

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JOSEPH WAYNE CARROLL,

Plaintiff,

v.

ASTRAZENECA PHARMACEUTICALS LP;
ASTRAZENECA LP; MERCK & CO. INC., D/B/A
MERCK, SHARP & DOHME CORPORATION; THE
PROCTOR & GAMBLE COMPANY; THE PROCTOR
& GAMBLE MANUFACTURING COMPANY;
PFIZER, INC.; TAKEDA PHARMACEUTICALS
USA, INC.; TAKEDA PHARMACEUTICALS
AMERICA, INC.; TAKEDA DEVELOPMENT
CENTER AMERICAS, INC., F/K/A TAKEDA
GLOBAL RESEARCH & DEVELOPMENT CENTER,
INC.; and TAKEDA PHARMACEUTICAL
COMPANY LIMITED

Defendants.

Case No.: 2:19-CV- 9092

**COMPLAINT AND
DEMAND FOR JURY TRIAL**

Plaintiff, by his attorneys, **AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, P.L.L.C.**,
upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceed \$75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiffs resides.

NATURE OF THE CASE

2. This action is brought on behalf of Plaintiff, JOSEPH WAYNE CARROLL, who used prescription brand Protonix and over-the-counter Prilosec (hereinafter “Prilosec OTC”) for treatment of Plaintiff’s peptic disorder(s).

3. Plaintiff seeks compensatory damages as a result of Plaintiff's use of Protonix and Prilosec OTC , which have caused Plaintiff to suffer and continue to suffer from stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of additional health consequences.

4. Defendants, AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Merck & Co. Inc., d/b/a Merck, Sharp & Dohme Corporation; The Proctor & Gamble Company; The Proctor & Gamble Manufacturing Company, Pfizer, Inc.; Takeda Pharmaceuticals Usa, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc., F/K/A Takeda Global Research & Development Center, Inc.; and Takeda Pharmaceutical Company Limited (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Protonix and Prilosec OTC.

5. When warning of safety and risks of Protonix and Prilosec OTC, Defendants negligently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as the "FDA"), the Plaintiff's treating physicians, and the public in general, that Protonix and Prilosec OTC had been tested and were found to be safe and/or effective for their indicated use in treating peptic disorders.

6. Defendants concealed their knowledge of Protonix and Prilosec OTC's defects, specifically the fact that it causes stomach cancer, from Plaintiff's treating physicians, hospitals, pharmacies, the FDA, the public in general and/or the medical community.

7. These representations were made by Defendants with the intent of defrauding and deceiving the Plaintiff's physicians, 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 community in particular, to recommend, dispense and/or purchase Protonix and Prilosec

OTC for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

8. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer serious and dangerous side effects including inter alia stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any additional health consequences.

9. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's use of Protonix and Prilosec OTC , which have caused Plaintiff to suffer from stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTIES

10. Plaintiff, JOSEPH WAYNE CARROLL, is a citizen of the United States of America, and is a citizen of Virginia.

11. Plaintiff, JOSEPH WAYNE CARROLL, was born on September 16, 1960.

12. Plaintiff, JOSEPH WAYNE CARROLL, first began using prescription brand Protonix in or around 2006, and later used Prilosec OTC starting in at least 2007. Plaintiff used prescription brand Protonix and/or Prilosec OTC through at least 2010.

13. As result of Plaintiff's ingestion of Defendants' Protonix and Prilosec OTC , Plaintiff JOSEPH WAYNE CARROLL has suffered and continues to suffer from renal failure which was diagnosed on or before May 15, 2017, and stomach cancer which was diagnosed on or

about March 30, 2017, as well as any and all of its sequelae and attendant pain, suffering, and emotional distress.

14. The injuries and damages sustained by Plaintiff, JOSEPH WAYNE CARROLL, were caused by Defendants' Protonix and Prilosec OTC and their unlawful conduct with respect to its design, manufacture, marketing and sale.

15. Defendant AstraZeneca Pharmaceuticals, LP is, and at all times relevant to this action was, a limited partnership organized under the laws of the State of Delaware with its headquarters and principal place of business located at 1800 Concord Pike, Wilmington, Delaware.

16. AstraZeneca Pharmaceutical LP's general partner is AstraZeneca AB, a corporation incorporated under the laws of the nation of Sweden with its principal place of business in Sweden. AstraZeneca Pharmaceutical LP's sole limited partner is Zeneca Inc., which is a corporation incorporated under the laws of the State of Delaware with its principal place of business in Delaware.

17. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals, LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Protonix and Prilosec OTC products.

18. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals, LP was present and doing business in the States of Delaware, New Jersey and Virginia.

19. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited, and conducted business in the States of Delaware, New Jersey and Virginia and derived substantial revenue from such business.

20. Upon information and belief, at all times relevant hereto, Defendant AstraZeneca Pharmaceuticals, LP expected or should have expected that its acts would have consequences within the United States of America, and the States of Delaware, New Jersey and Virginia.

21. Defendant AstraZeneca LP is, and at all times relevant to this action was, a limited partnership organized under the laws of the State of Delaware with its headquarters and principal place of business located at 1800 Concord Pike, Wilmington, Delaware.

22. Defendant AstraZeneca LP's sole general partner is AstraZeneca Pharmaceuticals LP. Defendant AstraZeneca LP has no limited partners. AstraZeneca Pharmaceutical LP's general partner is AstraZeneca AB, a corporation incorporated under the laws of the nation of Sweden with its principal place of business in Sweden. AstraZeneca Pharmaceutical LP's sole limited partner is Zeneca Inc., a corporation incorporated under the laws of the State of Delaware with its principal place of business in Delaware.

23. Defendants AstraZeneca Pharmaceuticals, LP and AstraZeneca LP are referred to collectively herein as "AZ Defendants."

24. AstraZeneca LP is the holder of approved New Drug Applications ("NDAs") 21-153 and 21-154 for Nexium (Esomeprazole Magnesium), and it manufactures and markets Nexium (Esomeprazole Magnesium) in the United States.

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

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

27. Upon information and belief, at all times relevant hereto, the AZ Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Protonix and Prilosec OTC products.

28. Upon information and belief, at all relevant times, AZ Defendants were present and

doing business in the States of Delaware, New Jersey and Virginia.

29. Upon information and belief, at all relevant times, AZ Defendants transacted, solicited, and conducted business in the States of Delaware, New Jersey and Virginia, and derived substantial revenue from such business.

30. Upon information and belief, at all times relevant hereto, AZ Defendants expected or should have expected that its acts would have consequences within the United States of America, and the States of Delaware, New Jersey and Virginia.

31. Upon information and belief, each AZ Defendant was the agent and employee of each other AZ Defendant, and in doing the things alleged was acting within the course and scope of such agency and employment and with each other AZ Defendant's actual and implied permission, consent, authorization, and approval.

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

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

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

35. 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.

36. 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.

37. 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.

38. Defendant AZ Pharm is the holder of approved NDA 019810 for Prilosec Delayed-Release Capsule Pellets and 022056 for Prilosec Delayed-Release Oral Suspension.

39. Defendant AZ 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.

40. The AZ Defendants manufacture and market each of these Prilosec formulations in the United States.

41. 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.

42. 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 Protonix and Prilosec OTC products, under a royalty-bearing license.

43. 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.

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

45. 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 Protonix and Prilosec OTC.

46. Defendant Merck had and may still have, a financial interest in prescription and over-the-counter formulations of Prilosec.

47. 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.

48. Defendant Merck, through the Joint Venture, also designed, researched, manufactured, tested, advertised, marketed, sold and distributed Prilosec and Prilosec OTC.

49. 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.

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

51. 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.

52. Defendant Merck manufactures and markets Protonix and Prilosec OTC in the United States.

53. Defendant Merck has transacted and conducted business related to Protonix and Prilosec OTC in each of the States and Territories of the United States.

54. Defendant Merck has derived substantial revenue from Protonix and Prilosec OTC in each of the States and Territories of the United States.

55. 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 Protonix and Prilosec OTC.

56. 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.

57. Defendant The 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.

58. 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 The Procter & Gamble Manufacturing Company.

59. Defendant The Procter & Gamble Company and Defendant The Procter & Gamble Manufacturing Company are referred to collectively herein as the “Procter & Gamble Defendants.”

60. 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.

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

62. 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.

63. 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.

64. 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.

65. 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.

66. 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.

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

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

69. 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.

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

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

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

78. 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.

79. 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.

80. 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.

81. 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.

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

83. 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.

84. 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.

85. 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.

86. 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.

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

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

89. 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.

90. 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.

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

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

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

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

95. 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.

96. Defendants AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Merck & Co. Inc., d/b/a Merck, Sharp & Dohme Corporation; The Proctor & Gamble Company; and The Proctor & Gamble Manufacturing Company, Pfizer, Inc., Takeda Pharmaceutical Company Limited, Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc., Takeda Pharmaceuticals America, Inc., and Takeda Pharmaceuticals USA, Inc. shall herein be collectively referred to as “Defendants.”

FACTUAL BACKGROUND

97. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff JOSEPH WAYNE CARROLL suffering renal failure and stomach cancer caused by Plaintiff’s ingestion of the proton pump inhibitors, Prilosec OTC and Protonix.

98. Upon information and belief, Pfizer and Takeda Defendants marketed and sold Protonix.

99. Upon information and belief, the AstraZeneca, Merck and Proctor & Gamble Defendants began marketing and selling Prilosec OTC since at least 1997.

100. Plaintiff began taking prescription brand Protonix in or around 2006 and Prilosec OTC in or about 2007 and continued to use Protonix and/or Prilosec OTC products through at least 2010.

101. At all relevant times, Defendants heavily marketed Protonix and Prilosec OTC to treat peptic disorders, including but not limited to gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

102. Defendants' marketing of Protonix and Prilosec OTC included advertisements, press releases, web site publications, sales representative pitches and other communications.

103. Materials including advertisements, press releases, webs site publications and other communications regarding Protonix and Prilosec OTC are part of the labeling of the drug and could be altered by Defendants without prior FDA approval.

104. Proton pump inhibitors ("PPIs"), including Defendants' Protonix and Prilosec, are commonly prescribed medications in the United States.

105. More than 15 million Americans used prescription PPIs in 2013, costing more than \$10 billion.

106. However, it has been estimated that between 25% and 70% of these prescriptions have no appropriate indication.

107. Up to 70% of PPIs may be used inappropriately for indications or durations that were never tested or approved.

108. Further, 25% of long-term PPI users could discontinue therapy without developing any symptoms.

109. Protonix and Prilosec products are PPIs that work by reducing acid in the stomach.

110. During the period in which Protonix and Prilosec have been sold in the United States, hundreds of reports of injuries, including renal failure and stomach cancer, have been submitted to the FDA in association with ingestion of these and other PPIs.

111. Defendants have had notice of serious adverse health outcomes regarding renal failure and stomach cancer associated with their Protonix and Prilosec products through case reports, clinical studies and post-market surveillance.

112. As such, these numerous reports of renal failure and stomach cancer put Defendants on notice as to the excessive risks of kidney injuries related to the use of Protonix and Prilosec products.

113. Several observational studies have linked PPI use, including Protonix and Prilosec OTC use, to serious adverse health outcomes, including stomach cancer, acute interstitial nephritis and acute kidney injury.

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

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

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

116. A study from 2015 shows that acute kidney injuries increased 250% in elderly patients that were newly prescribed PPIs. The acute kidney injuries occurred within 120 days of the patients starting the PPIs.

117. A study by Lai, et al., published by GUT in April 2018, found that Long-term proton pump inhibitors and risk of gastric cancer development. Shih-Wei Lai, Hsueh-Chou Lai, Cheng-Li Lin and Kuan-Fu Liao. *Proton Pump Inhibitors and Risk of Gastric Cancer in a Case-Control Study*. Gut (2018).

118. A 2018 study by Cheung found an association among long-term proton pump inhibitors and risk of gastric cancer development. Cheung, KS, Chan, EW, Wong, AYS, Chen, L, Wong, ICK, Leung, WK. *Long-term Proton Pump Inhibitors and Risk of Gastric Cancer Development after Treatment for Helicobacter Pylori: A Population-Based Study*. Gut (2018).

119. Other recent articles, such as Brusselaers and Lai, found a similar risk of gastric cancer development with proton pump inhibitor use. Brusselaers N, Wahlin, K, Engstrand, L, et al. *Maintenance Therapy with Proton Pump Inhibitors and Risk of Gastric Cancer: A Nationwide*

Population-based Cohort Study in Sweden. BMJ Open (2017); Lai, SW, Liao KF, Lai HC, Lin CL, Sung FC. *Use of Proton Pump Inhibitors Correlates with Increased Risk of Colorectal Cancer in Taiwan*. Asia Pac. J. Clin. Oncol. (2013);

120. There are other studies, and articles in the medical community, as well as other evidence that associates PPIs with stomach cancer.

121. The FDA's Office of Surveillance and Epidemiology ("OSE") identified signals of new safety risks for users of proton pump inhibitors. New safety risks included "polyps of stomach and duodenum. In response to this alert, the FDA commenced a Tracked Safety Issue ("TSI") for proton pump inhibitors, and in September of 2017, the FDA decided this gastric risk required further regulatory review.

122. To date, Defendants' prescription Protonix and Prilosec OTC lack detailed risk information for stomach cancer, despite science stating otherwise.

123. Defendants knew or should have known of the risk of stomach cancer 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.

124. Despite their knowledge of the risks of stomach cancer associated with their proton pump inhibitors, Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Protonix and Prilosec OTC did not pose any risks of stomach cancer. They promoted and marketed Protonix and Prilosec OTC as safe and effective for persons such as Plaintiff JOSEPH WAYNE CARROLL throughout the United States, including Virginia.

125. Defendants knew of the significant risk of stomach cancer that could result from Protonix and Prilosec OTC use, but Defendants did not adequately and sufficiently warn consumers, including Plaintiff's physician or the medical community in a timely manner.

126. Even if used as directed, Defendants failed to adequately warn against the negative effects and risks associated with this s and Prilosec including, but not necessarily limited to, long term usage and the cumulative effects of long term usage.

127. In omitting, concealing, and inadequately providing critical safety information regarding the use of Protonix and Prilosec OTC in order to induce its purchase and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiff. This conduct is fraudulent, unfair, and unlawful.

128. Despite clear knowledge that Protonix and Prilosec OTC cause a significantly increased risk of stomach cancer, CKD, acute kidney injuries, Defendants continued to market and sell Protonix and Prilosec OTC without warning consumers or healthcare providers of the significant risks of stomach cancer, CKD and acute kidney injuries.

129. Even if used as directed, persons who ingested Protonix and Prilosec OTC, such as the Plaintiff JOSEPH WAYNE CARROLL, has been exposed to significant risks stemming from unindicated and/or long-term usage.

130. Consumers, including Plaintiff JOSEPH WAYNE CARROLL, and Plaintiff's physicians relied on the Defendants' false representations and were misled as to Nexium's and Prilosec's safety.

131. Had the Plaintiff JOSEPH WAYNE CARROLL known of the risks of stomach cancer associated with Defendants' Protonix and Prilosec OTC, Plaintiff would not have used Defendants' Protonix and Prilosec OTC.

132. At all relevant times, Plaintiff JOSEPH WAYNE CARROLL had alternative safer methods for treating peptic disorders that provided the same benefits but acted through a different mechanism and were not associated with stomach cancer.

133. One alternative was H2 antagonists, also called H2 blockers, a class of medications that block the action of histamine at the histamine H2 receptors of the parietal cells in the stomach. The use of H2 receptor antagonists, which are prescribed for the same indication as PPIs, is not associated with stomach cancer.

134. As a result of Defendants' action and inactions as outlined herein, Plaintiff was injured due to Plaintiff's ingestion of Protonix and Prilosec OTC, which caused Plaintiff and continues to cause Plaintiff to suffer from stomach cancer and any and all of its sequelae.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

135. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

136. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Protonix and Prilosec OTC into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

137. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Protonix and Prilosec OTC into interstate commerce in that Defendants knew or should have known that using Protonix and Prilosec OTC could proximately cause Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and

warning of Protonix and Prilosec OTC. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

- (a) Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that plaintiff would suffer a serious injury or death by ingesting Protonix and Prilosec OTC;
- (b) Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Protonix and Prilosec OTC in unsafe doses;
- (c) Failure to use reasonable care in testing and inspecting Protonix and Prilosec OTC so as to ascertain whether or not they were safe for the purpose for which they were designed, manufactured and sold;
- (d) Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Protonix and Prilosec OTC;
- (e) Failure to use reasonable care in the process of manufacturing Protonix and Prilosec OTC in a reasonably safe condition for the use for which it was intended;
- (f) Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using Protonix and Prilosec OTC in unsafe doses; and
- (g) Such further acts and/or omissions that may be proven at trial.

138. The above-described acts and/or omissions of Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff.

139. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- (a) Manufacturing, producing, promoting, formulating, creating, and/or designing Protonix and Prilosec OTC without thoroughly testing it;
- (b) Manufacturing, producing, promoting, formulating, creating, and/or designing Protonix and Prilosec OTC without adequately testing it;
- (c) Not conducting sufficient testing programs to determine whether or not Protonix and Prilosec OTC were safe for use; in that Defendants

herein knew or should have known that Protonix and Prilosec OTC were unsafe and unfit for use by reason of the dangers to its users;

- (d) Selling Protonix and Prilosec OTC without making proper and sufficient tests to determine the dangers to its users;
- (e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Protonix and Prilosec OTC;
- (f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Protonix and Prilosec OTC;
- (g) Failing to test Protonix and Prilosec OTC and/or failing to adequately, sufficiently, and properly test Protonix and Prilosec OTC.
- (h) Negligently advertising and recommending the use of Protonix and Prilosec OTC without sufficient knowledge as to their dangerous propensities;
- (i) Negligently representing that Protonix and Prilosec OTC was safe for use for its intended purpose, when, in fact, it was unsafe;
- (j) Negligently designing Protonix and Prilosec OTC in a manner which was dangerous to its users;
- (k) Negligently manufacturing Protonix and Prilosec OTC in a manner which was dangerous to its users;
- (l) Negligently producing Protonix and Prilosec OTC in a manner which was dangerous to its users;
- (m) Negligently assembling Protonix and Prilosec OTC in a manner which was dangerous to its users;
- (n) Concealing information from the Plaintiff in knowing that Protonix and Prilosec OTC was unsafe, dangerous, and/or non-conforming with FDA regulations.

140. Defendants under-reported, underestimated and downplayed the serious dangers of Protonix and Prilosec OTC.

141. Defendants negligently compared the safety risk and/or dangers of Protonix and Prilosec OTC with other forms of treatment of peptic disorders, which include gastroesophageal

reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

142. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Protonix and Prilosec OTC in that they:

- (a) Failed to use due care in designing and manufacturing Protonix and Prilosec OTC so as to avoid the aforementioned risks to individuals when Protonix and Prilosec OTC were used for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug - induced gastropathy;
- (b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the uses of Protonix and Prilosec OTC;
- (c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Protonix and Prilosec OTC;
- (d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Protonix and Prilosec OTC;
- (e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
- (f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Protonix and Prilosec OTC;
- (g) Failed to warn Plaintiff, prior to actively encouraging the sale of Protonix and Prilosec OTC, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;
- (h) Were otherwise careless and/or negligent.

143. Despite the fact that Defendants knew or should have known that Protonix and Prilosec OTC caused unreasonably dangerous side effects, Defendants continued and continue to

market, manufacture, distribute and/or sell Protonix and Prilosec OTC to consumers, including the Plaintiff.

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

145. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff, JOSEPH WAYNE CARROLL, suffered and/or will continue to suffer.

146. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

148. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY)

149. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

150. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Protonix and Prilosec OTC as hereinabove described that was used by the Plaintiff.

151. That Protonix and Prilosec OTC was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

152. At those times, Protonix and Prilosec OTC was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

153. The Protonix and Prilosec OTC 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 manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Protonix and Prilosec OTC.

154. The Protonix and Prilosec OTC 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, they were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect.

155. At all times herein mentioned, Protonix and Prilosec OTC was in a defective condition and unsafe, and Defendants knew or had reason to know that said products were defective and unsafe, especially when used in the form and manner as provided by the Defendants.

156. Defendants knew or should have known that at all times herein mentioned its Protonix and Prilosec OTC were in a defective condition and were and are inherently dangerous and unsafe.

157. At the time of the Plaintiff's uses of Protonix and Prilosec OTC, Protonix and Prilosec OTC were being used for the purposes and in a manner normally intended for the treatment of peptic disorders, which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

158. Defendants with this knowledge voluntarily designed Protonix and Prilosec OTC in a dangerous condition for use by the public, and in particular the Plaintiff.

159. Defendants had a duty to create products that were not unreasonably dangerous for its normal, intended use.

160. Defendants created products unreasonably dangerous for their normal, intended use.

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

162. The Protonix and Prilosec OTC 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 the Defendants' Protonix and Prilosec OTC was manufactured.

163. 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 to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

164. The Plaintiff could not, by the exercise of reasonable care, have discovered Protonix and Prilosec OTC's defects herein mentioned and perceived its danger.

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

166. Protonix and Prilosec OTC were designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

167. Protonix and Prilosec OTC were designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, stomach cancer and kidney injuries, as well as other severe and permanent health consequences from Protonix and Prilosec OTC, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Protonix and Prilosec OTC.

168. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Protonix and Prilosec OTC.

169. Defendants' defective design, manufacturing defect, and inadequate warnings of Protonix and Prilosec OTC were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

170. That said defects in Defendants' drug Protonix and Prilosec OTC were a substantial factor in causing Plaintiff's injuries.

171. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

173. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

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

174. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

175. Defendants expressly warranted that Protonix and Prilosec OTC were safe and well accepted by users.

176. Protonix and Prilosec OTC does not conform to these express representations because Protonix and Prilosec OTC are not safe and have numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the

breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

177. Plaintiff did rely on the express warranties of the Defendants herein.

178. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Protonix and Prilosec OTC in recommending, prescribing, and/or dispensing Protonix and Prilosec OTC.

179. The Defendants herein breached the aforesaid express warranties, as their drug Protonix and Prilosec OTC was defective.

180. Defendants expressly represented to Plaintiff's physicians, healthcare providers, and/or the FDA that Protonix and Prilosec OTC were safe and fit for use for the purposes intended, that it was of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

181. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Protonix and Prilosec OTC was 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.

182. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

183. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Protonix and Prilosec OTC drug.

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

185. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

186. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

187. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Protonix and Prilosec OTC and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Protonix and Prilosec OTC for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

188. At the time Defendants marketed, sold, and distributed Protonix and Prilosec OTC for use by Plaintiff, Defendants knew of the uses for which Protonix and Prilosec OTC was

intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

189. The Defendants impliedly represented and warranted to the users of Protonix and Prilosec OTC and their physicians, healthcare providers, and/or the FDA that Protonix and Prilosec OTC was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

190. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Protonix and Prilosec OTC was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

191. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

192. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Protonix and Prilosec OTC was of merchantable quality and safe and fit for its intended use.

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

194. The Defendants herein breached the aforesaid implied warranties, as their drug Protonix and Prilosec OTC was not fit for its intended purposes and uses.

195. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including

diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

197. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

FIFTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUDULENT MISREPRESENTATION)

198. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

199. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said products, Protonix and Prilosec OTC had been tested and were found to be safe and/or effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

200. That representations made by Defendants were, in fact, false.

201. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

202. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, 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 said product, Protonix and Prilosec OTC, for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

203. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used Protonix and Prilosec OTC, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

204. In reliance upon said representations, the Plaintiff was induced to and did use Protonix and Prilosec OTC, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

205. Said Defendants knew and were aware or should have been aware that Protonix and Prilosec OTC had not been sufficiently tested, were defective in nature, and/or that they lacked adequate and/or sufficient warnings.

206. Defendants knew or should have known that Protonix and Prilosec OTC had a potential to, could, and would cause severe and grievous injury to the users of said products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

207. Defendants brought Protonix and Prilosec OTC to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

208. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

210. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

SIXTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUDULENT CONCEALMENT)

211. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

212. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Protonix and Prilosec OTC for its intended use.

213. Defendants knew or were reckless in not knowing that their representations were false.

214. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

- (a) that Protonix and Prilosec OTC were not as safe as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug - induced gastropathy;
- (b) that the risks of adverse events with Protonix and Prilosec OTC were higher than those with other forms of treatment of peptic disorders which include gastroesophageal reflux

disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

- (c) that the risks of adverse events with Protonix and Prilosec OTC were not adequately tested and/or known by Defendants;
- (d) that Defendants were aware of dangers in Protonix and Prilosec OTC, in addition to and above and beyond those associated with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;
- (e) that Protonix and Prilosec OTC were defective, and that they caused dangerous side effects, including but not limited to stomach cancer;
- (f) that patients needed to be monitored more regularly than normal while using Protonix and Prilosec OTC;
- (g) that Protonix and Prilosec OTC were manufactured negligently;
- (h) that Protonix and Prilosec OTC were manufactured defectively;
- (i) that Protonix and Prilosec OTC were manufactured improperly;
- (j) that Protonix and Prilosec OTC were designed negligently;
- (k) that Protonix and Prilosec OTC were designed defectively; and
- (l) that Protonix and Prilosec OTC were designed improperly.

215. Defendants were under a duty to disclose to Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Protonix and Prilosec OTC, including but not limited to the heightened risks of stomach cancer.

216. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Protonix and Prilosec OTC, including the Plaintiff, in particular.

217. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Protonix and Prilosec OTC were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and Plaintiff's physicians, hospitals and healthcare providers into reliance, continued use of Protonix and Prilosec OTC, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Protonix and Prilosec OTC and/or use the products.

218. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Protonix and Prilosec OTC, as set forth herein.

219. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

220. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

222. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

SEVENTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENT MISREPRESENTATION)

223. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

224. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said products, Protonix and Prilosec OTC, had been tested and found to be safe and effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

225. The representations made by Defendants were, in fact, false.

226. Defendants failed to exercise ordinary care in the representation of Protonix and Prilosec OTC, while involved in their manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented Protonix and Prilosec OTC's high risks of unreasonable, dangerous side effects.

227. Defendants breached their duty in representing Protonix and Prilosec OTC's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

228. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

230. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

EIGHTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(FRAUD AND DECEIT)

231. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

232. Defendants conducted research and used Protonix and Prilosec OTC as part of their research.

233. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that Protonix and Prilosec OTC was safe and effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

234. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

235. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.

236. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

237. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug Protonix and Prilosec OTC were safe and effective for use for treatment of peptic disorders, which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

238. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug Protonix and Prilosec OTC carried the same risks, hazards, and/or dangers as other forms of treatment for treatment of peptic disorders, which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

239. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Protonix and Prilosec OTC was not injurious to the health and/or safety of its intended users.

240. The information distributed to the public, the FDA, and the Plaintiffs, by Defendants intentionally included false representations that Protonix and Prilosec OTC was as potentially injurious to the health and/or safety of its intended as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

241. These representations were all false and misleading.

242. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Protonix

and Prilosec OTC were not safe as a means of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

243. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiffs, regarding the safety of Protonix and Prilosec OTC, specifically but not limited to Protonix and Prilosec OTC not having dangerous and serious health and/or safety concerns.

244. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiffs, regarding the safety of Protonix and Prilosec OTC, specifically but not limited to Protonix and Prilosec OTC being safe means for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

245. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Protonix and Prilosec OTC induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Protonix and Prilosec OTC.

246. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiffs that Protonix and Prilosec OTC was fit and safe for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

247. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that

Protonix and Prilosec OTC were fit and safe for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

248. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Protonix and Prilosec OTC did not present serious health and/or safety risks.

249. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Protonix and Prilosec OTC did not present health and/or safety risks greater than other oral forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

250. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

251. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including Plaintiff's respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or Plaintiff's respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Protonix and Prilosec OTC.

252. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Protonix and Prilosec OTC to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

253. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Protonix and Prilosec OTC by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Protonix and Prilosec OTC.

254. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as Plaintiff's respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Protonix and Prilosec OTC and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

255. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's respective healthcare professionals would rely upon the information being disseminated.

256. Defendants utilized direct to consumer advertising to market, promote, and/or advertise Protonix and Prilosec OTC.

257. That the Plaintiff and/or Plaintiff's respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

258. That at the time the representations were made, the Plaintiff and/or Plaintiff's respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Protonix and Prilosec OTC.

259. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

260. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Protonix and Prilosec OTC, Plaintiff would not have purchased, used and/or relied on Defendants' drug Protonix and Prilosec OTC.

261. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

262. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Stomach Cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

264. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**NINTH CAUSE OF ACTION AS
AGAINST THE DEFENDANTS
(VIOLATION OF THE NEW JERSEY
CONSUMER FRAUD ACT)**

265. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

266. At all times relevant, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq., prohibits “[the] act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise...” and declares such acts or practices as unlawful.

267. Defendants violated the New Jersey Consumer Fraud Act by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Protonix and Prilosec OTC. Defendants communicated the purported benefits of Protonix and Prilosec OTC while failing to disclose the serious and dangerous side effects related to the use of Protonix and Prilosec OTC with the intent that consumers, including Plaintiff, and Plaintiff’s healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe Protonix and Prilosec OTC, respectively.

268. As a result of violating the New Jersey Consumer Fraud Act, Defendants caused Plaintiff to be prescribed and to use Protonix and Prilosec OTC, causing severe injuries and damages as previously described herein.

TENTH CAUSE OF ACTION AS
AGAINST THE DEFENDANTS
(PRODUCT LIABILITY –DESIGN DEFECT)
(N.J.S.A. 2A:58C-1 et seq))

269. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

270. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed Protonix and Prilosec OTC,

including the Protonix and Prilosec OTC used by Plaintiff, JOSEPH WAYNE CARROLL, was in a defective and unreasonably dangerous condition.

271. Defendants expected Protonix and Prilosec OTC to reach, and it did in fact reach, Plaintiff without substantial change in the condition in which each was manufactured and sold by the Defendants.

272. At all times relevant hereto, Defendants' Protonix and Prilosec OTC was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for use by the public and in particular by Plaintiff.

273. At all times relevant to this action, Protonix and Prilosec OTC, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by the Defendants, was defective in design and formulation in one or more of the following particulars:

- (a) When placed in the stream of commerce, Protonix and Prilosec OTC contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the drug;
- (b) When placed in the stream of commerce, Protonix and Prilosec OTC were defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;
- (c) Protonix and Prilosec OTC were insufficiently tested;
- (d) Protonix and Prilosec OTC caused harmful side effects that outweighed any potential utility;

- (e) Defendants were aware at the time Protonix and Prilosec OTC were marketed that ingestion of Protonix and Prilosec OTC would result in an increased risk of Stomach Cancer, AKI, CKD, ESRD, and other injuries;
- (f) Inadequate post-marketing surveillance; and/or
- (g) There were safer alternative designs and formulations that were not utilized.

223. Protonix and Prilosec OTC was defective, failed to perform safely, and was unreasonably dangerous when used by ordinary consumers, including Plaintiff, as intended and in a reasonably foreseeable manner.

224. Protonix and Prilosec OTC, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in its design or formulation, in that it was unreasonably dangerous and its foreseeable risks exceeded the alleged benefits associated with Protonix and Prilosec OTC's design or formulation.

225. Protonix and Prilosec OTC, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in design or formulation in that it posed a greater likelihood of injury than other proton-pump inhibitors and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

226. At all times relevant to this action, Defendants knew or had reason to know that Protonix and Prilosec OTC was in a defective condition and was inherently dangerous and unsafe when used in the manner instructed, provided, and/or promoted by Defendants.

227. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and

otherwise ensure that Protonix and Prilosec OTC was not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

228. When Defendants placed Protonix and Prilosec OTC into the stream of commerce, they knew each would be prescribed to treat peptic disorders, and they marketed and promoted Protonix and Prilosec OTC as safe for treating peptic disorders.

229. Plaintiff was prescribed, purchased, and used Protonix and Prilosec OTC. Plaintiff used Protonix and Prilosec OTC for their intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

230. Neither Plaintiff nor Plaintiff's health care professionals, by the exercise of reasonable care, could have discovered the defects and risks associated with Protonix and Prilosec OTC before Plaintiff's ingestion of Protonix and Prilosec OTC.

231. The harm caused by Protonix and Prilosec OTC far outweighed its benefit, rendering Protonix and Prilosec OTC more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed Protonix and Prilosec OTC to make it less dangerous. When Defendants designed Protonix and Prilosec OTC, the state of the industry's scientific knowledge was such that a less risky design was attainable.

232. At the time Protonix and Prilosec OTC left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the reasonably anticipated or intended function of Protonix and Prilosec OTC. This was demonstrated by the existence of other peptic disorder medications that had a more established safety profile and a considerably lower risk profile.

233. Defendants' defective design of Protonix and Prilosec OTC was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Protonix and Prilosec OTC. Defendants' conduct was motivated by greed and the intentional

decision to value profits over the safety and well-being of the consumers of Protonix and Prilosec OTC.

234. The defects in Protonix and Prilosec OTC were substantial and contributing factors in causing Plaintiff's injuries. But for Defendants' acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

235. Due to the unreasonably dangerous condition of Protonix and Prilosec OTC, Defendants are liable to Plaintiff.

236. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of Protonix and Prilosec OTC, including Plaintiff, with knowledge of the safety problems associated with Protonix and Prilosec OTC, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

237. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered, and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

ELEVENTH CAUSE OF ACTION AS
AGAINST THE DEFENDANTS
PRODUCTS LIABILITY – FAILURE TO WARN
(N.J.S.A. 2A:58C-1 et seq.)

238. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

239. Defendants have engaged in the business of designing, developing, researching, testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or distributing Protonix and Prilosec OTC. Through that conduct, Defendants knowingly and intentionally placed Protonix and Prilosec OTC into the stream of commerce with full knowledge that it reaches consumers, such as Plaintiff, JOSEPH WAYNE CARROLL, who ingested it.

240. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released Protonix and Prilosec OTC into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted Protonix and Prilosec OTC to the FDA, health care professionals, Plaintiff, and other consumers, and therefore had a duty to warn of the risks associated with the use of Protonix and Prilosec OTC.

241. Defendants expected Protonix and Prilosec OTC to reach, and they did in fact reach, prescribing health care professionals and consumers, including Plaintiff and Plaintiff's prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

242. Protonix and Prilosec OTC, as manufactured and/or supplied by Defendants, were defective due to inadequate warnings or instructions. Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

243. Protonix and Prilosec OTC were defective and unsafe such that it was unreasonably dangerous when it left Defendants' possession and/or control, were distributed by Defendants, and ingested by Plaintiff. Protonix and Prilosec OTC contained warnings insufficient to alert

consumers, including Plaintiff, to the dangerous risks and reactions associated with Protonix and Prilosec OTC, including the development of Plaintiff's injuries.

244. This defect caused serious injury to Plaintiff, who used Protonix and Prilosec OTC for their intended purpose and in a reasonably anticipated manner.

245. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as are necessary to ensure Protonix and Prilosec OTC did not cause users to suffer from unreasonable and dangerous risks.

246. Defendants negligently and recklessly labeled, distributed, and promoted Protonix and Prilosec OTC.

247. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Protonix and Prilosec OTC.

248. Defendants, as manufacturers, sellers, or distributors of prescription drugs, are held to the knowledge of an expert in the field.

249. Plaintiff could not have discovered any defects in Protonix and Prilosec OTC through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

250. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that Protonix and Prilosec OTC caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of Protonix and Prilosec OTC, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

251. Protonix and Prilosec OTC, as manufactured and/or supplied by Defendants, were unreasonably dangerous when used by consumers, including Plaintiff, in a reasonably and intended manner without knowledge of this risk of serious bodily harm.

252. Each of the Defendants knew or should have known that the limited warnings disseminated with Protonix and Prilosec OTC were inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

253. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended. In particular, Defendants:

- (a) disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of Protonix and Prilosec OTC;
- (b) continued to aggressively promote Protonix and Prilosec OTC even after Defendants knew or should have known of the unreasonable risks from use;
- (c) failed to accompany their products with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Protonix and Prilosec OTC and the comparative severity of such adverse effects;

- (d) failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with Protonix and Prilosec OTC's capacity to cause its users to suffer;
- (e) failed to adequately warn users, consumers, and physicians about the need to monitor renal function in patients who do not already suffer from renal impairment; and
- (f) overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of Protonix and Prilosec OTC.

254. To this day, Defendants have failed to adequately and accurately warn of the true risks of injuries associated with the use of Protonix and Prilosec OTC.

255. Due to these deficiencies and inadequacies, Protonix and Prilosec OTC was unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants.

256. Had Defendants properly disclosed and disseminated the risks associated with Protonix and Prilosec OTC, Plaintiff would have avoided the risk of developing injuries as alleged herein.

257. The Defendants are liable to Plaintiff for injuries caused by their negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of Protonix and Prilosec OTC and the risks associated with its use.

258. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered, and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and

will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

TWELFTH CAUSE OF ACTION AS
AGAINST THE DEFENDANTS
(PRODUCT LIABILITY – MANUFACTURING DEFECT
(N.J.S.A. 2A:58C-1 *et seq.*))

259. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

260. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Protonix and Prilosec OTC.

261. At all times material to this action, Protonix and Prilosec OTC was expected to reach, and did reach, consumers in the States of, New Jersey, and throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

262. At all times material to this action, Protonix and Prilosec OTC was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

- (a) When placed in the stream of commerce, Protonix and Prilosec OTC contained manufacturing defects which rendered the product unreasonably dangerous;

- (b) The subject product's manufacturing defects occurred while the product was in the possession and control of Defendants;
- (c) The subject product was not made in accordance with Defendants' specifications or performance standards; and/or
- (d) The subject product's manufacturing defects existed before it left the control of Defendants.

263. As a direct and proximate result of the design defect and Defendants' misconduct set forth herein, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

**THIRTEENTH CAUSE OF ACTION AS
AGAINST THE DEFENDANTS
(PUNITIVE DAMAGES UNDER COMMON LAW,
THE PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15 *et seq.*)
AND THE PRODUCTS LIABILITY ACT (N.J.S.A. 2A:58C-1 *et seq.*))**

264. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

265. Plaintiff is entitled to punitive damages because Defendants misrepresented and/or withheld information and materials from the FDA, the medical community and the public at large, including the Plaintiff, concerning the safety profile, and, more specifically the serious side effects and/or complications associated with Protonix and Prilosec OTC.

266. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks

associated with the use of Protonix and Prilosec OTC, despite available information that Protonix and Prilosec OTC were likely to cause serious side effects and/or complications.

267. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of Protonix and Prilosec OTC, despite available information that Protonix and Prilosec OTC were likely to cause serious side effects and/or complications.

268. Defendants' failure to provide the necessary materials and information to the FDA, as well as their failure warn physicians and consumers of the serious side effects and/or complications, was reckless and without regard for the public's safety and welfare.

269. Defendants were or should have been in possession of evidence demonstrating that Protonix and Prilosec OTC causes serious side effects. Nevertheless, Defendant continued to market Protonix and Prilosec OTC by providing false and misleading information with regard to safety and efficacy.

270. Defendants failed to provide the FDA, physicians and consumers with available materials, information and warnings that would have ultimately dissuaded physicians from prescribing Protonix and Prilosec OTC to consumers, from purchasing and consuming Protonix and Prilosec OTC, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Protonix and Prilosec OTC.

PRAYER FOR RELIEF

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

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained

by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. 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 to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff reasonable attorneys' fees;
4. Awarding Plaintiff the costs of these proceedings; and
5. Such other and further relief as this Court deems just and proper.

Dated: March 28, 2019

Respectfully Submitted,

/s/James D. Barger

James D. Barger

PA Bar # 310056

Aylstock, Witkin, Kreis & Overholtz, PLLC

17 E. Main Street, Suite 200

Pensacola, Florida 32502

Phone: (850) 202-1010

Fax: (850) 916-7449

Email: jbarger@awkolaw.com

ATTORNEY FOR PLAINTIFF

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: March 28, 2019

Respectfully Submitted,

/s/James D. Barger

James D. Barger

PA Bar # 310056

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ATTORNEY FOR PLAINTIFF

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Joseph Wayne Carroll

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

(c) Attorneys (Firm Name, Address, and Telephone Number)

Aylstock, Witkin, Kreis & Overholtz, PLLC, 17 East Main Street, Suite 200, Pensacola, FL 32502-5998, (850) 202-1010

DEFENDANTS

ASTRAZENECA PHARMACEUTICALS, LP, ET AL.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

28 U.S.C. §1332

Brief description of cause:

Pharmaceutical personal injury product liability after ingestion of PPIs

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE

DOCKET NUMBER

DATE

03/28/2019

SIGNATURE OF ATTORNEY OF RECORD

/s/ James D. Barger

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE