IN THE UNITED STATES DISTRICT COURT Eastern District of Pennsylvania

GAYLON MALLARD AND MARILYN

Civil Action No.

MALLARD, h/w

COMPLAINT AND DEMAND FOR

Plaintiffs, : JURY TRIAL

.

ASTRAZENECA

PHARMACEUTICALS LP and

v.

ASTRAZENECA LP

Defendants.

COMPLAINT

Plaintiffs, Gaylon and Marilyn Mallard, by way of Complaint against Defendants, AstraZeneca Pharmaceuticals LP and AstraZeneca LP, (collectively "Defendants) allege as follows:

INTRODUCTION

1. This is an action for personal injury, statutory, compensatory and punitive damages suffered by Plaintiffs, Gaylon and Marilyn Mallard, 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 a proton pump inhibitor ("PPI") drug known as Nexium (esomeprazole magnesium) and/or other Nexium-branded products with the same active ingredient collectively referred to herein as "Nexium".

THE PARTIES

- 2. Plaintiff, Gaylon Mallard, is a citizen of the United States of America, and at all times relevant hereto, was and is a resident of the state of Tennessee.
- 3. Plaintiff, Marilyn Mallard, spouse of Gaylon Mallard, is a citizen of the United States of America, and at all times relevant hereto, was and is a resident of the state of Tennessee.

AstraZeneca Pharmaceuticals LP

- 4. Defendant AstraZeneca Pharmaceuticals LP is, and all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.
- 5. 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.
- 6. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in Plaintiffs' state of residency as well as the Commonwealth of Pennsylvania.
- 7. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP was registered to do business in the Commonwealth of Pennsylvania as a foreign corporation.
- 8. 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.

- 9. 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, Plaintiffs' state of residency and the Commonwealth of Pennsylvania, in particular.
- 10. Defendant AstraZeneca Pharmaceuticals LP is the holder of approved New Drug Applications ("NDAs") for the following forms of Nexium:
 - a. Delayed-Release Capsule Pellets (20 mg and 40 mg), with NDA #021153, approved on 2/20/2001;
 - b. Delayed-Release Oral Suspension Packets (2.5MG, 5MG, 20MG, 40MG), with NDA # 021957, approved on 10/20/2006;
 - c. Delayed-Release Oral Suspension Packets (10MG), with NDA # 022101, approved on 02/27/2008; and
 - d. Injection (20MG VIAL, 40MG VIAL), with NDA # 022101, approved on 03/31/2005.

AstraZeneca LP

- 11. 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 products.
- 12. Defendant AstraZeneca LP is, and all times relevant to this action was, a Delaware Corporation with its corporate headquarters in Wilmington, Delaware.
- 13. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business in Plaintiffs' 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 Plaintiffs' 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 States of America, Plaintiffs' state of residency and the Commonwealth of Pennsylvania, in particular.

Defendants' Unity of Interest

- 17. Upon information and belief, at all relevant times, each of the Defendants 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.
- 18. Upon information and belief, at all relevant times, each Defendant was 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 Plaintiffs' injury, losses and damages.
- 19. Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP are thus collectively referred to herein as "Defendants" or "AstraZeneca".

JURISIDCTION AND VENUE

- 20. 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.
- 21. 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 Plaintiffs' 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.
- 22. 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.
- 23. 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.

- 24. 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 Plaintiffs' claims arise in part from conduct Defendants purposefully directed to the Commonwealth of Pennsylvania as well as Plaintiffs' home state. Upon information and belief, Defendants' Nexium 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 Plaintiffs' home state of Tennessee.
- 25. Upon information and belief, Defendants avail themselves of numerous advertising and promotional materials regarding their defective Nexium products specifically intended to reach consumers in the Commonwealth of Pennsylvania and Plaintiffs' 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 Plaintiffs' home state and the Commonwealth of Pennsylvania.
- 26. Plaintiffs' claims arise out of Defendants' design, marketing and sale of Nexium products throughout the United States including the Commonwealth of Pennsylvania.
- 27. Defendants regularly conduct or solicit business and derive substantial revenue from goods used or consumed in, inter alia, the Commonwealth of Pennsylvania.
- 28. At all relevant times, Defendants placed Nexium products ingested by Plaintiff into the stream of interstate commerce.

- 29. Defendants named herein are conclusively presumed to have been doing business in this state and are subject to Pennsylvania and Tennessee long arm jurisdiction.
- 30. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States, Plaintiffs' home state and the Commonwealth of Pennsylvania.

GENERAL FACTUAL ALLEGATIONS

A. Proton Pump Inhibitors Generally

- 31. 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.
- 32. 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.
- 33. Nexium (esomeprazole magnesium) 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.
- 34. AstraZeneca sold Nexium with National Drug Code ("NDC") numbers 0186-5020, 0186-5022, 0186-5040, 0186-5042, 0186-40100186-4020, and 0186-4040.
- 35. 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.

B. Dangers Associated with PPIs

- 36. During the period in which Nexium has been sold in the United States, hundreds of reports of injury have been submitted to the FDA regarding the 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 have received numerous case reports of several types of kidney injuries in patients who ingested Nexium, including: Acute Interstitial Nephritis ("AIN"); Chronic Kidney Disease ("CKD"); Renal/Kidney Failure; and Acute Kidney Injury ("AKI").
- 37. These reports put Defendants on notice of the excessive risk of kidney injury related to the use of Nexium. However, Defendants took no action to inform Plaintiff or Plaintiff's physicians of these risks. Instead, Defendants continued to represent that Nexium did not pose any risk of kidney injuries.

C. Acute Interstitial Nephritis Dangers Associated with PPIs

- 38. 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.
- 39. 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 Nexium are at a three times greater risk than the general population to suffer AIN.
- 40. By July 2011, the World Health Organization adverse drug reaction report included nearly 500 cases of AIN already reported that year.

- 41. On or about October 30, 2014, the FDA notified Defendants that it had determined that PPIs, including Nexium, pose additional risks not previously disclosed.
- 42. 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."
- 43. 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

- 44. 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.
- 45. In the early stages of CKD, patients may have few signs or symptoms. CKD may not become apparent until kidney function is significantly impaired.
- 46. 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.
- 47. CKD is associated with a substantially increased risk of death and cardiovascular events.

- 48. 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.
- 49. In at least one study, the use of PPIs for *any* period of time, was shown to increase the risk of CKD by 10%.
- 50. Currently, the Nexium product labeling does not contain any warning regarding the increased risk of CKD.

E. Acute Kidney Injury Dangers Associated with PPIs

- 51. Studies indicate that those using PPIs such as Nexium are at a more than 2.5 times greater risk than the general population to suffer Acute Kidney Injury ("AKI").
- 52. Studies also indicated that those who develop AIN are at a significant risk of AKI even though they may not obviously exhibit kidney dysfunction.
- 53. Currently, the Nexium product labeling does not contain any warning regarding the increased risk of AKI.

F. Safer Alternatives to PPIs

- 54. Despite the fact that Nexium 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

- 55. Defendants knew or should have known about the correlation between the use of Nexium 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, including the negative effects on the kidney.
- 56. In omitting, concealing, and inadequately providing critical safety information regarding the use of Nexium to Plaintiffs and Plaintiffs' healthcare providers, Defendants engaged in, and continue to engage in, conduct likely to mislead consumers, including Plaintiffs and Plaintiffs' healthcare providers. This conduct is fraudulent, unfair and unlawful.
- 57. Despite clear knowledge that Nexium causes a significantly increased risk of CKD, AKI and other renal impairment, Defendants continue to market and sell Nexium without warning consumers or healthcare providers of the significant risks to the kidney.

H. Plaintiffs' Use of Nexium and Resulting Harm

- 58. Plaintiff, Gaylon Mallard, is and was, at all relevant times, a citizen of the state of Tennessee.
 - 59. Plaintiff was born on July 19, 1954.

- 60. Plaintiff was prescribed Nexium on numerous occasions, upon information and belief, beginning as early as 2011 and consistently thereafter into 2016. Plaintiff ingested Nexium as prescribed by his prescribing physicians.
- 61. Plaintiff would not have used Nexium had he been properly warned of the kidney risks associated with its ingestion.
- 62. As a result of using Defendants' Nexium, on or about 2014, Plaintiff was diagnosed with Chronic Kidney Disease. In 2015, Plaintiff was diagnosed with Acute Kidney Failure. Subsequently, he was diagnosed with End Stage Renal Disease. Thereafter, Plaintiff started dialysis and has sustained severe and permanent personal injuries, pain, suffering, economic loss, and emotional distress.
- 63. The aforementioned injuries and damages sustained by Plaintiff were caused by the ingestion of Defendants' Nexium.
- 64. Plaintiff, Marilyn Mallard, is the spouse of Gaylon Mallard and sustained damages from a loss of consortium.

TOLLING OF THE STATUTE OF LIMITATIONS

- 65. Defendants negligently represented to the medical and healthcare community the FDA, to Plaintiffs and the public that Nexium had been tested and was found to be safe and/or effective for its indicated use.
- 66. Defendants, at all relevant times, knew or should have known of the risks and defects with Nexium products, however Defendants concealed their knowledge of Nexium's risks and defects and failed to notify Plaintiffs, the FDA, the public and the medical community including Plaintiff's prescribing physicians.

- 67. Defendants undertook such action with the intent of defrauding and deceiving the public and the medical community at large, including Plaintiff and his prescribing physicians, with the intent of inducing the prescription, dispensing, and/or purchasing of Nexium for the treatment of GERD, all of which evidenced a callous, reckless, willful indifference to the health, safety and welfare of Plaintiff herein.
- 68. 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.
- 69. Plaintiffs only recently discovered that these injuries could have been caused by the use of Nexium.

<u>COUNT I</u> <u>AS TO ALL DEFENDANTS</u> Strict Products Liability

- 70. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.
- 71. At all relevant times, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Nexium which was ingested by Plaintiff.
- 72. Nexium was 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.
- 73. At all relevant times, Nexium was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff.

- 74. 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 possession of Defendants it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.
- 75. Defendants knew or should have known that Nexium was defective, inherently dangerous and unsafe, especially when used in the form and manner as provided by the Defendants.
- 76. At the time of Plaintiffs' use of Nexium, 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.
- 77. Defendants, with this knowledge, voluntarily designed Nexium in a dangerous condition for use by the public, and in particular Plaintiff.
- 78. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.
- 79. Defendants created a product unreasonably dangerous for its normal, intended use.
- 80. The Nexium designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Nexium left the possession of Defendants in a defective condition and was unreasonably dangerous to its intended users.

- 81. The Nexium 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.
- 82. 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.
- 83. The Nexium 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 Nexium 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.
- 84. Plaintiffs could not, by the exercise of reasonable care, have discovered Nexium's defects alleged herein and perceived its danger.
- 85. Defendants, as manufacturers and/or distributors of Nexium, are held to the level of knowledge of an expert in the field.
- 86. Defendants, the manufacturers and/or distributors of Nexium, failed to warn consumers and healthcare providers, including Plaintiff and his healthcare providers, of the true and accurate risk of kidney injuries associated with the ingestion of Nexium, including, but not limited to: AIN, CKD, AKI and renal/kidney failure.

- 87. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.
- 88. The Nexium 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 but not limited to kidney injuries, as well as other severe and permanent health consequences from Nexium, Defendants failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote Nexium.
- 89. Plaintiff, Gaylon Mallard, individually, and his healthcare providers, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.
- 90. At all relevant times, Nexium was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:
 - a. When placed in the stream of commerce, Nexium contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the 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 was defective in design and formulation making the use of Nexium 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 existed before it left the control of Defendants;
- d. Nexium was insufficiently and inadequately tested;
- e. Nexium caused harmful side effects that outweighed any potential utility; and
- f. Nexium was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff and Plaintiffs' healthcare providers, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.
- 91. In addition, at the time Nexium left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiffs' 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 Plaintiffs' injuries without substantially impairing the product's utility.
- 92. By reason of the foregoing, Defendants have become strictly liable in tort to the Plaintiffs for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Nexium.
- 93. By reason of the foregoing, Defendants are in violation of the Tennessee Products Liability Act, T.C.A. §§29-28-101 *et seq*.

- 94. Defendants' defective design and manufacturing of Nexium, as well as inadequate warnings, were acts that amount to willful, wanton, and/or reckless conduct by Defendants.
- 95. The said defects in Defendants' Nexium were a substantial factor in causing Plaintiffs' injuries.
- 96. As a result of the foregoing acts and omissions, Plaintiff, Gaylon Mallard, was caused to suffer serious and dangerous side effects including, Acute Kidney Failure, Chronic Kidney Disease and End Stage Renal Failure, 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.
- 97. As a result of the foregoing acts and omissions Plaintiff, Gaylon Mallard, requires and/or will require additional health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiff, Gaylon Mallard, will, in the future, be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' 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

98. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.

- 99. 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 into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.
- 100. 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 into interstate commerce in that Defendants knew or should have known that using Nexium could proximately cause Plaintiffs' 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. 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 Plaintiffs and Plaintiffs' healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer a serious kidney injury or death by ingesting Nexium;
 - 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;
 - c. Failure to use reasonable care implementing and/or utilizing a reasonably safe design in the manufacture of Nexium;

- d. Failure to use reasonable care in the process of manufacturing Nexium 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 Plaintiffs and Plaintiffs' healthcare providers as to the danger and risks of using Nexium in unsafe doses; and
- f. Such further acts and/or omissions that may be proven at trial.
- 101. 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 Plaintiffs.
- 102. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:
 - Manufacturing, producing, promoting, formulating, creating, and/or designing
 Nexium without thoroughly and/or adequately testing it;
 - b. Negligently failing to adequately warn Plaintiffs, Plaintiffs' healthcare providers, the public, the medical and healthcare profession, and the FDA of the dangers of Nexium;
 - 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;
 - d. Negligently advertising and recommending the use of Nexium without sufficient knowledge as to its dangerous propensities;

- e. Negligently representing that Nexium was safe for use for its intended purpose, when, in fact, it was unsafe;
- f. Negligently designing Nexium in a manner which was dangerous to its users;
- g. Negligently manufacturing Nexium in a manner which was dangerous to its users;
- h. Concealing information from the Plaintiffs and Plaintiffs' healthcare providers in knowing that Nexium was unsafe, dangerous, and/or non-conforming with FDA regulations;
- i. Failure 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 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;
- k. Failure to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Nexium;
- Failure to warn Plaintiffs, 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; and
- m. Were otherwise careless and/or negligent.

- 103. Defendants under-reported, underestimated and downplayed the serious dangers of Nexium.
- 104. Defendants negligently compared the safety risk and/or dangers of Nexium with other forms of treatment of peptic disorders which include GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
- 105. Despite the fact that Defendants knew or should have known that Nexium caused unreasonably dangerous side effects, Defendants continued and still continue to market, manufacture, distribute and/or sell Nexium to consumers, including Plaintiffs.
- 106. Defendants knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.
- 107. Defendants' negligence was the proximate cause of Plaintiffs' injuries, harm and economic loss which Plaintiffs suffered and/or will continue to suffer.
- 108. As a result of the foregoing acts and omissions, Plaintiff, Gaylon Mallard, was caused to suffer serious and dangerous side effects including, Acute Kidney Failure, Chronic Kidney Disease 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.
- 109. As a result of the foregoing acts and omissions, Plaintiff, Gaylon Mallard, requires and/or will require additional health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that

Plaintiff, Gaylon Mallard, will, in the future, be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' 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

- 110. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.
- 111. Defendants expressly represented to Plaintiffs, other consumers, and the medical community, that Nexium was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.
- 112. Nexium 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.
- 113. 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 was to be used and warranted Nexium to be fit, safe, effective, and proper in all respects for such purpose. Nexium was unreasonably dangerous because it failed to conform to an express warranty of Defendants.

- 114. 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 was 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.
- 115. The Defendants herein breached the aforesaid express warranties, as their drug Nexium was defective.
- 116. At all relevant times, Nexium did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.
- 117. Plaintiffs, other consumers and the medical community reasonably relied upon Defendants' express warranties and Plaintiffs were harmed by such reliance.
- 118. As a result of the foregoing acts and omissions, the Plaintiff, Gaylon Mallard, was caused to suffer serious and dangerous side effects including, Acute Kidney Failure, Chronic Kidney Disease 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.
- 119. As a result of the foregoing acts and omission, Plaintiff, Gaylon Mallard, was caused to suffer serious and dangerous side effects including, Acute Kidney Failure, Chronic Kidney Disease 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.

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

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' 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

- 121. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.
- 122. At all times herein mentioned, 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 GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
- 123. At the time Defendant marketed, sold, and distributed Nexium for use by Plaintiffs, 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.

- 124. 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.
- 125. 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.
- 126. Plaintiffs, other consumers and the medical community reasonably did rely on said implied warranty of merchantability of fitness for a particular use and purpose.
- 127. Plaintiffs and Plaintiffs' healthcare providers 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.
- 128. 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.
- 129. The Defendants herein breached the aforesaid implied warranties, as their drug Nexium was not fit for its intended purposes and uses.
- 130. As a result of the foregoing acts and omissions, Plaintiff, Gaylon Mallard, was caused to suffer serious and dangerous side effects including, Acute Kidney Failure, Chronic Kidney Disease 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.

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

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' 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

- 132. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.
- 133. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiffs, 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 GERD, peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
- 134. These representations were included in information distributed to the public, the FDA, and Plaintiffs 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.

- 135. The aforementioned representations made by Defendants were, in fact, false.
- 136. In representations to Plaintiffs, and/or Plaintiffs' 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 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 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 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 should be contraindicated for individuals with predisposition or other risk factors for kidney injury;
- h. That Nexium was manufactured negligently;
- i. That Nexium was manufactured defectively;
- i. That Nexium was manufactured improperly;
- k. That Nexium was designed negligently;
- 1. That Nexium was designed defectively; and
- m. That Nexium was designed improperly.
- 137. Defendants were under a duty to disclose to Plaintiffs, and Plaintiffs' healthcare providers, and/or the FDA the defective nature of Nexium, including but not limited to the heightened risks of kidney injury.
- 138. 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 Plaintiffs, in particular.
- 139. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Nexium was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiffs, and Plaintiffs' 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.
- 140. Defendant knew that Plaintiffs, and Plaintiffs' 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, as set forth herein.

- 141. Plaintiffs, as well as Plaintiffs' 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.
- 142. 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.
- 143. These representations were made by Defendants with the intent of defrauding and deceiving Plaintiffs, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Nexium, 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 Plaintiffs herein.
- 144. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff, Gaylon Mallard, used Nexium, Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.
- 145. In reliance upon said representations, Plaintiff, Gaylon Mallard, 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.

- 146. 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.
- 147. Upon information and belief, Defendants intentionally suppressed, concealed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Nexium was 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.
- 148. 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.
- 149. 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 Plaintiffs, 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 Plaintiffs' healthcare providers would dispense, prescribe, and/or recommend the same.
- 150. 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 Plaintiffs, as well as Plaintiffs' healthcare providers would rely upon the information being disseminated.

- 151. Defendants utilized direct to consumer advertising to market, promote, and/or advertise Nexium.
- 152. Plaintiff and/or his 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.
- 153. By reason of the foregoing, Defendants are in violation of the Tennessee Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, et seq.
- 154. Defendant brought Nexium to the market, and acted fraudulently, wantonly and maliciously to the detriment of Plaintiffs.
- 155. As a result of the foregoing acts and omissions, Plaintiff, Gaylon Mallard, was caused to suffer serious and dangerous side effects including, Acute Kidney Failure, Chronic Kidney Disease 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.
- 156. As a result of the foregoing acts and omissions, Plaintiff, Gaylon Mallard, requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed, believe and further allege that Plaintiff, Gaylon Mallard, will be required to obtain further medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' 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

- 157. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.
- 158. The acts, omissions, and representations of Defendants regarding the manufacturing, distribution and marketing of Nexium 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 then intentionally and/or recklessly concealed material information about Nexium's potential serious adverse effects from Plaintiffs and Plaintiffs' healthcare providers.
- 159. Defendants knew that Plaintiffs would suffer mental distress and anxiety upon learning that Nexium possessed a likelihood of serious adverse effects and complications such as life-threatening kidney damages.
- 160. As a result of the foregoing acts and omissions, Plaintiffs were 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.
- 161. As a result of the foregoing acts and omissions Plaintiff, Gaylon Mallard, requires and/or will require more health care and services and did incur medical, health, incidental and

related expenses. Plaintiffs are informed and believe and further allege that Plaintiff, Gaylon Mallard, will, in the future, be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' 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

- 162. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.
- 163. Defendants negligently and carelessly manufactured, sold, and distributed Nexium to Plaintiffs which was defective.
- 164. Defendants negligently and carelessly concealed the defective nature of Nexium from Plaintiffs and Plaintiffs' healthcare providers.
- 165. Defendants negligently and carelessly misrepresented the usefulness, quality and safety of Nexium to Plaintiffs and Plaintiffs' healthcare providers.
- 166. Defendants' negligence and carelessness directly impacted Plaintiff, Gaylon Mallard, in that Plaintiff was induced to purchase and ingest the defective and dangerous Nexium.
- 167. As a result of the foregoing acts and omissions, Plaintiff, Gaylon Mallard, 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.

168. As a result of the foregoing acts and omissions, Plaintiff, Gaylon Mallard, 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 use such as life-threatening kidney damage. Plaintiffs are informed and believe and further allege that Plaintiff, Gaylon Mallard, will, in the future, be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' 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

- 169. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.
- 170. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiffs. 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 Plaintiffs and Plaintiffs' healthcare providers.

- 171. Plaintiffs relied on Defendants' representations and suffered injuries as a proximate result of this reliance.
 - 172. Plaintiffs therefore assert a claim for punitive and exemplary damages.
- 173. Plaintiffs also allege that the acts and omissions of Defendants, whether taken singularly or in conjunction with others, constitute gross negligence that proximately caused the injuries to Plaintiffs.
- 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 Plaintiffs, by making intentionally false and fraudulent misrepresentations about the safety of Nexium. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of Nexium, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting Nexium, despite their knowledge and awareness of these serious side effects and risks.
- 175. Defendants had knowledge of, and were in possession of evidence demonstrating that Nexium 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.

- 176. Although Defendants knew or recklessly disregarded the fact that Nexium causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute Nexium to consumers, including Plaintiffs, without disclosing these side effects when there were safer alternative methods available.
- 177. Defendants failed to provide adequate warnings that would have dissuaded healthcare professionals from prescribing Nexium and consumer from purchasing and ingesting Nexium, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming Nexium.
- 178. Defendants knew of Nexium'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 Plaintiffs, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by Nexium.
- 179. 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 Plaintiffs and other Nexium users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Nexium. 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.
- 180. Prior to the manufacture, sale, and distribution of Nexium, Defendants knew that the drug was 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 Plaintiffs. As such, Defendants unreasonably subjected consumers of Nexium to risk of injury or death.

- 181. 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 failed to adequately warn the public, including Plaintiffs, 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 knowing these actions would expose Plaintiffs and others to serious danger in order to advance Defendants' pecuniary interest and monetary profits.
- 182. Defendants' conduct was committed with willful and conscious disregard for the safety of Plaintiffs, entitling Plaintiffs to exemplary damages.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' 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 IX AS TO ALL DEFENDANTS Loss of Consortium

- 183. Plaintiffs incorporate by reference the preceding paragraphs as if fully set forth herein.
- 184. At all relevant times, Plaintiff, Marilyn Mallard, was and is the wife and spouse of Plaintiff Gaylon Mallard.
- 185. As a result of the injuries sustained by Plaintiff Gaylon Mallard, as set forth above, Plaintiff Marilyn Mallard has suffered loss of consortium, including but not limited to,

mental anguish and the loss of her husband's support, services, society, companionship, comfort, affection, love, and solace.

186. As a result of the injuries sustained by Plaintiff Gaylon Mallard as set forth above, Plaintiffs Gaylon and Marilyn Mallard have sustained damage to their marital relationship.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' 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, Plaintiffs pray 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

Plaintiffs demand a jury trial as to all claims and issues triable of right by a jury.

Respectfully submitted,

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