

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

JOEY BURNETT,	)	
	)	
Plaintiff,	)	CASE NO. 2:16-cv-894
	)	
v.	)	JUDGE
	)	
ASTRAZENECA PHARMACEUTICALS LP;	)	MAGISTRATE JUDGE
ASTRAZENECA LP; ASTRA USA INC.; KBI	)	
SUB INC.; ZENECA INC.; ASTRA USA	)	
HOLDINGS CORPORATION;	)	<b><u>JURY DEMAND ENDORSED</u></b>
ASTRAZENECA, AB; ASTRAZENECA, PLC;	)	<b><u>HEREON</u></b>
and ASTRAZENECA, UK LIMITED,	)	
	)	
Defendants.	)	

**COMPLAINT**

Plaintiff Joey Burnett (“Plaintiff” or “Burnett”) for his complaint states, by and through counsel and upon information and belief, 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, JOEY BURNETT, who used Nexium for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

3. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's use of the Nexium, which has caused Plaintiff to suffer from 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, and fear of developing any of the above named health consequences. Defendants, AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra USA Inc., KBI SUB Inc., Zeneca Inc., Astra USA Holdings Corporation, AstraZeneca, AB, AstraZeneca, PLC, and AstraZeneca, UK Limited, (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Nexium. When warning of safety and risks of Nexium, Defendants negligently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as the "FDA"), to Plaintiff and the public in general, that Nexium had been tested and was found to be safe and/or effective for its indicated use.

4. Defendants concealed their knowledge of Nexium's defects from Plaintiff, the FDA, the public in general and/or the medical community specifically.

5. These representations were made by Defendants with the intent of defrauding and deceiving 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 community in particular, to recommend, dispense and/or purchase Nexium 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.

6. 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 life-threatening 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, and fear of developing any of the above named health consequences. Plaintiff herein has sustained certain of the above health consequences due to Plaintiff's use of Nexium.

7. Defendants concealed their knowledge of the defects in their products from the Plaintiff, and Plaintiff's physicians, hospitals, pharmacists, the FDA, and the public in general.

8. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's use of the Nexium, which has caused Plaintiff to suffer from 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, and fear of developing any of the above named health consequences.

#### **PARTY PLAINTIFF**

9. Plaintiff, JOEY BURNETT, is a citizen of the United States of America, and is a resident of Ohio.

10. Plaintiff, JOEY BURNETT, was born on July 9, 1956.

11. Plaintiff, JOEY BURNETT, first began using Nexium in or about 2014.

12. Plaintiff, JOEY BURNETT, was diagnosed with End Stage Renal Disease on September 18, 2014.

13. As result of using Defendants' Nexium, Plaintiff JOEY BURNETT, was caused to suffer End Stage Renal Disease after taking Nexium, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

14. The injuries and damages sustained by Plaintiff, JOEY BURNETT, were directly and proximately caused by Defendants' Nexium.

#### **PARTY DEFENDANTS**

15. Defendant AstraZeneca Pharmaceuticals LP is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware. Defendant AstraZeneca Pharmaceuticals LP is registered to do business in the state of Ohio.

16. 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 Nexium products.

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

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

19. 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 Ohio.

20. Defendant AstraZeneca LP is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware. Defendant AstraZeneca LP is registered to do business in the state of Ohio.

21. At all times relevant hereto, Defendant AstraZenca LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

22. Upon information and belief, at all relevant times, Defendant AstraZenca LP was present and doing business in the State of Delaware and Ohio.

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

24. Defendant Astra USA Inc. is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

25. At all times relevant hereto, Defendant Astra USA Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

26. Upon information and belief, at all relevant times, Defendant Astra USA Inc., was present and doing business in the State of Delaware and Ohio.

27. Upon information and belief, at all relevant times, Defendant Astra USA Inc. transacted, solicited, and conducted business in the State of Delaware and Ohio and derived substantial revenue from such business.

28. Defendant KBI SUB Inc. is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

29. At all times relevant hereto, Defendant KBI SUB Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

30. Upon information and belief, at all relevant times, Defendant KBI SUB Inc. was present and doing business in the State of Delaware and Ohio.

31. Upon information and belief, at all relevant times, Defendant KBI SUB Inc. transacted, solicited, and conducted business in the State of Delaware and Ohio and derived substantial revenue from such business.

32. Defendant Zeneca Inc. is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

33. At all times relevant hereto, Defendant Zeneca Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

34. Upon information and belief, at all relevant times, Defendant Zeneca Inc. was present and doing business in the State of Delaware and Ohio.

35. Upon information and belief, at all relevant times, Defendant Zeneca Inc. transacted, solicited, and conducted business in the State of Delaware and Ohio and derived substantial revenue from such business.

36. Defendant Astra USA Holding Corporation is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

37. At all times relevant hereto, Defendant Astra USA Holdings Corporation was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

38. Upon information and belief, at all relevant times, Defendant Astra USA Holdings Corporation was present and doing business in the State of Delaware and Ohio.

39. Upon information and belief, at all relevant times, Defendant Astra USA Holdings Corporation transacted, solicited, and conducted business in the State of Delaware and Ohio and derived substantial revenue from such business.

40. Defendant AstraZeneca AB is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware. Defendant AstraZeneca AB is registered to do business in the state of Ohio.

41. At all times relevant hereto, Defendant AstraZeneca AB was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

42. Upon information and belief, at all relevant times, Defendant AstraZeneca AB was present and doing business in the State of Delaware and Ohio.

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

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

45. At all times relevant hereto, Defendant AstraZeneca PLC was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

46. Upon information and belief, at all relevant times, Defendant AstraZeneca PLC was present and doing business in the State of Delaware and Ohio.

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

48. Defendant AstraZeneca UK Limited is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

49. At all times relevant hereto, Defendant AstraZeneca UK Limited was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium products.

50. Upon information and belief, at all relevant times, Defendant AstraZeneca UK Limited was present and doing business in the State of Delaware and Ohio.

51. Upon information and belief, at all relevant times, Defendant AstraZeneca UK Limited transacted, solicited, and conducted business in the State of Delaware and Ohio and derived substantial revenue from such business.

52. Upon information and belief, Defendants AstraZeneca LP; AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Astra USA Inc.; KBI SUB Inc.; Zeneca Inc.; Astra USA Holdings Corporation; AstraZeneca, AB ; AstraZeneca, PLC, and AstraZeneca, UK Limited, shall herein be collectively referred to as “Defendants” or “AstraZeneca.”

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



54. 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 Nexium Products.

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

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

57. 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 Ohio.

58. Upon information and belief, Defendants AstraZeneca LP; AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Astra USA Inc.; KBI SUB Inc.; Zeneca Inc.; Astra USA Holdings Corporation; AstraZeneca, AB ; AstraZeneca, PLC, and AstraZeneca, UK Limited, shall herein be collectively referred to as “Defendants” or “AstraZeneca.”

59. Upon information and belief, each 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.

60. 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 Nexium products.

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

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

63. 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 Ohio.

64. Upon information and belief, 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 Nexium Products.

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

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

67. 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 Ohio.

68. Upon information and belief, Defendants AstraZeneca LP; AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Astra USA Inc.; KBI SUB Inc.; Zeneca Inc.; Astra USA Holdings Corporation; AstraZeneca, AB ; AstraZeneca, PLC, and AstraZeneca, UK Limited, shall herein be collectively referred to as “Defendants” or “AstraZeneca.”

69. Upon information and belief, each 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.

### **FACTUAL BACKGROUND**

70. Proton pump inhibitors ("PPI") are one of the most commonly prescribed medications in the United States.

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

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

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

74. AstraZeneca sold Nexium with National Drug Code (NDC) numbers 0186-5020, 0186-5022, 0186-5040, 0186-5042, 0186-4010, 0186-4020, and 0186-4040.

75. Nexium is AstraZeneca's largest-selling drug and, in the world market, the third largest selling drug overall. In 2005, AstraZeneca's sales of Nexium exceeded \$5.7 billion dollars. In 2008, Nexium sales exceeded \$5.2 billion dollars.

76. Nexium (esomeprazole magnesium) is a PPI that works by reducing hydrochloric acid in the stomach.

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

78. During the period in which Nexium has been sold in the United States, hundreds of reports of injury have been submitted to the FDA in association with ingestion of Nexium and other PPIs. Defendants have had notice of serious adverse health outcomes through case reports, clinical studies and post-market surveillance. Specifically, Defendants had received numerous case reports of kidney injuries in patients that had ingested Nexium by as early as 1989. These reports of numerous kidney injuries put Defendants on notice as to the excessive risks of kidney injuries related to the use of Nexium. However, Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Nexium did not pose any risks of kidney injuries.

79. As a result of Defendants' action and inactions, Plaintiff was injured due to his ingestion of Nexium, which caused and will continue to cause Plaintiff various injuries and damages.

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

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

82. Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Nexium did not pose any risks of kidney injuries.

83. Since the introduction of PPIs to the US market in 1989, several observational studies have linked PPI use to serious adverse health outcomes, including hip fracture,

community acquired pneumonia, Clostridium difficile infection, acute interstitial nephritis and acute kidney injury (“AKI”). A study from 2015 shows that acute kidney injuries increased 250% in elderly patients that were newly prescribed PPIs. The acute kidney injuries occurred with 120 days of the patients starting the PPIs.

84. Recent studies have shown the long term use of PPIs 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. In one of those studies, the use of PPIs for any period of time was shown to increase the risk of CKD by 10%.

85. 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.

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

87. 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.

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

89. 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.

90. Creatinine levels may be normal in the early stages of CKD, so the condition may also be discovered by urinalysis. To fully investigate the scope of the kidney damage, various forms of medical imaging, blood tests and a kidney biopsy are employed.

91. Screening of at-risk people is important because treatments exist that delay the progression of CKD.

92. Practical and technically feasible alternatives to PPIs are and were available that provide the same benefits but act through a different mechanism.

93. One alternative is 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.

94. The higher risks of CKD are specific to PPI medications. The use of H2 receptor antagonists, which are prescribed for the same indication as PPIs, is not associated with CKD.

95. Similar findings were demonstrated for the outcome of AKI and collectively suggest that PPI use is an independent risk factor for CKD and for AKI.

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

97. Defendants failed to adequately warn against the negative effects and risks associated with Nexium. Defendants have totally failed to provide any warnings regarding CKD.

98. In omitting, concealing, and inadequately providing critical safety information regarding the use of Nexium 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.

99. Defendants knew or should have known about the correlation between the use of Nexium and the significantly increased risk of CKD and acute kidney injuries.

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

**FIRST CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**(NEGLIGENCE)**

101. 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.

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

103. 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 Nexium into interstate commerce in that Defendants knew or should have known that using Nexium 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 Nexium. 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 Nexium;
- (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 Nexium in unsafe doses;
- (c) Failure to use reasonable care in testing and inspecting Nexium 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 Nexium;
- (e) Failure to use reasonable care in the process of manufacturing Nexium 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 Nexium in unsafe doses; and
- (g) Such further acts and/or omissions that may be proven at trial.

104. 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.

105. 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 Nexium without thoroughly testing it;
- (b) Manufacturing, producing, promoting, formulating, creating, and/or designing Nexium without adequately testing it;



- (c) Not conducting sufficient testing programs to determine whether or not Nexium was safe for use; in that Defendants herein knew or should have known that Nexium was unsafe and unfit for use by reason of the dangers to its users;
- (d) Selling Nexium 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 Nexium;
- (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, Nexium;
- (g) Failing to test Nexium and/or failing to adequately, sufficiently and properly test Nexium.
- (h) Negligently advertising and recommending the use of Nexium without sufficient knowledge as to its dangerous propensities;
- (i) Negligently representing that Nexium was safe for use for its intended purpose, when, in fact, it was unsafe;
- (j) Negligently designing Nexium in a manner which was dangerous to its users;
- (k) Negligently manufacturing Nexium in a manner which was dangerous to its users;
- (l) Negligently producing Nexium in a manner which was dangerous to its users;
- (m) Negligently assembling Nexium in a manner which was dangerous to its users;
- (n) Concealing information from the Plaintiff in knowing that Nexium was unsafe, dangerous, and/or non-conforming with FDA regulations.

106. Defendants under-reported, underestimated and downplayed the serious dangers of Nexium.

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

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

- (a) Failed to use due care in designing and manufacturing Nexium so as to avoid the aforementioned risks to individuals when Nexium was 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 Nexium;
- (c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Nexium;
- (d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Nexium;
- (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 Nexium;
- (g) Failed to warn Plaintiff, prior to actively encouraging the sale of Nexium, 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.

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

110. 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.

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

112. 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.

113. 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.

114. 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)**

115. 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.

116. 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 Nexium as hereinabove described that was used by the Plaintiff.

117. That Nexium 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.

118. At those times, Nexium was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

119. The Nexium 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 Nexium.

120. The Nexium 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.

121. At all times herein mentioned, Nexium was 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.

122. Defendants knew, or should have known that at all times herein mentioned its Nexium was in a defective condition, and was and is inherently dangerous and unsafe.

123. At the time of the Plaintiff's use of Nexium, Nexium was 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.

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

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

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

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

128. The Nexium 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' Nexium was manufactured.

129. 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.

130. The Plaintiff could not, by the exercise of reasonable care, have discovered Nexium's defects herein mentioned and perceived its danger.

131. Nexium was 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, 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.

132. Nexium was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

133. Nexium was 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, kidney injuries, as well as other severe and permanent health consequences from Nexium, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Nexium.

134. 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, Nexium.

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

136. That said defects in Defendants' drug Nexium were a substantial factor in causing Plaintiff's injuries.

137. 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.

138. 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.

139. 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)**

140. 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.

141. Defendants expressly warranted that Nexium was safe and well accepted by users.

142. Nexium does not conform to these express representations because Nexium is not safe and has 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.

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

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

145. The Defendants herein breached the aforesaid express warranties, as their drug Nexium was defective.

146. Defendants expressly represented to Plaintiff, his physicians, healthcare providers, and/or the FDA that Nexium was safe and fit for use for the purposes intended, that it was of merchantable quality, that it 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.

147. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Nexium 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.



148. 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.

149. 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' Nexium drug.

150. 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.

151. 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)**

152. 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.

153. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Nexium and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Nexium for the

treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

154. At the time Defendants marketed, sold, and distributed Nexium for use by Plaintiff, Defendants knew of the use for which Nexium was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

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

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

157. 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.

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

159. Nexium 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.

160. The Defendants herein breached the aforesaid implied warranties, as their drug Nexium was not fit for its intended purposes and uses.

161. 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.

162. 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.

163. 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)**

164. 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.

165. 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 product, Nexium had been tested and was 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.

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

167. 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.

168. 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, Nexium, 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.

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

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

171. Said Defendants knew and were aware or should have been aware that Nexium had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

172. Defendants knew or should have known that Nexium had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was

inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

173. Defendants brought Nexium to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

174. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Interstitial Nephritis and 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.

175. 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.

176. 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)**

177. 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.

178. 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 Nexium for its intended use.

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

180. 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 Nexium was 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 Nexium 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 Nexium were not adequately tested and/or known by Defendants;
- (d) that Defendants were aware of dangers in Nexium, 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 Nexium was defective, and that it caused dangerous side effects, including but not limited to kidney injuries;
- (f) that patients needed to be monitored more regularly than normal while using Nexium;
- (g) that Nexium was manufactured negligently;
- (h) that Nexium was manufactured defectively;
- (i) that Nexium was manufactured improperly;
- (j) that Nexium was designed negligently;
- (k) that Nexium was designed defectively; and
- (l) that Nexium was designed improperly.

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

182. 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 Nexium, including the Plaintiff, in particular.

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

184. 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 Nexium, as set forth herein.

185. 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.

186. 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.

187. 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.

188. 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)**

189. 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.

190. 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 product, Nexium, 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.

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

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

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



194. 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.

195. 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.

196. 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)**

197. 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.

198. Defendants conducted research and used Nexium as part of their research.

199. 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 Nexium 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.

200. 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.

201. 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.

202. 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.

203. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug Nexium was 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.

204. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug Nexium 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.

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

206. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Nexium 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.

207. These representations were all false and misleading.

208. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Nexium was 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.

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

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

211. 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 Nexium induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Nexium.

212. 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 Nexium 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.

213. 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 Nexium 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.

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

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

216. 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.

217. 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 Nexium.

218. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Nexium 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.

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

220. 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 Nexium and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

221. 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.

222. Defendants utilized direct to consumer advertising to market, promote, and/or advertise Nexium.

223. 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.

224. 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 Nexium.

225. 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.

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

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

228. 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.

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).

NINTH CAUSE OF ACTION AS  
AGAINST THE DEFENDANTS  
(OHIO PRODUCTS LIABILITY)

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 are the manufacturer or supplier of Nexium. To the extent any Defendant is a supplier, upon information and belief, such Defendant is owned by or owns the manufacturer Defendant.

233. Nexium was defectively designed or formulated and there are available practical and technically feasible alternatives as set forth in the preceding allegations.

234. Defendants failed to exercise reasonable care in adequately warning Plaintiff or healthcare professionals of the detrimental side effects of Nexium as set forth in the preceding allegations.

235. Nexium did not conform to the representations made by Defendants as set forth in the preceding allegations.

236. Plaintiff was injured as set forth in the preceding allegations as a result of Defendants' defectively designed or formulated Nexium, Defendants failure to adequately warn Plaintiff and healthcare professionals about detrimental side effects, and Nexium's lack of conformity with representations made by Defendants.

237. 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 demands judgment against the Defendants on each of the above-referenced claims and Causes of Action as follows:

1. 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;
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: September 16, 2016

/s/ David J. Butler

David J. Butler (0068455), Trial Attorney

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OF COUNSEL (*pro hac vice* motion forthcoming)

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Ph: (212) 566-7500

Fax: (212) 566-7501

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands trial by jury as to all issues.

*/s/ David J. Butler*

\_\_\_\_\_  
David J. Butler

## 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**

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

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

**DEFENDANTS**

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 type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input 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	<b>PERSONAL INJURY</b> <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	<b>PERSONAL INJURY</b> <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>LABOR</b> <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	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <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)) <b>FEDERAL TAX SUITS</b> <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
<b>REAL PROPERTY</b> <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	<b>CIVIL RIGHTS</b> <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	<b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <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 <b>Other:</b> <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):

Brief description of cause:

**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

SIGNATURE OF ATTORNEY OF RECORD

**FOR OFFICE USE ONLY**

RECEIPT # \_\_\_\_\_

AMOUNT \_\_\_\_\_

APPLYING IFP \_\_\_\_\_

JUDGE \_\_\_\_\_

MAG. JUDGE \_\_\_\_\_