IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

CHERYL LEAR,	§	
	§	
Plaintiff,	§	**Case No.:** 3:17-cv-240-J-34MCR
	§	
vs.	§	**COMPLAINT AND DEMAND FOR JURY TRIAL**
	§	
ASTRAZENECA PHARMACEUTICALS LP, WYETH PHARMACEUTICALS, INC., AND PFIZER, INC.,	§	
	§	
Defendants.	§	

COMPLAINT

Plaintiff, by her attorneys, **DOUGLAS & LONDON, P.C.** and **LEVIN, PAPANTONIO, THOMAS, MITCHELL, RAFFERTY & PROCTOR, P.A.**, 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 Plaintiff exceeds $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 Plaintiff resides.

NATURE OF THE CASE

2. This action is brought on behalf of Plaintiff, CHERYL LEAR, who used prescription brand Prilosec and prescription brand Protonix for treatment of her peptic disorders, which include gastroesophageal reflux disease ("GERD").

3. Plaintiff seeks compensatory damages as a result of Plaintiff's use of Prilosec and Protonix, which has caused Plaintiff to suffer and continue to suffer from Acute Kidney Injury

("AKI"), 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 and AstraZeneca LP (hereinafter collectively referred to as "the AstraZeneca Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Prilosec.

5. Defendants, Pfizer, Inc. and Wyeth Pharmaceuticals, Inc. designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Protonix.

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

7. The Defendants concealed their knowledge of Prilosec and Protonix's defects, specifically the fact that they cause serious kidney injuries, from Plaintiff, her treating physicians, hospitals, pharmacies, the FDA, the public in general and/or the medical community.

8. These representations were made by the Defendants with the intent of defrauding and deceiving Plaintiff, her 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 Prilosec and Ptotonix 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.

9. 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 acute kidney injury, 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.

10. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's use of Prilosec and Protonix, which has caused Plaintiff to suffer from Acute Kidney Injury, 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.

PARTY PLAINTIFF

11. Plaintiff, CHERYL LEAR, is a citizen of the United States of America, and is domiciled in and a resident of Florida.

12. Plaintiff, CHERYL LEAR, was born in 1959.

13. Plaintiff, CHERYL LEAR, first began using prescription brand Prilosec in or about March 2012, and she used prescription brand Prilosec up through September 2013.

14. Plaintiff, CHERYL LEAR, first began using prescription brand Protonix in or about February 2013, and she used prescription brand Protonix up through September 2013

15. As result of her ingestion of Defendants' Prilosec and Protonix, Plaintiff Cheryl Lear has suffered and continues to suffer from Acute Kidney Injury which was diagnosed in or

about March 2013, as well as any and all of its sequelae and attendant pain, suffering, and emotional distress.

16. The injuries and damages sustained by Plaintiff, CHERYL LEAR, were caused by Defendants' Prilosec and Protonix and their unlawful conduct with respect to their design, manufacture, marketing and sale.

17. As a result of Defendants' failure to warn and/or concealment of its knowledge that their Prilosec and Protonix caused kidney injuries, such as the one suffered by Plaintiff CHERYL LEAR, Chery Lear did not discover, nor did she have reason to discovery, their wrongful conduct as alleged herein until July 2016.

PARTY DEFENDANTS

18. Defendant AstraZeneca Pharmaceuticals, LP is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

19. 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 Prilosec products.

20. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals, LP was present and doing business in the State of Delaware and Florida.

21. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited, and conducted business in the State of Delaware and Florida and derived substantial revenue from such business.

22. 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 State of Delaware and Florida.

23. Upon information and belief, Defendant AstraZeneca LP is, and at all times relevant to this action was, a Delaware corporation.

24. Defendant AstraZeneca LP is the holder of approved New Drug Applications ("NDAs") 22-056, 19-810/S-74 and 21-229 etc. for Prilosec (Omeprazole Magnesium), and it manufactures and markets Prilosec (Omeprazole Magnesium) in the United States.

25. Upon information and belief, at all times relevant hereto Defendant AstraZeneca LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Prilosec Products.

26. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business in the State of Delaware and Florida.

27. Upon information and belief, at all relevant times, Defendant AstraZeneca LP transacted, solicited, and conducted business in the State of Delaware and Florida, and derived substantial revenue from such business.

28. Upon information and belief, at all times relevant hereto, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences within the United States of America, and the State of Delaware and Florida.

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

30. Defendant Wyeth is, and at all times relevant to this action was, a Delaware corporation. Defendant Wyeth is the holder of approved New Drug Application ("NDA") 020987 for Protonix (pantoprazole), and it manufactures and markets Protonix (pantoprazole) in the United States.

31. Upon information and belief, Defendant Wyeth was a Delaware corporation with its headquarters at 5 Giralda Farms, Madison, New Jersey 07940.

32. Wyeth, formerly known as American Home Products, Inc., was the parent of Wyeth Laboratories, Inc., and Wyeth Pharmaceuticals, Inc., formerly known as Wyeth-Ayerst Laboratories, Inc.

33. At all times relevant to the allegations herein, the management, supervision, control, reporting, and financial exchanges by and between Wyeth, Wyeth Pharmaceuticals, Inc., and Wyeth Laboratories, Inc., were so inextricably intertwined that in effect they operated as one single entity.

34. On October 15, 2009, defendant Pfizer acquired Wyeth, and on November 9, 2009, Wyeth converted into a Delaware limited liability company, Wyeth LLC. Wyeth LLC is now a wholly-owned subsidiary of Pfizer.

35. Defendant Wyeth is, and at all times relevant to this action was, a Delaware corporation. Defendant Wyeth is the holder of approved New Drug Application ("NDA") 020987 for Protonix (pantoprazole), and it manufactures and markets Protonix (pantoprazole) in the United States.

36. Defendant Wyeth is, and at all times relevant to this action was, a Delaware corporation having a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940. As part of its business, Wyeth is involved in the research, development, sales and marketing of pharmaceutical products including Protonix.

37. Upon information and belief, Defendant, Wyeth has transacted and conducted business in the State of New Jersey and Florida, the Plaintiff's state of residence.

38. Upon information and belief, Defendant, Wyeth has derived substantial revenue from goods and products used in the State of New Jersey and Florida.

39. Upon information and belief, Defendant, Wyeth, expected or should have expected its acts to have consequence within the State of New Jersey and Florida, and derived substantial revenue from interstate commerce within the United States, and the State of New Jersey and Florida.

40. Upon information and belief, and at all relevant times, Defendant, Wyeth, was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Protonix for use which primary purpose being a proton pump inhibitor.

41. Upon information and belief, Defendant Pfizer, Inc. is a Delaware corporation, having a principal place of business in New York. As part of its business, Pfizer, Inc. is involved in the research, development, sales and marketing of pharmaceutical products including Protonix.

42. Upon information and belief, Defendant, Pfizer, Inc.., has transacted and conducted business in the State of New York and Florida, the Plaintiff's state of residence.

43. Upon information and belief, Defendant, Pfizer, Inc.., has derived substantial revenue from goods and products used in the State of New York and Florida.

44. Upon information and belief, Defendant, Pfizer, Inc.., expected or should have expected its acts to have consequence within the State of New York and Florida, and derived substantial revenue from interstate commerce within the United States, and the State of New York and Florida.

45. Upon information and belief, and at all relevant times, Defendant, Pfizer, Inc.., was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Protonix for use which primary purpose being a proton pump inhibitor.

FACTUAL BACKGROUND

46. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff CHERYL LEAR suffering acute kidney injury caused by her ingestion of the proton pump inhibitors, Prilosec and Protonix.

47. Upon information and belief, the AstraZeneca Defendants began marketing and selling prescription brand Prilosec in 1989.

48. Plaintiff began taking prescription brand Prilosec in March 2012.

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

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

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

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

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

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

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

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

57. The AstraZeneca Defendants sold Prilosec with National Drug Code (NDC) numbers 00186-0606; 00186-0610; 00186-0625; 00186-0742 and 00186-0743.

58. Upon information and belief, Wyeth began marketing and selling prescription brand Protonix in 2000.

59. Plaintiff began taking prescription brand Protonix in March 2013.

60. Wyeth sold Protonix with National Drug Code (NDC) number 0067-6286

61. Prilosec (Omeprazole Magnesium) and Protonix (Pantoprazole) are PPIs that work by reducing hydrochloric acid in the stomach.

62. During the period in which Prilosec and Protonix were being sold in the United States, hundreds of reports of injuries, including kidney injuries, have been submitted to the FDA in association with ingestion of Prilosec, Protonix and other PPIs.

63. Defendants have had notice of serious adverse health outcomes regarding kidney disease associated with their Prilosec and Protonix through case reports, clinical studies and post-market surveillance.

64. Specifically, Defendants had received numerous case reports of kidney injuries in patients that had ingested Prilosec as early as 1989 and Protonix as early as 2000. As such, these reports of numerous kidney injuries put Defendants on notice as to the excessive risks of kidney injuries related to the use of Prilosec and Protonix.

65. In October of 1992, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article associating PPI usage with kidney injuries in the American Journal of Medicine, followed by years of reports from national adverse drug registries describing the association.

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

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

68. 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.

69. At the time of the August 23, 2011 filing, the petition stated that there "was no detailed risk information on any PPI for this adverse effect."

70. On October, 31, 2014, more than three years after Public Citizen's petition, the FDA responded by requiring risk of acute interstitial nephritis on all prescription PPIs.

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

72. 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.*

73. 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 staring the PPIs.

74. From the findings identified above, PPIs and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate acute interstitial nephritis.

75. In February 2016, a study published in the Journal of the American Society of Nephrology found that PPI use including Prilosec, was independently associated with a 20% to 50% higher risk of incident chronic kidney disease ("CKD"), after adjusting for several potential confounding variables, including demographics, socioeconomic status, clinical measurements, prevalent comorbidities, and concomitant use of medications.

76. CKD, also called chronic kidney failure, describes the gradual loss of kidney function. Kidneys filter wastes and excess fluids from the blood, which are then excreted. When chronic kidney disease reaches an advanced stage, dangerous levels of fluid, electrolytes and wastes can build up in the body. End state renal disease is the last stage of chronic kidney disease.

77. In the early stages of CKD, patients may have few signs or symptoms, so CKD may not become apparent until kidney function is significantly impaired.

78. Treatment for CKD focuses on slowing the progression of the kidney damage, usually by attempting to control the underlying cause. CKD can progress to end-stage kidney failure, which is fatal without artificial filtering, dialysis or a kidney transplant. Early treatment is often key to avoiding the most negative outcomes.

79. CKD is associated with a substantially increased risk of death and cardiovascular events.

80. CKD is identified by a blood test for creatinine, which is a breakdown product of muscle metabolism. Higher levels of creatinine indicate a lower glomerular filtration rate and as a result a decreased capability of the kidneys to excrete waste products.

81. In addition to the above studies, one study has linked the acute kidney injuries caused by PPIs, such as acute interstitial nephritis, to a later increased risk of CKD. The study noted that PPI induced acute kidney disease is often subtle and slowly diagnosed. Thus, the delay in diagnosis causes damage to the kidney to be increased and the patient has a higher risk of later developing CKD.

82. To date, Defendants' prescription Prilosec and Protonix lack detailed risk information for CKD.

83. Defendants knew or should have known of the risk of kidney disease 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.

84. Despite their knowledge of the risks of kidney injuries associated with their Prilosec and Protonix, Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Prilosec and Protonix did not pose any risks of kidney injuries. They promoted and marketed Prilosec as safe and effective for persons such as Plaintiff CHERYL LEAR throughout the United States, including Florida.

85. Defendants knew of the significant risk of kidney damage that could result from long-term Prilosec and Protonix use, but Defendants did not adequately and sufficiently warn consumers, including Plaintiff, her physician or the medical community in a timely manner.

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

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

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

89. Even if used as directed, persons who ingested Prilosec and Protonix, such as the Plaintiff CHERYL LEAR, have been exposed to significant risks stemming from unindicated and/or long term usage.

90. Consumers, including Plaintiff CHERYL LEAR, and their physicians relied on the Defendants' false representations and were misled as to the safety of Prilosec and Protonix.

91. Had the Plaintiff CHERYL LEAR known of the risks of kidney disease associated with Defendants' Prilosec, she would not have used Defendants' Prilosec or Protonix.

92. At all relevant times, Plaintiff CHERYL LEAR had alternative safer methods for treating peptic disorders that provided the same benefits but acted through a different mechanism and were not associated with kidney disease.

93. 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 CKD.

94. As a result of Defendants' action and inactions as outlined herein, Plaintiff was injured due to his ingestion of Prilosec and Protonix, which caused her and continues to cause her to suffer from acute kidney injury and any and all of its sequelae.

95. Prior to July 2016, Plaintiff CHERYL LEAR did not know about the causal link between his end-stage renal disease and ingestion of Defendants' Prilosec and Protonix.

96. It was not until about July 2016 that Plaintiff CHERYL LEAR first learned of the possible causal link.

97. Prior to the July 2016, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of chronic kidney disease associated with the use of Prilosec or Protonix.

FIRST CAUSE OF ACTION
NEGLIGENCE

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

99. 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 Prilosec and Protonix into interstate commerce in that Defendants knew or should have known that using Prilosec and Protonix 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 Prilosec and Protonix. 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 Prilosec and Protonix;

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 Prilosec and Protonix in unsafe doses;

c. Failure to use reasonable care in testing and inspecting Prilosec and Protonix so as to ascertain whether or not it was safe for the purpose for which it was designed, manufactured and sold;

d. Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Prilosec and Protonix;

e. Failure to use reasonable care in the process of manufacturing Prilosec and Protonix 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 Prilosec and Protonix in unsafe doses; and

g. Such further acts and/or omissions that may be proven at trial.

100. 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.

101. 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 Prilosec and Protonix without thoroughly testing them;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing Prilosec and Protonix without adequately testing them;

c. Not conducting sufficient testing programs to determine whether or not Prilosec and Protonix were safe for use; in that Defendants herein knew or should have known that Prilosec and Protonix was unsafe and unfit for use by reason of the dangers to its users;

d. Selling Prilosec and Protonix 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 Prilosec and Protonix;

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, Prilosec and Protonix;

g. Failing to test Prilosec and Protonix and/or failing to adequately, sufficiently and properly test Prilosec and Protonix.

h. Negligently advertising and recommending the use of Prilosec and Protonix without sufficient knowledge as to its dangerous propensities;

i. Negligently representing that Prilosec and Protonix were safe for use for its intended purpose, when, in fact, they were unsafe;

j. Negligently designing Prilosec and Protonix in a manner which was dangerous to its users;

k. Negligently manufacturing Prilosec and Protonix in a manner which was dangerous to its users;

l. Negligently producing Prilosec and Protonix in a manner which was dangerous to its users;

m. Negligently assembling Prilosec and Protonix in a manner which was dangerous to its users; and

n. Concealing information from the Plaintiff in knowing that Prilosec and Protonix was unsafe, dangerous, and/or non-conforming with FDA regulations.

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

103. Defendants negligently compared the safety risk and/or dangers of Prilosec and Protonix with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug-induced gastropathy.

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

a. Failed to use due care in designing and manufacturing Prilosec and Protonix so as to avoid the aforementioned risks to individuals when Prilosec and Protonix 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 use of Prilosec and Protonix;

c. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Prilosec and Protonix;

d. Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Prilosec and Protonix;

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 Prilosec and Protonix;

g. Failed to warn Plaintiff, prior to actively encouraging the sale of Prilosec and Protonix, 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; and

h. Were otherwise careless and/or negligent.

105. Despite the fact that Defendants knew or should have known that Prilosec and Protonix caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Prilosec and Protonix to consumers, including the Plaintiff.

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

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

108. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, End Stage Renal Disease, 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.

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

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

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY

111. 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 Prilosec and Protonix as hereinabove described that was used by the Plaintiff.

112. That Prilosec and Protonix were 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.

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

114. The Prilosec and Protonix designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Prilosec and Protonix.

115. The Prilosec and Protonix designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

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

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

118. At the time of the Plaintiff's use of Prilosec and Protonix the drugs 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.

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

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

121. Defendants created a product unreasonably dangerous for its normal, intended use.

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

123. The Prilosec and Protonix 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' Prilosec and Protonix was manufactured.

124. 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.

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

126. The Prilosec and Protonix designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate

warnings or instructions as the Defendants knew or should have known that the products created a risk of serious and dangerous side effects including 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.

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

128. The Prilosec and Protonix designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were 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, kidney injuries, as well as other severe and permanent health consequences from Prilosec and Protonix, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their products, Prilosec and Protonix.

129. 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 defective products, Prilosec and Protonix.

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

131. That said defects in Defendants' drugs Prilosec and Protonix were a substantial factor in causing Plaintiff's injuries.

132. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, kidney injuries, 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.

133. 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.

134. 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
BREACH OF EXPRESS WARRANTY

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

136. Prilosec and Protonix do not conform to these express representations because Prilosec and Protonix 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.

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

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

139. The Defendants herein breached the aforesaid express warranties, as their drugs, Prilosec and Protonix, were defective.

140. Defendants expressly represented to Plaintiff, his physicians, healthcare providers, and/or the FDA that Prilosec and Protonix were safe and fit for use for the purposes intended, that they 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 they did produce were accurately reflected in the warnings and that they were adequately tested and fit for their intended use.

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

142. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Acute Kidney Injury, 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.

143. 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' Prilosec and Protonix drugs.

144. 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.

145. 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
BREACH OF IMPLIED WARRANTIES

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

147. At the time Defendants marketed, sold, and distributed Prilosec and Protonix for use by Plaintiff, Defendants knew of the use for which Prilosec and Protonix were intended and impliedly warranted the products to be of merchantable quality and safe and fit for such use.

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

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

150. 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.

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

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

153. The Defendants herein breached the aforesaid implied warranties, as their drugs, Prilosec and Protonix were not fit for its intended purposes and uses.

154. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, kidney injuries, 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.

155. 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.

156. 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
FRAUDULENT MISREPRESENTATION

157. 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,

Prilosec and Protonix 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.

158. These representations made by Defendants were, in fact, false.

159. 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.

160. 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 products, Prilosec and Protonix, 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.

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

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

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

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

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

166. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Acute Kidney Injury, 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.

167. 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.

168. 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
FRAUDULENT CONCEALMENT

169. 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 Prilosec and Protonix for their intended use.

170. Defendants knew or were reckless in not knowing that its representations were false.

171. 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 Prilosec and Protonix 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 Prilosec and Protonix 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 Prilosec and Protonix were not adequately tested and/or known by Defendants;

d. that Defendants were aware of dangers in Prilosec and Protonix, 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 Prilosec and Protonix were defective, and that they caused dangerous side effects, including but not limited to kidney injuries;

f. that patients needed to be monitored more regularly than normal while using Prilosec and Protonix;

g. that Prilosec and Protonix were manufactured negligently;

h. that Prilosec and Protonix were manufactured defectively;

i. that Prilosec and Protonix were manufactured improperly;

j. that Prilosec and Protonix were designed negligently;

k. that Prilosec and Protonix were designed defectively; and

l. that Prilosec and Protonix were designed improperly.

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

173. 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 Prilosec and Protonix, including the Plaintiff, in particular.

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

175. 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 Prilosec and Protonix, as set forth herein.

176. 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.

177. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, kidney injuries, 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.

178. 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.

179. 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
NEGLIGENT MISREPRESENTATION

180. 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, Prilosec and Protonix, 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.

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

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

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

184. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, kidney injuries, 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.

185. 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.

186. 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
FRAUD AND DECEIT

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

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

189. 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.

190. 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.

191. 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.

192. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drugs, Prilosec and Protonix 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.

193. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drugs Prilosec and Protonix 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.

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

195. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Prilosec and Protonix were 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.

196. These representations were all false and misleading.

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

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

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

200. 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 Prilosec and Protonix, to induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Prilosec and Protonix.

201. 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 Prilosec and Protonix 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.

202. 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 Prilosec and Protonix 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.

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

204. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Prilosec and Protonix 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.

205. 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.

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

207. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Prilosec and Protonix 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.

208. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Prilosec and Protonix by concealing and

suppressing material facts regarding the dangerous and serious health and/or safety concerns of Prilosec and Protonix.

209. 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 his respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Prilosec and Protonix and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

210. 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.

211. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Prilosec and Protonix.

212. That the Plaintiff and/or his 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.

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

214. 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.

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

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

217. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, End Stage Renal Disease, 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.

218. 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.

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

PRAYER FOR RELIEF

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

A. Awarding compensatory damages to Plaintiffs 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;

B. 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;

C. Awarding Plaintiff reasonable attorneys' fees;

D. Awarding Plaintiff the costs of these proceedings; and

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

DEMAND FOR JURY TRIAL

Plaintiff respectfully demands a trial by jury on all counts and as to all issues.

Dated: March 2, 2016

Respectfully submitted,

/s/ Brandon L. Bogle
Brandon L. Bogle, Esq. FL Bar #52624
Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A.
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Pensacola, FL 32502
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Attorney for Plaintiff

JS 44 (Rev. 07/16)

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
CHERYL LEAR

(b) County of Residence of First Listed Plaintiff CLAY COUNTY, FL
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
BRANDON L. BOGLE, ESQUIRE
316 SOUTH BAYLEN STREET, SUITE 600
PENSACOLA, FLORIDA 32502 (850) 435-7043

DEFENDANTS
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA LP, WYETH PHARMACEUTICALS, INC., AND PFIZER, INC.

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

Attorneys *(If Known)*

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
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- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
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- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
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REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
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PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
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- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

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- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
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- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
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- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

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- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

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- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable Sat TV
- ☐ 850 Securities Commodities Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - 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, Diversity
Brief description of cause:
Personal Injury - Pharmaceutical Product Liability

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
03/02/2017

SIGNATURE OF ATTORNEY OF RECORD
/s/ Brandon L. Bogle

FOR OFFICE USE ONLY
RECEIPT # _____ AMOUNT $400 APPLYING IFP ✓ JUDGE 34 MAG. JUDGE MCR

JAX023202