UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

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	IAM

Plaintiff,

Case No.:

v.

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; MERCK & CO. INC; PROCTER & GAMBLE MANUFACTURING COMPANY; THE PROCTER & GAMBLE COMPANY; PFIZER INC.,

COMPLAINT AND
DEMAND FOR JURY TRIAL

Defendants.

Plaintiffs, by their attorneys, **DOUGLAS & LONDON**, **P.C.**, upon information and belief, at all times hereinafter mentioned, allege as follows:

JURISDICTION AND VENUE

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

NATURE OF THE CASE

- 2. This action is brought on behalf of Plaintiff, STEWART WILLIAMS, who used prescription brand Nexium, Nexium 24HR, Prilosec, and Prilosec OTC for treatment of Plaintiff's peptic disorder.
- 3. Plaintiff seeks compensatory damages as a result of Plaintiff's use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, which has caused Plaintiff to suffer and continue to

suffer from stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of additional health consequences.

- 4. Defendants, AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Merck & Co. Inc., Procter & Gamble Manufacturing Company, The Procter & Gamble Company, and Pfizer Inc, (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Nexium.
- 5. When warning of safety and risks of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, Defendants negligently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as the "FDA"), the Plaintiff's treating physicians, and the public in general, that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC had been tested and were found to be safe and/or effective for their indicated use in treating peptic disorders.
- 6. Defendants concealed their knowledge of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC's defects, specifically the fact that it causes stomach cancer, from Plaintiff's treating physicians, hospitals, pharmacies, the FDA, the public in general and/or the medical community.
- 7. These representations were made by Defendants with the intent of defrauding and deceiving the Plaintiff's physicians, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Nexium, Nexium 24HR, Prilosec, and Prilosec OTC for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory

drug induced gastropathy, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

- 8. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer serious and dangerous side effects including <u>inter alia</u> stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any additional health consequences.
- 9. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's use of Nexium, which has caused Plaintiff to suffer from stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTIES

- 10. Plaintiff, STEWART WILLIAMS, is a citizen of the United States of America, and is a citizen of Maryland.
 - 11. Plaintiff, STEWART WILLIAMS, was born on May 6, 1983.
- 12. Plaintiff, STEWART WILLIAMS, first began using prescription brand Nexium in or about January 2013, and Plaintiff used prescription brand Nexium up through October 2015.
- 13. Plaintiff STEWART WILLIAMS, first began using prescription brand Prilosec in or about January 2013, and Plaintiff used prescription brand Prilosec up through October 2015.
- 14. Plaintiff STEWART WILLIAMS, first began using brand Nexium 24HR in or about January 2013, and Plaintiff used brand Nexium 24HR up through October 2015.

- 15. Plaintiff STEWART WILLIAMS, first began using brand Prilosec OTC in or about January 2013, and Plaintiff used brand Prilosec OTC up through October 2015.
- 16. As result of Plaintiff's ingestion of Defendants' Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, Plaintiff STEWART WILLIAMS has suffered and continues to suffer from stomach cancer which was diagnosed on or about October 12, 2015, as well as any and all of its sequelae and attendant pain, suffering, and emotional distress.
- 17. The injuries and damages sustained by Plaintiff, STEWART WILLIAMS, were caused by Defendants' Nexium, Nexium 24HR, Prilosec, and Prilosec OTC and their unlawful conduct with respect to their design, manufacture, marketing and sale.
- 18. Defendant AstraZeneca Pharmaceuticals, LP is, and at all times relevant to this action was, a limited partnership organized under the laws of the State of Delaware with its headquarters and principal place of business located at 1800 Concord Pike, Wilmington, Delaware.
- 19. AstraZeneca Pharmaceutical LP's general partner is AstraZeneca AB, a corporation incorporated under the laws of the nation of Sweden with its principal place of business in Sweden. AstraZeneca Pharmaceutical LP's sole limited partner is Zeneca Inc., which is a corporation incorporated under the laws of the State of Delaware with its principal place of business in Delaware.
- 20. 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.
- 21. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals, LP was present and doing business in the States of Delaware, New Jersey and Maryland.

- 22. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited, and conducted business in the States of Delaware, New Jersey and Maryland and derived substantial revenue from such business.
- 23. Upon information and belief, at all times relevant hereto, Defendant AstraZeneca Pharmaceuticals, LP expected or should have expected that its acts would have consequences within the United States of America, and the States of Delaware, New Jersey and Maryland.
- 24. Defendant AstraZeneca LP is, and at all times relevant to this action was, a limited partnership organized under the laws of the State of Delaware with its headquarters and principal place of business located at 1800 Concord Pike, Wilmington, Delaware.
- 25. Defendant AstraZeneca LP's sole general partner is AstraZeneca Pharmaceuticals LP. Defendant AstraZeneca LP has no limited partners. AstraZeneca Pharmaceutical LP's general partner is AstraZeneca AB, a corporation incorporated under the laws of the nation of Sweden with its principal place of business in Sweden. AstraZeneca Pharmaceutical LP's sole limited partner is Zeneca Inc., a corporation incorporated under the laws of the State of Delaware with its principal place of business in Delaware.
- 26. Defendant AstraZeneca LP is the holder of approved New Drug Applications ("NDAs") 21-153 and 21-154 for Nexium (Esomeprazole Magnesium), and it manufactures and markets Nexium (Esomeprazole Magnesium) in the United States.
- 27. Upon information and belief, at all times relevant hereto Defendant AstraZeneca LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Nexium products.
- 28. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business in the States of Delaware, New Jersey and Maryland.

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- 29. Upon information and belief, at all relevant times, Defendant AstraZeneca LP transacted, solicited, and conducted business in the States of Delaware, New Jersey and Maryland, and derived substantial revenue from such business.
- 30. Upon information and belief, at all times relevant hereto, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences within the United States of America, and the States of Delaware, New Jersey and Maryland.
- 31. Upon information and belief, each AstraZeneca Defendant was the agent and employee of each other AstraZeneca Defendant, and in doing the things alleged was acting within the course and scope of such agency and employment and with each other AstraZeneca Defendant's actual and implied permission, consent, authorization, and approval.
- 32. In 1982, the AstraZeneca Defendants entered a joint venture with Defendant Merck to design and develop the first proton pump inhibitor.
- 33. The result of this joint-venture was the development of omeprazole, which was ultimately marketed and sold under the brand name Prilosec.
- 34. In anticipation of the expiration of the patent for prescription Prilosec, the AstraZeneca Defendants launched an internal program called Operation Shark Fin for the purpose of developing a second PPI Product in order to capitalize on the market for PPI Products. The result of Operation Shark Fin was the development of Nexium (esomeprazole).
- 35. In December 1999, Defendant AstraZeneca Pharmaceutical LP submitted its first NDA for a Nexium product, NDA 021153, to the FDA for approval to market Nexium in the United States.
- 36. Defendant Merck & Co. Inc. d/b/a Merck, Sharp & Dohme Corporation (hereinafter "Defendant Merck") is and, all times relevant to this action, has been a New Jersey corporation

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having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

- 37. In 1982, Defendant Merck entered into an agreement with the AstraZeneca Defendants, under the terms of which Defendant Merck developed and marketed the AstraZeneca Defendants' products, including Nexium and Prilosec products, under a royalty-bearing license.
- 38. In 1993, Merck's total sales of the AstraZeneca Defendants' products reached a level that triggered the first step in the establishment of a joint venture business (the "Joint Venture") in which Defendant Merck and the AstraZeneca Defendants each owned a 50% share. This Joint Venture, formed in 1994, was called Astra Merck Inc. and was responsible for the sale of Prilosec and other of the AstraZeneca Defendants' products.
- 39. Until 2014, Defendant Merck had a contractual and ownership interest in the Joint Venture. Through these interests, between 2009 and 2014, Defendant Merck earned at least \$7 billion, based on the sales of prescription and over-the-counter formulations of Nexium.
- 40. Defendant Merck currently has, and will continue to have until 2018, a financial interest in prescription and over-the-counter formulations of Nexium.
- 41. As a part of their business and at all relevant times, Defendant Merck has been and is involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription and over-the-counter formulations of Nexium.
- 42. Defendant Merck, through the Joint Venture, also designed, researched, manufactured, tested, advertised, marketed, sold and distributed Nexium.
- 43. Defendant Merck has had a contractual, ownership and financial interest in the following FDA approved forms of Nexium: Delayed-Release Capsule Pellets, NDA 021153; Delayed-Release Oral Suspension, NDAs 02195 and 022010; and Intravenous Injectable Solution,

NDA 021689.

- 44. Defendant Merck manufactures and markets Nexium in the United States.
- 45. Defendant Merck has transacted and conducted business related to Nexium in each of the States and Territories of the United States.
- 46. Defendant Merck has derived substantial revenue from Nexium in each of the States and Territories of the United States.
- 47. Defendant Merck has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Nexium.
- 48. Defendant AstraZeneca LP is the holder of approved New Drug Applications ("NDAs") 22-056, 19-810/S-74 and 21-229 etc. for Prilosec (Omeprazole Magnesium), and it manufactures and markets Prilosec (Omeprazole Magnesium) in the United States.
- 49. Upon information and belief, at all times relevant hereto Defendant AstraZeneca LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Prilosec products.
- 50. Defendants Procter & Gamble Manufacturing Company and The Procter & Gamble Company are the holders of approved New Drug Application ("NDA") 021229 for Prilosec OTC (Omeprazole Magnesium), and it manufactures and markets Prilosec OTC (Omeprazole Magnesium) in the United States.
- 51. Upon information and belief, Defendant Procter & Gamble Manufacturing Company, is, and at all times relevant to this action was, an Ohio corporation that is registered to do business and conducts substantial business in this state, which has a principal place of business

at 1 Procter & Gamble Plaza, Cincinnati, OH 45202.

- 52. 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 for use which primary purpose being a proton pump inhibitor.
- 53. Upon information and belief, Defendant, Procter & Gamble Manufacturing Company has transacted and conducted business in the States of Ohio, New Jersey and Maryland.
- 54. Upon information and belief, Defendant, Procter & Gamble Manufacturing Company, has derived substantial revenue from goods and products used in the States of Ohio, New Jersey, and Maryland.
- 55. Upon information and belief, Defendant, Procter & Gamble Manufacturing Company, expected or should have expected its acts to have consequence within Ohio and Maryland, and derived substantial revenue from interstate commerce within the United States, Ohio, New Jersey and Maryland.
- 56. Upon information and belief, Defendant The Procter & Gamble Company is an Ohio corporation that is registered to do business and conducts substantial business in this state, which has its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, OH 45202.
- 57. Upon information and belief, and at all relevant times, Defendant The Procter & Gamble Company is either the direct or indirect owner of substantially all the stock or ownership interests of Defendant Procter & Gamble Manufacturing Company.
- 58. 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 for use which primary purpose being

a proton pump inhibitor.

- 59. Upon information and belief, Defendant, The Procter & Gamble Company, has transacted and conducted business in the States of Ohio, New Jersey and Maryland.
- 60. Upon information and belief, Defendant, The Procter & Gamble Company has derived substantial revenue from goods and products used in the States of Ohio, New Jersey and Maryland.
- 61. Defendant Pfizer Inc. is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in New York, New York.
- 62. At all times relevant hereto, Defendant Pfizer Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium 24HR.
- 63. Upon information and belief, at all relevant times, Defendant Pfizer Inc. was present and doing business in Deleware, New Jersey and Maryland.
- 64. At all relevant times, Defendant Pfizer Inc. transacted, solicited, and conducted business in Plaintiff's state of residency and derived substantial revenue from such business.
- 65. At all times relevant hereto, Defendant Pfizer Inc. expected or should have expected that its acts would have consequences within the United States, and Plaintiff's state of residency in particular.
- 66. Defendant Pfizer Inc. acquired global over-the-counter rights to Nexium 24HR from AstraZeneca in August 2012 and made Nexium 24HR available for purchase in the United States on or about May 27, 2014.

- 67. Defendant Pfizer Inc. is also the holder of an approved NDA for Nexium 24HR Delayed-Release Tablets (20 mg), with NDA # 207920, approved on November 23, 2015.
- 68. Defendants AstraZeneca LP, AstraZeneca Pharmaceuticals LP, Procter & Gamble Manufacturing Company, The Procter & Gamble Company, and Pfizer Inc.. shall herein be collectively referred to as "Defendants."

FACTUAL BACKGROUND

- 69. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff STEWART WILLIAMS suffering stomach cancer caused by Plaintiff's ingestion of the proton pump inhibitors, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 70. Upon information and belief, the AstraZeneca Defendants began marketing and selling prescription brand Nexium in 2001.
 - 71. Plaintiff began taking prescription brand Nexium in or about January 2013.
- 72. At all relevant times, Defendants heavily marketed Nexium and to treat peptic disorders, including but not limited to gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
- 73. Procter & Gamble Defendants sold Prilosec OTC with National Drug Code (NDC) numbers 37000-455 and 37000-459.
- 74. Upon information and belief, the AstraZeneca Defendants began marketing and selling prescription brand Prilosec in 1989.
 - 75. Plaintiff began taking prescription brand Prilosec in or about January 2013.
- 76. Upon information and belief, the Procter & Gamble Defendants began marketing and selling brand Prilosec OTC in 2003.

- 77. Plaintiff began taking brand Prilosec OTC in or about January 2013.
- 78. At all relevant times, Defendants heavily marketed Prilosec OTC to treat frequent heartburn.
- 79. The AstraZeneca Defendants sold Nexium with National Drug Code (NDC) numbers 00186-5020; 00186-5022; 00186-5040; 00186-5042; 0186-4010; 0186-4020 and 00186-4040.
 - 80. Plaintiff began taking brand Nexium 24HR in or about January 2013
- 81. Nexium (Esomeprazole Magnesium), is a PPI that works by reducing hydrochloric acid in the stomach.
- 82. AstraZeneca sold Prilosec with National Drug Code (NDC) numbers 00186-0606; 00186-0610; 00186-0625; 00186-0742 and 00186-0743.
- 83. Pfizer Inc. sold Nexium 24HR with NDC numbers 0573-2450-14, 0573-2450-15, 0573-2450-17, 0573-2450-28, 0573-2450-42, 0573-2450-43, 0573-2450-44, 0573-2450-56, 0573-2451-14, and 0573-2451-42.
- 84. Prilosec (Omeprazole Magnesium), is a PPI that works by reducing hydrochloric acid in the stomach.
- 85. Defendants' marketing of Prilosec OTC included advertisements, press releases, web site publications, sales representative pitches and other communications.
- 86. Defendants' marketing of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC and included advertisements, press releases, web site publications, sales representative pitches and other communications.

- 87. Materials including advertisements, press releases, webs site publications and other communications regarding Nexium, Nexium 24HR, Prilosec, and Prilosec OTC are part of the labeling of the drug and could be altered by Defendants without prior FDA approval.
- 88. Proton pump inhibitors ("PPIs"), including Defendants' Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, are some of the most commonly prescribed medications in the United States.
- 89. More than 15 million Americans used prescription and over the counter PPIs in 2013, costing more than \$10 billion.
- 90. However, it has been estimated that between 25% and 70% of these prescriptions and over the counter medications have no appropriate indication.
- 91. Up to 70% of PPIs may be used inappropriately for indications or durations that were never tested or approved.
- 92. Further, 25% of long-term PPI users could discontinue therapy without developing any symptoms.
- 93. During the period in which Nexium, Nexium 24HR, Prilosec, and Prilosec OTC have been sold in the United States, hundreds of reports of injuries, including stomach cancer, have been submitted to the FDA in association with ingestion of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, and other PPIs.
- 94. Defendants have had notice of serious adverse health outcomes regarding stomach cancer associated with their Nexium, Nexium 24HR, Prilosec, and Prilosec OTC through case reports, clinical studies and post-market surveillance.

- 95. As such, these numerous reports of stomach cancer put Defendants on notice as to the excessive risks of kidney injuries related to the use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 96. Several observational studies have linked PPI use, including Nexium, Nexium 24HR, Prilosec, and Prilosec OTC use, to serious adverse health outcomes, including stomach cancer, acute interstitial nephritis and acute kidney injury.
- 97. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a petition with the U.S. FDA to add black box warnings and other safety information concerning several risks associated with PPIs, including acute interstitial nephritis.
 - 98. In December of 2014, the labels of prescription PPIs were updated to read:

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

- 99. A study from 2015 shows that acute kidney injuries increased 250% in elderly patients that were newly prescribed PPIs. The acute kidney injuries occurred with 120 days of the patients staring the PPIs.
- 100. A study by Lai, et al., published by GUT in April 2018, found that Long-term proton pump inhibitors and risk of gastric cancer development. Shih-Wei Lai, Hsueh-Chou Lai, Cheng-Li Lin and Kuan-Fu Liao. *Proton Pump Inhibitors and Risk of Gastric Cancer in a Case-Control Study*. Gut (2018).
- 101. A 2018 study by Cheung found an association among long-term proton pump inhibitors and risk of gastric cancer develop. Cheung, KS, Chan, EW, Wong, AYS, Chen, L, Wong, ICK, Leung, WK. Long-term Proton Pump Inhibitors and Risk of Gastric Cancer

Development after Treatment for Helicobacter Pylori: A Population-Based Study, Gut (2018).

- 102. Other recent articles, such as Brusselaers and Lai, found a similar risk of gastric cancer development with proton pump inhibitor use. Brusselaers N, Wahlin, K, Engstrand, L, et al. Maintenance Therapy with Proton Pump Inhibitors and Risk of Gatric Cancer: A Nationwide Population-based Cohort Study in Sweden. BMJ Open (2017); Lai, SW, Liao KF, Lai HC, Lin CL, Sung FC. Use of Proton Pump Inhibitors Correlates with Increased Risk of Colorectal Cancer in Taiwan. Asia Pac. J. Clin. Oncol. (2013);
- 103. There are other studies, and articles in the medical community, as well as other evidence that associates PPIs with stomach cancer.
- 104. The FDA's Office of Surveillance and Epidemiology ("OSE") identified signals of new safety risks for users of proton pump inhibitors. New safety risks included "polyps of stomach and duodenum. In response to this alert, the FDA commenced a Tracked Safety Issue ("TSI") for proton pump inhibitors, and in September of 2017, the FDA decided this gastric risk required further regulatory review.
- 105. To date, Defendants' prescription Nexium, Nexium 24HR, Prilosec, and Prilosec OTC lacks detailed risk information for stomach cancer, despite science stating otherwise.
- 106. Defendants knew or should have known of the risk of stomach cancer based on the data available to them or that could have been generated by them, including but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, pre-clinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.
- 107. Despite their knowledge of the risks of stomach cancer associated with their proton pump inhibitors, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, Defendants took no action

to inform Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC did not pose any risks of stomach cancer. They promoted and marketed Nexium, Nexium 24HR, Prilosec, and Prilosec OTC as safe and effective for persons such as Plaintiff STEWART WILLIAMS throughout the United States, including Maryland.

- 108. Defendants knew of the significant risk of stomach cancer that could result from Nexium, Nexium 24HR, Prilosec, and Prilosec OTC use, but Defendants did not adequately and sufficiently warn consumers, including Plaintiff's physician or the medical community in a timely manner.
- 109. Even if used as directed, Defendants failed to adequately warn against the negative effects and risks associated with this Nexium, Nexium 24HR, Prilosec, and Prilosec OTC including, but not necessarily limited to, long term usage and the cumulative effects of long term usage.
- 110. In omitting, concealing, and inadequately providing critical safety information regarding the use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC in order to induce its purchase and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiff. This conduct is fraudulent, unfair, and unlawful.
- 111. Despite clear knowledge that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC cause a significantly increased risk of stomach cancer, CKD, acute kidney injuries, Defendants continued to market and sell Nexium, Nexium 24HR, Prilosec, and Prilosec OTC without warning consumers or healthcare providers of the significant risks of stomach cancer, CKD and acute kidney injuries.
 - 112. Even if used as directed, persons who ingested Nexium, Nexium 24HR, Prilosec,

and Prilosec OTC, such as the Plaintiff STEWART WILLIAMS, have been exposed to significant

risks stemming from unindicated and/or long-term usage.

113. Consumers, including Plaintiff STEWART WILLIAMS, and Plaintiff's physicians

relied on the Defendants' false representations and were misled as to Nexium, Nexium 24HR,

Prilosec, and Prilosec OTC's safety.

114. Had the Plaintiff STEWART WILLIAMS known of the risks of stomach cancer

associated with Defendants' Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, Plaintiff would

not have used Defendants' Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.

115. At all relevant times, Plaintiff STEWART WILLIAMS had alternative safer

methods for treating peptic disorders that provided the same benefits but acted through a different

mechanism and were not associated with stomach cancer.

116. One alternative was H2 antagonists, also called H2 blockers, a class of medications

that block the action of histamine at the histamine H2 receptors of the parietal cells in the stomach.

The use of H2 receptor antagonists, which are prescribed for the same indication as PPIs, is not

associated with stomach cancer.

117. As a result of Defendants' action and inactions as outlined herein, Plaintiff was

injured due to Plaintiff's ingestion of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, which

caused Plaintiff and continues to cause Plaintiff to suffer from stomach cancer and any and all of

its sequelae.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

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- 118. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 119. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.
- 120. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC into interstate commerce in that Defendants knew or should have known that using Nexium could proximately cause Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:
 - (a) Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that plaintiff would suffer a serious injury or death by ingesting Nexium, Nexium 24HR, Prilosec, and Prilosec OTC;
 - (b) Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Nexium, Nexium 24HR, Prilosec, and Prilosec OTC in unsafe doses;
 - (c) Failure to use reasonable care in testing and inspecting Nexium, Nexium 24HR, Prilosec, and Prilosec OTC so as to ascertain

- whether or not they were safe for the purpose for which they were designed, manufactured and sold;
- (d) Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC;
- (e) Failure to use reasonable care in the process of manufacturing Nexium, Nexium 24HR, Prilosec, and Prilosec OTC in a reasonably safe condition for the use for which it was intended;
- (f) Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using Nexium, Nexium 24HR, Prilosec, and Prilosec OTC in unsafe doses; and
- (g) Such further acts and/or omissions that may be proven at trial.
- 121. 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.
- 122. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:
 - (a) Manufacturing, producing, promoting, formulating, creating, and/or designing Nexium, Nexium 24HR, Prilosec, and Prilosec OTC without thoroughly testing it;
 - (b) Manufacturing, producing, promoting, formulating, creating, and/or designing Nexium, Nexium 24HR, Prilosec, and Prilosec OTC without adequately testing it;
 - (c) Not conducting sufficient testing programs to determine whether or not Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were safe for use; in that Defendants herein knew or should have known that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were unsafe and unfit for use by reason of the dangers to its users;
 - (d) Selling Nexium, Nexium 24HR, Prilosec, and Prilosec OTC without making proper and sufficient tests to determine the dangers to its users;

- (e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC;
- (f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC;
- (g) Failing to test Nexium, Nexium 24HR, Prilosec, and Prilosec OTC and/or failing to adequately, sufficiently and properly test Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- (h) Negligently advertising and recommending the use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC without sufficient knowledge as to their dangerous propensities;
- (i) Negligently representing that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was safe for use for its intended purpose, when, in fact, it was unsafe;
- (j) Negligently designing Nexium, Nexium 24HR, Prilosec, and Prilosec OTC in a manner which was dangerous to its users;
- (k) Negligently manufacturing Nexium, Nexium 24HR, Prilosec, and Prilosec OTC in a manner which was dangerous to its users;
- (l) Negligently producing Nexium, Nexium 24HR, Prilosec, and Prilosec OTC in a manner which was dangerous to its users;
- (m) Negligently assembling Nexium, Nexium 24HR, Prilosec, and Prilosec OTC in a manner which was dangerous to its users;
- (n) Concealing information from the Plaintiff in knowing that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was unsafe, dangerous, and/or non-conforming with FDA regulations.
- 123. Defendants under-reported, underestimated and downplayed the serious dangers of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 124. Defendants negligently compared the safety risk and/or dangers of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC with other forms of treatment of peptic disorders which

include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal antiinflammatory drug induced gastropathy.

- 125. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC in that they:
 - (a) Failed to use due care in designing and manufacturing Nexium, Nexium 24HR, Prilosec, and Prilosec OTC so as to avoid the aforementioned risks to individuals when Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were used for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;
 - (b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the uses of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC;
 - (c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC;
 - (d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Nexium, Nexium 24HR, Prilosec, and Prilosec OTC;
 - (e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
 - (f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC;
 - (g) Failed to warn Plaintiff, prior to actively encouraging the sale of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

(h) Were otherwise careless and/or negligent.

126. Despite the fact that Defendants knew or should have known that Nexium. Nexium

24HR, Prilosec, and Prilosec OTC caused unreasonably dangerous side effects, Defendants

continued and continue to market, manufacture, distribute and/or sell Nexium to consumers,

including the Plaintiff.

127. Defendants knew or should have known that consumers such as the Plaintiff,

STEWART WILLIAMS, 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, STEWART WILLIAMS suffered and/or will continue to suffer.

129. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer

serious and dangerous side effects including, stomach cancer, as well as other severe and personal

injuries which are permanent and lasting in nature, physical pain and mental anguish, including

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

medications.

130. As a result of the foregoing acts and omissions the Plaintiff requires and/or will

require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be

required to obtain further medical and/or hospital care, attention, and services.

131. By reason of the foregoing, Plaintiff has been damaged as against the Defendants

in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

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

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- 132. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 133. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Nexium, Nexium 24HR, Prilosec, and Prilosec OTC as hereinabove described that was used by the Plaintiff.
- 134. That Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.
- 135. At those times, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.
- 136. The Nexium, Nexium 24HR, Prilosec, and Prilosec OTC designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 137. The Nexium, Nexium 24HR, Prilosec, and Prilosec OTC designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants

manufacturers and/or suppliers, they were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect.

- 138. At all times herein mentioned, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was in a defective condition and unsafe, and Defendants knew or had reason to know that said products were defective and unsafe, especially when used in the form and manner as provided by the Defendants.
- 139. Defendants knew or should have known that at all times herein mentioned its Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were in a defective condition and were and are inherently dangerous and unsafe.
- 140. At the time of the Plaintiff's uses of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was being used for the purposes and in a manner normally intended for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
- 141. Defendants with this knowledge voluntarily designed Nexium, Nexium 24HR, Prilosec, and Prilosec OTC in a dangerous condition for use by the public, and in particular the Plaintiff.
- 142. Defendants had a duty to create products that were not unreasonably dangerous for its normal, intended use.
- 143. Defendants created products unreasonably dangerous for their normal, intended use.
- 144. The Nexium, Nexium 24HR, Prilosec, and Prilosec OTC designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were

manufactured defectively in that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

- 145. The Nexium, Nexium 24HR, Prilosec, and Prilosec OTC designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was manufactured.
- 146. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.
- 147. The Plaintiff could not, by the exercise of reasonable care, have discovered Nexium, Nexium 24HR, Prilosec, and Prilosec OTC 's defects herein mentioned and perceived its danger.
- 148. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, stomach cancer, kidney injuries, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.
- 149. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

- 150. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, stomach cancer and kidney injuries, as well as other severe and permanent health consequences from Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Nexium, Nexium 24HR, Prilosec, and Prilosec, and Prilosec OTC.
- 151. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Nexium.
- 152. Defendants' defective design, manufacturing defect, and inadequate warnings of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were acts that amount to willful, wanton, and/or reckless conduct by Defendants.
- 153. That said defects in Defendants' drug Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were a substantial factor in causing Plaintiff's injuries.
- 154. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.
- 155. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

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

- 157. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 158. Defendants expressly warranted that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was safe and well accepted by users.
- 159. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC did not conform to these express representations because Nexium, Nexium 24HR, Prilosec, and Prilosec OTC are not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.
 - 160. Plaintiff did rely on the express warranties of the Defendants herein.
- 161. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC in recommending, prescribing, and/or dispensing Nexium.
- 162. The Defendants herein breached the aforesaid express warranties, as their drug Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were defective.

- 163. Defendants expressly represented to Plaintiff's physicians, healthcare providers, and/or the FDA that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were safe and fit for use for the purposes intended, that it was of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.
- 164. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.
- 165. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.
- 166. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Nexium, Nexium 24HR, Prilosec, and Prilosec OTC drugs.
- 167. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

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

- 169. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 170. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Nexium and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Nexium, Nexium 24HR, Prilosec, and Prilosec OTC for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
- 171. At the time Defendants marketed, sold, and distributed Nexium for use by Plaintiff, Defendants knew of the uses for which Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.
- 172. The Defendants impliedly represented and warranted to the users of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC and their physicians, healthcare providers, and/or the FDA that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.
 - 173. That said representations and warranties aforementioned were false, misleading,

and inaccurate in that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

- 174. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.
- 175. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were of merchantable quality and safe and fit for its intended use.
- 176. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC 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.
- 177. The Defendants herein breached the aforesaid implied warranties, as their drugs Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were not fit for its intended purposes and uses.
- 178. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.
- 179. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

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

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

- 181. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 182. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said products, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC had been tested and were found to be safe and/or effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
 - 183. That representations made by Defendants were, in fact, false.
- 184. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.
- 185. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, for treatment of peptic disorders

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

- 186. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.
- 187. In reliance upon said representations, the Plaintiff was induced to and did use Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.
- 188. Said Defendants knew and were aware or should have been aware that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC had not been sufficiently tested, were defective in nature, and/or that they lacked adequate and/or sufficient warnings.
- 189. Defendants knew or should have known that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC had a potential to, could, and would cause severe and grievous injury to the users of said products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.
- 190. Defendants brought Nexium, Nexium 24HR, Prilosec, and Prilosec OTC to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.
- 191. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including

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

- 192. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiffs are informed and believe and further allege that Plaintiffs will in the future be required to obtain further medical and/or hospital care, attention, and services.
- 193. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

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

- 194. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 195. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC for their intended use.
- 196. Defendants knew or were reckless in not knowing that its representations were false.
- 197. 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, Nexium 24HR, Prilosec, and Prilosec OTC were not as safe as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux

- disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;
- (b) that the risks of adverse events with Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were higher than those with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory druginduced gastropathy;
- (c) that the risks of adverse events with Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were not adequately tested and/or known by Defendants;
- (d) that Defendants were aware of dangers in Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, in addition to and above and beyond those associated with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;
- (e) that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were defective, and that it caused dangerous side effects, including but not limited to stomach cancer;
- (f) that patients needed to be monitored more regularly than normal while using Nexium, Nexium 24HR, Prilosec, and Prilosec OTC;
- (g) that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were manufactured negligently;
- (h) that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were manufactured defectively;
- (i) that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were manufactured improperly;
- (j) that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were designed negligently;
- (k) that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were designed defectively; and

- (l) that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were designed improperly.
- 198. Defendants were under a duty to disclose to Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, including but not limited to the heightened risks of stomach cancer.
- 199. 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, Nexium 24HR, Prilosec, and Prilosec OTC, including the Plaintiff, in particular.
- 200. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and Plaintiff's physicians, hospitals and healthcare providers into reliance, continued use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Nexium, Nexium 24HR, Prilosec, and Prilosec OTC and/or use the products.
- 201. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, as set forth herein.
- 202. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

- 203. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, stomach cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.
- 204. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.
- 205. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

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

- 206. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 207. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said products, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, had been tested and found to be safe and effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
 - 208. The representations made by Defendants were, in fact, false.

209. Defendants failed to exercise ordinary care in the representation of Nexium,

Nexium 24HR, Prilosec, and Prilosec OTC, while involved in their manufacture, sale, testing,

quality assurance, quality control, and/or distribution of said product into interstate commerce, in

that Defendants negligently misrepresented Nexium, Nexium 24HR, Prilosec, and Prilosec OTC's

high risks of unreasonable, dangerous side effects.

210. Defendants breached their duty in representing Nexium, Nexium 24HR, Prilosec,

and Prilosec OTC 's serious side effects to the medical and healthcare community, to the Plaintiff,

the FDA and the public in general.

211. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer

serious and dangerous side effects including, stomach cancer, as well as other severe and personal

injuries which are permanent and lasting in nature, physical pain and mental anguish, including

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

medications.

212. As a result of the foregoing acts and omissions the Plaintiff requires and/or will

require more health care and services and did incur medical, health, incidental and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be

required to obtain further medical and/or hospital care, attention, and services.

213. By reason of the foregoing, Plaintiff has been damaged as against the Defendants

in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

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

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- 214. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 215. Defendants conducted research and used Nexium, Nexium 24HR, Prilosec, and Prilosec OTC as part of their research.
- 216. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that Nexium was safe and effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
- 217. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.
- 218. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.
- 219. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.
- 220. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug Nexium, Nexium 24HR, Prilosec, and

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

- 221. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug Nexium, Nexium 24HR, Prilosec, and Prilosec OTC carried the same risks, hazards, and/or dangers as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
- 222. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were not injurious to the health and/or safety of its intended users.
- 223. The information distributed to the public, the FDA, and the Plaintiffs, by Defendants intentionally included false representations that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were as potentially injurious to the health and/or safety of its intended as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
 - 224. These representations were all false and misleading.
- 225. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were not safe as a means of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

- 226. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiffs, regarding the safety of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, specifically but not limited to Nexium, Nexium 24HR, Prilosec, and Prilosec OTC not having dangerous and serious health and/or safety concerns.
- 227. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiffs, regarding the safety of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, specifically but not limited to Nexium, Nexium 24HR, Prilosec, and Prilosec OTC being safe means for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
- 228. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 229. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiffs that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were fit and safe for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
- 230. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that

Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were fit and safe for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

- 231. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC did not present serious health and/or safety risks.
- 232. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC did not present health and/or safety risks greater than other oral forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
- 233. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.
- 234. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including Plaintiff's respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or Plaintiff's respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Nexium.
- 235. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including

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

- 236. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 237. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as Plaintiff's respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Nexium, Nexium 24HR, Prilosec, and Prilosec OTC and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.
- 238. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's respective healthcare professionals would rely upon the information being disseminated.
- 239. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 240. That the Plaintiff and/or Plaintiff's respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

- 241. That at the time the representations were made, the Plaintiff and/or Plaintiff's respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 242. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.
- 243. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, Plaintiff would not have purchased, used and/or relied on Defendants' drug Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 244. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.
- 245. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Stomach Cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.
- 246. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.
- 247. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

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

- 248. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 249. At all times relevant, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et. seq., prohibits "[the] act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise..." and declares such acts or practices as unlawful.
- 250. Defendants violated the New Jersey Consumer Fraud Act by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC. Defendants communicated the purported benefits of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC while failing to disclose the serious and dangerous side effects related to the use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC with the intent that consumers, including Plaintiff, and Plaintiff's healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, respectively.
- 251. As a result of violating the <u>New Jersey Consumer Fraud Act</u>, Defendants caused Plaintiff to be prescribed and to use Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, causing severe injuries and damages as previously described herein.

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

- 252. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 253. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, including the Nexium, Nexium 24HR, Prilosec, and Prilosec OTC used by Plaintiff, STEWART WILLIAMS, was in a defective and unreasonably dangerous condition.
- 254. Defendants expected Nexium, Nexium 24HR, Prilosec, and Prilosec OTC to reach, and it did in fact reach, Plaintiff without substantial change in the condition in which it was manufactured and sold by the Defendants.
- 255. At all times relevant hereto, Defendants' Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for use by the public and in particular by Plaintiff.
- 256. At all times relevant to this action, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by the Defendants, was defective in design and formulation in one or more of the following particulars:
 - (a) When placed in the stream of commerce, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC contained unreasonably dangerous design defects and was not

- reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the drug;
- (b) When placed in the stream of commerce, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;
- (c) Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were insufficiently tested;
- (d) Nexium, Nexium 24HR, Prilosec, and Prilosec OTC caused harmful side effects that outweighed any potential utility;
- (e) Defendants were aware at the time Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were marketed that ingestion of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC would result in an increased risk of Stomach Cancer, AKI, CKD, ESRD, and other injuries;
- (f) Inadequate post-marketing surveillance; and/or
- (g) There were safer alternative designs and formulations that were not utilized.
- 223. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were defective, failed to perform safely, and was unreasonably dangerous when used by ordinary consumers, including Plaintiff, as intended and in a reasonably foreseeable manner.
- 224. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in its design or formulation, in that it was unreasonably

dangerous and its foreseeable risks exceeded the alleged benefits associated with Nexium, Nexium 24HR, Prilosec, and Prilosec OTC's design or formulation.

- 225. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in design or formulation in that it posed a greater likelihood of injury than other proton-pump inhibitors and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.
- 226. At all times relevant to this action, Defendants knew or had reason to know that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were in a defective condition and was inherently dangerous and unsafe when used in the manner instructed, provided, and/or promoted by Defendants.
- 227. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and otherwise ensure that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.
- 228. When Defendants placed Nexium, Nexium 24HR, Prilosec, and Prilosec OTC into the stream of commerce, they knew it would be prescribed to treat peptic disorders, and they marketed and promoted Nexium, Nexium 24HR, Prilosec, and Prilosec OTC as safe for treating peptic disorders.
- 229. Plaintiff was prescribed, purchased, and used Nexium, Nexium 24HR, Prilosec, and Prilosec OTC. Plaintiff used Nexium, Nexium 24HR, Prilosec, and Prilosec OTC for their intended

purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

- 230. Neither Plaintiff nor Plaintiff's health care professionals, by the exercise of reasonable care, could have discovered the defects and risks associated with Nexium, Nexium 24HR, Prilosec, and Prilosec OTC before Plaintiff's ingestion of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 231. The harm caused by Nexium, Nexium 24HR, Prilosec, and Prilosec OTC far outweighed its benefit, rendering Nexium, Nexium 24HR, Prilosec, and Prilosec OTC more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed Nexium, Nexium 24HR, Prilosec, and Prilosec OTC to make it less dangerous. When Defendants designed Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, the state of the industry's scientific knowledge was such that a less risky design was attainable.
- 232. At the time Nexium, Nexium 24HR, Prilosec, and Prilosec OTC left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the reasonably anticipated or intended function of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC. This was demonstrated by the existence of other peptic disorder medications that had a more established safety profile and a considerably lower risk profile.
- 233. Defendants' defective design of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC. Defendants' conduct was

motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.

- 234. The defects in Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were substantial and contributing factors in causing Plaintiff's injuries. But for Defendants' acts and omissions, Plaintiff would not have suffered the injuries complained of herein.
- 235. Due to the unreasonably dangerous condition of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, Defendants are liable to Plaintiff.
- 236. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, including Plaintiff, with knowledge of the safety problems associated with Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.
- 237. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered, and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

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

- 238. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 239. Defendants have engaged in the business of designing, developing, researching, testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or distributing Nexium, Nexium 24HR, Prilosec, and Prilosec OTC. Through that conduct, Defendants knowingly and intentionally placed Nexium, Nexium 24HR, Prilosec, and Prilosec OTC into the stream of commerce with full knowledge that it reaches consumers, such as Plaintiff, STEWART WILLIAMS, who ingested it.
- 240. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released Nexium, Nexium 24HR, Prilosec, and Prilosec OTC into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted Nexium, Nexium 24HR, Prilosec, and Prilosec OTC to the FDA, health care professionals, Plaintiff, and other consumers, and therefore had a duty to warn of the risks associated with the use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 241. Defendants expected Nexium, Nexium 24HR, Prilosec, and Prilosec OTC to reach, and it did in fact reach, prescribing health care professionals and consumers, including Plaintiff and Plaintiff's prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.
- 242. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, as manufactured and/or supplied by Defendants, was defective due to inadequate warnings or instructions. Defendants knew or

should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

- 243. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were defective and unsafe such that it was unreasonably dangerous when it left Defendants' possession and/or control, was distributed by Defendants, and ingested by Plaintiff. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, including the development of Plaintiff's injuries.
- 244. This defect caused serious injury to Plaintiff, who used Nexium, Nexium 24HR, Prilosec, and Prilosec OTC for their intended purpose and in a reasonably anticipated manner.
- 245. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as are necessary to ensure Nexium, Nexium 24HR, Prilosec, and Prilosec OTC did not cause users to suffer from unreasonable and dangerous risks.
- 246. Defendants negligently and recklessly labeled, distributed, and promoted Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 247. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 248. Defendants, as manufacturers, sellers, or distributors of prescription drugs, are held to the knowledge of an expert in the field.

- 249. Plaintiff could not have discovered any defects in Nexium, Nexium 24HR, Prilosec, and Prilosec OTC through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.
- 250. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.
- 251. Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Plaintiff, in a reasonably and intended manner without knowledge of this risk of serious bodily harm.
- 252. Each of the Defendants knew or should have known that the limited warnings disseminated with Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of peptic disorders which include gastroesophageal reflux

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

- 253. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended. In particular, Defendants:
 - (a) disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC;
 - (b) continued to aggressively promote Nexium, Nexium 24HR, Prilosec, and Prilosec OTC even after Defendants knew or should have known of the unreasonable risks from use;
 - (c) failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC and the comparative severity of such adverse effects;
 - (d) failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with Nexium, Nexium 24HR, Prilosec, and Prilosec OTC's capacity to cause its users to suffer;

- (e) failed to adequately warn users, consumers, and physicians about the need to monitor renal function in patients who do not already suffer from renal impairment; and
- (f) overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 254. To this day, Defendants have failed to adequately and accurately warn of the true risks of injuries associated with the use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 255. Due to these deficiencies and inadequacies, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants.
- 256. Had Defendants properly disclosed and disseminated the risks associated with Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, Plaintiff would have avoided the risk of developing injuries as alleged herein.
- 257. The Defendants are liable to Plaintiff for injuries caused by their negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC and the risks associated with its use.
- 258. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered, and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life,

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

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

- 259. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
- 260. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 261. At all times material to this action, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were expected to reach, and did reach, consumers in the States of, New Jersey, and throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.
- 262. At all times material to this action, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC 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 particulars:

(a) When placed in the stream of commerce, Nexium, Nexium 24HR, Prilosec, and Prilosec OTC contained manufacturing defects which rendered the product

unreasonably dangerous;

(b) The subject product's manufacturing defects occurred while the product was in the

possession and control of Defendants;

(c) The subject product was not made in accordance with Defendants' specifications or

performance standards; and/or

(d) The subject product's manufacturing defects existed before it left the control of

Defendants.

263. As a direct and proximate result of the design defect and Defendants' misconduct set

forth herein, Plaintiff has suffered and will continue to suffer serious and permanent physical and

emotional injuries, has expended and will continue to expend large sums of money for medical

care and treatment, has suffered and will continue to suffer economic loss, and have otherwise

been physically, emotionally and economically injured.

THIRTEENTH CAUSE OF ACTION AS

AGAINST THE DEFENDANTS

(PUNITIVE DAMAGES UNDER COMMON LAW,
THE PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15 et seq.)

AND THE PRODUCTS LIABILITY ACT (N.J.S.A. 2A:58C-1 et seq.))

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

fully set forth herein.

- 265. Plaintiff is entitled to punitive damages because Defendants misrepresented and/or withheld information and materials from the FDA, the medical community and the public at large, including the Plaintiff, concerning the safety profile, and, more specifically the serious side effects and/or complications associated with Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.
- 266. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, despite available information that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC were likely to cause serious side effects and/or complications.
- 267. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, despite available information that Nexium was likely to cause serious side effects and/or complications.
- 268. Defendants' failure to provide the necessary materials and information to the FDA, as well as their failure warn physicians and consumers of the serious side effects and/or complications, was reckless and without regard for the public's safety and welfare.
- 269. Defendants were or should have been in possession of evidence demonstrating that Nexium, Nexium 24HR, Prilosec, and Prilosec OTC causes serious side effects. Nevertheless, Defendant continued to market Nexium, Nexium 24HR, Prilosec, and Prilosec OTC by providing false and misleading information with regard to safety and efficacy.

270. Defendants failed to provide the FDA, physicians and consumers with available materials, information and warnings that would have ultimately dissuaded physicians from prescribing Nexium, Nexium 24HR, Prilosec, and Prilosec OTC to consumers, from purchasing and consuming Nexium, Nexium 24HR, Prilosec, and Prilosec OTC, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Nexium, Nexium 24HR, Prilosec, and Prilosec OTC.

PRAYER FOR RELIEF

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

- 1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;
- 2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct:
 - 3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

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

Dated: October 11, 2018

MICHAEL A. LONDON (ML-7510) DOUGLAS & LONDON, P.C. 59 Maiden Lane, 6th Floor New York, New York 10038

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ATTORNEY FOR PLAINTIFF

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

Dated: October 11, 2018

MICHAEL A. LONDON (ML-7510) DOUGLAS & LONDON, P.C. 59 Maiden Lane, 6th Floor New York, New York 10038

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ATTORNEY FOR PLAINTIFF

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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

L (a) PLAINTIFFS Stewart Williams				DEFENDAN Astrazeneca L	TS P., e	t al.						
(b) County of Residence of First Listed Plaintiff Baltimore County (EXCEPT IN U.S. PLAINTIFF CASES) (c) Attorneys (Firm Name, Address, and Telephone Number) Douglas & London, P.C. 59 Maiden Lane. Floor 6				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)								
New York, NY 10038												
II. BASIS OF JURISDI	CTION (Place an "X" in C	ne Box Only)	III. CI	TIZENSHIP O	FPI	RINC	[PA]	L PARTIES				
U.S. Government				PTF Citizen of This State								
☐ 2 U.S. Government Defendant	✓ 4 Diversity (Indicate Citizenship of Parties in Item III)			Citizen of Another State			2	Incorporated and it of Business In		□ 5	2 5	
IV. NATURE OF CUIT				Citizen or Subject of a Foreign Country				Foreign Nation		□ 6	1 6	
IV. NATURE OF SUIT (Place an "X" in One Box Only) CONTRACT TORIS				Click here for: Nature of Suit Code Descriptions. FORFEITURE/PENALTY BANKRUPICY OTHER STATULES								
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 REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property	PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel &	PERSONAL INJURY PERSONAL INJURY 365 Personal Injury - Product Liability 367 Health Care/ Pharmaceutical Personal Injury Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPER 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage Property Damage Product Liability PRISONER PETITION Habeas Corpus: 463 Alien Detainee 510 Motions to Vacate Sentence 530 General 535 Death Penalty Other: 540 Mandamus & Othe 550 Civil Rights 555 Prison Condition 560 Civil Detainee - Conditions of Confinement	TTY	DRFEITURE/PENAL. 5 Drug Related Seizure of Property 21 USC : 00 Other LABOR 0 Fair Labor Standards Act 10 Labor/Management Relations 10 Railway Labor Act 11 Family and Medical Leave Act 10 Cother Labor Litigatio 11 Employee Retirement Income Security Act IMMIGRATION 12 Naturalization Applic 15 Other Immigration Actions	; 8881 t	PRC	Appea Withd: 28 US DPER Copyri Patent Patent TALS HIA (1 Black DIWC SSSID 1 Taxes or Def RS — 'Care RS — 'C	I 28 USC 158 rawal C 157 IY RIGHTS ights - Abbreviated orug Application mark SECURITY (395ff) Lung (923) //DIWW (405(g)) Fitle XVI	375 False C 376 Qui Tar 3729(a 400 State K 410 Antitrus 430 Banks a 450 Comme 460 Deports 470 Rackete 470 Rackete 480 Consum 490 Cable/S 850 Securiti Exchan 890 Other S 891 Agricul 893 Environ 895 Freedor Act 896 Arbitrat 899 Admini Act/Rev	laims Act m (31 USC l) capportions st md Bankin cree tition Organizati cer Credit at TV es/Commo ge tatutory Ac tural Acts mental Mat n of Inforn strative Pro- riew or Api Decision utionality of	ment g ced and cions ditties/ ctions sters nation	
VI. CAUSE OF ACTION COMPLAINT: VIII. RELATED CASE	Cite the U.S. Civil Sta 28 USC 1332 (Di Brief description of ca Severe and perm CHECK IF THIS UNDER RULE 2	Appellate Court tute under which you are versity) use: anent personal injul IS A CLASS ACTION	e filing (I	pened Ar (sp Do not cite jurisdictions	nother ecify) al state ndan on pe	ts' pro r cause punitives	ss dive	pump inhibito ECK YES only	r if demanded in	Multidis Litigatio Direct Fi	on - le	
IF ANY	(Dec man denom).	JUDGE				DOC	CKET	NUMBER				
DATE 10/11/2018 FOR OFFICE USE ONLY		SIGNATURE OF ATT	ORNEY	F RECORD		CONTRACTOR OF THE PARTY OF THE	CONTRACTOR CO.					
RECEIPT# AN	MOUNT	APPLYING IFP		JUDG	ΉE			MAG. JUE	OGE			