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9 **IN THE UNITED STATES DISTRICT COURT**
10 **IN AND FOR THE DISTRICT OF ARIZONA**

11 GERALDINE GRIFFIN,

12 Plaintiff,

13 v.

14 TAKEDA PHARMACEUTICALS
15 USA INC. (fka TAKEDA PHARMACEUTICALS
16 NORTH AMERICA, INC.); TAKEDA
17 PHARMACEUTICAL COMPANY LIMITED;
18 TAKEDA PHARMACEUTICALS
19 LLC; TAKEDA PHARMACEUTICALS
20 INTERNATIONAL, INC.; TAKEDA GLOBAL
21 RESEARCH DEVELOPMENT CENTER, INC.;
22 TAKEDA CALIFORNIA INC.
(fka TAKEDA SAN DIEGO, INC.);
23 ASTRAZENECA PHARMACEUTICALS LP; and
24 ASTRAZENECA LP,

25 Defendants.

Case No. 2:17-cv-99907

COMPLAINT AND
DEMAND FOR JURY TRIAL

26 Plaintiff, by Plaintiff's attorneys, **DOUGLAS & LONDON, P.C. and BURG**
27 **SIMPSON, ELDRIDGE, HERSH & JARDINE P.C.**, 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 Plaintiff exceeds \$75,000.00, exclusive of

1 interest and costs, and because Defendants are incorporated and have their principal
2 places of business in states other than the state in which the named Plaintiff resides.

3 **NATURE OF THE CASE**

4 2. This action is brought on behalf of Plaintiff, GERALDINE GRIFFIN, who
5 used prescription brand Prevacid and Nexium for treatment of Plaintiff's peptic disorder.

6 3. Plaintiff seeks compensatory damages as a result of Plaintiff's use of
7 Prevacid and Nexium, which has caused Plaintiff to suffer and continue to suffer from
8 Chronic Kidney Disease ("CKD"), as well as other severe and personal injuries which are
9 permanent and lasting in nature, physical pain and mental anguish, including diminished
10 enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or
11 medications, and fear of developing any of additional health consequences.

12 4. Defendants, Takeda Pharmaceuticals USA, Inc. (fka Takeda
13 Pharmaceuticals North America, Inc.); Takeda Pharmaceutical Company Limited; Takeda
14 Pharmaceuticals LLC.; Takeda Pharmaceuticals International Inc.; Takeda Global
15 Research & Development Center Inc. and Takeda California Inc. (fka Takeda San Diego
16 Inc.), (hereinafter collectively referred to as "Defendants") designed, researched,
17 manufactured, tested, advertised, promoted, marketed, sold, and distributed Prevacid.

18 5. Defendants, AstraZeneca Pharmaceuticals LP and AstraZeneca LP
19 (hereinafter collectively referred to as "Defendants") designed, researched, manufactured,
20 tested, advertised, promoted, marketed, sold, and distributed Nexium.

21 6. When warning of safety and risks of Prevacid and Nexium, Defendants
22 negligently represented to the medical and healthcare community, the Food and Drug
23 Administration (hereinafter referred to as the "FDA"), the Plaintiff's treating physicians,
24 and the public in general, that Prevacid and Nexium had been tested and were found to be
25 safe and/or effective for their indicated use in treating peptic disorders.

1 7. Defendants concealed their knowledge of Prevacid and Nexium's defects,
2 specifically the fact that it causes serious kidney injuries, from Plaintiff's treating
3 physicians, hospitals, pharmacies, the FDA, the public in general and/or the medical
4 community.

5 8. These representations were made by Defendants with the intent of
6 defrauding and deceiving the Plaintiff's physicians, the public in general, and the medical
7 and healthcare community in particular, and were made with the intent of inducing the
8 public in general, and the medical community in particular, to recommend, dispense
9 and/or purchase Prevacid and Nexium for the treatment of peptic disorders which include
10 gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-
11 inflammatory drug induced gastropathy, all of which evinced a callous, reckless, willful,
12 depraved indifference to health, safety and welfare of the Plaintiff herein.

13 9. As a result of the foregoing acts and omissions, the Plaintiff was and still is
14 caused to suffer serious and dangerous side effects including inter alia CKD, as well as
15 other severe and personal injuries which are permanent and lasting in nature, physical pain
16 and mental anguish, including diminished enjoyment of life, as well as the need for
17 lifelong medical treatment, monitoring and/or medications, and fear of developing any
18 additional health consequences.

19 10. Consequently, Plaintiff seeks compensatory damages as a result of
20 Plaintiff's use of Prevacid and Nexium, which has caused Plaintiff to suffer from CKD, as
21 well as other severe and personal injuries which are permanent and lasting in nature,
22 physical pain and mental anguish, including diminished enjoyment of life, as well as the
23 need for lifelong medical treatment, monitoring and/or medications, and fear of
24 developing any of the above named health consequences.

PARTIES

1
2 11. Plaintiff, GERALDINE GRIFFIN, is a citizen of the United States of
3 America, and is a resident of Peoria, Arizona (Maricopa County).

4 12. Plaintiff, GERALDINE GRIFFIN, first began using prescription brand
5 Prevacid in or about May 2006, and Plaintiff used prescription brand Prevacid up through
6 January 2009.

7 13. Plaintiff, GERALDINE GRIFFIN, first began using prescription brand
8 Nexium in or about April 2013, and Plaintiff used prescription brand Nexium up through
9 October 2016.

10 14. As result of Plaintiff's ingestion of Defendants' Prevacid and Nexium,
11 Plaintiff GERALDINE GRIFFIN has suffered and continues to suffer from CKD which
12 was diagnosed on or about August 12, 2014, as well as any and all of its sequelae and
13 attendant pain, suffering, and emotional distress.

14 15. The injuries and damages sustained by Plaintiff, GERALDINE GRIFFIN,
15 were caused by Defendants' Prevacid and Nexium and their unlawful conduct with
16 respect to their design, manufacture, marketing and sale.

17 16. Defendant Takeda Pharmaceuticals USA, Inc. is, and at all times relevant
18 to this action was, an Illinois corporation. Defendant Takeda Pharmaceuticals USA, Inc.
19 is the holder of approved New Drug Applications ("NDAs") 020406, 021428 and 021281
20 for Prevacid (lansoprazole), and it manufactures and markets Prevacid (lansoprazole) in
21 the United States.

22 17. Upon information and belief, Defendant Takeda Pharmaceuticals USA Inc.
23 is a Delaware corporation, having a principal place of business at One Takeda Parkway,
24 Deerfield, Illinois 60015. As part of its business, Takeda Pharmaceuticals USA, Inc. is
25 involved in the design, research, manufacture, test, advertise, promote, market, sell, and
26

1 distribute the drug Prevacid for use which primary purpose being a proton pump inhibitor.

2 18. Upon information and belief, Defendant, Takeda Pharmaceuticals USA, Inc.
3 has transacted and conducted business in the States of Illinois, South Carolina and
4 Arizona.

5 19. Upon information and belief, Defendant, Takeda Pharmaceuticals USA,
6 Inc., has derived substantial revenue from goods and products used in the States of
7 Illinois, South Carolina and Arizona.

8 20. Upon information and belief, Defendant, Takeda Pharmaceuticals USA,
9 Inc., expected or should have expected its acts to have consequence within Illinois and
10 Arizona, and derived substantial revenue from interstate commerce within the United
11 States, Illinois, South Carolina and Arizona.

12 21. Upon information and belief, Defendant Takeda Pharmaceutical Company
13 Limited is a Japanese corporation having a principal place of business at 1-1, Doshomachi
14 4-chome, Chuoku, Osaka, Japan and is the parent/holding company of Defendants Takeda
15 Pharmaceuticals International Inc., Takeda Pharmaceuticals USA, Inc., Takeda
16 Pharmaceuticals LLC, Takeda Global Research & Development Center Inc., and Takeda
17 California Inc.

18 22. Upon information and belief, and at all relevant times, Defendant Takeda
19 Pharmaceutical Company Limited exercised and exercises dominion and control over
20 Defendants Takeda Pharmaceuticals International Inc., Takeda Pharmaceuticals USA,
21 Inc., Takeda Pharmaceuticals LLC, Takeda Global Research & Development Center Inc.,
22 and Takeda California Inc.

23 23. Upon information and belief, Defendant, Takeda Pharmaceutical Company
24 Limited, has transacted and conducted business in the States of Illinois, South Carolina
25 and Arizona.

1 24. Upon information and belief, Defendant, Takeda Pharmaceutical Company
2 Limited has derived substantial revenue from goods and products used in the States of
3 Illinois, South Carolina and Arizona.

4 25. Upon information and belief, Defendant, Takeda Pharmaceutical Company
5 Limited expected or should have expected its acts to have consequence within the United
6 States of America, the State of Illinois and Arizona, and derived substantial revenue from
7 interstate commerce within the United States of America, Illinois, South Carolina and
8 Arizona.

9 26. Upon information and belief, and at all relevant times, Defendant, Takeda
10 Pharmaceutical Company Limited, was in the business of and did design, research,
11 manufacture, test, advertise, promote, market, sell, and distribute the drug Prevacid for use
12 which primary purpose is being a proton pump inhibitor.

13 27. Upon information and belief, Defendant Takeda Pharmaceuticals LLC. is a
14 Delaware limited liability company, having a principal place of business at One Takeda
15 Parkway, Deerfield, Illinois 60015.

16 28. Upon information and belief, Defendant, Takeda Pharmaceuticals, LLC is
17 an Illinois limited liability company owned by Takeda Pharmaceuticals America, Inc. and
18 Takeda Pharmaceuticals USA, Inc. is a Delaware corporation having a principal place of
19 business in Illinois, and is wholly owned by Takeda Pharmaceuticals USA, Inc. Takeda
20 Pharmaceuticals USA, Inc.

21 29. Upon information and belief, Defendant, Takeda Pharmaceuticals LLC. has
22 transacted and conducted business in the States of Illinois, South Carolina and Arizona.

23 30. Upon information and belief, Defendant, Takeda Pharmaceuticals LLC. has
24 derived substantial revenue from goods and products used in the State of Illinois, South
25 Carolina and Arizona.

1 31. Upon information and belief, Defendant, Takeda Pharmaceuticals LLC.
2 expected or should have expected its acts to have consequence within Illinois, South
3 Carolina and Arizona, and derived substantial revenue from interstate commerce within
4 the United States, Illinois, South Carolina and Arizona.

5 32. Upon information and belief, and at all relevant times, Defendant, Takeda
6 Pharmaceuticals LLC. was in the business of and did design, research, manufacture, test,
7 advertise, promote, market, sell, and distribute the drug Prevacid for use which primary
8 purpose is being a proton pump inhibitor.

9 33. Upon information and belief, Defendant Takeda Pharmaceuticals
10 International Inc. is a Delaware corporation, having a principal place of business at One
11 Takeda Parkway, Deerfield, IL 60015.

12 34. Upon information and belief, Defendant Takeda California, Inc. is a
13 Delaware Corporation, having a principal place of business in California.

14 35. Upon information and belief, Defendant Takeda California, Inc., has
15 transacted and conducted business in the States of California, South Carolina and Arizona

16 36. Upon information and belief, Defendant Takeda Global Research &
17 Development Center Inc. is a Delaware corporation, having a principal place of business
18 at One Takeda Parkway, Deerfield, IL 60015. As part of its business Takeda Global
19 Research & Development Center Inc. is involved in the research, development, sales and
20 marketing of pharmaceutical products including Prevacid.

21 37. Upon information and belief, Defendant, Takeda Global Research &
22 Development Center Inc. has transacted and conducted business in the States of Illinois,
23 South Carolina and Arizona.

24 38. Upon information and belief, each Defendant was the agent and employee of
25 each other Defendant, and in doing the things alleged was acting within the course and
26

1 scope of such agency and employment and with each other Defendant's actual and implied
2 permission, consent, authorization, and approval.

3 39. Defendant AstraZeneca Pharmaceuticals, LP is, and at all times relevant to
4 this action was, a limited partnership organized under the laws of the State of Delaware
5 with its headquarters and principal place of business located at 1800 Concord Pike,
6 Wilmington, Delaware.

7 40. AstraZeneca Pharmaceutical LP's general partner is AstraZeneca AB, a
8 corporation incorporated under the laws of the nation of Sweden with its principal place of
9 business in Sweden. AstraZeneca Pharmaceutical LP's sole limited partner is Zeneca
10 Inc., which is a corporation incorporated under the laws of the State of Delaware with its
11 principal place of business in Delaware.

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

15 42. Upon information and belief, at all relevant times, Defendant AstraZeneca
16 Pharmaceuticals, LP was present and doing business in the States of Delaware, South
17 Carolina and Arizona.

18 43. Upon information and belief, at all relevant times, Defendant AstraZeneca
19 Pharmaceuticals LP transacted, solicited, and conducted business in the States of
20 Delaware, South Carolina and Arizona and derived substantial revenue from such
21 business.

22 44. Upon information and belief, at all times relevant hereto, Defendant
23 AstraZeneca Pharmaceuticals, LP expected or should have expected that its acts would
24 have consequences within the United States of America, and the States of Delaware,
25 South Carolina and Arizona.

1 45. Defendant AstraZeneca LP is, and at all times relevant to this action
2 was, a limited partnership organized under the laws of the State of Delaware with its
3 headquarters and principal place of business located at 1800 Concord Pike, Wilmington,
4 Delaware.

5 46. Defendant AstraZeneca LP's sole general partner is AstraZeneca
6 Pharmaceuticals LP. Defendant AstraZeneca LP has no limited partners. AstraZeneca
7 Pharmaceutical LP's general partner is AstraZeneca AB, a corporation incorporated under
8 the laws of the nation of Sweden with its principal place of business in Sweden.
9 AstraZeneca Pharmaceutical LP's sole limited partner is Zeneca Inc., a corporation
10 incorporated under the laws of the State of Delaware with its principal place of business in
11 Delaware.

12 47. Defendant AstraZeneca LP is the holder of approved New Drug
13 Applications ("NDAs") 21-153 and 21-154 for Nexium (Esomeprazole Magnesium), and
14 it manufactures and markets Nexium (Esomeprazole Magnesium) in the United States.

15 48. Upon information and belief, at all times relevant hereto Defendant
16 AstraZeneca LP was engaged in the business of designing, developing, manufacturing,
17 testing, packaging, promoting, marketing, distributing, labeling and/or selling Nexium
18 products.

19 49. Upon information and belief, at all relevant times, Defendant AstraZeneca
20 LP was present and doing business in the States of Delaware, South Carolina and Arizona.

21 50. Upon information and belief, at all relevant times, Defendant AstraZeneca
22 LP transacted, solicited, and conducted business in the States of Delaware, South
23 Carolina and Arizona, and derived substantial revenue from such business.

24 51. Upon information and belief, at all times relevant hereto, Defendant
25 AstraZeneca LP expected or should have expected that its acts would have consequences
26

1 within the United States of America, and the States of Delaware, South Carolina and
2 Arizona.

3 52. Upon information and belief, each AstraZeneca Defendant was the agent
4 and employee of each other AstraZeneca Defendant, and in doing the things alleged was
5 acting within the course and scope of such agency and employment and with each other
6 AstraZeneca Defendant's actual and implied permission, consent, authorization, and
7 approval.

8 **FACTUAL BACKGROUND**

9 53. This action seeks, among other relief, general and special damages and
10 equitable relief due to Plaintiff GERALDINE GRIFFIN suffering CKD caused by
11 Plaintiff's ingestion of the proton pump inhibitors, Prevacid and Nexium.

12 54. Takeda sold Prevacid with National Drug Code (NDC) numbers 64764-
13 046 and 64764-046-13.

14 55. At all times Defendants were responsible for, or involved in, designing,
15 manufacturing, marketing, advertising, distributing and/or selling Prevacid.

16 56. In 1998, the United States Food and Drug Administration approved Takeda
17 Pharmaceuticals' compound Lansoprazole for various uses, including the treatment of
18 heartburn, acid reflux, ulcers and inflammation of the esophagus. Lansoprazole is
19 marketed by Takeda Pharmaceuticals as Prevacid.

20 57. Prevacid is also used to treat and prevent stomach and intestinal ulcers,
21 erosive [esophagitis](#) (damage to the esophagus from stomach acid), and other conditions
22 involving excessive stomach acid such as [Zollinger-Ellison syndrome](#).

23 58. In 2002, Takeda's sales of Prevacid exceeded \$2.9 billion dollars. When
24 ranked by total expenditures in 2004, for adults age 18-64, Prevacid ranked third with \$2.67

1 billion in sales. In 2005, Prevacid was the nation's fourth-best-selling brand name prescription
2 in the United States. In 2006 sales of Prevacid exceeded \$5.7 billion dollars.

3 59. Upon information and belief, the AstraZeneca Defendants began marketing
4 and selling prescription brand Nexium in 2001.

5 60. Plaintiff began taking prescription brand Nexium in or about April 2013.

6 61. At all relevant times, Defendants heavily marketed Nexium and to treat
7 peptic disorders, including but not limited to gastroesophageal reflux disease (GERD),
8 peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

9 62. Defendants' marketing of Nexium and included advertisements, press
10 releases, web site publications, sales representative pitches and other communications.

11 63. Materials including advertisements, press releases, webs site publications
12 and other communications regarding Nexium are part of the labeling of the drug and could
13 be altered by Defendants without prior FDA approval.

14 64. Proton pump inhibitors ("PPIs"), including Defendants' Nexium, are one of
15 the most commonly prescribed medications in the United States.

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

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

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

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

24 69. The AstraZeneca Defendants sold Nexium with National Drug Code
25 (NDC) numbers 00186-5020; 00186-5022; 00186-5040; 00186-5042; 0186-4010; 0186-

1 4020 and 00186-4040.

2 70. Nexium (Esomeprazole Magnesium), is a PPI that works by reducing
3 hydrochloric acid in the stomach.

4 71. During the period in which Nexium has been sold in the United States,
5 hundreds of reports of injuries, including kidney injuries, have been submitted to the
6 FDA in association with ingestion of Nexium and other PPIs.

7 72. Defendants have had notice of serious adverse health outcomes regarding
8 kidney disease associated with their Nexium through case reports, clinical studies and
9 post-market surveillance.

10 73. Specifically, Defendants had received numerous case reports of kidney
11 injuries in patients that had ingested Nexium as early as 2001. As such, these reports of
12 numerous kidney injuries put Defendants on notice as to the excessive risks of kidney
13 injuries related to the use of Nexium.

14 74. Defendants concealed and continue to conceal their knowledge of Prevacid
15 and Nexium 's lack of long-term benefits from Plaintiff, other consumers and the medical
16 community. Defendants failed to conduct adequate and sufficient post-marketing
17 surveillance of Prevacid and Nexium after they began marketing, advertising, distributing
18 and selling the drug.

19 75. As a result of Defendants' action and inactions, Plaintiff was injured due to
20 Plaintiff's ingestion of Prevacid and Nexium, which caused and will continue to cause
21 Plaintiff various injuries and damages.

22 76. Consumers, including the Plaintiff, who has used Prevacid and Nexium for
23 treatment of acid reflux, have several alternative safer products available to treat the
24 conditions and have not been adequately warned about the significant risks and lack of
25 benefits associated with long-term Prevacid and Nexium therapy.

1 77. Defendants knew of the significant risk of kidney damage that could result
2 from long-term Prevacid and Nexium use, but Defendants did not adequately and
3 sufficiently warn consumers, including Plaintiff, Plaintiff's physician or the medical
4 community in a timely manner.

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

8 79. During the period in which Prevacid and Nexium have been sold in the
9 United States, hundreds of reports of injury have been submitted to the FDA in association
10 with ingestion of PPIs. Defendants have had notice of serious adverse health outcomes
11 through case reports, clinical studies and post-market surveillance.

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

15 81. Since the introduction of PPIs to the US market in 1989, several
16 observational studies have linked PPI use to serious adverse health outcomes, including hip
17 fracture, community acquired pneumonia, Clostridium difficile infection, acute interstitial
18 nephritis and acute kidney injury ("AKI"). A study from 2015 shows that acute kidney
19 injuries increased 250% in elderly patients that were newly prescribed PPIs. The acute
20 kidney injuries occurred within 120 days of the patients starting the PPIs.

21 82. Recent studies have shown the long term use of PPIs was independently
22 associated with a 20% to 50% higher risk of incident Chronic Kidney Disease ("CKD"),
23 after adjusting for several potential confounding variables, including demographics,
24 socioeconomic status, clinical measurements, prevalent comorbidities, and concomitant
25 use of medications. In one of those studies, the use of PPIs for any period of time was

1 shown to increase the risk of CKD by 10%.

2 83. CKD, describes the gradual loss of kidney function. Kidneys filter wastes
3 and excess fluids from the blood, which are then excreted. When chronic kidney disease
4 reaches an advanced stage, dangerous levels of fluid, electrolytes and wastes can build up
5 in the body.

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

8 85. Treatment for CKD focuses on slowing the progression of the kidney
9 damage, usually by attempting to control the underlying cause. CKD can progress to
10 end-stage kidney failure, which is fatal without artificial filtering, dialysis or a kidney
11 transplant. Early treatment is often key to avoiding the most negative outcomes.

12 86. CKD is associated with a substantially increased risk of death and
13 cardiovascular
14 events.

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

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

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

25 90. Alternatives to PPIs are and were available that provide the same benefits
26
27

1 but act through a different mechanism.

2 91. One alternative is H2 antagonists, also called H2 blockers, a class of
3 medications that block the action of histamine at the histamine H2 receptors of the parietal
4 cells in the stomach.

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

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

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

14 95. Defendants failed to adequately warn against the negative effects and risks
15 associated with Prevacid and Nexium. Defendants have totally failed to provide any
16 warnings regarding CKD.

17 96. In omitting, concealing, and inadequately providing critical safety
18 information regarding the use of Prevacid and Nexium in order to induce their purchase
19 and use, Defendants engaged in and continue to engage in conduct likely to mislead
20 consumers including Plaintiff. This conduct is fraudulent, unfair, and unlawful.

21 97. Defendants knew or should have known about the correlation between the
22 use of Prevacid and Nexium and the significantly increased risk of CKD and acute kidney
23 injuries.

24 98. Despite clear knowledge that Prevacid and Nexium cause a significantly
25 increased risk of CKD and acute kidney injuries, Defendants continued to market and sell
26

1 Prevacid and Nexium without warning consumers or healthcare providers of the significant
2 risks of CKD and acute kidney injuries.

3 99. As a result of Defendants' action and inactions as outlined herein, Plaintiff
4 was injured due to Plaintiff's ingestion of Prevacid and Nexium, which caused Plaintiff
5 and continues to cause Plaintiff to suffer from CKD and any and all of its sequelae.

6 100. Prior to Summer 2016, Plaintiff GERALDINE GRIFFIN did not know
7 about the causal link between Plaintiff's CKD and ingestion of Defendants' Prevacid and
8 Nexium.

9 101. It was not until about Summer 2016 that Plaintiff GERALDINE GRIFFIN
10 first learned of the possible causal link.

11 102. Prior to Summer 2016, Plaintiff did not have access to or actually receive
12 any studies or information recognizing the increased risk of CKD associated with
13 Prevacid and Nexium use.

14 **COUNT I**
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

15 103. Plaintiff repeats, reiterates and realleges each and every allegation of this
16 Complaint contained in each of the foregoing paragraphs inclusive, with the same force
17 and effect as if more fully set forth herein.

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

23 105. Defendants failed to exercise ordinary care in the designing, researching,
24 manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality
25

1 assurance, quality control, and/or distribution of Prevacid and Nexium into interstate
2 commerce in that Defendants knew or should have known that using Prevacid and
3 Nexium could proximately cause Plaintiff's injuries. Specifically, Defendants failed to
4 meet their duty to use reasonable care in the testing, creating, designing, manufacturing,
5 labeling, packaging, marketing, selling, and warning of Prevacid and Nexium. Defendants
6 are liable for acts and/or omissions amounting to negligence, gross negligence and/or
7 malice including, but not limited to the following:

- 8 (a) Failure to adequately warn Plaintiff and Plaintiff's
9 physicians of the known or reasonably foreseeable danger
10 that plaintiff would suffer a serious injury or death by
11 ingesting Prevacid and Nexium;
- 12 (b) Failure to adequately warn Plaintiff and Plaintiff's
13 physicians of the known or reasonably foreseeable danger
14 that Plaintiff would suffer a serious injury or death by
15 ingesting Prevacid and Nexium in unsafe doses;
- 16 (c) Failure to use reasonable care in testing and inspecting
17 Prevacid and Nexium so as to ascertain whether or not it was
18 safe for the purpose for which it was designed, manufactured
19 and sold;
- 20 (d) Failure to use reasonable care in implementing and/or
21 utilizing a reasonably safe design in the manufacture of
22 Prevacid and Nexium;
- 23 (e) Failure to use reasonable care in the process of
24 manufacturing Prevacid and Nexium in a reasonably safe
25 condition for the use for which it was intended;
- 26 (f) Failure to use reasonable care in the manner and method of
27 warning Plaintiff and Plaintiff's physicians as to the danger
and risks of using Prevacid and Nexium in unsafe doses; and
- (g) Such further acts and/or omissions that may be proven at trial.

106. 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.

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

- 3 (a) Manufacturing, producing, promoting, formulating, creating,
4 and/or designing Prevacid and Nexium without thoroughly
5 testing it;
- 6 (b) Manufacturing, producing, promoting, formulating, creating,
7 and/or designing Prevacid and Nexium without adequately
8 testing them;
- 9 (c) Not conducting sufficient testing programs to determine
10 whether or not Prevacid and Nexium was safe for use; in that
11 Defendants herein knew or should have known that Prevacid
12 and Nexium were unsafe and unfit for use by reason of the
13 dangers to their users;
- 14 (d) Selling Prevacid and Nexium without making proper and
15 sufficient tests to determine the dangers to their users;
- 16 (e) Negligently failing to adequately and correctly warn the
17 Plaintiff, the public, the medical and healthcare profession,
18 and the FDA of the dangers of Prevacid and Nexium;
- 19 (f) Failing to provide adequate instructions regarding safety
20 precautions to be observed by users, handlers, and persons
21 who would reasonably and foreseeably come into contact
22 with, and more particularly, use, Prevacid and Nexium;
- 23 (g) Failing to test Prevacid and Nexium and/or failing to
24 adequately, sufficiently and properly test Prevacid and
25 Nexium.
- 26 (h) Negligently advertising and recommending the use of
27 Prevacid and Nexium without sufficient knowledge as to
their dangerous propensities;
- (i) Negligently representing that Prevacid and Nexium were
safe for use for their intended purpose, when, in fact, it was
unsafe;
- (j) Negligently designing Prevacid and Nexium in a manner
which was dangerous to their users;
- (k) Negligently manufacturing Prevacid and Nexium in a
manner which was dangerous to their users;
- (l) Negligently producing Prevacid and Nexium in a manner
which was dangerous to their users;

1 (m) Negligently assembling Prevacid and Nexium in a manner
2 which was dangerous to their users;

3 (n) Concealing information from the Plaintiff in knowing that
4 Prevacid and Nexium were unsafe, dangerous, and/or non-
5 conforming with FDA regulations.

6 108. Defendants under-reported, underestimated and downplayed the serious
7 dangers of Prevacid and Nexium.

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

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

15 (a) Failed to use due care in designing and manufacturing
16 Prevacid and Nexium so as to avoid the aforementioned
17 risks to individuals when Prevacid and Nexium were used
18 for treatment of peptic disorders which include
19 gastroesophageal reflux disease (GERD), peptic ulcer
20 disease, and nonsteroidal anti-inflammatory drug induced
21 gastropathy;

22 (b) Failed to accompany their product with proper and/or
23 accurate warnings regarding all possible adverse side effects
24 associated with the use of Prevacid and Nexium;

25 (c) Failed to accompany their product with proper warnings
26 regarding all possible adverse side effects concerning the
27 failure and/or malfunction of Prevacid and Nexium;

(d) Failed to accompany their product with accurate warnings
regarding the risks of all possible adverse side effects
concerning Prevacid and Nexium;

(e) Failed to warn Plaintiff of the severity and duration of such
adverse effects, as the warnings given did not accurately
reflect the symptoms, or severity of the side effects;

- 1 (f) Failed to conduct adequate testing, including pre-clinical and
2 clinical testing and post-marketing surveillance to determine
3 the safety of Prevacid and Nexium;
- 4 (g) Failed to warn Plaintiff, prior to actively encouraging the
5 sale of Prevacid and Nexium, either directly or indirectly,
6 orally or in writing, about the need for more comprehensive,
7 more regular medical monitoring than usual to ensure early
8 discovery of potentially serious side effects;
- 9 (h) Were otherwise careless and/or negligent.

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

14 112. Defendants knew or should have known that consumers such as the
15 Plaintiff, GERALDINE GRIFFIN, would foreseeably suffer injury as a result of
16 Defendants' failure to exercise ordinary care, as set forth above.

17 113. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm
18 and economic loss which Plaintiff, GERALDINE GRIFFIN suffered and/or will continue
19 to suffer.

20 114. As a result of the foregoing acts and omissions, the Plaintiff was caused to
21 suffer serious and dangerous side effects including, CKD, as well as other severe and
22 personal injuries which are permanent and lasting in nature, physical pain and mental
23 anguish, including diminished enjoyment of life, as well as the need for lifelong medical
24 treatment, monitoring and/or medications.

25 115. As a result of the foregoing acts and omissions the Plaintiff requires and/or
26 will require more health care and services and did incur medical, health, incidental and
27 related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will

1 in the future be required to obtain further medical and/or hospital care, attention, and
2 services.

3 **COUNT II**
4 **AS AGAINST THE DEFENDANTS**
5 **(STRICT PRODUCTS LIABILITY)**

6 116. Plaintiff repeats, reiterates and realleges each and every allegation of this
7 Complaint contained in each of the foregoing paragraphs inclusive, with the same force
8 and effect as if more fully set forth herein.

9 117. At all times herein mentioned, the Defendants designed, researched,
10 manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have
11 recently acquired the Defendants who have designed, researched, manufactured, tested,
12 advertised, promoted, marketed, sold and distributed Prevacid and Nexium as hereinabove
13 described that was used by the Plaintiff.

14 118. That Prevacid and Nexium was expected to and did reach the usual
15 consumers, handlers, and persons coming into contact with said product without sub-
16 stantial change in the condition in which it was produced, manufactured, sold, distributed,
17 and marketed by the Defendants.

18 119. At those times, Prevacid and Nexium was in an unsafe, defective, and
19 inherently dangerous condition, which was dangerous to users, and in particular, the
20 Plaintiff herein.

21 120. The Prevacid and Nexium designed, researched, manufactured, tested,
22 advertised, promoted, marketed, sold and distributed by Defendants was defective in
23 design or formulation in that, when it left the hands of the manufacturer and/or suppliers,
24 the foreseeable risks exceeded the benefits associated with the design or formulation of
25 Prevacid and Nexium.

1 121. The Prevacid and Nexium designed, researched, manufactured, tested,
2 advertised, promoted, marketed, sold and distributed by Defendants was defective in
3 design and/or formulation, in that, when it left the hands of the Defendants manufacturers
4 and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an
5 ordinary consumer would expect.

6 122. At all times herein mentioned, Prevacid and Nexium were in a defective
7 condition and unsafe, and Defendants knew or had reason to know that said product was
8 defective and unsafe, especially when used in the form and manner as provided by the
9 Defendants.

10 123. Defendants knew, or should have known that at all times herein mentioned
11 its Prevacid and Nexium were in a defective condition, and was and is inherently
12 dangerous and unsafe.

13 124. At the time of the Plaintiff's use of Prevacid and Nexium, Prevacid and
14 Nexium were being used for the purposes and in a manner normally intended for the
15 treatment of peptic disorders which include gastroesophageal reflux disease (GERD),
16 peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

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

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

21 127. Defendants created a product unreasonably dangerous for its normal,
22 intended use.

23 128. The Prevacid and Nexium designed, researched, manufactured, tested,
24 advertised, promoted, marketed, sold and distributed by Defendants was manufactured
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1 defectively in that Prevacid and Nexium left the hands of Defendants in a defective
2 condition and was unreasonably dangerous to their intended users.

3 129. The Prevacid and Nexium designed, researched, manufactured, tested,
4 advertised, promoted, marketed, sold and distributed by Defendants reached their intended
5 users in the same defective and unreasonably dangerous condition in which the
6 Defendants' Prevacid and Nexium were manufactured.

7 130. Defendants designed, researched, manufactured, tested, advertised,
8 promoted, marketed, sold and distributed a defective product which created an
9 unreasonable risk to the health of consumers and to the Plaintiff in particular, and
10 Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

11 131. The Plaintiff could not, by the exercise of reasonable care, have discovered
12 Prevacid and Nexium's defects herein mentioned and perceived their danger.

13 132. Prevacid and Nexium were designed, researched, manufactured, tested,
14 advertised, promoted, marketed, sold and distributed by Defendants was defective due to
15 inadequate warnings or instructions as the Defendants knew or should have known that
16 the product created a risk of serious and dangerous side effects including, kidney injuries,
17 as well as other severe and personal injuries which are permanent and lasting in nature
18 and the Defendants failed to adequately warn of said risk.

19 133. Prevacid and Nexium were designed, researched, manufactured, tested,
20 advertised, promoted, marketed, sold and distributed by Defendants was defective due to
21 inadequate warnings and/or inadequate testing.

22 134. Prevacid and Nexium were designed, researched, manufactured, tested,
23 advertised, promoted, marketed, sold and distributed by Defendants was defective due to
24 inadequate post-marketing surveillance and/or warnings because, after Defendants knew
25 or should have known of the risks of serious side effects including, kidney injuries, as
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1 well as other severe and permanent health consequences from Prevacid and Nexium, they
2 failed to provide adequate warnings to users or consumers of the product, and continued
3 to improperly advertise, market and/or promote their product, Prevacid and Nexium.

4 135. By reason of the foregoing, the Defendants have become strictly liable in
5 tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling
6 of a defective product, Prevacid and Nexium.

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

10 137. That said defects in Defendants' drugs Prevacid and Nexium were
11 substantial factors in causing Plaintiff's injuries.

12 138. As a result of the foregoing acts and omissions, the Plaintiff was caused to
13 suffer serious and dangerous side effects including, kidney injuries, as well as other severe
14 and personal injuries which are permanent and lasting in nature, physical pain and mental
15 anguish, including diminished enjoyment of life, as well as the need for lifelong medical
16 treatment, monitoring and/or medications.

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

22 **COUNT III**
(MANUFACTURING DEFECT)

23 140. Plaintiffs repeat, reiterate and re-allege each and every allegation of this
24 Complaint contained in each of the foregoing paragraphs inclusive, with the same force
25 and effect as if more fully set forth herein.

1 141. Prevacid and Nexium was designed, manufactured, marketed, promoted,
2 sold, and introduced into the stream of commerce by Defendants.

3 142. When it left the control of Defendants, Prevacid and Nexium was expected
4 to, and did reach Plaintiff GERALDINE GRIFFIN without substantial change from the
5 condition in which it left Defendants' control.

6 143. Prevacid Nexium was defective when it left Defendants' control and was
7 placed in the stream of commerce, in that there were foreseeable risks that exceeded the
8 benefits of the product and/or that it deviated from product specifications and/or
9 applicable federal requirements, and posed a risk of serious injury and death.

10 144. Prevacid and Nexium was more likely to cause serious and dangerous side
11 effects including, kidney injuries, as well as other severe and personal injuries than other
12 PPI's.

13 145. Plaintiff GERALDINE GRIFFIN used Prevacid and Nexium in
14 substantially the same condition it was in when it left the control of Defendants and any
15 changes or modifications were foreseeable by Defendants.

16 146. Plaintiff and her healthcare providers did not misuse or materially alter her
17 Prevacid and Nexium.

18 147. As a direct and proximate result of the use of Prevacid and Nexium, Plaintiff
19 GERALDINE GRIFFIN suffered serious physical injury, harm, damages and economic
20 loss, and will continue to suffer such harm, damages and economic loss in the future.

21 **COUNT IV**
22 **(DESIGN DEFECT)**

23 148. Plaintiffs repeat, reiterate and re-allege each and every allegation of this
24 Complaint contained in each of the foregoing paragraphs inclusive, with the same force
25 and effect as if more fully set forth herein.
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1 149. Prevacid and Nexium was not merchantable and/or reasonably suited to the
2 use intended, and its condition when sold was the proximate cause of the injuries
3 sustained by Plaintiff.

4 150. Defendants placed Prevacid and Nexium into the stream of commerce with
5 wanton and reckless disregard for public safety.

6 151. Prevacid and Nexium was in an unsafe, defective, and inherently dangerous
7 condition.

8 152. Prevacid and Nexium contains defects in its design which render the drug
9 dangerous to consumers, such as Plaintiff GERALDINE GRIFFIN, when used as
10 intended or as reasonably foreseeable to Defendants. The design defects render Prevacid
11 and Nexium more dangerous than other PPI's and cause an unreasonable increased risk
12 of injury, including but not limited to serious and dangerous side effects including, kidney
13 injuries, as well as other severe and personal injuries.

14 153. Prevacid and Nexium was in a defective condition and unsafe, and
15 Defendants knew, had reason to know, or should have known that Prevacid and Nexium
16 was defective and unsafe, even when used as instructed.

17 154. The nature and magnitude of the risk of harm associated with the design of
18 Prevacid and Nexium, including the risk of serious and dangerous side effects including,
19 kidney injuries, as well as other severe and personal injuries is high in light of the
20 intended and reasonably foreseeable use of Prevacid and Nexium.

21 155. The risks of harm associated with the design of Prevacid and Nexium are
22 higher than necessary.

23 156. It is highly unlikely that Prevacid and Nexium users would be aware of the
24 risks associated with Prevacid and Nexium through either warnings, general knowledge or
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1 otherwise, and Plaintiff GERALDINE GRIFFIN was not aware of these design defects,
2 nor would she expect them.

3 157. The design did not conform to any applicable public or private product
4 standard that was in effect when Prevacid and Nexium left the Defendants' control.

5 158. Prevacid and Nexium's design is more dangerous than a reasonably prudent
6 consumer would expect when used in its intended or reasonably foreseeable manner. It
7 was more dangerous than Plaintiff expected.

8 159. The intended or actual utility of Prevacid and Nexium is not of such benefit
9 to justify the risk of serious and dangerous side effects including, kidney injuries, as well
10 as other severe and personal injuries.

11 160. At the time Prevacid and Nexium left Defendants' control, it was both
12 technically and economically feasible to have an alternative design that would not cause
13 serious and dangerous side effects including, kidney injuries, as well as other severe and
14 personal injuries or an alternative design that would have substantially reduced the risk of
15 these injuries.

16 161. It was both technically and economically feasible to provide a safer
17 alternative product that would have prevented the harm suffered by Plaintiff.

18 162. Defendants' conduct was extreme and outrageous. Defendants risked the
19 lives of consumers and users of their products, including Plaintiff, with the knowledge of
20 the safety and efficacy problems and suppressed this knowledge from the general public.
21 Defendants made conscious decisions not to redesign, re-label, warn or inform the
22 unsuspecting consuming public and medical community. Defendants' outrageous conduct
23 warrants an award of punitive damages.

24 163. The unreasonably dangerous nature of Prevacid and Nexium caused serious
25 harm to Plaintiff, GERALDINE GRIFFIN.

1 170. When it left Defendants' control, Prevacid and Nexium was defective and
2 unreasonably dangerous for failing to warn of the risk of serious and dangerous side
3 effects including, kidney injuries, as well as other severe and personal injuries.

4 171. Plaintiff used Prevacid and Nexium for its approved purpose and in a
5 manner normally intended and reasonably foreseeable by the Defendants.

6 172. Plaintiff and Plaintiff's healthcare providers could not, by the exercise of
7 reasonable care, have discovered the defects or perceived their danger because the risks
8 were not open or obvious.

9 173. Defendants, as the manufacturers and distributors of Prevacid and Nexium,
10 are held to the level of knowledge of an expert in the field.

11 174. As alleged herein, the warnings that were given by Defendants were not
12 accurate or clear, and were false and ambiguous.

13 175. The warnings that were given by the Defendants failed to properly warn
14 patients and physicians of the risks associated with Prevacid and Nexium, subjecting
15 Plaintiff GERALDINE GRIFFIN to risks that exceeded the benefits to the Plaintiff.
16 Plaintiff, individually and through his physicians, reasonably relied upon the skill,
17 superior knowledge and judgment of the Defendants.

18 176. Defendants had a continuing duty to warn Plaintiff and his prescriber of the
19 dangers associated with its product.

20 177. Had Plaintiff or her healthcare providers received adequate warnings
21 regarding the risks associated with the use of Prevacid and Nexium, they would not have
22 used it.

23 178. The Plaintiff GERALDINE GRIFFIN'S injuries were the direct and
24 proximate result of Defendants' failure to warn of the dangers of Prevacid and Nexium.

1 179. Defendants' conduct, as described above, was extreme and outrageous.
2 Defendants risked the lives of consumers and users of their products, including Plaintiff,
3 with knowledge of the safety and efficacy problems and suppressed this knowledge from
4 the general public. Defendants made conscious decisions not to redesign, re-label, warn
5 or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants
6 an award of punitive damages

7 **COUNT VI**
8 **AS AGAINST THE DEFENDANTS**
9 **(BREACH OF EXPRESS WARRANTY)**

10 180. Plaintiff repeats, reiterates and realleges each and every allegation of this
11 Complaint contained in each of the foregoing paragraphs inclusive, with the same force
12 and effect as if more fully set forth herein.

13 181. Defendants expressly warranted that Prevacid and Nexium were safe and
14 well accepted by users.

15 182. Prevacid and Nexium do not conform to these express representations
16 because Prevacid and Nexium are not safe and have numerous serious side effects, many
17 of which were not accurately warned about by Defendants. As a direct and proximate
18 result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer
19 severe and permanent personal injuries, harm and economic loss.

20 183. Plaintiff did rely on the express warranties of the Defendants herein.

21 184. Members of the medical community, including physicians and other
22 healthcare professionals, relied upon the representations and warranties of the Defendants
23 for use of Prevacid and Nexium in recommending, prescribing, and/or dispensing
24 Prevacid and Nexium.

25 185. The Defendants herein breached the aforesaid express warranties, as their
26 drug Prevacid and Nexium were defective.
27

1 186. Defendants expressly represented to Plaintiff's physicians, healthcare
2 providers, and/or the FDA that Prevacid and Nexium were safe and fit for use for the
3 purposes intended, that it was of merchantable quality, that it did not produce any
4 dangerous side effects in excess of those risks associated with other forms for treatment of
5 peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer
6 disease, and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects
7 it did produce were accurately reflected in the warnings and that it was adequately tested
8 and fit for its intended use.

9 187. Defendants knew or should have known that, in fact, said representations
10 and warranties were false, misleading and untrue in that Prevacid and Nexium were not
11 safe and fit for the use intended, and, in fact, produced serious injuries to the users that
12 were not accurately identified and represented by Defendants.

13 188. As a result of the foregoing acts and omissions, the Plaintiff was caused to
14 suffer serious and dangerous side effects including, CKD, as well as other severe and
15 personal injuries which are permanent and lasting in nature, physical pain and mental
16 anguish, including diminished enjoyment of life, as well as the need for lifelong medical
17 treatment, monitoring and/or medications.

18 189. By reason of the foregoing, Plaintiff has been severely and permanently
19 injured, and will require more constant and continuous medical monitoring and treatment
20 than prior to Plaintiff's use of Defendants' Prevacid and Nexium drugs.

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

COUNT VII
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

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3 191. Plaintiff repeats, reiterates and realleges each and every allegation of this
4 Complaint contained in each of the foregoing paragraphs inclusive, with the same force
5 and effect as if more fully set forth herein.

6 192. At all times herein mentioned, the Defendants manufactured, compounded,
7 portrayed, distributed, recommended, merchandized, advertised, promoted and sold
8 Prevacid and Nexium and/or have recently acquired the Defendants who have
9 manufactured, compounded, portrayed, distributed, recommended, merchandized,
10 advertised, promoted and sold Prevacid and Nexium for the treatment of peptic disorders
11 which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and
12 nonsteroidal anti-inflammatory drug induced gastropathy.

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

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

21 195. That said representations and warranties aforementioned were false,
22 misleading, and inaccurate in that Prevacid and Nexium were unsafe, unreasonably
23 dangerous, improper, not of merchantable quality, and defective.

1 196. Plaintiff, and/or members of the medical community and/or healthcare
2 professionals did rely on said implied warranty of merchantability of fitness for a
3 particular use and purpose.

4 197. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably
5 relied upon the skill and judgment of Defendants as to whether Prevacid and Nexium were
6 of merchantable quality and safe and fit for their intended use.

7 198. Prevacid and Nexium were injected into the stream of commerce by the
8 Defendants in a defective, unsafe, and inherently dangerous condition and the products
9 and materials were expected to and did reach users, handlers, and persons coming into
10 contact with said products without substantial change in the condition in which they were
11 sold.

12 199. The Defendants herein breached the aforesaid implied warranties, as their
13 drugs Prevacid and Nexium were not fit for their intended purposes and uses.

14 200. As a result of the foregoing acts and omissions, the Plaintiff was caused to
15 suffer serious and dangerous side effects including, kidney injuries, as well as other severe
16 and personal injuries which are permanent and lasting in nature, physical pain and mental
17 anguish, including diminished enjoyment of life, as well as the need for lifelong medical
18 treatment, monitoring and/or medications.

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

24 **COUNT VIII**
25 **AS AGAINST THE DEFENDANTS**
26 **(FRAUDULENT MISREPRESENTATION)**

1 202. Plaintiff repeats, reiterates and realleges each and every allegation of this
2 Complaint contained in each of the foregoing paragraphs inclusive, with the same force
3 and effect as if more fully set forth herein.

4 203. The Defendants falsely and fraudulently represented to the medical and
5 healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that
6 said products, Prevacid and Nexium had been tested and was found to be safe and/or
7 effective for treatment of peptic disorders which include gastroesophageal reflux disease
8 (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced
9 gastropathy.

10 204. That representations made by Defendants were, in fact, false.

11 205. When said representations were made by Defendants, they knew those
12 representations to be false and it willfully, wantonly and recklessly disregarded whether
13 the representations were true.

14 206. These representations were made by said Defendants with the intent of
15 defrauding and deceiving the Plaintiff, the public in general, and the medical and
16 healthcare community in particular, and were made with the intent of inducing the public
17 in general, and the medical and healthcare community in particular, to recommend,
18 prescribe, dispense and/or purchase said products, Prevacid and Nexium, for treatment of
19 peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer
20 disease, and nonsteroidal anti-inflammatory drug induced gastropathy, all of which
21 evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare
22 of the Plaintiff herein.

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

1 214. Plaintiff repeats, reiterates and realleges each and every allegation of this
2 Complaint contained in each of the foregoing paragraphs inclusive, with the same force
3 and effect as if more fully set forth herein.

4 215. At all times during the course of dealing between Defendants and Plaintiff,
5 and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the
6 safety of Prevacid and Nexium for their intended use.

7 216. Defendants knew or were reckless in not knowing that its representations
8 were false.

9 217. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or
10 the FDA, Defendants fraudulently concealed and intentionally omitted the following
11 material information:

- 12 (a) that Prevacid and Nexium were not as safe as other
13 forms of treatment for treatment of peptic disorders
14 which include gastroesophageal reflux disease
15 (GERD), peptic ulcer disease, and nonsteroidal anti-
16 inflammatory drug induced gastropathy;
17 (b) that the risks of adverse events with Prevacid and
18 Nexium were higher than those with other forms of
19 treatment of peptic disorders which include
20 gastroesophageal reflux disease (GERD), peptic ulcer
21 disease, and nonsteroidal anti-inflammatory drug -
22 induced gastropathy;
23 (c) that the risks of adverse events with Prevacid and
24 Nexium were not adequately tested and/or known by
25 Defendants;
26 (d) that Defendants were aware of dangers in Prevacid
27 and Nexium, in addition to and above and beyond
those associated with other forms of treatment of
peptic disorders which include gastroesophageal
reflux disease (GERD), peptic ulcer disease, and
nonsteroidal anti-inflammatory drug induced
gastropathy;
(e) that Prevacid and Nexium were defective, and that it
caused dangerous side effects, including but not
limited to kidney injuries;

- 1 (f) that patients needed to be monitored more regularly
2 than normal while using Prevacid and Nexium;
- 3 (g) that Prevacid and Nexium were manufactured
4 negligently;
- 5 (h) that Prevacid and Nexium were manufactured
6 defectively;
- 7 (i) that Prevacid and Nexium were manufactured
8 improperly;
- 9 (j) that Prevacid and Nexium were designed negligently;
- 10 (k) that Prevacid and Nexium were designed defectively;
11 and
- 12 (l) that Prevacid and Nexium were designed improperly.

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

16 219. Defendants had sole access to material facts concerning the defective nature
17 of the product and its propensity to cause serious and dangerous side effects, and hence,
18 cause damage to persons who used Prevacid and Nexium, including the Plaintiff, in
19 particular.

20 220. Defendants' concealment and omissions of material facts concerning, inter
21 alia, the safety of Prevacid and Nexium was made purposefully, willfully, wantonly,
22 and/or recklessly, to mislead Plaintiff, and Plaintiff's physicians, hospitals and healthcare
23 providers into reliance, continued use of Prevacid and Nexium, and actions thereon, and to
24 cause them to purchase, prescribe, and/or dispense Prevacid and Nexium and/or use the
25 products.

26 221. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals,
27 healthcare providers, and/or the FDA had no way to determine the truth behind

1 Defendants' concealment and omissions, and that these included material omissions of
2 facts surrounding Prevacid and Nexium as set forth herein.

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

6 223. As a result of the foregoing acts and omissions, the Plaintiff was caused to
7 suffer serious and dangerous side effects including, CKD, as well as other severe and
8 personal injuries which are permanent and lasting in nature, physical pain and mental
9 anguish, including diminished enjoyment of life, as well as the need for lifelong medical
10 treatment, monitoring and/or medications.

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

16 **COUNT X**
AS AGAINST THE DEFENDANTS
(NEGLIGENT MISREPRESENTATION)

17 225. Plaintiff repeats, reiterates and realleges each and every allegation of this
18 Complaint contained in each of the foregoing paragraphs inclusive, with the same force
19 and effect as if more fully set forth herein.

20 226. Defendants had a duty to represent to the medical and healthcare
21 community, and to the Plaintiff, the FDA and the public in general that said products,
22 Prevacid and Nexium, had been tested and found to be safe and effective for treatment of
23 peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer
24 disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

1 233. Defendants conducted research and used Prevacid and Nexium as part of
2 their research.

3 234. As a result of Defendants' research and testing, or lack thereof, Defendants
4 blatantly and intentionally distributed false information, including but not limited to
5 assuring the public, the Plaintiff, Plaintiff's doctors, hospitals, healthcare professionals,
6 and/or the FDA that Prevacid and Nexium were safe and effective for treatment of peptic
7 disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease,
8 and nonsteroidal anti-inflammatory drug induced gastropathy.

9 235. As a result of Defendants' research and testing, or lack thereof, Defendants
10 intentionally omitted certain results of testing and research to the public, healthcare
11 professionals, and/or the FDA, including the Plaintiff.

12 236. Defendants had a duty when disseminating information to the public to
13 disseminate truthful information and a parallel duty not to deceive the public and the
14 Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.

15 237. The information distributed to the public, the FDA, and the Plaintiff by
16 Defendants, including but not limited to reports, press releases, advertising campaigns,
17 television commercials, print ads, magazine ads, billboards, and all other commercial
18 media contained material representations of fact and/or omissions.

19 238. The information distributed to the public, the FDA, and the Plaintiff by
20 Defendants intentionally included representations that Defendants' drugs Prevacid and
21 Nexium were safe and effective for use for treatment of peptic disorders which include
22 gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-
23 inflammatory drug induced gastropathy.

24 239. The information distributed to the public, the FDA, and the Plaintiff, by
25 Defendants intentionally included representations that Defendants' drugs Prevacid and
26

1 Nexium carried the same risks, hazards, and/or dangers as other forms of treatment for
2 treatment of peptic disorders which include gastroesophageal reflux disease (GERD),
3 peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

4 240. The information distributed to the public, the FDA, and the Plaintiff, by
5 Defendants intentionally included false representations that Prevacid and Nexium were
6 not injurious to the health and/or safety of their intended users.

7 241. The information distributed to the public, the FDA, and the Plaintiff, by
8 Defendants intentionally included false representations that Prevacid and Nexium were as
9 potentially injurious to the health and/or safety of their intended as other forms of
10 treatment for treatment of peptic disorders which include gastroesophageal reflux disease
11 (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced
12 gastropathy.

13 242. These representations were all false and misleading.

14 243. Upon information and belief, Defendants intentionally suppressed, ignored
15 and disregarded test results not favorable to the Defendants, and results that demonstrated
16 that Prevacid and Nexium were not safe as a means of treatment for treatment of peptic
17 disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease,
18 and nonsteroidal anti-inflammatory drug induced gastropathy.

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

23 245. Defendants intentionally made material representations to the FDA and the
24 public in general, including the medical profession, and the Plaintiff, regarding the safety
25 of Prevacid and Nexium, specifically but not limited to Prevacid and Nexium being a safe
26

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

4 246. That it was the purpose of Defendants in making these representations to
5 deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the
6 public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality
7 and fitness for use of Prevacid and Nexium induce the public, and/or the Plaintiff to
8 purchase, request, dispense, prescribe, recommend, and/or continue to use Prevacid and
9 Nexium.

10 247. Defendants made the aforementioned false claims and false representations
11 with the intent of convincing the public, healthcare professionals, the FDA, and/or the
12 Plaintiff that Prevacid and Nexium were fit and safe for use for treatment of peptic
13 disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease,
14 and nonsteroidal anti-inflammatory drug induced gastropathy.

15 248. Defendants made the aforementioned false claims and false representations
16 with the intent of convincing the public, healthcare professionals, the FDA, and/or the
17 Plaintiff that Prevacid and Nexium were fit and safe for use for treatment of peptic
18 disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease,
19 and nonsteroidal anti-inflammatory drug induced gastropathy.

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

23 250. That Defendants made claims and representations in its documents
24 submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that
25 Prevacid and Nexium did not present health and/or safety risks greater than other oral
26

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

4 251. That these representations and others made Defendants were false when
5 made, and/or were made with a pretense of actual knowledge when knowledge did not
6 actually exist, and/or were made recklessly and without regard to the actual facts.

7 252. That these representations and others, made by Defendants, were made with
8 the intention of deceiving and defrauding the Plaintiff, including Plaintiff's respective
9 healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff
10 and/or Plaintiff's respective healthcare professionals to rely upon misrepresentations and
11 caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or
12 prescribe Prevacid and Nexium.

13 253. That Defendants, recklessly and intentionally falsely represented the
14 dangerous and serious health and/or safety concerns of Prevacid and Nexium to the public
15 at large, the Plaintiff in particular, for the purpose of influencing the marketing of a
16 product known to be dangerous and defective and/or not as safe as other alternatives,
17 including other forms of treatment of peptic disorders which include gastroesophageal
18 reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug -
19 induced gastropathy.

20 254. That Defendants willfully and intentionally failed to disclose the material
21 facts regarding the dangerous and serious safety concerns of Prevacid and Nexium by
22 concealing and suppressing material facts regarding the dangerous and serious health
23 and/or safety concerns of Prevacid and Nexium.

24 255. That Defendants willfully and intentionally failed to disclose the truth,
25 failed to disclose material facts and made false representations with the purpose and
26

1 design of deceiving and lulling the Plaintiff, as well as Plaintiff's respective healthcare
2 professionals into a sense of security so that Plaintiff would rely on the representations
3 and purchase, use and rely on Prevacid and Nexium and/or that Plaintiff's respective
4 healthcare providers would dispense, prescribe, and/or recommend the same.

5 256. Defendants, through their public relations efforts, which included but were
6 not limited to the public statements and press releases, knew or should have known that
7 the public, including the Plaintiff, as well as Plaintiff's respective healthcare professionals
8 would rely upon the information being disseminated.

9 257. Defendants utilized direct to consumer advertising to market, promote, and/or
10 advertise Prevacid and Nexium.

11 258. That the Plaintiff and/or Plaintiff's respective healthcare professionals did in
12 fact rely on and believe the Defendants' representations to be true at the time they were
13 made and relied upon the representations as well as the superior knowledge of treatment
14 of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer
15 disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

16 259. That at the time the representations were made, the Plaintiff and/or
17 Plaintiff's respective healthcare providers did not know the truth with regard to the
18 dangerous and serious health and/or safety concerns of Prevacid and Nexium.

19 260. That the Plaintiff did not discover the true facts with respect to the
20 dangerous and serious health and/or safety concerns, and the false representations of
21 Defendants, nor could the Plaintiff with reasonable diligence have discovered the true
22 facts.

23 261. That had the Plaintiff known the true facts with respect to the dangerous and
24 serious health and/or safety concerns of Prevacid and Nexium, Plaintiff would not have
25 purchased, used and/or relied on Defendants' drugs Prevacid and Nexium.

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS
(b) County of Residence of First Listed Plaintiff
(c) Attorneys (Firm Name, Address, and Telephone Number)

DEFENDANTS
County of Residence of First Listed Defendant
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.
Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)
1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
Citizen of This State
Citizen of Another State
Citizen or Subject of a Foreign Country
PTF DEF
1 1 Incorporated or Principal Place of Business In This State
2 2 Incorporated and Principal Place of Business In Another State
3 3 Foreign Nation
4 4
5 5
6 6

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

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Contains various legal categories and checkboxes.

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

VI. CAUSE OF ACTION (Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)

VII. Previous Bankruptcy Matters (For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.)

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

IX. RELATED CASE(S) IF ANY (See instructions): JUDGE DOCKET NUMBER

X. This case (check one box) Is not a refiling of a previously dismissed action is a refiling of case number previously dismissed by Judge

DATE SIGNATURE OF ATTORNEY OF RECORD