

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: PROTON-PUMP INHIBITOR
PRODUCTS LIABILITY LITIGATION
(NO. II)

DONNA GILBERTI, on behalf of the Estate of
DORIS ANN GILBERTI, Deceased,
and DONNA GILBERTI, Individually,

Plaintiffs,

v.

PROCTER & GAMBLE MANUFACTURING
COMPANY; THE PROCTER & GAMBLE
COMPANY; ASTRAZENECA
PHARMACEUTICALS LP and
ASTRAZENECA LP,

Defendants.

17-md-2789 (CCC)(MF)

(MDL 2789)

**COMPLAINT AND DEMAND
FOR JURY TRIAL**

CIVIL ACTION NO.: _____

Plaintiff, Donna Gilberti (hereinafter “Plaintiff”) on behalf of the Estate of Doris Ann Gilberti (hereinafter “Plaintiff-decedent”), and Donna Gilberti individually (hereinafter collectively referred to as “Plaintiffs”), by their attorneys, **BERNSTEIN LIEBHARD LLP**, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

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

2. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 in that Defendants conduct business here and are subject to personal jurisdiction in this District. Furthermore, Defendants sell, market, and/or distribute Prilosec OTC within Massachusetts and this District.¹

NATURE OF THE CASE

4. This action is brought on behalf of Plaintiff-decedent, Doris Ann Gilberti, who used brand Prilosec OTC for treatment of Plaintiff-decedent's peptic disorder.

5. Plaintiff seeks compensatory damages as a result of Plaintiff-decedent's use of Prilosec OTC, which has caused Plaintiff-decedent to suffer from Acute Renal Failure and Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, fear of developing any of additional health consequences, and sudden death.

6. Defendants, Procter & Gamble Manufacturing Company, The Procter & Gamble Company, AstraZeneca Pharmaceuticals LP and AstraZeneca LP (hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Prilosec OTC.

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

¹ Pursuant to the August 2, 2017 JPML Transfer Order, all cases in this litigation would be transferred to the District of New Jersey and assigned to the Honorable Claire C. Cecchi for coordinated or consolidated pretrial proceedings.

8. Defendants concealed their knowledge of Prilosec OTC's defects, specifically the fact that it causes serious kidney injuries, from Plaintiff-decedent's treating physicians, hospitals, pharmacies, the FDA, the public in general and/or the medical community.

9. These representations were made by Defendants with the intent of defrauding and deceiving the Plaintiff-decedent'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 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-decedent herein.

10. As a result of the foregoing acts and omissions, Plaintiff-decedent was and still is caused to suffer serious and dangerous side effects including inter alia Acute Renal Failure and Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and premature death.

11. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff-decedent's use of Nexium, which has caused Plaintiff-decedent to suffer from Acute Renal Failure and Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and premature death.

PARTY PLAINTIFF

12. Plaintiff, Donna Gilberti, is a citizen of the United States of America, and is a resident of Massachusetts.

13. At all relevant times, Plaintiff-decedent Doris Ann Gilberti was a citizen of the United States of America, and was a resident of the State of Massachusetts.

14. Plaintiff, Donna Gilberti, is the daughter of Plaintiff-decedent, Doris Ann Gilberti.

15. Plaintiff-decedent, Doris Ann Gilberti, was born on May 4, 1937.

16. Plaintiff-decedent Doris Ann Gilberti, first began using brand Prilosec OTC in or about June 2007, and Plaintiff-decedent used brand Prilosec OTC up October 2014.

17. As result of Plaintiff-decedent's ingestion of Defendants' Prilosec OTC, Plaintiff-decedent was caused to suffer from Acute Renal Failure which was diagnosed in or about December 2009, and Chronic Kidney Disease which was diagnosed in or about early 2010, as well as any and all of its sequelae and attendant pain, suffering, and emotional distress.

18. As a result of the foregoing, Plaintiff-decedent Doris Ann Gilberti was caused to suffer sudden death on October 21, 2014.

19. The injuries and damages sustained by Plaintiff-decedent, Doris Ann Gilberti, were caused by Defendants' Prilosec OTC and their unlawful conduct with respect to its design, manufacture, marketing and sale.

PARTY DEFENDANTS

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

21. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals, LP was engaged in the business of designing, developing, manufacturing, testing, and/or selling Prilosec

OTC products.

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

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

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

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

26. Upon information and belief, at all times relevant hereto Defendant AstraZeneca LP was engaged in the business of designing, developing, manufacturing, testing, and/or selling Prilosec OTC products.

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

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

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

30. 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.

31. 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.

32. 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.

33. 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.

34. Upon information and belief, Defendant, Procter & Gamble Manufacturing Company has transacted and conducted business in the State of Ohio and Massachusetts.

35. Upon information and belief, Defendant, Procter & Gamble Manufacturing Company, has derived substantial revenue from goods and products used in the State of Ohio and Massachusetts.

36. Upon information and belief, Defendant, Procter & Gamble Manufacturing Company, expected or should have expected its acts to have consequence within Ohio and Massachusetts, and derived substantial revenue from interstate commerce within the United

States, Ohio and Massachusetts.

37. 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.

38. 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.

39. 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.

40. Upon information and belief, Defendant, The Procter & Gamble Company, has transacted and conducted business in the State of Ohio and Massachusetts.

41. Upon information and belief, Defendant, The Procter & Gamble Company has derived substantial revenue from goods and products used in the State of Ohio and Massachusetts.

42. Upon information and belief, Defendant, The Procter & Gamble Company expected or should have expected its acts to have consequence within the United States of America, the State of Ohio and Massachusetts, and derived substantial revenue from interstate commerce within the United States of America, Ohio and Massachusetts.

FACTUAL BACKGROUND

43. This action seeks, seeks, among other relief, general and special damages and equitable relief due to Plaintiff-decedent Doris Ann Gilberti suffering Acute Renal Failure and

Chronic Kidney Disease caused by Plaintiff-decedent's ingestion of the proton pump inhibitor, Prilosec OTC.

44. Procter & Gamble Defendants sold Prilosec OTC with National Drug Code (NDC) numbers 37000-455 and 37000-459.

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

46. Upon information and belief, the Procter & Gamble Defendants began marketing and selling brand Prilosec OTC in 2003.

47. Plaintiff-decedent began taking brand Prilosec OTC in or about June 2007.

48. At all relevant times, Defendants heavily marketed Prilosec OTC to treat peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

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

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

51. Proton pump inhibitors ("PPIs"), including Defendants' Prilosec OTC, are one of the most commonly used medications in the United States.

52. More than 15 million Americans used prescription and over the counter PPIs in 2013, costing more than \$10 billion.

53. However, it has been estimated that between 25% and 70% of these prescriptions and over the counter PPIs have no appropriate indication.

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

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

56. Sales of over-the-counter (“OTC”), non-prescription versions of PPIs are estimated at \$3 billion annually.

57. Prilosec OTC (Omeprazole Magnesium), is a PPI that works by reducing hydrochloric acid in the stomach.

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

59. During the period in which Prilosec OTC has been sold in the United States, hundreds of reports of injury have been submitted to the FDA in association with ingestion of Prilosec OTC and other PPIs. Defendants have had notice of serious adverse health outcomes through case reports, clinical studies and post-market surveillance. Specifically, Defendants had received numerous case reports of kidney injuries in patients that had ingested Prilosec OTC by as early as 2003. These reports of numerous kidney injuries put Defendants on notice as to the excessive risks of kidney injuries related to the use of Prilosec OTC. However, Defendants took no action to inform Plaintiff-decedent or Plaintiff-decedent’s physicians of this known risk. Instead, Defendants continued to represent that Prilosec OTC did not pose any risks of kidney injuries.

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

surveillance.

61. Specifically, Defendants had received numerous case reports of kidney injuries in patients that had ingested Prilosec OTC as early as 2003. As such, these reports of numerous kidney injuries put Defendants on notice as to the excessive risks of kidney injuries related to the use of Prilosec OTC.

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

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

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

65. 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.

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

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

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

69. 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.

70. A study from 2015 shows that acute kidney injuries increased 250% in elderly patients that were newly prescribed PPIs. The acute kidney injuries occurred within 120 days of the patients starting the PPIs.

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

72. In February 2016, a study published in the *Journal of the American Society of Nephrology* found that PPI use including Prilosec OTC, was independently associated with a 20% to 50% higher risk of incident Chronic Kidney Disease, after adjusting for several potential confounding variables, including demographics, socioeconomic status, clinical measurements, prevalent comorbidities, and concomitant use of medications.

73. Chronic Kidney Disease (“CKD”) describes the gradual loss of kidney function. Kidneys filter wastes and excess fluids from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and wastes can build up in the body. End stage renal disease is the last stage of CKD.

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

75. Treatment for CKD focuses on slowing the progression of the kidney damage, usually by attempting to control the underlying cause. CKD can progress to end-stage kidney

failure, which is fatal without artificial filtering, dialysis or a kidney transplant. Early treatment is often key to avoiding the most negative outcomes.

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

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

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

79. To date, Defendants' Prilosec OTC lacks detailed risk information for CKD.

80. Defendants knew or should have known of the risk of kidney disease based on the data available to them or that could have been generated by them, including but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, pre-clinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

81. Despite their knowledge of the risks of kidney injuries and sudden death associated with their proton pump inhibitor, Nexium, Defendants took no action to inform Plaintiff-decedent or Plaintiff-decedent's physicians of this known risk. Instead, Defendants continued to represent that Prilosec OTC did not pose any risks of kidney injuries and sudden

death. They promoted and marketed Prilosec OTC as safe and effective for persons such as Plaintiff-decedent Doris Ann Gilberti throughout the United States, including Massachusetts.

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

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

84. In omitting, concealing, and inadequately providing critical safety information regarding the use of 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-decedent. This conduct is fraudulent, unfair, and unlawful.

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

86. Even if used as directed, persons who ingested Prilosec OTC, such as the Plaintiff-decedent Doris Ann Gilberti, have been exposed to significant risks stemming from unindicated and/or long term usage.

87. Consumers, including Plaintiff-decedent Doris Ann Gilberti, and Plaintiff-decedent's physicians relied on the Defendants' false representations and were misled as to Prilosec OTC's safety.

88. Had the Plaintiff-decedent Doris Ann Gilberti known of the risks of kidney disease

and sudden death associated with Defendants' Prilosec OTC, Plaintiff would not have used Defendants' Prilosec OTC.

89. At all relevant times, Plaintiff-decedent Doris Ann Gilberti had alternative safer methods for treating peptic disorders that provided the same benefits but acted through a different mechanism and were not associated with kidney disease and sudden death.

90. One alternative was H2 antagonists, also called H2 blockers, a class of medications that block the action of histamine at the histamine H2 receptors of the parietal cells in the stomach. The use of H2 receptor antagonists, which are prescribed for the same indication as PPIs, is not associated with CKD.

91. As a result of Defendants' action and inactions as outlined herein, Plaintiff-decedent was injured due to Plaintiff-decedent's ingestion of Prilosec OTC, Plaintiff-decedent to suffer from Acute Renal Failure and Chronic Kidney Disease, any and all of its sequelae, and sudden death.

92. Prior to July 2016, Plaintiff Donna Gilberti did not know about the causal link between Plaintiff-decedent's Acute Renal Failure and Chronic Kidney Disease and ingestion of Defendants' Prilosec OTC.

93. It was not until about July 2016 that Plaintiff Donna Gilberti first learned of the possible causal link.

94. Prior to July 2016, Plaintiff and Plaintiff-decedent did not have access to or actually receive any studies or information recognizing the increased risk of Acute Renal Failure and Chronic Kidney Disease associated with Prilosec OTC use.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

95. 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.

96. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of 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.

97. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Prilosec OTC into interstate commerce in that Defendants knew or should have known that using Prilosec OTC could proximately cause Plaintiff-decedent's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Prilosec 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-decedent and Plaintiff-decedent's physicians of the known or reasonably foreseeable danger that Plaintiff-decedent would suffer a serious injury or death by ingesting Prilosec OTC;
- (b) Failure to adequately warn Plaintiff-decedent and Plaintiff-decedent's physicians of the known or reasonably foreseeable danger that Plaintiff-decedent would suffer a serious injury or death by ingesting Prilosec OTC in unsafe doses;
- (c) Failure to use reasonable care in testing and inspecting Prilosec OTC so as to ascertain whether or not it was safe for the purpose for which it was designed, manufactured and sold;
- (d) Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Prilosec OTC;

- (e) Failure to use reasonable care in the process of manufacturing 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-decedent and Plaintiff-decedent's physicians as to the danger and risks of using Prilosec OTC in unsafe doses; and
- (g) Such further acts and/or omissions that may be proven at trial.

98. 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-decedent.

99. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- (a) Manufacturing, producing, promoting, formulating, creating, and/or designing Prilosec OTC without thoroughly testing it;
- (b) Manufacturing, producing, promoting, formulating, creating, and/or designing Prilosec OTC without adequately testing it;
- (c) Not conducting sufficient testing programs to determine whether or not Prilosec OTC was safe for use; in that Defendants herein knew or should have known that Prilosec OTC was unsafe and unfit for use by reason of the dangers to its users;
- (d) Selling 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, Plaintiff-decedent, and the public, the medical and healthcare profession, and the FDA of the dangers of 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, Prilosec OTC;
- (g) Failing to test Prilosec OTC and/or failing to adequately, sufficiently and properly test Prilosec OTC.

- (h) Negligently advertising and recommending the use of Prilosec OTC without sufficient knowledge as to its dangerous propensities;
- (i) Negligently representing that Prilosec OTC was safe for use for its intended purpose, when, in fact, it was unsafe;
- (j) Negligently designing Prilosec OTC in a manner which was dangerous to its users;
- (k) Negligently manufacturing Prilosec OTC in a manner which was dangerous to its users;
- (l) Negligently producing Prilosec OTC in a manner which was dangerous to its users;
- (m) Negligently assembling Prilosec OTC in a manner which was dangerous to its users;
- (n) Concealing information from the Plaintiff and Plaintiff-decedent in knowing that Prilosec OTC was unsafe, dangerous, and/or non-conforming with FDA regulations.

100. Defendants under-reported, underestimated and downplayed the serious dangers of Prilosec OTC.

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

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

- (a) Failed to use due care in designing and manufacturing Prilosec OTC so as to avoid the aforementioned risks to individuals when Prilosec OTC was used for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

- (b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Prilosec OTC;
- (c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Prilosec OTC;
- (d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Prilosec OTC;
- (e) Failed to warn Plaintiff and Plaintiff-decedent of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
- (f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Prilosec OTC;
- (g) Failed to warn Plaintiff-decedent, prior to actively encouraging the sale of 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.

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

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

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

106. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, Acute Renal Failure and Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and sudden death.

107. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

108. By reason of the foregoing, Plaintiffs have 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)

109. 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.

110. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Prilosec OTC as hereinabove described that was used by the Plaintiff-decedent.

111. That 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.

112. At those times, Prilosec OTC was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff-decedent herein.

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

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

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

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

117. At the time of the Plaintiff-decedent's use of Prilosec OTC, 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.

118. Defendants with this knowledge voluntarily designed its Prilosec OTC in a dangerous condition for use by the public, and in particular the Plaintiff-decedent.

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

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

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

122. The 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' Prilosec OTC was manufactured.

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

124. The Plaintiff-decedent could not, by the exercise of reasonable care, have discovered Prilosec OTC's defects herein mentioned and perceived its danger.

125. 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, 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.

126. 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.

127. 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, kidney injuries, as well as other severe and permanent health consequences from 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, Prilosec OTC.

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

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

130. That said defects in Defendants' drug Prilosec OTC were a substantial factor in causing Plaintiff-decedent's injuries.

131. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, Acute Renal Failure and Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and sudden death.

132. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

133. By reason of the foregoing, Plaintiffs have 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)

134. 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.

135. Defendants expressly warranted that Prilosec OTC was safe and well accepted by users.

136. Prilosec OTC does not conform to these express representations because Prilosec OTC is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff-decedent suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

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

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

139. The Defendants herein breached the aforesaid express warranties, as their drug Prilosec OTC was defective.

140. Defendants expressly represented to Plaintiff-decedent's physicians, healthcare

providers, and/or the FDA that Prilosec OTC was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

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

142. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, Acute Renal Failure and Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and sudden death.

143. By reason of the foregoing, the Plaintiff-decedent has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff-decedent's use of Defendants' Prilosec OTC drug.

144. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

145. By reason of the foregoing, Plaintiffs have 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)

146. 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.

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

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

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

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

151. Plaintiff-decedent, 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.

152. Plaintiff-decedent and Plaintiff-decedent's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Prilosec

OTC was of merchantable quality and safe and fit for its intended use.

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

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

155. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, Acute Renal Failure and Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and sudden death.

156. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

157. By reason of the foregoing, Plaintiffs have 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)

158. 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.

159. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff-decedent, and/or the FDA, and the public in general, that said product, Prilosec OTC had been tested and was found to be safe and/or effective for treatment of

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

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

161. 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.

162. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff-decedent, 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, dispense and/or purchase said product, 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, depraved indifference to the health, safety and welfare of the Plaintiff-decedent herein.

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

164. In reliance upon said representations, the Plaintiff-decedent was induced to and did use 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.

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

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

167. Defendants brought Prilosec OTC to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff-decedent.

168. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, Acute Renal Failure and Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and sudden death.

169. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

170. By reason of the foregoing, Plaintiffs have 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)

171. 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.

172. At all times during the course of dealing between Defendants and Plaintiff-decedent, and/or Plaintiff-decedent's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Prilosec OTC for its intended use.

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

174. In representations to Plaintiff-decedent, and/or Plaintiff-decedent's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

- (a) that Prilosec OTC was not as safe as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;
- (b) that the risks of adverse events with 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 drug induced gastropathy;
- (c) that the risks of adverse events with Prilosec OTC were not adequately tested and/or known by Defendants;
- (d) that Defendants were aware of dangers in 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 Prilosec OTC was defective, and that it caused dangerous side effects, including but not limited to kidney injuries;
- (f) that patients needed to be monitored more regularly than normal while using Prilosec OTC;
- (g) that Prilosec OTC was manufactured negligently;
- (h) that Prilosec OTC was manufactured defectively;
- (i) that Prilosec OTC was manufactured improperly;
- (j) that Prilosec OTC was designed negligently;

(k) that Prilosec OTC was designed defectively; and

(l) that Prilosec OTC was designed improperly.

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

176. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Prilosec OTC, including the Plaintiff-decedent, in particular.

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

178. Defendants knew that Plaintiff-decedent, and Plaintiff-decedent's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Prilosec OTC, as set forth herein.

179. Plaintiff-decedent, as well as Plaintiff-decedent'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.

180. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, Acute Renal Failure and Chronic Kidney

Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and sudden death.

181. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

182. By reason of the foregoing, Plaintiffs have 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)

183. 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.

184. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff-decedent, the FDA and the public in general that said product, 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.

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

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

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

188. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, Acute Renal Failure and Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and sudden death.

189. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

190. By reason of the foregoing, Plaintiffs have 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)

191. 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.

192. Defendants conducted research and used Prilosec OTC as part of their research.

193. 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-decedent, Plaintiff-decedent's doctors, hospitals, healthcare professionals, and/or the FDA that Prilosec OTC 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.

194. 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-decedent.

195. 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-decedent, as well as Plaintiff-decedent's respective healthcare providers and/or the FDA.

196. The information distributed to the public, the FDA, and the Plaintiff-decedent 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.

197. The information distributed to the public, the FDA, and the Plaintiff-decedent by Defendants intentionally included representations that Defendants' drug Prilosec OTC was safe and effective for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

198. The information distributed to the public, the FDA, and the Plaintiff-decedent, by Defendants intentionally included representations that Defendants' drug 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.

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

200. The information distributed to the public, the FDA, and the Plaintiff-decedent, by Defendants intentionally included false representations that Prilosec OTC was as potentially injurious to the health and/or safety of its intended as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

201. These representations were all false and misleading.

202. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Prilosec OTC was not safe as a means of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

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

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

205. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff-decedent, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff-decedent, to falsely ensure the

quality and fitness for use of Prilosec OTC induce the public, and/or the Plaintiff-decedent to purchase, request, dispense, recommend, and/or continue to use Prilosec OTC.

206. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff-decedent that Prilosec OTC was fit and safe for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

207. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff-decedent that Prilosec OTC was fit and safe for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

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

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

210. 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.

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

212. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Prilosec OTC to the public at large, the Plaintiff-decedent 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.

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

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

215. 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-decedent, as well as Plaintiff-decedent's respective healthcare professionals would rely upon the information being disseminated.

216. Defendants utilized direct to consumer advertising to market, promote, and/or advertise Prilosec OTC.

217. That the Plaintiff-decedent and/or Plaintiff-decedent'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.

218. That at the time the representations were made, the Plaintiff-decedent and/or Plaintiff-decedent's respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Prilosec OTC.

219. That the Plaintiff-decedent 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-decedent with reasonable diligence have discovered the true facts.

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

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

222. As a result of the foregoing acts and omissions, the Plaintiff-decedent was caused to suffer serious and dangerous side effects including, Acute Renal Failure and Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, and sudden death.

223. As a result of the foregoing acts and omissions the Plaintiff-decedent did require more health care and services and did incur medical, health, incidental and related expenses.

224. By reason of the foregoing, Plaintiffs have 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
(WRONGFUL DEATH)

225. Plaintiffs repeat, reiterate and reallege 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.

226. As a result of the foregoing, on October 21, 2014 Plaintiff-decedent, Doris Ann Gilberti died from complications proximately related to the Defendants' Prilosec OTC.

227. Plaintiff-decedent, Doris Ann Gilberti, left heirs, next-of-kin and/or distributees surviving who, by reason of the Plaintiff-decedent's death have suffered a pecuniary and/or non-pecuniary loss including, but not limited to support, income, services and guidance of the Plaintiff-decedent, Doris Ann Gilberti, and were all permanently damaged thereby.

228. At all times herein mentioned, the actions of the named Defendants and their agents, servants, and/or employees, were wanton, grossly negligent, reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of the general public and to the decedent in particular.

229. As a result Plaintiff-decedent's estate has been damaged in the sum of TEN MILLION DOLLARS (\$10,000,000.00) and punitive damages.

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

230. 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.

231. 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.

232. 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 Prilosec OTC. Defendants communicated the purported benefits of Prilosec OTC while failing to disclose the serious and dangerous side effects related to the use of Prilosec OTC with the intent that consumers, including Plaintiff-decedent Doris Ann Gilberti, and Plaintiff-decedent's healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe Prilosec OTC, respectively.

233. As a result of violating the New Jersey Consumer Fraud Act, Defendants caused Plaintiff-decedent to use Prilosec OTC, causing severe injuries and damages as previously described herein.

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

234. 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.

235. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed Prilosec OTC, including the Prilosec OTC used by Plaintiff-decedent, Doris Ann Gilberti, was in a defective and unreasonably dangerous condition.

236. Defendants expected Prilosec OTC to reach, and it did in fact reach, Plaintiff-decedent without substantial change in the condition in which it was manufactured and sold by the Defendants.

237. At all times relevant hereto, Defendants' Prilosec OTC was 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-decedent.

238. At all times relevant to this action, 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, Prilosec OTC contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff-decedent to risks that exceeded the benefits of the drug;

- (b) When placed in the stream of commerce, Prilosec OTC was 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) Prilosec OTC was insufficiently tested;
- (d) Prilosec OTC caused harmful side effects that outweighed any potential utility;
- (e) Defendants were aware at the time Prilosec OTC was marketed that ingestion of Prilosec OTC would result in an increased risk of 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.

239. Prilosec OTC was defective, failed to perform safely, and was unreasonably dangerous when used by ordinary consumers, including Plaintiff-decedent, as intended and in a reasonably foreseeable manner.

240. 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 Prilosec OTC's design or formulation.

241. 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 and sudden death than other

proton-pump inhibitors and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

242. At all times relevant to this action, Defendants knew or had reason to know that Prilosec OTC was in a defective condition and was inherently dangerous and unsafe when used in the manner instructed, provided, and/or promoted by Defendants.

243. 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 Prilosec OTC was not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

244. When Defendants placed Prilosec OTC into the stream of commerce, they knew it would be used to treat peptic disorders, and they marketed and promoted Prilosec OTC as safe for treating peptic disorders.

245. Plaintiff-decedent was purchased, and used brand Prilosec OTC. Plaintiff-decedent used brand Prilosec OTC for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

246. Neither Plaintiff-decedent nor Plaintiff-decedent's health care professionals, by the exercise of reasonable care, could have discovered the defects and risks associated with Prilosec OTC before Plaintiff-decedent's ingestion of Prilosec OTC.

247. The harm caused by Prilosec OTC far outweighed its benefit, rendering Prilosec OTC more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed Prilosec OTC to make it less dangerous. When Defendants designed Prilosec OTC, the state of the industry's scientific knowledge was such that a less risky design was attainable.

248. At the time Prilosec OTC left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm Plaintiff-decedent suffered without substantially impairing the reasonably anticipated or intended function of 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.

249. Defendants' defective design of Prilosec OTC was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of 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 Prilosec OTC.

250. The defects in Prilosec OTC were substantial and contributing factors in causing Plaintiff-decedent's injuries. But for Defendants' acts and omissions, Plaintiff-decedent would not have suffered the injuries complained of herein.

251. Due to the unreasonably dangerous condition of Prilosec OTC, Defendants are liable to Plaintiff-decedent.

252. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of Prilosec OTC, including Plaintiff-decedent, with knowledge of the safety problems associated with 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.

253. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff-decedent suffered Acute Renal Failure and Chronic Kidney Disease, and other related health complications. In addition, Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff-decedent also has suffered

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-decedent's direct medical losses and costs include physician care, monitoring, and treatment.

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

254. 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.

255. Defendants have engaged in the business of designing, developing, researching, testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or distributing Prilosec OTC. Through that conduct, Defendants knowingly and intentionally placed Prilosec OTC into the stream of commerce with full knowledge that it reaches consumers, such as Plaintiff-decedent, Doris Ann Gilberti, who ingested it.

256. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released Prilosec OTC into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted Prilosec OTC to the FDA, health care professionals, Plaintiff-decedent, and other consumers, and therefore had a duty to warn of the risks associated with the use of Prilosec OTC.

257. Defendants expected Prilosec OTC to reach, and it did in fact reach, prescribing health care professionals and consumers, including Plaintiff-decedent and Plaintiff-decedent's prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

258. 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.

259. Prilosec OTC was 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-decedent. Prilosec OTC contained warnings insufficient to alert consumers, including Plaintiff-decedent, to the dangerous risks and reactions associated with Prilosec OTC, including the development of Plaintiff-decedent's injuries.

260. This defect caused serious injury and sudden death to Plaintiff-decedent, who used Prilosec OTC for its intended purpose and in a reasonably anticipated manner.

261. 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 Prilosec OTC did not cause users to suffer from unreasonable and dangerous risks.

262. Defendants negligently and recklessly labeled, distributed, and promoted Prilosec OTC.

263. Defendants had a continuing duty to warn Plaintiff-decedent of the dangers associated with Prilosec OTC.

264. Defendants, as manufacturers, sellers, or distributors of prescription drugs, are held to the knowledge of an expert in the field.

265. Plaintiff-decedent could not have discovered any defects in Prilosec OTC through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

266. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that 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 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 recommend the drug to their patients.

267. Prilosec OTC, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Plaintiff-decedent, in a reasonably and intended manner without knowledge of this risk of serious bodily harm.

268. Each of the Defendants knew or should have known that the limited warnings disseminated with 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 recommend 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.

269. 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 recommend 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 Prilosec OTC;
- (b) continued to aggressively promote 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 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 Prilosec OTC's capacity to cause its users to suffer Acute Renal Failure and Chronic Kidney Disease;
- (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 Prilosec OTC.

270. To this day, Defendants have failed to adequately and accurately warn of the true risks of injuries associated with the use of Prilosec OTC.

271. Due to these deficiencies and inadequacies, Prilosec OTC was unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants.

272. Had Defendants properly disclosed and disseminated the risks associated with Prilosec OTC, Plaintiff-decedent would have avoided the risk of developing injuries and sudden death as alleged herein.

273. The Defendants are liable to Plaintiff-decedent 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 Prilosec OTC and the risks associated with its use.

274. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff-decedent suffered Acute Renal Failure and Chronic Kidney Disease, and other related health complications. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff-decedent also has suffered 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-decedent's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff-decedent has incurred mental and physical pain and suffering.

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

275. 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.

276. 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 Prilosec OTC.

277. At all times material to this action, Prilosec OTC was expected to reach, and did reach, consumers in the States of Delaware, New Jersey, Massachusetts and throughout the United States, including Plaintiff-decedent, Doris Ann Gilberti, without substantial change in the condition in which it was sold.

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

- (a) When placed in the stream of commerce, 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.

279. As a direct and result of the design defect and Defendants' misconduct set forth herein, Plaintiff-decedent has suffered serious and permanent physical and emotional injuries,

sudden death, has expended large sums of money for medical care and treatment, has suffered economic loss, and have otherwise been physically, emotionally and economically injured.

FOURTEENTH 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.*)

280. 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.

281. Plaintiff Donna Gilberti and Plaintiff-decedent Doris Ann Gilberti are 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-decedent, concerning the safety profile, and, more specifically the serious side effects and/or complications associated with Prilosec OTC.

282. 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 Prilosec OTC, despite available information that Prilosec OTC was likely to cause serious side effects and/or complications.

283. 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 Prilosec OTC, despite available information that Prilosec OTC was likely to cause serious side effects and/or complications.

284. 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.

285. Defendants were or should have been in possession of evidence demonstrating that Prilosec OTC causes serious side effects. Nevertheless, Defendant continued to market Prilosec OTC by providing false and misleading information with regard to safety and efficacy.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff-decedent, 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 18, 2017

Respectfully submitted,

/s/ Dae Y. Lee

Dae Y. Lee (NJS Bar No. 033702012)

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Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

DATED: October 18, 2017

RESPECTFULLY SUBMITTED,

/s/ Dae Y. Lee

Dae Y. Lee

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

DONNA GILBERTI, on behalf of the Estate of DORIS ANN GILBERTI, Deceased, and DONNA GILBERTI, Individually

(b) County of Residence of First Listed Plaintiff Essex Co., MA (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) Bernstein Liebhard LLP 10 East 40th Street, New York, New York 10016 (212) 779-1414

DEFENDANTS

Procter & Gamble Manufacturing Company et al.

County of Residence of First Listed Defendant Hamilton Co., OH (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship and business location (Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country).

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

Large table with categories: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

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

- 1 Original Proceeding
2 Removed from State Court
3 Remanded from Appellate Court
4 Reinstated or Reopened
5 Transferred from Another District (specify)
6 Multidistrict Litigation - Transfer
8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. 1332(a)
Brief description of cause: Products Liability Litigation involving Proton Pump Inhibitors

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: X Yes [] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Claire C. Cecchi DOCKET NUMBER 1:17-md-2789

DATE 10/18/2017 SIGNATURE OF ATTORNEY OF RECORD /s/ Dae Y. Lee

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE