged, marketed, advertised, distributed, and sold PPIs, placing the products into the stream of commerce.

161. At all relevant and material times, PPIs were designed, manufactured, packaged, marketed, advertised, distributed, and sold by Defendants in a defective and unreasonably dangerous condition.

162. PPIs were expected to reach, and did reach, users and consumers, including Plaintiff, without any alterations or changes in the defective and unreasonably dangerous condition in which they left Defendants' control.

163. Plaintiff used PPIs in a foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

164. When each of the PPI Products used by Plaintiff entered the stream of commerce, they were defective and unreasonably dangerous in one or more of the following manners:

a. PPIs contained manufacturing and design defects in that each product caused and/or increased the risk of experiencing an adverse event, including, but not limited to AKI, AIN, CKD, ESRD or renal failure, as well as life-threatening complications thereof and even death;

b. PPIs were not safe because the health risks associated with each PPI Product outweighed the benefits;

c. PPIs were marketed and promoted for use when they carried an unreasonable and unnecessary risk of serious injury;

d. PPIs were insufficiently and/or inadequately tested by Defendants;

e. PPIs were not safe due, in part, to inadequate and defective instructions and inadequate and defective warnings provided by Defendants;

f. PPIs were unreasonably dangerous in that, as designed, the risks of serious injury posed by using the products exceeded any benefits the products were designed to or might in fact bestow;

g. PPIs were defective in design in that the products neither bore, nor were packaged with, nor were accompanied by, warnings adequate to alert users, including Plaintiff, of the increased risks associated with using the products, including, but not limited to, the risk of AKI, AIN, CKD, and ESRD or renal failure, and even death;

h. PPIs were not accompanied by adequate warnings and instructions for use that included adequate information to fully apprise users, consumers, and the medical, pharmaceutical and scientific communities of the potential risks and serious side effects associated with using the products;

i. PPIs were unsafe for normal or reasonably anticipated use. Said products were defective and unreasonably dangerous in design, construction, and/or composition;

j. PPIs were defective and unreasonably dangerous, because the products did not conform to an express warranty of the manufacturer about the product;

k. PPIs were defective and unreasonably dangerous due to inadequate warnings, inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study; and

l. PPIs were defective in that there were safer and technically feasible alternative designs and products for the condition at issue that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product.

165. PPIs, as manufactured and supplied by the Defendants, were defective due to inadequate warnings and instructions because after Defendants knew or should have known of the risk of injuries from use, Defendants failed to provide adequate warnings to the medical

community and the consumers to whom the drugs were directly marketed and advertised; and, further, Defendants continued to affirmatively promote PPIs as safe and effective.

166. A reasonable person who had actual knowledge of the increased risks associated with using PPIs would have concluded that PPIs should not have been marketed to or used by Plaintiff and Plaintiff's physicians.

167. Despite the fact Defendants knew or should have known of the defective nature of PPIs, Defendants continued to design, manufacture, and sell PPIs so as to maximize sales and profits at the expense of the public health and safety. Defendant thus acted with conscious and deliberate disregard of the foreseeable harm caused by PPIs.

168. Plaintiff and the non-defendant health care providers involved could not, through the exercise of reasonable care, have discovered the risk of serious injury associated with and/or caused by PPIs.

169. Plaintiff was not aware of the aforementioned defects at any time prior to the injuries caused by PPIs.

170. Had adequate information regarding the safety (or lack thereof) of PPIs been provided to Plaintiff, Plaintiff would not have used PPIs.

171. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

172. As a direct and proximate result of the actions and inactions of Defendants as set forth above, Plaintiff purchased unsafe products and incurred monetary expenses, as well as risk to their person, and was thereby caused to suffer kidney injuries and were hospitalized and received extensive treatment, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish and diminished enjoyment of life. Plaintiff

endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff suffered these serious and dangerous side effects.

173. Defendants' actions, inactions, misstatements and omissions, as well as the active concealment thereof, were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and enhanced compensatory damages against Defendants.

COUNT II

STRICT LIABILITY – FAILURE TO WARN

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action, and further alleges as follows:

174. PPIs were unreasonably dangerous, even when used in a foreseeable manner as designed and intended by Defendants.

175. At all times relevant and material hereto, PPIs were designed, manufactured, packaged, marketed, advertised, distributed, and sold solely by Defendants, who alone placed these products into the stream of commerce for sale to and use by members of the consuming public, including Plaintiff.

176. At all times relevant and material hereto, Defendants designed, manufactured, packaged, marketed, advertised, distributed, and sold PPIs in a defective and unreasonably dangerous condition.

177. The PPIs manufactured by Defendants were in a defective and unreasonably dangerous condition when they left Defendants' control and entered into the stream of commerce. The PPIs reached Plaintiff without substantial change to the condition in which they

left Defendants' control. The PPIs were defective and unreasonably dangerous when used by Plaintiff, and Plaintiff ingested PPIs as instructed by Defendants, and as directed and prescribed by Plaintiff's physicians.

178. Plaintiff was administered, or was prescribed and used, PPIs for their intended purposes.

179. On information and belief, Plaintiff used PPIs in a foreseeable manner, the manner in which Defendants intended, recommended, promoted, and marketed PPIs for use at all times relevant to this cause of action.

180. Defendants failed to warn and/or inadequately warned Plaintiff, consumers, physicians including Plaintiff's physicians, and healthcare professionals about the increased health risks associated with using PPIs.

181. Plaintiff and Plaintiff's prescribing physicians did not have the same knowledge as Defendants and no adequate warning was communicated to them.

182. Neither Plaintiff nor any of Plaintiff's prescribing physicians could have discovered any defect in the PPIs through the exercise of reasonable care and/or reasonable diligence.

183. As manufacturers of PPIs, Defendants are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known those warnings and other clinically relevant information and data, which they distributed regarding the risks of injuries and death associated with the use of PPIs, was incomplete and inadequate.

184. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to

Plaintiff's treating physicians. The warnings given by Defendants were inaccurate, unclear, ambiguous, and/or incomplete.

185. At all times relevant and material hereto, Defendants had and have a continuing duty to provide consumers, including Plaintiff, and Plaintiff's physicians with warnings and other clinically relevant information and data regarding the risks and dangers associated with PPIs, as it became or could have become available to Defendants.

186. Defendants marketed, promoted, distributed, and sold unreasonably dangerous and defective prescription PPIs to health care providers empowered to prescribe and dispense to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data. Through both omissions and affirmative misstatements, Defendants misled the medical community, including Plaintiff's prescribing physicians, about the risk/benefit balance of PPIs, which resulted in injuries to Plaintiff.

187. Defendants knew or should have known that PPIs caused unreasonable and dangerous side effects and they continued to promote and market PPIs without stating safer and more or equally effective alternative drug products existed and/or providing adequate clinically relevant information and data.

188. Defendants knew or should have known that consumers, including Plaintiff, would foreseeably and needlessly suffer injuries or death as a result of Defendants' conduct.

189. Defendants failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and to Plaintiff's intermediary physicians, in numerous ways, including but not limited to the following:

a. Defendants failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff's physicians to the dangerous risks of PPIs including, among other things, their tendency to increase the risk of, and/or cause AKI, AIN, CKD, and

ESRD or renal failure, as well as life-threatening complications thereof and death;

b. Defendants failed to inform Plaintiff and Plaintiff's physicians that Defendants did not adequately test PPIs and failed to determine the full extent of safety risks associated with their use;

c. Defendants failed to adequately update the labeling of their PPIs to include adequate post-marketing warnings and instructions after Defendants knew or should have known of the significant risks of kidney injuries caused by using PPIs; and

d. Defendants continued to aggressively promote and sell PPIs even after they knew or should have known of the unreasonable risks of developing kidney injuries caused by using PPIs.

190. Each and all Defendants had a duty to warn the FDA, the medical community, Plaintiff, and Plaintiff's physicians about the increased risks of these injuries, but failed to do so.

191. Defendants had a duty and obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to PPIs, and/or that safer alternative drugs with equal or greater efficacy existed and were available, but they failed to do so.

192. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to PPIs, and/or that safer alternative drugs with equal or greater efficacy existed and were available, Defendants breached their duty of reasonable care and safety.

193. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of the Plaintiff and the public.

194. As a direct and proximate result of the actions and inactions of Defendants as set forth above, Plaintiff purchased unsafe products and incurred monetary expenses, as well as risk to their person, and was thereby caused to suffer kidney injuries and were hospitalized and received extensive treatment, as well as other severe and personal injuries which are permanent

and lasting in nature, physical pain, mental anguish and diminished enjoyment of life. Plaintiff endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff suffered these serious and dangerous side effects.

195. Defendants' actions, inactions, misstatements and omissions, as well as the active concealment thereof, were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and enhanced compensatory damages against Defendants.

COUNT III

NEGLIGENCE

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges as follows:

196. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling and/or distributing their PPI Products into the stream of commerce, including a duty to assure that the PPI Products would not cause users to suffer unreasonable, dangerous side effects.

197. Defendants failed to exercise ordinary care in the design, research, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or distribution of their PPI Products in that Defendants knew or should have known that the drugs could proximately cause Plaintiff's injuries and/or presented an unreasonably high risk of injury.

198. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful, wanton, outrageous and reckless disregard for human life and safety in

manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their PPI Products, including but not limited to the following particular respects:

a. Failing to use due care in design and/or manufacture of the PPI Products so as to avoid the aforementioned risks to individuals;

b. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their PPI Products;

c. Failing to use reasonable and prudent care so as to conduct sufficient post-marketing pharmacovigilance and pharmacosurveillance;

d. Failing to recognize the significance of their own and other testing, and information regarding PPI Products, which testing and information evidenced such products are dangerous and potentially harmful to humans;

e. Failing to respond promptly and appropriately to their own and other testing, and information regarding PPI Products, and failing to promptly and adequately warn of the potential for kidney injuries including AIN, AKI and CKD when using their PPI Products;

f. Failing to promptly, adequately and appropriately recommend testing and monitoring of patients upon whom PPI Products were used in light of the PPI Products' dangers and potential harm to humans;

g. Failing to properly, appropriately and adequately monitor the post-market performance of their PPI Products and such products effects on patients;

h. Aggressively promoting, marketing, advertising and/or selling their PPI Products given their knowledge and experience of their PPI Products' potential harmful effects;

i. Failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of using their PPI Products, which were knowingly false and misleading, in order to influence patients, such as the Plaintiff, to use their PPI Products in excess and/or in preference to safer and effective alternative treatments;

j. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of kidney injury associated with the use of their PPI Products;

k. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of rebound acid hypersecretion associated with the use of their PPI Products.

l. Failing to disclose to Plaintiff and/or the medical community their full knowledge and experience regarding the potential dangers and harm associated with use of their PPI Products;

m. Failing to disclose to Plaintiff and/or the medical community in an appropriate and timely manner, facts relative to the potential dangers and harm associated with use of their PPI Products;

n. Failing to warn Plaintiff and/or Plaintiff's healthcare providers of the severity and duration of such adverse effects;

o. Failing to warn Plaintiff and/or Plaintiff's healthcare providers prior to actively encouraging the sale of their PPI Products, either directly or indirectly, orally or in writing, about the increased risk of kidney injury;

p. Placing and/or permitting the placement of PPI Products into the stream of commerce without adequate warnings that they are harmful to humans and/or without properly warning of said products' dangerousness;

q. Failing to withdraw their PPI Products from the market and stream of commerce, or restrict their use and/or warn of such products' potential dangers, given their knowledge of the dangers and harms associated with use of their PPI Products;

r. Failing to respond or react promptly and appropriately to reports of their PPI Products causing harm to patients;

s. Disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of their PPI Products and their potential harm to humans;

t. Under-reporting, underestimating and/or downplaying the serious dangers of their PPI Products;

u. Failing to exercise reasonable care in informing physicians and healthcare providers using PPI Products about their own knowledge regarding the potential dangers and harm associate with use of their PPI Products;

v. Failing to adequately warn Plaintiff and/or Plaintiff's healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious injuries or death by ingesting Defendants' PPI Products;

w. Promoting PPI Products in advertisements, websites and other modes of communication aimed at creating and/or increasing user and consumer demand without regard to the dangers and risks associated using PPI Products;

x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries associated with their PPI Products;

y. Failing to use due care under the circumstances; and

z. Other such acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

199. Despite the fact that Defendants knew or should have known that the PPI Products caused unreasonable, dangerous risk of kidney injury, Defendants continued to market the PPI Products to consumers, including the medical community and Plaintiff.

200. 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 described herein, including the failure to comply with federal requirements.

201. It was foreseeable to Defendants that Defendants' PPI Products, as designed and marketed, would cause serious injury to consumers, including Plaintiff.

202. Despite the fact that Defendants knew or should have known that their PPI Products caused unreasonable risks of harm when used as intended by the Defendants, the Defendants continued to advertise, market and sell their PPI Products to patients, including the Plaintiff and healthcare providers.

203. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

204. Defendants' knowingly and intentionally defectively designed and provided inadequate warnings relating to the design of the PPI Products in willful, wanton and reckless

disregard for the safety and well-being of all patients and consumers, including the Plaintiff, for the purpose of achieving profits and market share over safety.

205. Defendants acted in reckless disregard to public safety and well-being, including Plaintiff's safety and well-being, and with actual knowledge that the PPI Products were unsafe for their recommended use for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

206. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, Plaintiff, and/or Plaintiff's healthcare providers concerning the dangers of PPI Products, and consciously decided to aggressively market and sell their PPI Products, putting economic, financial and market share advantage over safety and efficacy considerations.

207. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

208. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff's, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of enhanced compensatory damages.

COUNT IV

BREACH OF EXPRESS WARRANTY

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges as follows:

209. The aforementioned manufacturing, compounding, packaging, designing, distributing, testing, constructing, fabricating, analyzing, recommending, merchandizing, advertising, promoting, supplying and selling of PPIs were expressly warranted to be safe for use by consumers and the general public, including Plaintiff.

210. Defendants expressly represented to Plaintiff, consumers and the medical community that PPIs were:

a. safe;

b. efficacious;

c. fit for use by persons with gastric acid secretion-related conditions;

d. of merchantable quality;

e. adequately tested;

f. well tolerated in adequate and well-controlled clinical studies; and

g. did not increase the risk of experiencing the serious kidney injuries, as well as life-threatening complications thereof or even death.

211. Defendants breached those express warranties as follows:

a. Defendants misrepresented the safety of PPIs in their labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions;

b. Defendants misrepresented the risks associated with using PPIs;

c. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury;

d. Defendants misrepresented that PPIs were as safe or safer than other available forms of treatment for Plaintiff's condition; and

e. PPIs were unaccompanied by adequate warnings of their dangerous propensities about which Defendants knew or could have known at the time of distribution.

212. PPIs did not conform to Defendants' express representations and warranties.

213. At all relevant times, PPIs did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

214. At all relevant times, PPIs did not perform in accordance with the Defendants' representations because PPIs are not safe and cause a serious increase in the risk of extremely dangerous and life-threatening side effects and even death.

215. The medical community, including Plaintiff's prescribing physicians, relied upon Defendants' express warranties when deciding to prescribe or administer PPIs. Consumers and the general public, including Plaintiff relied upon Defendants' express warranties when deciding to purchase and use PPIs.

216. As a direct and proximate consequence of Defendants' breach of express warranty, Plaintiff purchased unsafe products and incurred monetary expenses, as well as risk to their person, and was thereby caused to suffer kidney injuries and were hospitalized and received extensive treatment, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, mental anguish and diminished enjoyment of life. Plaintiff endured and continues to suffer the mental anguish and psychological trauma of living with the knowledge that Plaintiff suffered these serious and dangerous side effects.

217. Defendants' actions, inactions, misstatements and omissions, as well as the active concealment thereof, were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. Defendants' unconscionable conduct

thereby warrants an assessment of exemplary and enhanced compensatory damages against Defendants.

COUNT V

BREACH OF IMPLIED WARRANTY

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges as follows:

218. At the time Defendants marketed, distributed and sold their PPI Products to Plaintiff, Defendants warranted that they were merchantable and fit for the ordinary purposes for which it was intended.

219. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

220. The PPI Products were not merchantable and fit for their ordinary purpose, because they have a propensity to lead to the serious personal injuries described in this Complaint.

221. Plaintiff reasonably relied on Defendants' representations that the PPI Products were safe and free of defects and were a safe means of managing and treating symptoms associated with peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

222. At all relevant times hereto, Defendants knew or had reason to know of the purpose for and manner in which users of PPI Products, including Plaintiff, were using the PPI Products, and that those users were relying on Defendants' promotional and advertising materials in their selection of the product for that particular use.

223. Through aggressive healthcare provider promotion and patient advertising, educational, informational and marketing campaigns, Defendants participated in the selection of their PPI Products by healthcare providers, patients and consumers.

224. At all relevant times hereto, Defendants' PPI Products did not have the requisite clinical safety or efficacy profiles to be deemed fit for the particular purpose of treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

225. Defendants' PPI Products did not conform to this implied warranty of fitness for the use in treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

226. The Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and warranty of the Defendants in the choice to use Defendants' PPI Products.

227. The PPI Products were neither safe nor fit for their intended use nor of merchantable quality, as warranted by Defendants to the Plaintiff, in that PPI Products pose a dangerous risk when used as intended to cause serious kidney injuries.

228. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff's injuries.

229. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

230. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT VI

FRAUD AND FRAUDULENT MISREPRESENTATION

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges as follows:

231. Defendants fraudulently represented to the medical and healthcare community, patients, consumers and the general public, including the Plaintiff, that their PPI Products had been adequately tested, were safe for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and were accompanied by adequate warnings.

232. Defendants widely advertised, marketed and promoted their PPI Products as safe and effective medications for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and widely advertised, marketed and promoted PPIs as a safe for daily and extended use.

233. These representations were made by the Defendants with the intent of deceiving the medical and healthcare community, patients, consumers, the general public and the Plaintiff, with the intent of inducing the prescription and use of their PPI Products in circumstances that the Defendants knew were dangerous, unsafe and created a high risk of harm.

234. These representations made by Defendants were false and misleading.

235. Defendants knew these representations to be false when made and willfully, wantonly and recklessly disregarded whether the representations were true.

236. Defendants' conduct evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

237. At the time the Defendants made aforesaid representations, Plaintiff used Defendants' PPI Products and was unaware of the falsity of the representations and reasonably believed them to be true.

238. In reliance on Defendants' misrepresentations, the Plaintiff was induced to and did use Defendants' PPI Products, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

239. Defendants knew or should have known that their PPI Products had not been sufficiently tested, were defective in nature and/or that lacked adequate and/or sufficient warnings.

240. Defendants knew or should have known that their PPI Products had a potential to, could and would cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

241. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

242. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff's, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

COUNT VII

ENHANCED COMPENSATORY DAMAGES

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action and further alleges as follows:

243. Plaintiff is entitled to an award of enhanced compensatory and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of PPIs. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of PPIs, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting PPIs, despite Defendants' knowledge and awareness of the serious side effects and risk associated with PPIs.

244. Defendants had knowledge of, and were in possession of, evidence demonstrating that PPIs caused serious side effects. Notwithstanding Defendants' knowledge of the serious side effects of PPIs, Defendants continued to market the drug products by providing false and

misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, including Plaintiff and Plaintiff's healthcare providers.

245. Although Defendants knew or recklessly disregarded the fact that PPIs caused and causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute PPIs to consumers, including Plaintiff and Plaintiff's healthcare providers, without disclosing these side effects when there were safer alternative methods for treating gastric acid secretion-related conditions.

246. Defendants failed to provide warnings that would have dissuaded physicians from prescribing PPIs and consumers from purchasing and ingesting the PPI Products, thus preventing both from weighing the true risks against the benefits of prescribing, purchasing or consuming PPIs.

247. Defendants knew of the defective nature of PPIs as set forth herein, but continued to design, manufacture, market, distribute, sell and/or promote the drug as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff in a conscious or negligent disregard of the foreseeable harm caused by PPIs.

248. The aforementioned conduct of Defendants was committed with knowing, conscious, and deliberate disregard of the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to enhanced compensatory damages in the amount appropriate to punish Defendants and deter them from similar conduct in the future.

249. Defendants knowingly withheld or misrepresented information required to be submitted to the FDA which information was material and relevant to kidney injuries.

PRAYER FOR RELIEF

Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth here in full and further prays as follows:

WHEREFORE, to the furthest extent allowed by this Court and/or permitted at law, Plaintiff demands judgment against each Defendant and/or all Defendants, jointly and severally, on each of the foregoing Counts as follows:

a. All available compensatory damages for the described losses with respect to each cause of action;

b. Past and future medical expenses, as well as the cost associated with past and future life care;

c. Past and future lost wages and loss of earning capacity;

d. Past and future emotional distress;

e. Consequential damages;

f. All available noneconomic damages, including without limitation pain, suffering, and loss of enjoyment of life;

g. All wrongful death damages permitted by law, where applicable;

h. Enhanced compensatory and/or exemplary damages with respect to each cause of action for the wanton, willful, malicious, fraudulent, reckless acts of Defendants, who demonstrated a complete disregard for, and reckless indifference to the Plaintiff, in an amount sufficient to punish Defendant and deter future similar conduct;

i. Attorneys' fees, expenses, and costs of this action;

j. All interest recoverable; and

k. Such other and further relief at law or in equity as the Court deems just, appropriate and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury.

Respectfully submitted,

Wayne Samuels,

By his Attorneys,

UPTON & HATFIELD, LLP

Date: April 28, 2020

By: /s/ Russell F. Hilliard

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