

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
NEWARK DIVISION**

SHARON BLYTHE,

Plaintiff,

V.

**ASTRAZENECA
PHARMACEUTICALS LP;
ASTRAZENECA LP; TAKEDA
PHARMACEUTICALS USA, INC;
TAKEDA PHARMACEUTICALS
AMERICA, INC; TAKEDA
DEVELOPMENT CENTER
AMERICAS, INC; TAKEDA
PHARMACEUTICALS
INTERNATIONAL, INC; TAKEDA
PHARMACEUTICAL COMPANY
LIMITED,**

Defendants.

Civil Action No.

COMPLAINT AND DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff, Sharon Blythe, by way of Complaint alleges as follows:

NATURE OF THE ACTION

1. This is an action for personal injuries and economic damages suffered by Plaintiff, Sharon Blythe, as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and/or sale of the proton pump inhibiting ("PPI") drugs known as Nexium (esomeprazole magnesium) and/or other Nexium-branded products with the same active ingredient herein collectively referred to as "NEXIUM", and Dexilant

(dexlansoprazole) and/or other Dexilant-branded products with the same active ingredient herein collectively referred to as “DEXILANT.”

PARTIES

2. At all times referenced herein, Plaintiff, Sharon Blythe, was and is a citizen of the State of North Carolina.

AstraZeneca Pharmaceuticals LP

3. Defendant AstraZeneca Pharmaceuticals LP is, and all times relevant to this action was, a Limited Partnership with its principal place of business in Wilmington, Delaware.

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

5. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in Plaintiff’s state of residency and the State of New Jersey.

6. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited and conducted business in Plaintiff’s state of residency and the State of New Jersey and derived substantial revenue from such business.

7. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP expected or should have expected that its acts would have consequences throughout the United States of America including the State of New Jersey in particular.

8. Defendant AstraZeneca Pharmaceuticals LP is the holder of approved New Drug Applications (“NDAs”) for the following forms of Nexium: Delayed-Release Capsule Pellets (20 mg and 40 mg), with NDA #021153, approved on 2/20/2001; Delayed-Release Oral Suspension Packets (2.5MG, 5MG, 20MG, 40MG), with NDA # 021957, approved on 10/20/2006;

Delayed-Release Oral Suspension Packets (10MG), with NDA # 022101, approved on 02/27/2008; and Injection (20MG VIAL, 40MG VIAL), with NDA # 022101, approved on 03/31/2005.

AstraZeneca LP

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

10. Defendant AstraZeneca LP is, and all times relevant to this action was, a Limited Partnership with its principal place of business in Wilmington, Delaware.

11. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business in Plaintiff's state of residency and the State of New Jersey.

12. At all relevant times, Defendant AstraZeneca LP transacted, solicited and conducted business in Plaintiff's state of residency and the State of New Jersey and derived substantial revenue from such business.

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

Takeda Pharmaceuticals USA, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc.; Takeda Pharmaceuticals International, Inc.; and Takeda Pharmaceutical Company Limited

14. Defendant Takeda Pharmaceuticals USA, Inc. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

15. Defendant Takeda Pharmaceuticals America, Inc. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

16. Defendant Takeda Development Center Americas, Inc. is an Illinois corporation which has its principal place of business at 208 South LaSalle Street, Chicago, IL 60604.

17. Defendant Takeda Pharmaceuticals International, Inc. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

18. Defendant Takeda Pharmaceutical Company Limited is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645.

19. On information and belief, Takeda Pharmaceuticals USA, Inc. is either the direct or indirect owner of substantially all the stock or other ownership interests of Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc.; Takeda Pharmaceuticals International, Inc.; and Takeda Pharmaceutical Company Limited.

20. In doing the acts alleged herein, said Takeda Defendants (including Takeda Pharmaceuticals USA, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc.; Takeda Pharmaceuticals International, Inc.; and Takeda Pharmaceutical Company Limited) were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence, and ratification of each other (hereinafter Takeda Pharmaceuticals USA, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc.; Takeda Pharmaceuticals International, Inc.; and Takeda Pharmaceutical Company Limited are collectively referred to as "Takeda").

21. At all times relevant hereto, Takeda Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling DEXILANT products.

22. Upon information and belief, at all relevant times, Takeda Defendants was present and doing business in Plaintiff's state of residency.

23. At all relevant times, Takeda Defendants transacted, solicited, and conducted business in Plaintiff's state of residency and derived substantial revenue from such business.

24. At all times relevant hereto, Takeda Defendants expected or should have expected that their acts would have consequences within the United States of America, and Plaintiff's state of residency in particular.

25. Takeda Defendants are the holders of approved New Drug Application ("NDA") for the DEXILENT 30 mg capsules, with NDA #64764-0175-30.

Defendants' Unity of Interest

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

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

28. Defendants AstraZeneca LP, AstraZeneca Pharmaceuticals LP, Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., Takeda Development Center Americas, Inc., Takeda Pharmaceuticals International, Inc., and Takeda Pharmaceutical Company Limited shall herein be collectively referred to herein as "Defendants."

JURISDICTION AND VENUE

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

30. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) as a substantial part of the events and/or omissions giving rise to the Plaintiff's claims emanated from activities within this jurisdiction and Defendants transact substantial business within this jurisdiction.

31. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, the Court has personal jurisdiction over Defendants, because Defendants are present in the State of New Jersey, such that the exercise of jurisdiction does not offend traditional notions of fair play and substantial justice.

32. This Court has personal jurisdiction over Defendants pursuant to and consistent with the Constitutional requirements of Due Process because Defendants, acting through their agents or apparent agents, committed one or more of the following: transaction of business within the state of New Jersey; making of contracts within the state; the commission of a tortious act within this state; and the ownership, use, or possession of any real estate situated within this state as well as registered as foreign partnerships to do business within the state and maintaining a registered agent for service of process.

33. Requiring Defendants to litigate these claims in New Jersey does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution. All of Plaintiff's claims arise in part from conduct Defendants purposefully directed to the State of New Jersey. Upon information and belief, Defendants' Nexium and Dexilant products are sold at hundreds of local and national pharmacies, including, but not

limited to Wal-Mart, Target, CVS, and Walgreens throughout the Plaintiff's state of residency and the State of New Jersey.

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

35. Plaintiff's claims arise out of Defendants' design, marketing and/or sale of Nexium and Dexilant products in the State of New Jersey.

36. Defendants regularly conduct or solicit business and derive substantial revenue from goods used or consumed in, inter alia, the State of New Jersey.

37. At all relevant times, Defendants were present and doing business in the State of New Jersey.

38. At all times relevant hereto, Defendants transacted, solicited, and conducted business in the State of New Jersey and derived substantial revenue from such business.

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

40. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States, including Plaintiff's state of residency and the State of New Jersey in particular.

41. Defendants regularly file patent infringement claims against non New Jersey Corporations in New Jersey Federal Court thereby availing themselves of the benefits of New

Jersey courts, laws and jurisdiction. *See AstraZeneca Pharmaceuticals LP, et al. v. Teva Pharmaceuticals*, Case 1:17-CV-02448-RMB-KMW, filed April 10, 2017.

42. Defendants have obtained a Certificate of Registration with the New Jersey Department of Health Drug and Medical Devices, Registration No. 5003966; 5003887.

43. Defendants maintain a registered agent in Trenton, New Jersey.

44. Defendants, by and through their actions stated above, have consented to jurisdiction in state of New Jersey.

45. Defendants, by and through their actions stated above, are judicially estopped from challenging jurisdiction in New Jersey State and Federal Courts under the doctrine of Judicial Estoppel.

46. Defendants named herein are conclusively presumed to have been doing business in this state and are subject to New Jersey long arm jurisdiction.

GENERAL FACTUAL ALLEGATIONS

A. Proton Pump Inhibitors Generally

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

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

49. Nexium (esomeprazole magnesium) and Dexilant (dexlansoprazole) are PPIs that work by inhibiting the secretion of stomach acid. They shut down acid production of the active

acid pumps in the stomach thereby reducing hydrochloric acid in the stomach. The drugs bind with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

50. Nexium is AstraZeneca's largest-selling drug, and in the world market, the third largest selling drug overall. In 2005, AstraZeneca's sales of Nexium exceeded \$5.7 billion. In 2008, Nexium sales exceeded \$5.2 billion.

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

52. In 2002, Takeda's sales of Dexilant exceeded \$2.9 billion. When ranked by total expenditures in 2004, for adults age 18-64, Dexilant ranked third with \$2.67 billion in sales. In 2005, Dexilant was the nation's fourth-best-selling brand name prescription in the United States. In 2006, sales of Dexilant exceeded \$5.7 billion.

53. Takeda Defendants manufactured, marketed and sold Dexilant with National Drug Code ("NDC") numbers: 64764-046, 64764-541, 64764-543 and 64764-544.

B. Dangers Associated with PPIs

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

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

C. Acute Interstitial Nephritis Dangers Associated with PPIs

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

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

58. By July 2011, the World Health Organization adverse drug reaction report included nearly 500 cases of AIN already reported that year, however Defendants still did not warn the physicians or patients, including Plaintiff, of the risks of AIN associated with use of Nexium and Dexilant.

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

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

61. However, the current warning regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences.

D. Chronic Kidney Disease Associated with PPIs

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

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

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

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

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

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

68. A meta-analysis that was recently published in 2017 indicated that there was a significantly increased risk of CKD associated with use of PPI's in the absence of intervening acute kidney injury.

69. Currently, the Nexium and Dexilant product labeling do not contain any warning regarding the increased risk of CKD.

E. Acute Kidney Injury Dangers Associated with PPIs

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

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

72. Currently, the Nexium and Dexilant product labeling do not contain any warning regarding the increased risk of AKI.

F. Safer Alternatives to PPIs

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

- a. The use of over-the-counter calcium carbonate remedies tablets that have been available since the 1930s, such as Maalox and Tums; and/or
- b. The use of histamine H₂-receptor antagonists (also known as H₂ blockers) that were developed in the late 1960s. H₂ blockers act to prevent the production of stomach acid and work more quickly than PPIs and are prescribed for the same indications as PPI's. Examples of H₂ blockers include Zantac, Pepcid and

Tagamet. H2 receptor antagonists are not associated with an increased risk of renal injuries.

G. Allegations Common to All Causes of Action

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

75. In omitting, concealing, and inadequately providing critical safety information regarding the use of Nexium and Dexilant to Plaintiff and Plaintiff's healthcare providers, Defendants engaged in, and continue to engage in, conduct likely to mislead consumers, including Plaintiff and Plaintiff's healthcare providers. This conduct is fraudulent, unfair and unlawful.

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

77. Defendants still do not warn of the potential risks of CKD and AKI associated with the use of Nexium and Dexilant in the product labeling nor in direct to consumer advertising.

78. Plaintiff was not aware of the potential risks of CKD or AKI associated with the use of Nexium and Dexilant until recently nor was she aware that her injuries could have been caused by her use of Nexium and Dexilant.

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

79. Plaintiff, Sharon Blythe, is and was, at all relevant times, a citizen of the State of North Carolina.

80. Plaintiff was born on September 21, 1956.

81. Upon information and belief, Plaintiff was prescribed Nexium and Dexilant on numerous occasions, beginning as early as 2006, and consistently thereafter through 2014. Plaintiff ingested Nexium and Dexilant as prescribed by her prescribing physicians.

82. Plaintiff would not have used Nexium and Dexilant had she been properly warned of the kidney risks associated with their ingestion.

83. As a result of using Defendants' Nexium and Dexilant, Plaintiff suffers from Chronic Kidney Disease. Plaintiff sustained severe and permanent personal injuries, pain, suffering, economic loss, and emotional distress.

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

TOLLING OF THE STATUTE OF LIMITATIONS

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

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

87. Defendant concealed and continue to conceal their knowledge of Nexium's and Dexilant's unreasonably dangerous risks from Plaintiff, the FDA, the public and the medical community including Plaintiff's prescribing physicians. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the magnified risk of kidney injuries related to the use of Nexium and Dexilant.

88. Defendants concealed and continue to conceal their knowledge that Nexium and Dexilant can cause kidney injuries from Plaintiff, the FDA, the public and the medical community including Plaintiff's prescribing physicians. Specifically, Defendants have failed to adequately inform consumers and the prescribing medical community against the serious risks associated with Nexium and Dexilant and completely failed to warn against the risk of Chronic Kidney Disease.

89. To this day, Defendants continue to conceal their knowledge that Nexium and Dexilant can cause CKD and still do not warn consumers and the prescribing medical community of the serious and potential fatal risks of CKD associated with the use of Nexium and Dexilant.

90. To this day, Defendants deny that Nexium and Dexilant can cause CKD and actively conceal their knowledge relating to the true risks of CKD and other kidney injury related to the use of Nexium and Dexilant.

91. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's prescribing physicians the true and significant risks associated with the use of Nexium and Dexilant.

92. Defendants undertook such action with the intent of defrauding and deceiving the public and the medical community at large, including Plaintiff and Plaintiff's prescribing physicians, with the intent of inducing the prescription, dispensing, and/or purchasing of Nexium

and Dexilant for the treatment of GERD, all of which evidenced a callous, reckless, willful indifference to the health, safety and welfare of Plaintiff herein.

93. As a result of Defendants' actions, Plaintiff and Plaintiff's prescribing physicians were unaware, and could not have reasonably known or learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged herein, and that those risks were the direct and proximate result of Defendants' action, omissions, and misrepresentations.

94. Defendants are estopped from relying on any statute of limitations defense because of their concealment of the truth, quality and nature of Nexium and Dexilant. Defendants were under a duty to disclose the true character, quality and nature of Nexium and Dexilant because this was non-public information that Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, the FDA, the public and the medical community including Plaintiff's prescribing physicians.

95. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and Plaintiff's prescribing physicians could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants' representations.

96. Plaintiff could not have discovered the still unlabeled risks of kidney injury, including CKD, from using Nexium and Dexilant through the exercise of reasonable care.

97. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or Plaintiff's physicians.

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

99. Plaintiff only recently discovered that Plaintiff's injuries could have been caused by the use of Nexium and Dexilant.

COUNT I
PRODUCT LIABILITY- DEFECTIVE DESIGN

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

101. Nexium and Dexilant are defective in their design or formulation in that they are not reasonably fit, suitable, or safe for their intended purpose and/or their foreseeable risks exceed the benefits associated with their design and formulation.

102. At all times relevant hereto, Nexium and Dexilant were expected to reach, and did reach, consumers in Plaintiff's home state, the State of New Jersey, and throughout the United States, including receipt by Plaintiff, without substantial change in the condition in which it was sold.

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

- a. When placed in the stream of commerce, Nexium and Dexilant contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject

products, including, but not limited to, permanent personal injuries including, but not limited to, developing CKD and other serious injuries and side effects;

- b. When placed in the stream of commerce, Nexium and Dexilant were defective in design and formulation, making the use of Nexium and Dexilant more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat GERD and other stomach-acid-related ailments;
- c. The design of Nexium and Dexilant existed before they left the control of Defendants;
- d. Nexium and Dexilant were insufficiently and inadequately tested;
- e. Nexium and Dexilant caused harmful effects that outweighed any potential utility; and
- f. Nexium and Dexilant were not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with their use, thereby rendering Defendants liable to Plaintiff.

104. In addition, at the time the subject products left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the products. These safer alternative designs were economically and technologically feasible – indeed they were already on the market – and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the products' utility.

105. As a result of the subject products' defective design, Plaintiff was caused to suffer serious and dangerous side effects including Chronic Kidney Disease, as well as other severe and

personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT II
PRODUCT LIABILITY – FAILURE TO WARN

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

108. Nexium and Dexilant were defective and unreasonably dangerous when they left the possession of Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the subject products, including but not limited to their propensity to permanent physical injuries including, but not limited to, developing CKD and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for GERD and other stomach-acid-related ailments. Thus, the subject products were unreasonably dangerous because an adequate warning was not provided as required.

109. Nexium and Dexilant were under the exclusive control of Defendants and were unaccompanied by appropriate warnings regarding all of the risks associated with their use. The warnings given did not accurately reflect the risk, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendants further diluted or minimized the warnings given with the products.

110. The subject products manufactured and supplied by Defendants were defective and unreasonably dangerous when they left the possession of Defendant due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm for the use of the subject products, Defendants failed to provide an adequate warning to consumers and/or their healthcare providers of the defects of the products, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instruction, or recall, while knowing that the products could cause serious injury and/or death.

111. Plaintiff was prescribed and used the subject products for their intended purpose.

112. Plaintiff could not have discovered any defect in the subject products through the exercise of reasonable care.

113. Defendants, as manufacturers and/or distributors of the subject prescription products, are held to the level of knowledge of an expert in the field.

114. Defendants, the manufacturers and/or distributors of the subject prescription products, are held to a level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

115. Plaintiff did not have the same knowledge as Defendants and no adequate warnings were communicated to Plaintiff and Plaintiff's physicians.

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

117. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to, Acute Interstitial Nephritis (AIN), Chronic Kidney Disease (CKD), Renal/Kidney Failure, Acute Kidney Injury (AKI), and Clostridium difficile.

118. Plaintiff, individually and through Plaintiff's prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

119. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Nexium and Dexilant and by negligently and/or wantonly failing to adequately warn of the dangers associated with their use, Defendants breached its duty.

120. Had Plaintiff received adequate warnings regarding the risks of Nexium and Dexilant, Plaintiff would not have used them and/or chosen a different course of treatment.

121. As a direct and proximate result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects including Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

122. As a result of Nexium and Dexilant's defective and inappropriate warnings, Plaintiff has suffered and severe and permanent injuries and requires and/or will require additional health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges she will, in the future, be required to obtain further medical and/or hospital care, attention and services.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT III
BREACH OF EXPRESS WARRANTY

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

124. Defendants expressly represented to the medical and healthcare community, Plaintiff, Plaintiff's prescribing physicians, the general public, and/or the FDA, that Nexium and Dexilant were safe and fit for their intended purposes, were of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

125. Nexium and Dexilant do not conform to Defendants' express representations because they are not safe, have numerous and serious side effects, and cause severe and permanent injuries, including, but not limited to, developing CKD and other serious injuries and side effects.

126. At the time of making of the express warranties, to the medical and healthcare community, Plaintiff, Plaintiff's prescribing physicians, the general public, and/or the FDA, Defendants knew, or in the exercise of reasonable care should have known, of the purpose for which the subject products were to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject products were unreasonably dangerous because they failed to conform to an express warranty of Defendants.

127. At the time of the making of the express warranties, to the medical and healthcare community, Plaintiff, Plaintiff's prescribing physicians, the general public, and/or the FDA,

Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject products were not safe and fit for their intended use and, in fact, produces serious injuries to the user.

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

129. Plaintiff, Plaintiff's prescribing physicians, other consumers, and the medical community relied upon Defendants' express warranties.

130. Contrary to the express warranty for the subject products, Nexium and Dexilant were not of merchantable quality, and was not safe or fit for intended uses and purposes, as alleged herein.

131. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff was caused to suffer serious and dangerous side effects including Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, cost herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT IV
PUNITIVE DAMAGES ALLEGATIONS

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

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

135. Plaintiff relied on Defendant's representations and suffered injuries as a proximate result of this reliance.

136. Plaintiff therefore asserts claims for exemplary damages.

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

138. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical

community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety of Nexium and Dexilant. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of Nexium and Dexilant, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting Nexium and Dexilant, despite their knowledge and awareness of these serious side effects and risks.

139. Defendants had knowledge of, and were in possession of evidence demonstrating that Nexium and Dexilant caused serious side effects. Notwithstanding Defendants' knowledge, Defendants continued to market the drugs by providing false and misleading information with regard to the products' safety to regulatory agencies, the medical community, and consumers of Nexium and Dexilant.

140. Although Defendants knew or recklessly disregarded the fact that Nexium and Dexilant cause debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute Nexium and Dexilant to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating GERD.

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

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

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

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

145. Despite this knowledge, Defendants, acting through their officers, directors and managing agents, for the purposes of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Nexium and Dexilant and failed to adequately warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of Nexium and Dexilant knowing these actions would expose person to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

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

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

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

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, cost herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

RELIEF REQUESTED

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

1. Economic and non-economic damages, special damages and general damages, including pain and suffering, in an amount to be supported by the evidence at trial;
2. For compensatory damages for the acts complained of herein in an amount to be determined by a jury;
3. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;

4. Punitive damages for the acts complained of herein in an amount to be determined by a jury;
5. For an award of attorneys' fees and costs;
6. For prejudgment interest;
7. For the costs of suit;
8. For post-judgment interest; and
9. For such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMAND

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

Dated:
December 21, 2017

Respectfully submitted,

NAPOLI SHKOLNIK PLLC

/s/ W. Steven Berman

W. Steven Berman, Esq.
(New Jersey Bar No: 11971986)
One Greentree Center, Suite 201
10,000 Lincoln Drive East
Marlton, NJ 08053
WSBerman@NapoliLaw.com

Attorneys for Plaintiff

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 _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

DEFENDANTS

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known)

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 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)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

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

Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutional of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

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):

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE