**IN THE UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**
**NEWARK DIVISION**

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| **IN RE: PROTON-PUMP INHIBITOR PRODUCTS LIABILITY LITIGATION (NO. II)** | **17-md-2789 (CCC)(MF)** **(MDL 2789)** |

This document Relates to: **ALL ACTIONS**

# PLAINTIFFS' MASTER LONG FORM COMPLAINT AND JURY DEMAND

The Plaintiffs Steering Committee, pursuant to Case Management Order No. 7 ("CMO-7") and on behalf of Plaintiffs, file this Master Long Form Complaint against the following currently named Defendants: Abbott Laboratories, AstraZeneca Pharmaceuticals LP, AstraZeneca PLC, AstraZeneca AB, Zeneca Inc., Astra US Holding Corporation, Astra USA LLC, AstraZeneca LP, KBI Sub, Inc., GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, GlaxoSmithKline Consumer Healthcare LP, GlaxoSmithKline Consumer Healthcare Holdings (US) IP LLC, Merck & Co. Inc. d/b/a Merck, Sharp & Dohme Corporation, Novartis Corporation, Novartis Pharmaceutical Corporation, Novartis Vaccines and Diagnostics, Inc., Novartis Institutes for Biomedical Research, Inc., Novartis Consumer Health, Inc., Pfizer, Inc., The Procter & Gamble Company, Procter & Gamble Manufacturing Company, Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals International, Inc., Takeda California, Inc., Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. Takeda Pharmaceutical Company Limited, TAP Pharmaceutical Products, Inc. f/k/a TAP Holdings Inc., Wyeth Pharmaceuticals, Inc., Wyeth-Ayerst Laboratories and Wyeth LLC (collectively referred to as "Defendants").

This Master Long Form Complaint sets forth questions of fact and law common to those claims subsumed within the context of this multidistrict proceeding. Plaintiffs seek compensatory and punitive damages, monetary restitution and all other available remedies as a result of injuries caused by Defendants' defective pharmaceutical products. Plaintiffs make the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys' investigative efforts, regarding Defendants' prescription and over-the-counter Proton-Pump Inhibitor products (hereinafter together or individually, "the PPI Products" or "PPIs").

This Master Long Form Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court, nor is it intended to consolidate for any purpose the separate claims of the Plaintiffs herein. It is anticipated that individual plaintiffs may adopt this Master Long Form Complaint and the necessary causes of action herein through use of a separate Short Form Complaint. **(Attached hereto as Exhibit A, is the Short Form Complaint)**. Any separate facts and additional claims of individual plaintiffs will be set forth in the Short Form Complaints filed by the respective plaintiffs or their counsel. This Master Long Form Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, nor does any plaintiff relinquish the right to move to amend their individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may warrant.

As more particularly set forth herein, each plaintiff maintains that the PPI Products are defective in design, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lack proper warnings associated with their use.

## INTRODUCTION

1. These are personal injury actions 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 the PPI Products including, but not limited to Dexilant, Nexium, Nexium 24HR, Prevacid, Prevacid 24HR, Prilosec, Prilosec OTC and Protonix.

2. PPI Products 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.

## PARTIES

3. Pursuant to CMO-7, this Master Long Form Complaint is filed on behalf of all Plaintiffs and, if applicable, Plaintiffs' spouses, children, decedents, Estates or Wards who file a Short Form Complaint. By operation of CMO-7, all allegations pleaded herein are deemed pleaded in any Short Form Complaint.

4. Plaintiffs have suffered and were diagnosed with various forms of kidney injury, which were directly and proximately caused by their regular and prolonged use of the PPI Products. These kidney injuries include, but are not limited to, Acute Interstitial Nephritis ("AIN"), Acute Kidney Injury ("AKI"), Chronic Kidney Disease ("CKD"), and End-Stage Renal Disease ("ERSD") (collectively, "kidney injuries"), as well as any other injuries set forth in a Short Form Complaint, Plaintiff Fact Sheets or other responsive discovery.

5. Defendant Abbott Laboratories ("Defendant Abbott") is and, at all times relevant to this action, has been an Illinois Corporation having a principal place of business at 100 Abbott Park Rd., Abbott Park, Ill. 60064.

6. In and around 1977, Defendant Abbott and Defendant Takeda Pharmaceutical Company Limited entered into a joint venture resulting in the creation of TAP Holdings, Inc.

7. As a part of their business and at all relevant times, Defendant Abbott has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription Prevacid (lansoprazole) products.

8. Defendant Abbott manufactures and markets Prevacid in the United States.

9. Defendant Abbott has transacted and conducted business related to Prevacid in each of the States and Territories of the United States.

10. Defendant Abbott has derived substantial revenue from Prevacid in each of the States and Territories of the United States.

11. Defendant Abbott 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 Prevacid.

12. 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.

13. Defendant AstraZeneca PLC is and, at all times relevant to this action, has been a Delaware Corporation with its principal place of business at 1800 Concord Pike, Wilmington, DE 19850.

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

15. Defendant AstraZeneca AB, the general partner comprising Defendant AstraZeneca Pharmaceuticals LP, is a Swedish corporation having a principal place of business at SE-151 36 Sodentalje, Sweden.

16. Defendant Zeneca Inc., one of the three limited partners comprising Defendant AstraZeneca Pharmaceuticals LP, is and, at all times relevant to this action, has been a Delaware Corporation having its principal place of business at 1800 Concord Pike, Wilmington, DE 19850.

17. Defendant Astra US Holding Corporation, one of the three limited partners comprising Defendant AstraZeneca Pharmaceuticals LP, is and, at all times relevant to this action, has been a Delaware Corporation having its principal place at 1800 Concord Pike, Wilmington, DE 19850.

18. Defendant Astra U.S.A. LLC, one of the three limited partners comprising Defendant AstraZeneca Pharmaceuticals LP, is and, at all times relevant to this action, has been a New York Corporation having its principal place of business at 1800 Concord Pike, Wilmington, DE 19850.

19. 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.

20. Defendant AstraZeneca LP is comprised of two partners. Defendant AstraZeneca Pharmaceuticals LP is the general partner and Defendant KBI Sub, Inc. is the limited partner.

21. Defendant KBI Sub, Inc. is and, at all times relevant to this action, has been a Delaware corporation having a principal place of business at 1 Merck Drive, White House Station, NJ 08889.

22. Defendant AstraZeneca Pharmaceuticals LP, Defendant AstraZeneca PLC, Defendant AstraZeneca AB, Defendant Zeneca Inc., Defendant Astra US Holding Corporation, Defendant Astra U.S.A. LLC, Defendant AstraZeneca LP and Defendant KBI Sub, Inc. are referred to collectively herein as the "AstraZeneca Defendants."

23. 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.

24. 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.

25. 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.

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

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

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

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

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

36. 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).

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

38. 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).

39. 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.

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

41. 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.

42. 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.

43. 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.

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

45. 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.

46. 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.

47. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC is and, at all times relevant to this action, has been a Delaware limited liability corporation having a principal place of business at 184 Liberty Corner Road, Warren, NJ 07059.

48. Defendant GlaxoSmithKline Consumer Healthcare LP is and, at all times relevant to this action, has been a Delaware limited liability corporation having a principal place of business at 184 Liberty Corner Road, Warren, NJ 07059.

49. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) IP LLC is and, at all times relevant to this action, has been a Delaware limited liability corporation having a principal place of business at 5 Crescent Drive, Philadelphia, PA 19112.

50. Defendant GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, Defendant GlaxoSmithKline Consumer Healthcare LP and Defendant GlaxoSmithKline

Consumer Healthcare Holdings (US) IP LLC are referred to collectively herein as the "GlaxoSmithKline Defendants."

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

52. The GlaxoSmithKline Defendants, pursuant to an agreement with the Novartis Defendants, obtained the rights to market and sell the over-the-counter medication Prevacid 24Hr.

53. The GlaxoSmithKline Defendants, in collaboration and amongst themselves, designed and developed Prevacid 24HR.

54. As a part of their business and at all relevant times, the GlaxoSmithKline Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid 24HR products.

55. Defendant GlaxoSmithKline Consumer Healthcare (US) IP LLC is the holder of approved NDA 022327 for Prevacid 24HR.

56. The GlaxoSmithKline Defendants manufacture and market Prevacid 24HR in the United States.

57. The GlaxoSmithKline Defendants have transacted and conducted business related to Prevacid 24HR in each of the States and Territories of the United States.

58. The GlaxoSmithKline Defendants have derived substantial revenue from Prevacid 24HR in each of the States and Territories of the United States.

59. The GlaxoSmithKline 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 Prevacid 24HR.

60. 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.

61. 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.

62. 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.

63. In 1997, the Procter & Gamble Defendants formed a strategic alliance with the Joint Venture to develop and market Prilosec OTC.

64. Until 2014, Defendant Merck had a contractual and ownership interest in the Joint Venture. Through these interests, between 2009 and 2014, Defendant Merck earned at least $7 billion, based on the sales of prescription and over-the-counter formulations of Nexium and Prilosec.

65. Defendant Merck currently has, and will continue to have until 2018, a financial interest in prescription and over-the-counter formulations of Nexium and Prilosec.

66. As a part of their business and at all relevant times, Defendant Merck has been and is involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription and over-the-counter formulations of Prilosec and Nexium.

67. In 1989, Defendant Merck sponsored the first NDA for a Prilosec product, NDA 019810, which it submitted to the FDA for approval to market Prilosec. Under this NDA the following forms of Prilosec have been approved: Delayed-Release Capsule Pellets (20mg), approved on September 14, 1989; Delayed-Release Capsule Pellets (10mg), approved on October 5, 1995; and Delayed-Release Capsule Pellets (40mg) approved on January 15, 1998.

68. Defendant Merck has also had a contractual, ownership and financial interest in Prilosec Delayed-Release Oral Suspension, NDA 022056.

69. Defendant Merck, through the Joint Venture, also designed, researched, manufactured, tested, advertised, marketed, sold and distributed Nexium.

70. Defendant Merck has had a contractual, ownership and financial interest in the following FDA approved forms of Nexium: Delayed-Release Capsule Pellets, NDA 021153; Delayed-Release Oral Suspension, NDAs 02195 and 022010; and Intravenous Injectable Solution, NDA 021689.

71. Defendant Merck manufactures and markets Nexium products in the United States.

72. Defendant Merck manufactures and markets Prilosec products in the United States.

73. Defendant Merck has transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

74. Defendant Merck has derived substantial revenue from PPI Products in each of the States and Territories of the United States.

75. Defendant Merck 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.

76. Defendant Novartis Corporation is and, at all times relevant to this action, has been a Swiss corporation having a principal place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

77. Defendant Novartis Pharmaceutical Corporation is and, at all times relevant to this action, has been a Delaware corporation having a principal place of business at One Health Plaza, East Hanover, NJ 07936.

78. Defendant Novartis Vaccines and Diagnostics, Inc. is and, at all times relevant to this action, has been a Delaware corporation having a principal place of business at 4560 Horton Street, Emeryville, CA 94608.

79. Defendant Novartis Institutes for Biomedical Research, Inc. is and, at all times relevant to this action, has been a Delaware corporation having a principal place of business at 250 Massachusetts Avenue, Cambridge, MA 02139.

80. Defendant Novartis Consumer Health, Inc. is and, at all times relevant to this action, has been a Delaware corporation having a principal place of business at 200 Kimball Drive, Parsippany, NJ 07054.

81. Defendant Novartis Corporation is the parent/holding company of Defendant Novartis Pharmaceutical Corporation, Defendant Novartis Vaccines and Diagnostics, Inc., Defendant Novartis Institutes for Biomedical Research, Inc. and Defendant Novartis Consumer Health, Inc.

82. At all relevant times, Defendant Novartis Corporation has exercised and exercises dominion and control over Defendant Novartis Pharmaceutical Corporation, Defendant Novartis Vaccines and Diagnostics, Inc., Defendant Novartis Institutes for Biomedical Research, Inc. and Defendant Novartis Consumer Health, Inc.

83. Defendant Novartis Corporation, Defendant Novartis Pharmaceutical Corporation, Defendant Novartis Vaccines and Diagnostics, Inc., Defendant Novartis Institutes for Biomedical Research, Inc. and Defendant Novartis Consumer Health, Inc. are referred to collectively herein as the "Novartis Defendants."

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

85. In 2005, the Novartis Defendants obtained the rights to market the over-the-counter version of Prevacid, Prevacid 24HR, from Defendant TAP.

86. As a part of their business and at all relevant times, the Novartis Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid 24 HR.

87. The Novartis Defendants, in collaboration amongst themselves, designed and developed the Prevacid 24 HR.

88. Defendant Novartis Pharmaceuticals Corporation has been the holder of approved NDA 022327 for Prevacid 24HR.

89. The Novartis Defendants manufacture and market Prevacid 24HR in the United States.

90. The Novartis Defendants have transacted and conducted business related to Prevacid 24HR in each of the States and Territories of the United States.

91. The Novartis Defendants have derived substantial revenue from Prevacid 24HR in each of the States and Territories of the United States.

92. The Novartis 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 Prevacid 24HR.

93. 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.

94. On October 15, 2009, Defendant Pfizer Inc. acquired Defendant Wyeth Pharmaceuticals, Inc. and, since that time, has been the parent/holding company of the Wyeth Defendants.

95. 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.

96. 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.

97. 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.

98. 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.

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

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

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

102. 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.

103. Defendant The Procter & Gamble Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, OH 45202.

104. Defendant Procter & Gamble Manufacturing Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 3875 Reservoir Road, Lima, OH 45801.

105. At all times relevant to this action Defendant The Procter & Gamble Company has been the direct or indirect owner of substantially all of the stock or other ownership interests of Defendant Procter & Gamble Manufacturing Company.

106. Defendant The Procter & Gamble Company and Defendant Procter & Gamble Manufacturing Company are referred to collectively herein as the "Procter & Gamble Defendants."

107. Each of the Procter & Gamble Defendants was the agent and employee of the other Procter & Gamble Defendant, and in doing the things alleged were acting within the course and scope of such agency and employment and with the other Procter & Gamble Defendant's actual and implied permission, consent, authorization and approval.

108. The Procter & Gamble Defendants, in collaboration amongst themselves and the AstraZeneca Defendants, designed and developed Prilosec OTC.

109. As a part of their business and at all relevant times, the Procter & Gamble Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prilosec OTC.

110. In or about 1997, Defendant The Procter & Gamble Company entered into a marketing agreement with Defendant AstraZeneca LP whereby the Procter & Gamble Defendants acquired the rights to market Prilosec OTC products.

111. On or about January 27, 2000, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, submitted NDA 021229 for Prilosec OTC delayed release tablets.

112. On or about June 20, 2003, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, was granted approval for NDA 021229, Prilosec OTC.

113. The Procter & Gamble Defendants made Prilosec OTC available for purchase in the United States on or about October 2003 and continue to manufacture and market each formulation of Prilosec OTC in the United States.

114. The Procter & Gamble Defendants have transacted and conducted business related to Prilosec OTC in each of the States and Territories of the United States.

115. The Procter & Gamble Defendants have derived substantial revenue from Prilosec OTC in each of the States and Territories of the United States.

116. The Procter & Gamble 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 Prilosec OTC.

117. 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, Ill 60015.

118. 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, Ill 60015.

119. Defendant Takeda Pharmaceuticals LLC is and, at all times relevant to this action, has been an Illinois limited liability company having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

120. Defendant Takeda Pharmaceuticals, LLC, at all times relevant to this action, has been wholly owned by Defendant Takeda Pharmaceuticals America, Inc. and Defendant Takeda Pharmaceuticals USA, Inc.

121. Defendant Takeda Pharmaceuticals International, 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.

122. Defendant Takeda California, Inc. is and, at all times relevant to this action, has been a Delaware Corporation having a principal place of business at 10410 Science Center Drive, San Diego, CA 92121.

123. 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.

124. 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.

125. 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., Defendant Takeda Pharmaceuticals LLC, Defendant Takeda Pharmaceuticals International Inc., Defendant Takeda California Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

126. 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., Defendant Takeda Pharmaceuticals LLC, Defendant Takeda Pharmaceuticals International Inc., Defendant Takeda California Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

127. Defendant Takeda Pharmaceuticals USA, Inc., Defendant Takeda Pharmaceuticals America, Inc., Defendant Takeda Pharmaceuticals LLC, Defendant Takeda Pharmaceuticals International, Inc., Defendant Takeda California, 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."

128. 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.

129. 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, Prevacid 24HR and Protonix products.

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

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

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

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

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

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

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

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

138. 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.

139. Defendant TAP Pharmaceutical Products, Inc. f/k/a TAP Holdings, Inc. (hereinafter "Defendant TAP") is and, at all times relevant to this action, has been a Delaware corporation having a principal place of business in Lake Forest, Ill.

140. Defendant TAP was a joint venture created by and between Defendant Abbott and the Takeda Defendants in and around 1977.

141. Defendant TAP filed the Investigational New Drug Application for prescription Prevacid in 1987, and filed an NDA for prescription Prevacid in 1993

142. Defendant TAP Holdings, Inc. was the holder of NDA 020406 for prescription Prevacid, which was approved for sale in the United States in 1995.

143. In 2005, Defendant TAP sold the rights to market an over-the-counter version of Prevacid, Prevacid 24HR, to Defendant Novartis Consumer Healthcare.

144. Defendant TAP dissolved in 2008 and, at that time, the Takeda Defendants received the rights to Dexilant, Prevacid and Prevacid 24HR products in the United States.

145. Defendant TAP manufactured and marketed Prevacid in the United States.

146. Defendant TAP has transacted and conducted business related to Prevacid in each of the States and Territories of the United States.

147. Defendant TAP has derived substantial revenue from Prevacid in each of the States and Territories of the United States.

148. Defendant TAP 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 Prevacid.

149. Defendant Wyeth Pharmaceuticals Inc. is and, all times relevant to this action, has been a Delaware corporation having a principal place of business at 500 Arcola Rd. Collegeville, PA.

150. Defendant Wyeth-Ayerst Laboratories is and, all times relevant to this action, has been a Delaware corporation having a principal place of business at 500 Arcola Rd. Collegeville, PA.

151. Defendant Wyeth-Ayerst Laboratories is a wholly-owned subsidiary of Defendant Wyeth Pharmaceuticals, Inc.

152. In 2009 Defendant Pfizer Inc. acquired Defendant Wyeth Pharmaceuticals Inc. and, since that time, Defendant Wyeth Pharmaceuticals, Inc. has been a wholly owned subsidiary of Defendant Pfizer, Inc.

153. On November 9, 2009, Defendant Wyeth Pharmaceuticals, Inc. converted into a Delaware limited liability company, Wyeth LLC.

154. Defendant Wyeth LLC is and, all times relevant to this action, has been a Delaware corporation having a principal place of business at 500 Arcola Rd. Collegeville, PA, and is a wholly-owned subsidiary of Defendant Pfizer Inc.

155. Defendant Wyeth Pharmaceuticals, Inc., Defendant Wyeth-Ayerst Laboratories and Defendant Wyeth LLC are referred to collectively herein as the "Wyeth Defendants."

156. At all relevant times, Defendant Pfizer Inc. exercised and exercises dominion and control over the Wyeth Defendants.

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

158. As a part of their business and at all relevant times, the Wyeth Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription Protonix products.

159. The Wyeth Defendants, in collaboration amongst themselves, designed and developed the prescription Protonix products.

160. Defendant Wyeth-Ayerst Laboratories is the holder of approved NDAs 020987 and 020988 for Protonix.

161. Defendant Wyeth Pharmaceuticals, Inc. is the holder of approved NDA 022020 for Protonix.

162. The Wyeth Defendants manufacture and market Protonix in the United States.

163. The Wyeth Defendants have transacted and conducted business related to Protonix in each of the States and Territories of the United States.

164. The Wyeth Defendants have derived substantial revenue from Protonix in each of the States and Territories of the United States.

165. The Wyeth 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 Protonix.

166. Defendants John Does/Jane Does 1-30 are those persons, agents, employees, and/or representatives of the Defendants whose conduct as described herein caused or contributed to the damages of Plaintiffs, all of whose names and legal identities are unknown to Plaintiffs at this time, but will be substituted by amendment when ascertained, individually and jointly.

167. Defendants Unknown Businesses and/or Corporations A-Z are unknown entities whose conduct as described herein caused or contributed to the damages of Plaintiffs, all of whose names and legal identities are unknown to Plaintiffs at this time, but will be substituted by amendment when ascertained, individually and jointly.

## JURISDICTION AND VENUE

168. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d) because complete diversity exists between Plaintiffs and Defendants.

169. The amount in controversy alleged by each of the respective individual Plaintiffs will exceed the sum or value of $75,000.

170. Defendants have significant contacts with the federal judicial district identified in the Short Form Complaint such that they are subject to the personal jurisdiction of the court in said district.

171. Defendants are each multinational Fortune 500 companies that have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction

would be proper in any of them. Defendants have derived revenue from the sale of their respective PPI Product(s) in each of the States and Territories of the United States.

172. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in the Short Form Complaint. Pursuant to 28 U.S.C. § 1391(a), venue is proper in said district.

## FACTUAL ALLEGATIONS

### A. General Background: Proton Pump Inhibitors

173. 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.

174. 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.

175. 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.

176. 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.

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

178. 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.

**B. PPI Products Cause Severe Kidney Injuries**

179. 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.

180. 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. PPI-Induced Acute Interstitial Nephritis ("AIN")**

181. Since 1992, numerous case reports have been published in the medical literature documenting an association between the use of PPI Products and the development of AIN amongst patients.

182. 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 Product use, by way of AIN, left most patients "with some level of chronic kidney disease."

183. In 2007, F. Sierra et al. published an article in the *Journal of Alimentary Pharmacology and Therapeutics*, titled, "Systematic review: proton pump inhibitor-associated acute interstitial nephritis." The researchers concluded that long-term use of proton pump inhibitors is associated with interstitial nephritis.

184. In February 2007, Harmark et al. published their findings in the *British Journal of Clinical Pharmacology* that AIN could be induced by a variety of available PPI Products and was indicative of a class-effect and that this finding was further supported by adverse event data from the World Health Organization Collaborating Centre for International Drug Monitoring, "where PPI-induced AIN is disproportionately present in the database." Harmark et al., *Proton-pump inhibitor-induced acute interstitial nephritis*, BJ Clin. Pharm. (2007).

185. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a Citizen's Petition with the FDA seeking the addition of safety information concerning several risks associated with PPI Product usage, including, among others, PPI-induced AIN.

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

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

188. The FDA found that there was "reasonable evidence of a causal association" and therefore, concluded "that the prescription PPI labeling should be consistent with regard to this risk[.]"

189. In December of 2014, all labels for prescription PPI Products were required to include the following information:

> *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 [PPI] if acute interstitial nephritis develops.*

190. To this date, Defendants' over-the-counter PPI Products do not include a warning or any risk information about AIN.

191. 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 Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

192. 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.

193. 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.

194. 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.

195. 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).

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

197. Where AIN is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AIN can lead to Chronic Kidney Disease and End Stage Renal Disease requiring the patient to undergo permanent dialysis, kidney transplant or, in some cases, death.

198. 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")**

199. Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly.

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

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

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

203. 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")**

204. Chronic Kidney Disease is the gradual loss of kidney function. Kidneys filter waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

205. CKD can ultimately progress to End Stage Renal Disease in which total kidney function is lost and patients must either undergo dialysis or have a kidney transplant to survive.

206. 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.

207. 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."

208. 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."

209. 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.

210. 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).

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

### C. PPI Products Cause Rebound Acid Hypersensitivity, Worsening GERD and Acid Reflux, Creating Dependency

212. Users of PPI Products will, and have, experienced 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.

213. 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.

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

215. 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.

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

217. After Plaintiffs' 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 Plaintiffs to treat GERD as a more severe condition than that which existed when PPI Products were initiated.

218. 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.

219. 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.

220. 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.

**D. Safer Alternatives to PPIs**

221. 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.

222. 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).

223. Consumers, including Plaintiffs, 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.

**E. Injuries Resulting from PPI Products**

224. 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.

225. 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.

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

227. Consumers, including Plaintiffs, 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.

**F. Defendants' Actively Concealed the Dangers Associated with Use of PPI Products**

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

229. Defendants concealed and continue to conceal from Plaintiffs, other consumers and/or the medical community that Defendants' PPI Products can cause kidney injuries. Specifically, Defendants failed to adequately inform Plaintiffs, 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 Plaintiffs, other consumers, Plaintiffs' 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.

230. 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.

231. As a result of Defendants' actions, Plaintiffs and/or Plaintiffs healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiffs had been exposed to the risks identified in this Master Long Form Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations.

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

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

234. 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.

235. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPI Products and failed to warn about the risks of acute interstitial nephritis, acute kidney failure, chronic kidney disease and other kidney injuries.

236. 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.

237. 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, pre-clinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

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

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

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

241. 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.

**G. Defendants Violations of Federal Law**

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

243. 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.

244. 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 Plaintiffs.

**ESTOPPEL FROM PLEADING AND TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

245. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

246. Plaintiffs assert 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.

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

248. Despite diligent investigation by Plaintiffs into the cause of their injuries, the nature of Plaintiffs' injuries and damages and their relationship to the PPI Products 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 Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

249. 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 Plaintiffs and/or the consuming public of the true risks associated with the PPI Products. As a result of the

Defendants' fraudulent concealment, Plaintiffs and/or Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence, that Plaintiffs 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.

250. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPI Products. The Defendants were under a duty to disclose the true character, quality and nature of PPI Products 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 Plaintiffs, their medical providers and/or to their health facilities.

251. 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. Plaintiffs 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.

252. Defendants were and continue to be in possession of information and data that shows the risk and dangers of these products that is not otherwise in the possession or available to Plaintiffs and/or their healthcare providers.

253. At the time of Plaintiffs' injuries, Plaintiffs and/or Plaintiffs' healthcare providers were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because Plaintiffs and Plaintiffs' healthcare providers reasonably relied on Defendants' representations that PPI Products do not cause kidney injury.

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

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

256. Plaintiffs exercised reasonable diligence in an attempt to discover the cause of their kidney injuries. Plaintiffs relied on their physicians to advise them of any known complications. Plaintiffs had no reason to believe their 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.

257. The Plaintiffs 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 Plaintiffs could not have reasonably discovered the wrongdoing at the time of his injury.

258. At the time of Plaintiffs' injuries, Plaintiffs did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries with PPI Product use or have any discussions with their doctors that there was an association between their kidney injuries and PPI Product use.

## CAUSES OF ACTION

### COUNT I
### STRICT PRODUCT LIABILITY

259. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form

Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

260. At the time of Plaintiffs' injuries, the PPI Products manufactured by the Defendants were defective and unreasonably dangerous to foreseeable consumers, including Plaintiffs.

261. At the time of Plaintiffs' injuries, Defendants placed PPI Products into the stream of commerce that were defective and in an unreasonably dangerous condition to foreseeable users, including the Plaintiffs.

262. At all times herein mentioned, Defendants have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed PPI Products as described herein that were used by the Plaintiffs.

263. Defendants' PPI Products were expected to and did reach consumers, handlers and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by the Defendants.

264. Defendants' PPI Products were manufactured in an unsafe, defective and inherently dangerous condition, which was dangerous to users, including Plaintiffs.

265. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the PPI Products.

266. At all times herein mentioned, the PPI Products were in a defective condition and unsafe, and Defendants knew or had reason to know that their PPI Products were defective and unsafe, including when used in the formulation and manner recommended by the Defendants.

267. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants, manufacturers and/or suppliers, the PPI Products were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect, and more dangerous than other medications on the market designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

268. Defendants knew or should have known that at all times herein mentioned their PPI Products were in a defective condition and were and are inherently dangerous and unsafe.

269. At the time Plaintiffs used Defendants' PPI Products, the PPI Products were being used for the purposes and in a manner normally intended and foreseeable, namely to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

270. Defendants, with this knowledge, voluntarily designed their PPI Products in a dangerous condition for use by the public and the Plaintiffs.

271. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended and foreseeable use.

272. Defendants created a product unreasonably dangerous for its intended and foreseeable use.

273. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that PPI Products left the hands of Defendants in a defective condition and were unreasonably dangerous to its intended users.

274. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which they were manufactured.

275. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiffs.

276. Plaintiffs could not, by the exercise of reasonable care, have discovered the PPI Products' defects herein mentioned and perceived their danger.

277. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including kidney injuries and other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to adequately warn of said risk.

278. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including rebound acid hypersecrection, and the Defendants failed to adequately warn of said risk.

279. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products were

ineffective for their intended use of treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and that there were less dangerous alternatives on the market to treat peptic disorders.

280. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

281. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks and severe and permanent health consequences from ingesting PPI Products, they failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote their PPI Products.

282. The PPI Products ingested by Plaintiffs were in the same or substantially similar condition as they were when they left the possession of Defendants.

283. Plaintiffs did not misuse or materially alter the PPI Products.

284. Defendants are strictly liable for Plaintiffs' injuries in the following ways:

a. The PPI Products as designed, manufactured, sold and supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to properly market, design, manufacture, distribute, supply and sell their PPI Products;

c. Defendants failed to warn and place adequate warnings and instructions on their PPI Products;

d. Defendants failed to adequately test their PPI Products;

e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of PPI Products; and

f. Feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating Plaintiffs' conditions, while decreasing the risk of kidney injuries.

285. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiffs for the manufacturing, marketing, promoting, distribution, and selling of a defective PPI Products.

286. Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

287. These defects in Defendants' PPI Products were a substantial factor in causing Plaintiffs' injuries.

288. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

289. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT II**
**STRICT PRODUCT LIABILITY –DESIGN DEFECT**

290. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

291. At all times relevant, Defendants' PPI Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce.

292. Defendants' PPI Products were defective in design or formulation in that they were not merchantable, reasonably suitable and/or safe for their intended and foreseeable use, and their condition when sold was the proximate cause and/or a substantial factor of the injuries sustained by Plaintiffs.

293. Defendants' PPI Products did not perform safely or as Plaintiffs or an ordinary consumer would have expected.

294. At all times relevant, the PPI Products were used as intended or in a way reasonably foreseeable to the Defendants.

295. Defendants placed their PPI Products into the stream of commerce with wanton and reckless disregard for public safety.

296. At all times relevant, Defendants' PPI Products were expected to reach, and did reach, Plaintiffs, without substantial change in the condition in which they were sold.

297. The PPI Products were sold in an unsafe, defective and inherently dangerous condition.

298. The PPI Products contained defects in their design which render the drugs dangerous to consumers, including Plaintiffs, when used as intended or as reasonably foreseeable to Defendants. The design defects render the PPI Products more dangerous than other drugs designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and cause an unreasonable increased risk of injury, including but not limited to life-threatening kidney injuries.

299. The PPI Products were in a defective condition and unsafe, and Defendants knew, had reason to know or should have known that the PPI Products were defective and unsafe, even when used as instructed.

300. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of serious kidney injuries that may be irreversible, permanently disabling and life-threatening, is high in light of the intended and reasonably foreseeable use of the PPI Products.

301. The risks of harm associated with the design of Defendants' PPI Products are higher than necessary.

302. It is unlikely that users would be aware of the risks associated with Defendants' PPI Products, and Plaintiffs specifically were not aware of these risks, nor would they expect such risks.

303. The design of Defendants' PPI Products did not conform to any applicable public or private product standard that was in effect when the PPI Products left the Defendants' control.

304. The PPI Products' designs are more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner. The PPI Products are more dangerous than Plaintiffs expected.

305. The intended or actual utility of PPI Products is not of such benefit to justify the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

306. At the time the PPI Products left Defendants' control, it was both technically and economically feasible to have an alternative design that would not have caused kidney injuries that may be irreversible, permanently disabling and life-threatening, or an alternative design that would have substantially reduced the risk of these injuries.

307. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiffs.

308. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with the knowledge of the safety and efficacy problems and suppressed this knowledge from Plaintiffs, the medical community and the general public. Defendants made conscious decisions not to warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

309. The unreasonably dangerous nature of Defendants' PPI Products caused serious harm to Plaintiffs.

310. Defendants' PPI Products are defective in their design which renders the PPI Products dangerous to consumers, including Plaintiffs, when used as intended or as reasonably foreseeable to Defendants.

311. The design defects render the PPI Products more dangerous than other products used for the same intended purpose, and cause an unreasonable increased risk of harm.

312. The PPI Products' design is defective and unsafe, and Defendants knew or had reason to know that the PPI Products were defective and unsafe in their design when used as

instructed and in a foreseeable manner for the treatment of peptic disorders by consumers, including the Plaintiffs.

313. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of kidney injury that may lead to permanently disabling and life-threatening or life-ending conditions, was high in light of the intended and reasonably foreseeable use of PPI Products by patients for treatment of peptic disorders.

314. Users of PPI Products would not be aware of the risks of kidney injuries associated with either the defective design or warnings associated with PPI Products through warnings, general knowledge or otherwise, and the Plaintiffs were specifically unaware of these risks, and would not be expected to be aware of these risks.

315. The intended or actual utility and benefit of the PPI Products does not justify the risk of kidney injuries that may be irreversible, permanently disabling, life-threatening or life-ending.

316. The design of the PPI Products was negligently formulated by the Defendants in disregard of the known risk of kidney injury.

317. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of kidney injury.

318. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of rebound acid hypersecretion.

319. The defects in design and warnings caused and/or increased the risk of harm of Plaintiffs' injuries and damages.

320. The defective nature of the PPI Products was a substantial factor in causing Plaintiffs' injuries.

321. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

322. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## COUNT III
## STRICT PRODUCT LIABILITY – FAILURE TO WARN

323. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

324. Defendants manufactured, distributed and/or sold the PPI Products that were dangerous and presented a high risk of serious kidney and related personal injuries when used as intended or in foreseeable way.

325. Defendants had a duty to warn Plaintiffs and their healthcare providers regarding the risks associated with ingesting PPI Products and failed to warn of the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening.

326. Defendants knew, or in the exercise of reasonable care should have known, about the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening that are associated with use of their PPI Products.

327. Defendants failed to provide adequate warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of kidney injury that may be irreversible, permanently disabling and life-threatening in light of the likelihood that the PPI Products would cause these injuries.

328. Defendants failed to update warnings based on information received from surveillance and research conducted after their PPI Products were first approved by the FDA and marketed, sold and used in the United States and throughout the world.

329. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using PPI Products after FDA approval.

330. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

331. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of rebound acid hypersecretion that would assist healthcare providers and/or patients who suffer from this after ceasing use of PPI Products.

332. Plaintiffs used the PPI Products for their approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

333. Plaintiffs and/or Plaintiffs' healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived the danger of PPI Products because the risks were not open or obvious.

334. Defendants, as the manufacturers and distributors of the PPI Products, are held to the level of knowledge of an expert in the field.

335. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

336. The warnings that were given by the Defendants failed to properly warn Plaintiffs and/or Plaintiffs' healthcare providers of the risks associated with the PPI Products, subjecting Plaintiffs to risks that exceeded the benefits to the Plaintiffs. Plaintiffs, individually and/or Plaintiffs through their healthcare providers, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

337. Defendants had a continuing duty to warn Plaintiffs and/or Plaintiffs' healthcare providers of the dangers associated with their PPI Products.

338. Had Plaintiffs and/or their healthcare providers received adequate warnings regarding the risks associated with the use of PPI Products, they would not have used them or they would have altered the frequency or duration of use.

339. Defendants failed to update warnings based on information received after the PPI Products entered the market, and continued to market, promote, detail, distribute and sell PPI Products without appropriately updated and amended warnings.

340. A manufacturer exercising reasonable and prudent care would have updated warnings on the PPI Products on the basis of epidemiology studies and/or reports of injuries to individuals using PPI Products after FDA approval.

341. Plaintiffs and their healthcare providers were led to believe, through Defendants' use of aggressive and pervasive marketing, promotion and detailing, that Defendants' PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

342. The warnings and instructions that were given by Defendants to healthcare providers were not accurate or clear, and were, in fact, false and misleading.

343. The warnings that were given by the Defendants failed to properly warn physicians and/or other healthcare providers, including those of the Plaintiffs, of the risks associated with Defendants' PPI Products, thereby subjecting patients, including the Plaintiffs, to unreasonable and foreseeable risks that exceeded the purported and marketed benefits of Defendants' PPI Products.

344. Plaintiffs' healthcare providers reasonably relied upon the representations, warning and instructions provided by Defendants for use and administration of their PPI Products.

345. Had the Plaintiffs and/or their healthcare providers received adequate, appropriate and correct warnings regarding the risks associated with the use of Defendants' PPI Products, these healthcare providers would not have prescribed, recommended, continued to prescribe or continued the recommendation of the PPI Products, or would have altered the duration and frequency of use.

346. Defendants' conduct as described herein was a substantial factor in causing Plaintiffs' injuries.

347. The Plaintiffs' injuries (in some cases death) were the direct and proximate result of Defendants' failure to warn of the dangers of Defendants' PPI Products.

348. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

349. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT IV**
**NEGLIGENCE**

350. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

351. 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.

352. 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 Plaintiffs' injuries and/or presented an unreasonably high risk of injury.

353. 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 acute interstitial nephritis, acute kidney injuries and chronic kidney disease, 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 Plaintiffs, 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 Plaintiffs 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 Plaintiffs 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 Plaintiffs and/or Plaintiffs' healthcare providers of the severity and duration of such adverse effects;

o) Failing to warn Plaintiffs and/or Plaintiffs' 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 Plaintiffs and/or Plaintiffs' healthcare providers of the known or reasonably foreseeable danger that Plaintiffs 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.

354. 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 Plaintiffs.

355. Defendants knew or should have known that consumers such as the Plaintiffs 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.

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

357. 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 Plaintiffs and healthcare providers.

358. As a direct and proximate result of Defendants' negligence, Plaintiffs suffered serious physical injury, harm (in some cases death), damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

359. 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 Plaintiffs, for the purpose of achieving profits and market share over safety.

360. Defendants acted in reckless disregard to public safety and well-being, including Plaintiffs' 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.

361. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, Plaintiffs, and/or Plaintiffs' 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.

362. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

363. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge

from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## COUNT V
## NEGLIGENCE PER SE

364. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

365. Defendants violated the Federal Food, Drug and Cosmetic Act 21 U.S.C. §301, et seq., and regulations as described herein, including but not limited to 21 U.S.C. §352, 21, CFR § 201.5, 21 CFR § 201.56, 21 CFR § 201.57, 21 CFR § 201.66, 21 CFR § 210.1, 21 CFR § 210.122, 21 CFR § 211.165, 21 CFR § 211.198, 21 CFR § 310.303, 21 CFR §310.305, 21 CFR § 314.80, and 21 CFR § 312.32.

366. These statutes and regulations are aimed at preserving the health and safety of Plaintiffs and the general public.

367. Defendants' acts were the proximate cause and/or a substantial factor in bringing about the harm to the Plaintiffs as alleged herein.

368. Plaintiffs are among the class of individuals that these statutes and regulations were designed to protect.

369. Plaintiffs' injuries are the type that these federal statutes and regulations were intended to prevent.

370. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

371. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## COUNT VI
## BREACH OF EXPRESS WARRANTY

372. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

373. Defendants expressly warranted that their PPI Products were safe and effective to members of the consuming public, including Plaintiffs.

374. Defendants expressly warranted that their PPI Products were safe and effective products for use by members of the consuming public, including the Plaintiffs, for the treatment of peptic disorders and did not disclose the material risks that their PPI Products could cause serious kidney injury that may be irreversible, permanently disabling and life-threatening. The representations were not justified by the performance of the PPI Products.

375. Defendants expressly warranted that their PPI Products were safe and effective to use.

376. Defendants expressly represented to Plaintiffs, Plaintiffs' physicians, healthcare providers and/or the FDA that their PPI Products were safe and fit for use for the intended purpose, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects they did produce were accurately reflected in the warnings, and that they were adequately tested and fit for their intended use.

377. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that their PPI Products were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

378. Plaintiffs and/or their healthcare providers reasonably relied on Defendants' express representations.

379. Defendants' PPI Products do not conform to these express representations because they are not safe and have serious side effects, including kidney injuries and in some cases, death.

380. Defendants breached their express warranty in one or more of the following ways:

a) PPI Products, as designed, manufactured, sold and/or supplied by the Defendants, were defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b) Defendants failed to warn and/or place adequate warnings and instructions on their PPI Products;

c) Defendants failed to adequately test their PPI Products; and,

d) Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from PPI Products.

381. Defendants made statements, affirmations and representations of fact concerning their PPI Products through their advertisements, educational campaigns and multi-platform marketing and promotional initiatives directed at consumers, patients and healthcare providers promoting unnecessary and dangerous use and overuse of their PPI Products.

382. Defendants' statements, affirmations and representations of fact did reach the Plaintiffs, and formed a "basis of the bargain" for the Plaintiffs' decision to purchase or accept the prescription of PPI Products.

383. Defendants did not disclose material risk of kidney injuries alleged herein that PPI Products caused.

384. Defendants' representations concerning the safety and efficacy of their PPI Products were not justified by their performance or benefits.

385. Defendants expressly warranted that PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. In fact, Defendants, through their advertisements, promoted use of PPI Products for ongoing and daily use. Their PPI Products did not conform to Defendants' representations, statements and/or affirmations of fact in terms of the express warranties made to consumers and patients concerning the drugs' safety and efficacy as formulated for use.

386. The Plaintiffs reasonably and justifiably relied upon Defendants' representations, statements and/or affirmations of fact that their PPI Products were safe and effective when the Plaintiffs chose to purchase, use and continue to use them.

387. The Plaintiffs were unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including Defendants' PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and express warranty of the Defendants in the choosing to use Defendants' PPI Products.

388. Defendants herein breached the aforesaid express warranties as their PPI Products were defective.

389. Plaintiffs' injuries (and in some cases death) were the direct and proximate result of Defendants' breach of their express warranty.

390. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

391. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## COUNT VII
## BREACH OF IMPLIED WARRANTY

392. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

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

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

395. 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 Master Long Form Complaint.

396. Plaintiffs 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.

397. 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 Plaintiffs, 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.

398. 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.

399. 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.

400. 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.

401. The Plaintiffs were 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.

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

403. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiffs' injuries.

404. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal

injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

405. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT VIII**
**NEGLIGENT MISREPRESENTATION**

406. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

407. From the time Defendants' PPI Products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiffs, Plaintiffs' physicians and the general public, including but not limited to the misrepresentation that PPI Products were safe and effective for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale, use and overuse of their PPI Products and willfully deceived

Plaintiffs, Plaintiffs' physicians and the general public as to the health risks and consequences of the use of PPI Products.

408. Defendants had a duty to ensure that the representations they made about their PPI Products were true and complete when made. Defendants made the foregoing representation without any reasonable ground for believing them to be true.

409. At all relevant times hereto, Defendants conducted sales and marketing campaigns to promote the sale of their PPI Products and deceived patients, consumers, physicians and healthcare providers, including the Plaintiffs and their healthcare providers, as to the health risks and consequences of the use of their PPI Products.

410. The Defendants made these false and misleading representations without any reasonable ground for believing them to be true concerning the safety and efficacy of PPI Products for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

411. These representations were made directly by Defendants, their sales representatives and other authorized agents of the Defendants to physicians and other healthcare providers; in television media directed towards the general public; in publications, the popular press, and other written materials which were directed to physicians, patients, consumers and the general public; and on Internet websites and applications directed to consumers and physicians, including the Plaintiffs, with the intention of inducing and influencing the demand for, the ultimate prescription, purchase and use of their PPI Products.

412. The representations by the Defendants were in fact false, in that their PPI Products are not safe, fit and/or effective for human consumption as labeled, using PPIs Products is hazardous to consumers' health, and PPI Products have a serious propensity to cause serious

injuries to users, including but not limited to the kidney and related personal injuries suffered by Plaintiffs.

413. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of PPI Products.

414. In reliance on the misrepresentations by the Defendants, Plaintiffs were induced to purchase and use PPI Products. If Plaintiffs had known the truth and the facts concealed by the Defendants, Plaintiffs would not have used the PPI Products or would have used far fewer PPI Products. The reliance of Plaintiffs upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know all of the facts.

415. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

416. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT IX**
**FRAUD AND FRAUDULENT MISREPRESENTATION**

417. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

418. Defendants fraudulently represented to the medical and healthcare community, patients, consumers and the general public, including the Plaintiffs, 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.

419. 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.

420. These representations were made by the Defendants with the intent of deceiving the medical and healthcare community, patients, consumers, the general public and the Plaintiffs, 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.

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

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

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

424. At the time the Defendants made aforesaid representations, Plaintiffs used Defendants' PPI Products and were unaware of the falsity of the representations and reasonably believed them to be true.

425. In reliance on Defendants' misrepresentations, the Plaintiffs were 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.

426. 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.

427. 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.

428. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

429. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## COUNT X
## FRAUDULENT CONCEALMENT

430. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

431. Prior to Plaintiffs' use of Defendants' PPI Products and, during the period in which Plaintiffs actually used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of their PPI Products, including information regarding adverse events, pre and post marketing injuries, and epidemiological studies indicating unreasonable risks associated with using PPI Products.

432. Furthermore, Defendants fraudulently concealed the safety information about the use of their PPI Products. As described herein, Defendants' PPI Products present high risk of kidney injuries not present in other methods and drugs for the treatment of peptic disorders.

433. These representations and omissions were made by said Defendants with the intent of defrauding and deceiving the Plaintiffs, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase their PPI Products, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiffs herein.

434. At the time the aforesaid representations and omissions were made by the Defendants, and at the time the Plaintiffs used Defendants' PPI Products, the Plaintiffs were unaware of the falsity of said representations and reasonably believed them to be true.

435. Defendants fraudulently concealed the safety issues associated with PPI use to induce Plaintiffs to purchase and use, and physicians to prescribe and/or recommend their PPI Products.

436. Plaintiffs and/or their healthcare providers reasonably relied on Defendants' omissions and representations in using or prescribing the PPI Products, thereby causing Plaintiffs to sustain severe and permanent personal injuries. Defendants knew, were aware or should have been aware that their PPI Products had not been sufficiently tested, were defective in nature and/or that their PPI Products lacked adequate and/or sufficient warnings.

437. 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.

438. Defendants had a duty to provide consumers, patients and healthcare providers with full, complete, accurate and truthful information concerning their PPI Products, including the appropriate use of the product.

439. Defendants also had a duty to disclose material information about serious side-effects to consumers such as Plaintiffs.

440. By virtue of Defendants' omissions and partial disclosures about the medications, in which Defendants touted their PPI Products as a safe and effective medication, Defendants had

a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this Master Long Form Complaint.

441. Plaintiffs and/or Plaintiffs' healthcare providers reasonably relied on these material misrepresentations and omissions when deciding to prescribe, recommend, purchase and/or consume Defendants' PPIs Products.

442. Plaintiffs' healthcare providers were not provided the necessary information by the Defendants to provide an adequate warning to the Plaintiffs.

443. Plaintiffs were not provided the necessary information by Defendants to provide an adequate warning to the Plaintiffs.

444. The PPI Products were improperly marketed to the Plaintiffs and/or their healthcare providers as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about the risks associated with PPI use.

445. Plaintiffs would not know, in the exercise of reasonable diligence, that Defendants' statements concerning their PPI Products were knowingly and intentionally false and misleading, or that Defendants had not disclosed material facts and information to the Plaintiffs and/or the Plaintiffs' healthcare providers that would have been material to the choice of treatment.

446. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiffs and Plaintiffs' healthcare providers, Defendants caused or contributed to Plaintiffs' injuries (and in some cases death).

447. Prior to the Plaintiff's use of Defendants' PPI Products and during the period in which Plaintiffs used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of the drugs, including information regarding increased risk of kidney injuries.

448. Had Plaintiffs been aware of the hazards associated with the PPI Products, Plaintiffs would have used a safer alternative treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, would not have consumed the PPI Products and/or would have reduced the duration or quantity of use.

449. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested a reckless indifference for the safety and well-being of patients and consumers, including the Plaintiffs.

450. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from the Plaintiffs and Plaintiffs' healthcare providers, Defendants caused, and increased the risk of harm of, the injuries and damages suffered by the Plaintiffs from the use of Defendants' PPI Products.

451. Had Plaintiffs been aware of the hazards associated with PPI use as concealed by Defendants, Plaintiffs would have not have accepted PPI treatment and would have accepted a safer and more effective alternative.

452. Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with their PPI Products for the purpose of preventing consumers, such as Plaintiffs, from discovering these hazards.

453. Defendants conduct is outrageous and shocks the conscience, and knowingly and intentionally placed considerations of financial gain, revenues and profits, market share and marketing advantage over patient safety and well-being.

454. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal

injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

455. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## COUNT XI
## VIOLATION OF CONSUMER PROTECTION LAWS
## AND DECEPTIVE TRADE PRACTICES

456. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of the Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

457. Plaintiffs used Defendants' PPI Products and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

458. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the following consumer protection laws:

a) Ala. Code§§ 8-19-1 et seq.;

b) Alaska Stat. § 45.50.561 et seq.;

c) A.R.S. § 44-1521 et seq.;

d) A.C.A. § 4-88-101 et seq.;

e) Cal Bus & Prof Code § 17000 et seq. and § 17500 et seq.;

f) C.R.S. 6-1-101 et seq.;

g) Conn. Gen. Stat. § 42-110a et seq.;

h) Del. Code Ann. tit. 6, §§ 2511 et seq. and §§ 2531 et seq.

i) D.C. Code Ann.§§ 28-3901 et seq.;

j) Fla. Stat. Ann. §§ 501.201 et seq.;

k) O.C.G.A. §§ 10-1-372 et seq.;

l) Haw. Rev. Stat. §§ 480-1 et seq.;

m) Id. Code Ann.§§ 48-601 et seq.;

n) 815 ILCS 505/1 et seq.;

o) Ind. Code Ann. §§ 24-5-0.5-1 et seq.;

p) Iowa Code Ann. §§ 714.16 et seq.;

q) Kan. Stat. Ann. §§ 50-623 et seq.;

r) Ky. Rev. Stat. Ann.§§ 367.170 et seq.;

s) La. Rev. Stat. Ann.§§ 51:1401 et seq.;

t) Me. Rev. Stat. Ann. tit. 5, §§ 205-A et seq.;

u) Md. Code Ann., Com. Law§§ 13-101 et seq.;

v) Mass. Gen. Laws Ann. Ch. 93A et seq.;

w) Mich. Comp. Laws§§ 445.901 et seq.;

x) Minn. Stat. § 325F.68 et seq.;

y) Miss. Code Ann. § 75-24-5 et seq.;

z) § 407.020 R.S.Mo. et seq.;

aa) 30-14-101, MCA et seq.;

bb) R.R.S. Neb. § 59-1601 et seq.;

cc) Nev. Rev. Stat. Ann. § 598.0903 et seq.; and § 598A.010 et seq.;

dd) N. H. RSA 358-A:1 et seq.;

ee) N.J. Stat. § 56:8-1 et seq.;

ff) N.M. Stat. Ann.§§ 57-12-1 et seq.;

gg) N.Y. Gen. Bus. Law§§ 349 et seq. and §§ 350-e et seq.;

hh) N.C. Gen. Stat.§§ 75-1.1 et seq.;

ii) N.D. Cent. Code§§ 51-12-01 et seq. and §§ 51-15-01 et seq.;

jj) Ohio Rev. Code Ann. §§ 1345.01 et seq.;

kk) Okla. Stat. tit. 15 §§ 751 et seq.;

ll) Or. Rev. Stat. §§ 646.605 et seq.;

mm) 73 Pa. Stat.§§ 201-1 et seq.;

nn) 10 L.P.R.A. § 258 et seq.;

oo) R.I. Gen. Laws.§§ 6-13.1-1 et seq.;

pp) S.C. Code Ann. §§ 39-5-10 et seq.;

qq) S.D. Codified Laws§§ 37-24-1 et seq.;

rr) Tenn. Code Ann.§§ 47-18-101 et seq.;

ss) Tex. Bus. & Com. Code §§17.41 et seq.;

tt) Utah Code Ann.§§ 13-11-1 et seq.;

uu) Vt. Stat. Ann. tit. 9, §§ 2451 et seq.;

vv) Va. Code Ann.§§ 59.1-196 et seq.;

ww) Rev. Code Wash. (ARCW) § 15.04.410 et seq.;

xx) W. Va. Code § 46A-6-101 et seq.

yy) Wis. Stat. § 421.101 et seq.;

zz) Wyo. Stat. § 40-12-101 et seq.

459. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

460. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT XII**
**LOSS OF CONSORTIUM**

461. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

462. Plaintiffs were at all times relevant hereto the spouse of a Plaintiff and as such live and cohabit with said Plaintiff.

463. For the reasons set forth herein, Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future.

464. For the reasons set forth herein, Plaintiffs have been caused, presently and in the future, to suffer the loss of their spouse's companionship, services, society and the ability of the Plaintiffs' spouses have in those respects been impaired and depreciated, and the martial association between husband and wife has been altered, and, accordingly, the Plaintiffs have been caused great mental anguish.

465. Defendants misled both the medical community and the public at large, including Plaintiffs, by making false representations about the safety of their products. Defendants downplayed, understated and disregarded their knowledge of the serious and permanent injuries associated with the PPI use despite available information demonstrating that the product was likely to cause serious side-effects to its users.

466. Defendants were or should have been in possession of evidence demonstrating that their products caused serious side effects. Nevertheless, they continued to market the products by providing false and misleading information with regard to the safety and efficacy of the PPI Products.

467. Defendants' actions, as described herein, were performed willfully, intentionally and with reckless disregard for the rights of the Plaintiffs and the public.

468. As a result of the foregoing acts and omissions, Plaintiffs' spouses and/or significant others were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

469. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with

knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT XIII**
**WRONGFUL DEATH**

470. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

471. Plaintiffs bring this claim on behalf of the Estate and for the benefit of the Plaintiff Decedents' lawful beneficiaries.

472. Plaintiff-decedent left heirs, next-of-kin and/or distributes surviving who, by reason of the Plaintiff-decedent's death have suffered a pecuniary and/or non-pecuniary loss, including but not limited to support, income, services and guidance of the Plaintiff-decedent, and were all permanently damaged thereby.

473. As a direct and proximate result of the conduct of the Defendants and the defective nature of their PPI Products as outlined herein, Plaintiff Decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

474. As a direct and proximate cause of the conduct of Defendants, Plaintiff Decedents' beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths. Plaintiffs bring this claim on behalf of Decedents' lawful beneficiaries for these damages and for all pecuniary losses sustained by said beneficiaries pursuant to applicable state law.

475. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

**COUNT XIV**
**SURVIVAL ACTION**

476. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiffs plead all Counts of this Master Long Form Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiffs' resident State.

477. As a direct and proximate result of the conduct of Defendants, Plaintiff Decedents, prior to their death, were obligated to spend various sums of money to treat his or her injuries, which debts have been assumed by the Estate. As a direct and proximate cause of the aforesaid, Decedents were caused pain and suffering, mental anguish and impairment of the enjoyment of

life, until the date of their death; and, as a direct and proximate result of the aforesaid, Decedents suffered a loss of earnings and earning capacity. Plaintiffs bring this claim on behalf of the Decedents' estate for damages pursuant to applicable state law.

478. As a direct and proximate result of the conduct of Defendants, Plaintiff Decedents and their spouses, heirs, and next-of-kin until and after the time of Decedents' deaths, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, other symptoms of psychological stress, disorder, and emotional distress and mental anguish, generally. This claim is brought on behalf of the Estates of the Decedents pursuant to applicable state law. As a direct and proximate result of the conduct of Defendants, and including the observances of the suffering of the Decedents, until the date of their deaths, Plaintiffs suffered permanent and ongoing damage.

479. Plaintiff-decedent left heirs, next-of-kin and/or distributes surviving who, by reason of the Plaintiff-decedent's death have suffered a pecuniary and/or non-pecuniary loss, including but not limited to support, income, services and guidance of the Plaintiff-decedent, and were all permanently damaged thereby.

480. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Plaintiff Decedents until the date of their deaths, Plaintiffs have and will continue to suffer permanent and ongoing damage which may require future treatment. Plaintiffs' spouses, heirs, and/or next-of-kin as Administrators or beneficiaries of the estate of the Decedents, bring the claim on behalf of the estate for damages pursuant to applicable state law. Defendants' actions, as described herein, were performed willfully, intentionally, and with reckless disregard for the rights of the Plaintiffs and the public.

481. As a result of the foregoing acts and omissions, Plaintiffs were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

482. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiffs, and/or Plaintiffs' 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.

**WHEREFORE**, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

a) Awarding compensatory damages in excess of $75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, loss of consortium, wrongful death and other noneconomic damages in an amount to be determined at trial of this action;

b) Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;

c) Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

d) Prejudgment interest;

e) Post-judgment interest;

f) Awarding reasonable attorneys' fees;

g) Awarding the costs of these proceedings; and

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

**JURY DEMAND**

TAKE NOTICE that Plaintiffs demand trial by jury as to all issues herein.

Dated: February 2, 2018

RESPECTFULLY SUBMITTED,

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and

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**UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY**

**IN RE: PROTON-PUMP INHIBITOR PRODUCTS LIABILITY LITIGATION (NO. II)**

**MDL No. 2789 (CCC) (MF)**

**This document relates to:**

_____

_____

## SHORT FORM COMPLAINT AND JURY DEMAND

The Plaintiff(s) named below file(s) this *Short Form Complaint and Demand for Jury Trial* against Defendants named below by and through their undersigned counsel and as permitted by Case Management Order No. 7. Plaintiff(s) incorporate(s) by reference the allegations contained in *Plaintiffs' Master Long Form Complaint and Jury Demand in In re: Proton-Pump Inhibitor Products Liability Litigation*, MDL 2789, in the United States District Court for the District of New Jersey pursuant to Case Management Order No. 7.

In addition to those causes of action contained in *Plaintiffs' Master Long Form Complaint and Jury Demand*, where certain claims require specific pleadings and/or amendments, Plaintiff(s) shall add and include them herein.

## IDENTIFICATION OF PARTIES

**Identification of Plaintiff(s)**

1. Name of individual injured/deceased due to the use of PPI Product(s): _____

_____.

2. Consortium Claim(s): The following individual(s) allege damages for loss of consortium: _____.

3. Survival and/or Wrongful Death Claims:

a. Plaintiff, _____, is filing this case in a representative capacity as the _____ of the Estate of _____ , deceased.

b. Survival Claim(s): The following individual(s) allege damages for survival claims, as permitted under applicable state laws: _____

_____.

4. As a result of using PPI Products, Plaintiff/Decedent suffered pain and suffering, emotional distress, mental anguish, and personal and economic injur(ies) that are alleged to have been caused by the use of the PPI Products identified in Paragraph 10, below, but not limited to the following:

_____ injury to himself/herself

_____ injury to the person represented

_____ wrongful death

_____ survivorship action

_____ economic loss

_____ loss of services

_____ loss of consortium

_____ other: _____

_____

**Identification of Defendants**

5. Plaintiff(s)/Decedent is/are suing the following Defendant(s) (please check all that apply):

- ☐ Abbott Laboratories
- ☐ AstraZeneca Pharmaceuticals LP
- ☐ AstraZeneca PLC
- ☐ AstraZeneca AB
- ☐ Zeneca Inc.
- ☐ Astra US Holding Corporation
- ☐ Astra USA LLC
- ☐ AstraZeneca LP
- ☐ KBI Sub, Inc.
- ☐ GlaxoSmithKline Consumer Healthcare Holdings (US) LLC
- ☐ GlaxoSmithKline Consumer Healthcare LP
- ☐ GlaxoSmithKline Consumer Healthcare Holdings (US) IP LLC
- ☐ Merck & Co. Inc. d/b/a Merck, Sharp & Dohme Corporation
- ☐ Novartis Corporation
- ☐ Novartis Pharmaceutical Corporation
- ☐ Novartis Vaccines and Diagnostics, Inc.
- ☐ Novartis Institutes for Biomedical Research, Inc.
- ☐ Novartis Consumer Health, Inc.
- ☐ Pfizer, Inc.
- ☐ The Procter & Gamble Company
- ☐ Procter & Gamble Manufacturing Company
- ☐ Takeda Pharmaceuticals USA, Inc.
- ☐ Takeda Pharmaceuticals America, Inc.
- ☐ Takeda Pharmaceuticals LLC

- ☐ Takeda Pharmaceuticals International, Inc.
- ☐ Takeda California, Inc.
- ☐ Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc.
- ☐ Takeda Pharmaceutical Company Limited
- ☐ TAP Pharmaceutical Products, Inc. f/k/a TAP Holdings Inc.
- ☐ Wyeth Pharmaceuticals, Inc.
- ☐ Wyeth-Ayerst Laboratories
- ☐ Wyeth LLC
- ☐ Other(s) Defendant(s) (please identify):

_____

_____

_____

_____

## JURISDICTION & VENUE

**Jurisdiction:**

6. Jurisdiction in this Short Form Complaint is based on:

- ☐ Diversity of Citizenship
- ☐ Other (The basis of any additional ground for jurisdiction must be pled in sufficient detail as required by the applicable Federal Rules of Civil Procedure)._____

_____

**Venue:**

7. District Court(s) in which venue was proper where you might have otherwise filed this *Short Form Complaint* absent Case Management Order No. 7 entered by this Court

and/or to where remand could be ordered: _____

_____

**CASE SPECIFIC FACTS**

8. Plaintiff(s) currently reside(s) in (City, State): _____.

9. To the best of Plaintiff's knowledge, Plaintiff/Decedent used PPI Product(s) during the following time period: _____.

10. Plaintiff/Decedent used the following PPI Products, for which claims are being asserted:

- ☐ Dexilant
- ☐ Nexium
- ☐ Nexium 24HR
- ☐ Prevacid
- ☐ Prevacid 24HR
- ☐ Prilosec
- ☐ Prilosec OTC
- ☐ Protonix
- ☐ Other (List All):

11. The injuries suffered by Plaintiff/Decedent as a result of the use of PPI Products include, among others that will be set forth in Plaintiff's discovery responses and medical records:

- ☐ Acute Interstitial Nephritis (AIN)
- ☐ Acute Kidney Injury (AKI)
- ☐ Chronic Kidney Disease (CKD)
- ☐ End Stage Renal Disease (ESRD)

- ☐ Dialysis
- ☐ Death
- ☐ Other(s) (please specify):

_____

_____

_____

_____

12. At the time of the Plaintiff's/Decedent's diagnosis of injury, Plaintiff/Decedent resided in (City, State): _____.

**CAUSES OF ACTION**

13. Plaintiff(s), again, hereby adopt(s) and incorporate(s) by reference the *Master Long Form Complaint and Jury Demand* as if fully set forth herein.

14. The following claims and allegations asserted in the Master *Long Form Complaint and Jury Demand* are herein more specifically adopted and incorporated by reference by Plaintiff(s) please check all that apply):

- ☐ Count I: Strict Product Liability
- ☐ Count II: Strict Product Liability – Design Defect
- ☐ Count III: Strict Product Liability – Failure to Warn
- ☐ Count IV: Negligence
- ☐ Count V: Negligenc *Per Se*
- ☐ Count VI: Breach of Express Warranty
- ☐ Count VII: Breach of Implied Warranty
- ☐ Count VIII: Negligent Misrepresentation
- ☐ Count IX: Fraud and Fraudulent Misrepresentation

☐ Count X: Fraudulent Concealment

☐ Count XI: Violation of State Consumer Protection Laws of the State(s) of: _____.

☐ Count XII: Loss of Consortium

☐ Count XIII: Wrongful Death

☐ Count XIV: Survival Action

☐ Furthermore, Plaintiff(s) assert(s) the following additional theories and/or Causes of Action against Defendant(s) identified in Paragraph five (5) above. If Plaintiff(s) includes additional theories of recovery, to the extent they require specificity in pleadings, the specific facts and allegations supporting these theories must be pled by Plaintiff(s) in a manner complying with the requirements of the Federal Rules of Civil Procedure:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

**WHEREFORE**, Plaintiff(s) pray(s) for relief and judgment against Defendants of compensatory damages, punitive damages, interest, costs of suit and such further relief as the Court deems equitable and just, and as set forth in the *Master Long Form Complaint and Jury Demand*, as appropriate.

**JURY DEMAND**

Plaintiff(s) hereby demand a trial by jury as to all claims in this action.

Dated: _____

Respectfully Submitted,

_____
Attorney, Esq./*Pro se* Litigant name
Law Firm Name (if applicable)
Mailing Address
Phone:
Fax:
Email: