IN THE UNITED STATES DISTRICT COURT
Eastern District of Pennsylvania

WANDA STAFFORD,	:	**Civil Action No.**
	:	
Plaintiff,	:	
	:	
v.	:	**COMPLAINT AND DEMAND FOR JURY TRIAL**
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA LP, PROCTER & GAMBLE MANUFACTURING COMPANY, and THE PROCTER & GAMBLE COMPANY.	:	
Defendants.		

COMPLAINT

Plaintiff, Wanda Stafford, by way of Complaint against Defendants, AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Procter & Gamble Manufacturing Company, and The Procter & Gamble Company (collectively "Defendants) alleges as follows:

INTRODUCTION

1. This is an action for personal injury, statutory, compensatory and punitive damages suffered by Plaintiff, Wanda Stafford, as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and/or sale of proton pump inhibitor ("PPI") drugs known as Nexium (esomeprazole magnesium) and/or other Nexium-branded products with the same active ingredient collectively referred to herein as "Nexium" and Prilosec (Omeprazole Magnesium) and/or other Prilosec-branded products

including Prilosec OTC with the same active ingredient collectively referred to herein as "Prilosec".

THE PARTIES

2. Plaintiff, Wanda Stafford, is a citizen of the United States of America, and at all times relevant hereto, was and is a resident of the state of Kentucky.

AstraZeneca Pharmaceuticals LP

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

4. 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 and Prilosec products.

5. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in Plaintiff's state of residency as well as the Commonwealth of Pennsylvania.

6. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP was registered to do business in the Commonwealth of Pennsylvania as a foreign corporation.

7. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited and conducted business in the Commonwealth of Pennsylvania and derived substantial revenue from such business.

8. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP expected or should have expected that its acts would have consequences throughout the United States of America, Plaintiff's state of residency and the Commonwealth of Pennsylvania, in particular.

AstraZeneca LP

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

10. Defendant AstraZeneca LP is, and all times relevant to this action was, a Delaware Corporation with its corporate headquarters in Wilmington, Delaware.

11. Defendant AstraZeneca LP is the holder of approved New Drug Applications ("NDAs") for the following forms of Nexium: Delayed-Release Capsule Pellets (20 mg and 40 mg), with NDA #021153, approved on 2/20/2001; Delayed-Release Oral Suspension Packets (2.5MG, 5MG, 20MG, 40MG), with NDA # 021957, approved on 10/20/2006; Delayed-Release Oral Suspension Packets (10MG), with NDA # 022101, approved on 02/27/2008; and Injection (20MG VIAL, 40MG VIAL), with NDA # 022101, approved on 03/31/2005, and it manufactures and markets Nexium in the United States.

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

13. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business in Plaintiff's state of residency as well as the Commonwealth of Pennsylvania.

14. At all relevant times hereto, Defendant AstraZeneca LP was registered to do business in the Commonwealth of Pennsylvania as a foreign corporation.

15. At all relevant times, Defendant AstraZeneca LP transacted, solicited and conducted business in Plaintiff's state of residency as well as the Commonwealth of Pennsylvania and derived substantial revenue from such business.

16. At all relevant times, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences throughout the United State of America, Plaintiff's state of residency and the Commonwealth of Pennsylvania, in particular.

Procter & Gamble Manufacturing Company

17. Defendant Procter & Gamble Manufacturing Company is, and all times relevant to this action was, an Ohio corporation with its corporate headquarters in Cincinnati, Ohio.

18. At all times relevant hereto, Defendant Procter & Gamble Manufacturing Company was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Prilosec OTC products.

19. Upon information and belief, at all relevant times, Defendant Procter & Gamble Manufacturing Company was present and doing business in Plaintiff's state of residency as well as the Commonwealth of Pennsylvania.

20. At all relevant times, Defendant Procter & Gamble Manufacturing Company was registered to do business in the Commonwealth of Pennsylvania as a foreign corporation.

21. At all relevant times, Defendant Procter & Gamble Manufacturing Company transacted, solicited and conducted business in the Commonwealth of Pennsylvania and derived substantial revenue from such business.

22. At all relevant times, Defendant Procter & Gamble Manufacturing Company expected or should have expected that its acts would have consequences throughout the United States of America, Plaintiff's state of residency and the Commonwealth of Pennsylvania, in particular.

The Procter & Gamble Company

23. Defendant The Procter & Gamble Company is, and all times relevant to this action was, an Ohio corporation with its corporate headquarters in Cincinnati, Ohio.

24. Upon information and belief, Defendant The Procter & Gamble Company is either the direct or indirect owner of substantially all the stock or other ownership interests of Defendant Procter & Gamble Manufacturing Company.

25. At all times relevant hereto, Defendant The Procter & Gamble Company was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Prilosec OTC products.

26. Upon information and belief, at all relevant times, Defendant The Procter & Gamble Company was present and doing business in Plaintiff's state of residency as well as the Commonwealth of Pennsylvania.

27. At all relevant times, Defendant The Procter & Gamble Company was registered to do business in the Commonwealth of Pennsylvania as a foreign corporation.

28. At all relevant times, Defendant The Procter & Gamble Company transacted, solicited and conducted business in the Commonwealth of Pennsylvania and derived substantial revenue from such business.

29. At all relevant times, Defendant The Procter & Gamble Company expected or should have expected that its acts would have consequences throughout the United States of America, Plaintiff's state of residency and the Commonwealth of Pennsylvania, in particular.

Defendants' Unity of Interest

30. Upon information and belief, at all relevant times, each of the Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP and their directors and/or officers acted within the scope of their authority for and on behalf of the other Defendant. During all relevant

times, Defendants possessed a unity of interest between themselves and exercised control over their respective subsidiaries and affiliates.

31. Upon information and belief, at all relevant times, AstraZeneca Pharmaceuticals LP and AstraZeneca LP were the agent and employee of the other Defendant, and in performing the wrongful acts alleged, each Defendant was acting within the course and scope of such agency and employment with each Defendants' actual and implied permission, consent, authorization and approval. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's injury, losses and damages.

32. Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP are thus collectively referred to herein as "AstraZeneca Defendants" or "AstraZeneca".

33. Upon information and belief, at all relevant times, Defendants Procter & Gamble Manufacturing Company and The Procter & Gamble Company, and their directors and/or officers acted within the scope of their authority for and on behalf of the other Defendant. During all relevant times, Defendants possessed a unity of interest between themselves and exercised control over their respective subsidiaries and affiliates.

34. Upon information and belief, at all relevant times, Defendants Procter & Gamble Manufacturing Company and The Procter & Gamble Company, were the agent and employee of the other, and in performing the wrongful acts alleged, each was acting within the course and scope of such agency and employment with each Defendants' actual and implied permission, consent, authorization and approval. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's injury, losses and damages.

35. Defendants, The Procter & Gamble Manufacturing Company and The Procter & Gamble Company are thus collectively referred to herein as "Procter & Gamble Defendants" or "Procter & Gamble".

JURISDICTION AND VENUE

36. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) because this case is a civil action where the matter in controversy exceeds $75,000, exclusive of interest and costs, and is between citizens of different States.

37. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) as a substantial part of the events and/or omissions giving rise to the Plaintiff's claims emanated from activities within this jurisdiction, Defendants transact substantial business within this jurisdiction and Defendants are considered to be residents of the Commonwealth of Pennsylvania in accordance with 28 U.S.C. §1391(c) because they are subject to personal jurisdiction in the Commonwealth of Pennsylvania as foreign corporations registered to do business in the Commonwealth of Pennsylvania.

38. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, the Court has personal jurisdiction over Defendants, because Defendants are present in the Commonwealth of Pennsylvania, such that the exercise of jurisdiction does not offend traditional notions of fair play and substantial justice. Further, Defendants have registered to do business as foreign corporations in the Commonwealth of Pennsylvania, maintained registered agents in the Commonwealth of Pennsylvania and thereby consented to personal jurisdiction within the Commonwealth of Pennsylvania.

39. This Court has personal jurisdiction over Defendants pursuant to and consistent with the Constitutional requirements of Due Process because Defendants, acting through their

agents or apparent agents, committed one or more of the following: transaction of business within the state; making of contracts within the state; the commission of a tortious act within this state; and the ownership, use, or possession of any real estate situated within this state as well as registered as foreign corporations to do business within the state.

40. Requiring Defendants to litigate these claims in the Commonwealth of Pennsylvania does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution. All of Plaintiff's claims arise in part from conduct Defendants purposefully directed to the Commonwealth of Pennsylvania as well as Plaintiff's home state. Upon information and belief, Defendants' Prilosec products are sold at hundreds of local and national pharmacies, including, but not limited to Wal-Mart, Target, CVS, and Walgreens throughout the Commonwealth of Pennsylvania and Plaintiff's home state.

41. Upon information and belief, Defendants avail themselves of numerous advertising and promotional materials regarding their defective Prilosec products specifically intended to reach consumers in the Commonwealth of Pennsylvania and Plaintiff's home state, including but not limited to advertisements on local television programs, advertisements on local radio broadcasts, advertisements on billboards and advertisements in print publications delivered to consumers in Plaintiff's home state and the Commonwealth of Pennsylvania.

42. Plaintiff's claims arise out of Defendants' design, marketing and sale of Nexium and Prilosec products throughout the United States including the Commonwealth of Pennsylvania.

43. Defendants regularly conduct or solicit business and derive substantial revenue from goods used or consumed in, inter alia, the Commonwealth of Pennsylvania.

44. At all relevant times, Defendants placed Nexium and Prilosec products ingested by Plaintiff into the stream of interstate commerce.

45. Defendants named herein are conclusively presumed to have been doing business in this state and are subject to Pennsylvania and Kentucky long arm jurisdiction.

46. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States, Plaintiff's home state and the Commonwealth of Pennsylvania.

GENERAL FACTUAL ALLEGATIONS

A. Proton Pump Inhibitors Generally

47. Proton pump inhibitors ("PPIs") are one of the most commonly prescribed medications in the United States. In 2013, more than 15 million Americans used prescription PPIs, costing more than $10 billion.

48. PPIs are indicated for the treatment of conditions such as: Gastroesophageal reflux disease ("GERD"); dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

49. Nexium is a PPI that works by inhibiting the secretion of stomach acid. It shuts down acid production of the active acid pumps in the stomach thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

50. 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. In 2008, Nexium sales exceeded $5.2 billion.

51. AstraZeneca sold Nexium with National Drug Code ("NDC") numbers 0186-5020, 0186-5022, 0186-5040, 0186-5042, 0186-40100186-4020, and 0186-4040

52. Prilosec is a PPI that works by inhibiting the secretion of stomach acid. It shuts down acid production of the active acid pumps in the stomach thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

53. AstraZeneca Defendants sold Prilosec with National Drug Code ("NDC") numbers 00186-0606, 00186-0610, 00186-0625, 00186-0742, and 00186-0743.

54. Procter & Gamble Defendants sold Prilosec OTC with National Drug Code ("NDC") numbers 37000-455.

B. Dangers Associated with PPIs

55. During the period in which Nexium and Prilosec have been sold in the United States, hundreds of reports of injury have been submitted to the FDA regarding the ingestion of Nexium, Prilosec and other PPIs. Defendants have had notice of serious adverse health outcomes through case reports, clinical studies and post-market surveillance. Specifically, Defendants have received numerous case reports of several types of kidney injuries in patients who ingested Prilosec, including: Acute Interstitial Nephritis ("AIN"); Chronic Kidney Disease ("CKD"); Renal/Kidney Failure; and Acute Kidney Injury ("AKI").

56. These reports put Defendants on notice of the excessive risk of kidney injury related to the use of Nexium and Prilosec. However, Defendants took no action to inform Plaintiff or Plaintiff's physicians of these risks. Instead, Defendants continued to represent that Nexium and Prilosec did not pose any risk of kidney injuries.

C. Acute Interstitial Nephritis Dangers Associated with PPIs

57. Acute Interstitial Nephritis ("AIN") is the inflammation of the tubes and tissues of the kidneys. The most common symptoms of AIN are fatigue, nausea and weakness. Symptoms related to AIN can begin as soon as one week following PPI ingestion.

58. The risk of AIN among PPI users was first raised in 1992. Five years later, an additional study raised concerns. Between 2004 and 2007, at least three additional studies confirmed AIN related to PPI usage. More recent studies indicate that those using PPIs such as Prilosec are at a three times greater risk than the general population to suffer AIN.

59. By July 2011, the World Health Organization adverse drug reaction report included nearly 500 cases of AIN already reported that year.

60. On or about October 30, 2014, the FDA notified Defendants that it had determined that PPIs, including Nexium and Prilosec, pose additional risks not previously disclosed.

61. On December 19, 2014, labeling for PPIs was updated to include a warning about AIN. The new label added, for the first time, a section about AIN that read, in relevant part, that AIN "may occur at any point during PPI therapy."

62. The FDA did not require the consistent labeling regarding the risk of AIN on over-the-counter PPIs.

63. Prilosec OTC's label does not include a warning about AIN.

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

D. Chronic Kidney Disease Associated with PPIs

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

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

67. Treatment for CKD focuses on slowing the progression of kidney damage, usually by attempting to control the underlying cause. CKD can progress to end-stage kidney failure, which can be fatal absent artificial filtering, dialysis or a kidney transplant. Early treatment is often the key to avoiding the most negative outcomes.

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

69. Studies have shown the long term use of PPIs was independently associated with a 20% to 50% higher risk of CKD, after adjusting for several potential confounding variables, including demographics, socioeconomic status, clinical measurements, prevalent co-morbidities, and concomitant use of medications.

70. In at least one study, the use of PPIs for ***any*** period of time, was shown to increase the risk of CKD by 10%.

71. Currently, the Nexium, Prilosec and Prilosec OTC product labeling does not contain any warning regarding the increased risk of CKD.

E. Acute Kidney Injury Dangers Associated with PPIs

72. Studies indicate that those using PPIs such as Nexium and Prilosec are at a more than 2.5 times greater risk than the general population to suffer Acute Kidney Injury ("AKI").

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

74. Currently, the Nexium, Prilosec and Prilosec OTC product labeling does not contain any warning regarding the increased risk of AKI.

F. Safer Alternatives to PPIs

75. Despite the fact that Nexium, Prilosec and other PPIs lead to an increased risk of numerous injuries as outlined herein, several safer alternatives are available, including but not limited to:

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

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

G. Allegations Common to All Causes of Action

76. Defendants knew or should have known about the correlation between the use of Nexium and Prilosec and the significantly increased risks of AIN, CKD, AKI and other renal impairment. Yet, Defendants failed to adequately warn of these risks from ingestion of Nexium and Prilosec, including the negative effects on the kidney.

77. In omitting, concealing, and inadequately providing critical safety information regarding the use of Nexium and Prilosec to Plaintiff and Plaintiff's healthcare providers,

Defendants engaged in, and continue to engage in, conduct likely to mislead consumers, including Plaintiff and Plaintiff's healthcare providers. This conduct is fraudulent, unfair and unlawful.

78. Despite clear knowledge that Nexium and Prilosec causes a significantly increased risk of CKD, AKI and other renal impairment, Defendants continue to market and sell Nexium, Prilosec and Prilosec OTC without warning consumers or healthcare providers of the significant risks to the kidney.

H. Plaintiff's Use of Nexium and Prilosec and Resulting Harm

79. Plaintiff, Wanda Stafford, is and was, at all relevant times, a citizen of the state of Kentucky.

80. Plaintiff was born on November 27, 1954.

81. Plaintiff was prescribed Nexium on numerous occasions, beginning as early as 2004 and consistently thereafter through at least 2009. Plaintiff ingested Nexium as prescribed by her prescribing physicians.

82. Plaintiff was prescribed Prilosec and Prilosec OTC on numerous occasions, beginning as early as 2009 and consistently thereafter through 2015. Plaintiff ingested Prilosec and Prilosec OTC as prescribed by her prescribing physicians.

83. Plaintiff would not have used Nexium, Prilosec and Prilosec OTC had she been properly warned of the kidney risks associated with its ingestion.

84. As a result of using Defendants' Nexium and Prilosec products, upon information and belief, on or about 2009, she was diagnosed with Chronic Kidney Disease and sustained severe and permanent personal injuries, pain, suffering, economic loss, and emotional distress.

85. The aforementioned injuries and damages sustained by Plaintiff were caused by the ingestion of Defendants' Nexium and Prilosec.

TOLLING OF THE STATUTE OF LIMITATIONS

86. Defendants negligently represented to the medical and healthcare community the FDA, to Plaintiff and the public that Nexium and Prilosec had been tested and were found to be safe and/or effective for its indicated use.

87. Defendants, at all relevant times, knew or should have known of the risks and defects with Nexium and Prilosec products, however Defendants concealed their knowledge of Nexium and Prilosec's risks and defects and failed to notify Plaintiff, the FDA, the public and the medical community including Plaintiff's prescribing physicians.

88. Defendants undertook such action with the intent of defrauding and deceiving the public and the medical community at large, including Plaintiff and her prescribing physicians, with the intent of inducing the prescription, dispensing, and/or purchasing of Nexium and Prilosec for the treatment of GERD, all of which evidenced a callous, reckless, willful indifference to the health, safety and welfare of Plaintiff herein.

89. Any applicable statute of limitations has therefore been tolled by Defendants' knowledge, active concealment and denial of the facts alleged herein, which behavior is still ongoing.

90. Plaintiff only recently discovered that her injuries could have been caused by the use of Nexium and Prilosec.

COUNT I
AS TO ALL DEFENDANTS
Strict Products Liability

91. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

92. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Nexium, as well as Prilosec and Prilosec OTC, hereinafter collectively referred to as "Prilosec", which were ingested by Plaintiff.

93. Nexium and Prilosec were expected to and did reach the usual consumers without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendants.

94. At all relevant times, Nexium and Prilosec were in an unsafe, defective, and inherently dangerous condition, which were dangerous to users, and in particular, Plaintiff.

95. The Nexium and Prilosec designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when it left the possession of Defendants they were unreasonably dangerous, and they were more dangerous than an ordinary consumer would expect.

96. Defendants knew or should have known that Nexium and Prilosec were defective, inherently dangerous and unsafe, especially when used in the form and manner as provided by the Defendants.

97. At the time of Plaintiff's use of Nexium and Prilosec, it was being used for the purposes and in a manner normally intended for the treatment of peptic disorders which include GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

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

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

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

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

102. The Nexium and Prilosec designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached the intended users in the same defective and unreasonably dangerous condition in which it was manufactured.

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

104. The Nexium and Prilosec 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 Nexium and Prilosec created a risk of serious and dangerous side effects including but not limited to 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 risks.

105. Plaintiff could not, by the exercise of reasonable care, have discovered Nexium and Prilosec's defects alleged herein and perceived its danger.

106. Defendants, as manufacturers and/or distributors of Nexium and Prilosec, are held to the level of knowledge of an expert in the field.

107. Defendants, the manufacturers and/or distributors of Nexium and Prilosec, failed to warn consumers and healthcare providers, including Plaintiff and her healthcare providers, of the true and accurate risk of kidney injuries associated with the ingestion of Nexium and Prilosec, including, but not limited to: AIN, CKD, AKI and renal/kidney failure.

108. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

109. The Nexium and Prilosec 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 but not limited to kidney injuries, as well as other severe and permanent health consequences from Nexium and Prilosec, Defendants failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote Nexium and Prilosec.

110. Plaintiff, individually, and her healthcare providers, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

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

a. When placed in the stream of commerce, Nexium and Prilosec contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject product, including, but not limited to, permanent personal injuries including, but not limited to, developing AKI and CKD and other serious injuries and side effects;

b. When placed in the stream of commerce, Nexium and Prilosec were defective in design and formulation making the use of Nexium and Prilosec more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat GERD and other stomach-acid-related ailments;

c. The design defect of Nexium and Prilosec existed before it left the control of Defendants;

d. Nexium and Prilosec were insufficiently and inadequately tested;

e. Nexium and Prilosec caused harmful side effects that outweighed any potential utility; and

f. Nexium and Prilosec were not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff and Plaintiff's healthcare providers, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

112. In addition, at the time Nexium and Prilosec left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended

function of the product. These safer alternative designs were economically and technologically feasible – indeed they were already on the market – and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

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

114. By reason of the foregoing, Defendants are in violation of the Product Liability Act of Kentucky, KRS §411.300 to 411.340.

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

116. The said defects in Defendants' Nexium and Prilosec were a substantial factor in causing Plaintiff's injuries.

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

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

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interests, costs herein incurred, attorney's fees, and all such other and further relief as this Court deems just and proper.

COUNT II
AS TO ALL DEFENDANTS
Negligence

119. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

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

121. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, labeling, sale, testing, quality assurance, quality control, and/or distribution of Nexium and Prilosec into interstate commerce in that Defendants knew or should have known that using Nexium and Prilosec could proximately cause Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, researching, manufacturing, quality control, quality assurance, labeling, packaging, marketing, supplying, selling, packaging, distribution and warning of risks of Nexium and Prilosec. 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 healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer a serious kidney injury or death by ingesting Nexium and Prilosec;

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

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

d. Failure to use reasonable care in the process of manufacturing Nexium and Prilosec in a reasonably safe condition for the use for which it was intended;

e. Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's healthcare providers as to the danger and risks of using Nexium and Prilosec in unsafe doses; and

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

122. 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.

123. The negligence of 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 and Prilosec without thoroughly and/or adequately testing it;

b. Negligently failing to adequately warn Plaintiff, Plaintiff's healthcare providers, the public, the medical and healthcare profession, and the FDA of the dangers of Nexium and Prilosec;

c. 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/or use, Nexium and Prilosec;

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

e. Negligently representing that Nexium and Prilosec were safe for use for its intended purpose, when, in fact, it was unsafe;

f. Negligently designing Nexium and Prilosec in a manner which were dangerous to its users;

g. Negligently manufacturing Nexium and Prilosec in a manner which were dangerous to its users;

h. Concealing information from the Plaintiff and Plaintiff's healthcare providers in knowing that Nexium and Prilosec were unsafe, dangerous, and/or non-conforming with FDA regulations;

i. Failure to use due care in designing and manufacturing Nexium and Prilosec so as to avoid the aforementioned risks to individuals when Nexium and Prilosec were used for treatment of peptic disorders which include GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

j. Failure to accompany their product with proper, accurate and/or adequate warnings regarding all possible adverse side effects, and risks thereof, associated with the use of Nexium and Prilosec;

k. Failure to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Nexium and Prilosec;

l. Failure to warn Plaintiff, prior to actively encouraging the sale of Nexium and Prilosec, 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

m. Were otherwise careless and/or negligent.

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

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

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

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

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

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

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

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interests, costs herein incurred, attorney's fees, and all such other and further relief as this Court deems just and proper.

COUNT III
AS TO ALL DEFENDANTS
Breach of Express Warranty

131. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

132. Defendants expressly represented to Plaintiff, other consumers, and the medical community, that Nexium and Prilosec were safe and fit for its intended purposes, were of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

133. Nexium and Prilosec does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, many of which were not accurately warned about by Defendants, and causes severe and permanent injuries, including, but not limited to developing AIN, CKD, AKI, renal impairment and other serious injuries and side effects, along with harm and economic loss.

134. At the time Defendants made these express warranties, Defendants knew, or in the exercise of reasonable care should have known, of the purpose for which Nexium and Prilosec were to be used and warranted Nexium and Prilosec to be fit, safe, effective, and proper in all respects for such purpose. Nexium and Prilosec were unreasonably dangerous because it failed to conform to an express warranty of Defendants.

135. At the time Defendants made such express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue because Nexium and Prilosec were not safe and fit for its intended use and, in fact, produces serious injuries to the user that were not accurately identified and represented by Defendants.

136. The Defendants herein breached the aforesaid express warranties, as their drug Nexium and Prilosec were defective.

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

138. Plaintiff, other consumers and the medical community reasonably relied upon Defendants' express warranties and Plaintiff was harmed by such reliance.

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

140. As a result of the foregoing acts and omission, Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney 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.

141. As a result of the foregoing acts and omissions, 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 she will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interests, costs herein incurred, attorney's fees, and all such other and further relief as this Court deems just and proper.

COUNT IV
AS TO ALL DEFENDANTS
Breach of Implied Warranties

142. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

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

for the treatment of peptic disorders which include GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

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

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

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

147. Plaintiff, other consumers and the medical community reasonably did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

148. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the skill and judgment of Defendants as to whether Nexium and Prilosec were of merchantable quality and safe and fit for its intended use.

149. Nexium and Prilosec 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.

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

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

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

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interests, costs herein incurred, attorney's fees, and all such other and further relief as this Court deems just and proper.

COUNT V
AS TO ALL DEFENDANTS
Fraud

153. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

154. 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 and Prilosec, had been tested and were found to be safe and/or effective for treatment of peptic disorders which include GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

155. These representations were included in information distributed to the public, the FDA, and 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 misrepresentations of fact and/or omissions.

156. The aforementioned representations made by Defendants were, in fact, false.

157. 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 and Prilosec were not as safe as other forms of treatment for treatment of peptic disorders which include GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug-induced gastropathy;

b. That the risks of adverse events with Nexium and Prilosec were higher than those with other forms of treatment of peptic disorders which include GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

c. That the risks of adverse events with Nexium and Prilosec were not adequately tested and/or known by Defendants;

d. That Defendants were aware of dangers in Nexium and Prilosec, in addition to and above and beyond those associated with other forms of treatment of peptic disorders which include GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

e. That Nexium and Prilosec were 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 and Prilosec;

g. That Nexium and Prilosec should be contraindicated for individuals with predisposition or other risk factors for kidney injury;

h. That Nexium and Prilosec were manufactured negligently;

i. That Nexium and Prilosec were manufactured defectively;

j. That Nexium and Prilosec were manufactured improperly;

k. That Nexium and Prilosec were designed negligently;

l. That Nexium and Prilosec were designed defectively; and

m. That Nexium and Prilosec were designed improperly.

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

159. 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 and Prilosec, including the Plaintiff, in particular.

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

161. Defendant knew that Plaintiff, and Plaintiff's healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' fraudulent misrepresentations, concealment and omissions, and that these included material omissions of facts surrounding Nexium and Prilosec, as set forth herein.

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

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

164. 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 and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Nexium and Prilosec, for treatment of peptic disorders which include GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, all of which evidenced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

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

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

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

168. Upon information and belief, Defendants intentionally suppressed, concealed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Nexium and Prilosec were nephrotoxic and/or not safe as a means of treatment of peptic disorders which include GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

169. Defendants knew or should have known that Nexium and Prilosec 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.

170. 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 Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Nexium and Prilosec and/or that Plaintiff's healthcare providers would dispense, prescribe, and/or recommend the same.

171. 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 Plaintiff, as well as Plaintiff's healthcare providers would rely upon the information being disseminated.

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

173. Plaintiff and/or her respective healthcare professionals did in fact rely on and believe that 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 GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug included gastropathy.

174. By reason of the foregoing, Defendants are in violation of the Kentucky Consumer Protection Act, KRS § 367.110 to 367.300.

175. Defendant brought Nexium and Prilosec to the market, and acted fraudulently, wantonly and maliciously to the detriment of Plaintiff.

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

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

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interests, costs herein incurred, attorney's fees, and all such other and further relief as this Court deems just and proper.

COUNT VI
AS TO ALL DEFENDANTS
Intentional Infliction of Emotional Distress

178. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

179. The acts, omissions, and representations of Defendants regarding the manufacturing, distribution and marketing of Nexium and Prilosec as described in the foregoing paragraphs were intentional, reckless, extreme and outrageous. Defendants intentionally engaged in extreme and outrageous conduct when they intentionally and/or recklessly marketed Nexium and Prilosec and then intentionally and/or recklessly concealed material information about Nexium and Prilosec's potential serious adverse effects from Plaintiff and Plaintiff's healthcare providers.

180. Defendants knew that Plaintiff would suffer mental distress and anxiety upon learning that Nexium and Prilosec possessed a likelihood of serious adverse effects and complications such as life-threatening kidney damages.

181. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to emotional distress and mental anguish, as well as other severe and personal injuries which are permanent and lasting in nature as well as the need for lifelong medical treatment, monitoring and/or medication.

182. As a result of the foregoing acts and omissions 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.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interests, costs herein incurred, attorney's fees, and all such other and further relief as this Court deems just and proper.

COUNT VII
AS TO ALL DEFENDANTS
Negligent Infliction of Emotional Distress

183. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

184. Defendants negligently and carelessly manufactured, sold, and distributed Nexium and Prilosec to Plaintiff which were defective.

185. Defendants negligently and carelessly concealed the defective nature of Nexium and Prilosec from Plaintiff and Plaintiff's healthcare providers.

186. Defendants negligently and carelessly misrepresented the usefulness, quality and safety of Nexium and Prilosec to Plaintiff and Plaintiff's healthcare providers.

187. Defendants' negligence and carelessness directly impacted Plaintiff in that Plaintiff was induced to purchase and ingest the defective and dangerous Nexium and Prilosec.

188. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including but not limited to emotional distress and mental anguish, as well as other severe and personal injuries which are permanent and lasting in nature as well as the need for lifelong medical treatment, monitoring and/or medication.

189. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses from the fear of knowing there is a likelihood of serious adverse effects and complications of Nexium and Prilosec use such as life-threatening kidney damage. 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.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interests, costs herein incurred, attorney's fees, and all such other and further relief as this Court deems just and proper.

COUNT VIII
AS TO ALL DEFENDANTS
Punitive Damages

190. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

191. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, in that Defendants' conduct were specifically intended to cause substantial injury to Plaintiff. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, Defendants' conduct involved an extreme degree of risk. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious disregard for the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff and Plaintiff's healthcare providers.

192. Plaintiff relied on Defendants' representations and suffered injuries as a proximate result of this reliance.

193. Plaintiff therefore asserts a claim for exemplary damages.

194. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in conjunction with others, constitute gross negligence that proximately caused the injuries to Plaintiff.

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

196. Defendants had knowledge of, and were in possession of evidence demonstrating that Nexium and Prilosec caused serious side effects. Notwithstanding Defendants' knowledge, Defendant continued to market the drug by providing false and misleading information with regard to the product's safety to regulatory agencies, the medical community, and consumers of Nexium and Prilosec.

197. Although Defendants knew or recklessly disregarded the fact that Nexium and Prilosec causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute Nexium and Prilosec to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods available.

198. Defendants failed to provide adequate warnings that would have dissuaded healthcare professionals from prescribing Nexium and Prilosec and consumer from purchasing and ingesting Nexium and Prilosec, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming Nexium and Prilosec.

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

200. Defendants' acts, conduct, and omissions were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff and other Nexium and Prilosec users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Nexium and Prilosec. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example out of Defendants.

201. Prior to the manufacture, sale, and distribution of Nexium and Prilosec, Defendants knew that the drug were in a defective condition and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents knew that the drug presented a substantial and unreasonable risk of harm to the public including Plaintiff. As such, Defendants unreasonably subjected consumers of Nexium and Prilosec to risk of injury or death.

202. Despite their knowledge, Defendants, acting through their officers, directors and managing agents, for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defect in Nexium and Prilosec and failed to adequately warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects. Defendants

and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of Nexium and Prilosec knowing these actions would expose Plaintiff and others to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

203. Defendants' conduct was committed with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interests, costs herein incurred, attorney's fees, and all such other and further relief as this Court deems just and proper.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for judgment against all Defendants and additional relief as follows:

1. Economic and non-economic damages, special damages and general damages, including pain and suffering, in an amount to be supported by the evidence at trial;
2. Compensatory damages for the acts complained of herein in an amount to be determined by a jury;
3. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;
4. Punitive and/or exemplary damages for the acts complained of herein in an amount to be determined by a jury;
5. For an award of attorney's fees and costs;
6. For the costs of suit;
7. For post-judgment interest; and

8. For such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff demands a jury trial as to all claims and issues triable of right by a jury.

Respectfully submitted,

ANAPOL WEISS

Sol H. Weiss, Esquire
Tracy A. Finken, Esquire
One Logan Square
130 N. 18th St., Suite 1600
Philadelphia, PA 19103
215-735-1130 (P)
215-875-7701 (F)
sweiss@anapolweiss.com
tfinken@anapolweiss.com

Dated: January 9, 2017

JS 44 (Rev. 07/16)

CIVIL COVER SHEET

17-cv-00100

17 0100

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

Wanda Stafford
345 Shady Pond Lane
Shepherdsville, KY 40165

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Anapol Weiss
One Logan Square, 130 N. 18th Street, Suite 1600
Philadelphia, PA 19103

DEFENDANTS

ASTRAZENECA PHARMACEUTICALS LP, et al., Wilmington, DE
Procter & Gamble Manufacturing Co., et al., Cincinnati, OH

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
- ☐ 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
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

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

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 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

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

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 USC 1332(a)(1)

Brief description of cause:
Products Liability Litigation

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
01/09/2017

SIGNATURE OF ATTORNEY OF RECORD

JAN - 9 2017

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

17 0100

Address of Plaintiff: Wanda Stafford - 345 Shady Pond Lane, Shepherdsville, KY 40165

Address of Defendant: Wilmington, DE; Cincinnati, OH

Place of Accident, Incident or Transaction: KY

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☐

Does this case involve multidistrict litigation possibilities? Yes☒ No☐

RELATED CASE, IF ANY:

Case Number: _____ Judge _____ Date Terminated: JPML hearing scheduled for potential proton pump inhibitor MDL on January 26, 2017

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☐ No☒
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases*:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases

(Please specify) _____

B. *Diversity Jurisdiction Cases*:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☒ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases

(Please specify) _____

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Sol H. Weis, counsel of record do bereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 1/9/17 Attorney-at-Law 15925 Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 1/9/17 Attorney-at-Law 15925 Attorney I.D.# JAN -9 2017

CIV. 609 (5/2012)

JP

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

WANDA STAFFORD	:	CIVIL ACTION
v.	:	
ASTRAZENECA PHARMACEUTICALS LP., ET AL.	:	NO. 17 0100

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

January 9, 2017	Sol H. Weiss	Plaintiff
Date	**Attorney-at-law**	**Attorney for**
215-735-1130	215-875-7701	sweiss@anapolweiss.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

JAN - 9 2017