UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: PROTON-PUMP INHIBITOR PRODUCTS LIABILITY LITIGATION (NO. II) CLARICE ARMSTRONG, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP, Defendants.	17-md-2789 (CCC)(MF) (MDL 2789) **COMPLAINT AND DEMAND FOR JURY TRIAL** CIVIL ACTION NO.:_____

COMPLAINT

COMES NOW, Plaintiff, Clarice Armstrong (hereinafter "Plaintiff") by and through undersigned counsel, and files this Complaint against the Defendants, AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively "Defendants") and in support thereof alleges as follows:

INTRODUCTION

1. This is a personal injury case against Defendants who were responsible for designing, developing, researching, manufacturing, testing, packaging, promoting, marketing, advertising, distributing, labeling, and/or selling a class of drugs known as proton pump inhibitors ("PPI"s), which are prescription and over-the-counter ("OTC") medications referred to herein as PPIs.

2. PPIs are used to reduce acid production in order to lower the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as gastroesophageal reflux disease

(GERD), dyspepsia, acid peptic disease, and other hypersecretory conditions, including Zollinger-Ellison Syndrome.

3. As a result of the defective nature of PPIs, persons who ingested this product, including Plaintiff, have suffered and may continue to suffer from kidney injuries including acute interstitial nephritis ("AIN"), acute kidney injuries ("AKI"), chronic kidney disease ("CKD") and renal failure, also known as end-stage renal disease ("ESRD").

4. Defendants concealed and continue to conceal their knowledge of PPIs' unreasonably dangerous risks from Plaintiff, her physicians, other consumers, and the medical community. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the magnified risk of kidney injuries related to the use of PPIs.

5. As a result of Defendants' actions and inactions, Plaintiff was injured due to her ingestion of PPIs, which caused and will continue to cause Plaintiff's injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

PARTIES

6. Plaintiff, a resident of the State of Virginia, ingested the PPI, Nexium, between approximately July 2013, through January 2016, and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, recovery of costs of obtaining PPIs, including Nexium and recovery of all past, present, and future health and medical care costs related to his kidney related injuries caused by his ingestion of PPIs, including Nexium.

7. Defendant ASTRAZENECA PHARMACEUTICALS LP is a Delaware entity, which has its principal place of business at 1800 Concord Pike, Wilmington, DE 19897.

8. Defendant ASTRAZENECA LP is a Delaware entity, which has its principal place of business at 1800 Concord Pike, Wilmington, DE 19897.

9. In doing the acts alleged herein, said AstraZeneca Defendants (including ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA LP) 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 ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA LP and are collectively referred to as "ASTRAZENECA").

JURISDICTION AND VENUE

10. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because Defendants are all either incorporated and/or have their principal place of business outside of the state in which the Plaintiff resides.

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

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 in that Defendants conduct business here and are subject to personal jurisdiction in this District. Furthermore, Defendants sell, market, and/or distribute Nexium within Virginia and this District. [1]

FACTUAL ALLEGATIONS

13. Over 60 million Americans experience heartburn, a major symptom of GERD, at least once a month and some studies have suggested more than 15 million Americans experience heartburn on a daily basis.

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

14. About 21 million Americans used one or more prescription PPIs in 2009 accounting for nearly 20% of the drugs' global sales and earning an estimated $11 billion annually.

15. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

16. PPIs are one of the most commercially successful groups of medication in the United States. Upon information and belief, between the period of 2008 and 2013, prescription PPIs had sales of over $50 billion with approximately 240 million units dispensed.

17. Defendants, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed, promoted, and sold PPIs.

18. In October of 1992, three years after the FDA's initial PPI approval, researchers from the University of Arizona Health Sciences Center, led by Stephen Ruffenach, published the first article associating PPI usage with kidney injuries in *The American Journal of Medicine*, followed by years of reports from national adverse drug registries describing this association. In 1997, David Badov, et al., described two further case studies documenting the causal connection between omeprazole and interstitial nephritis in the elderly.[2]

19. Between 1995 and 1999, Nicholas Torpey, et al. conducted a single-center retrospective analysis of renal biopsy results from 296 consecutive patients to determine the etiology of acute tubule-interstitial nephritis (TIN).[3] Acute AIN was identified in 24 (8.1%)

---

[2] Badov, D., et al. Acute Interstitial Nephritis Secondary To Omeprazole, *Nephrol Dial Transplant* (1997) 12: 2414–2416.

[3] Torpey, N., et al. *Drug-Induced Tubulo-Interstitial Nephritis Secondary To Proton Pump Inhibitors: Experience From A Single UK Renal Unit*, Nephrol. Dial. Transplant. (2004) 19: 1441–1446.

biopsies. Eight out of fourteen cases with presumed drug-related AIN could be attributed to the PPIs omeprazole and lansoprazole.

20. Defendants knew or should have known that between 1992 and 2004 over 23 cases of biopsy-proven AIN secondary to omeprazole (Prilosec) had been reported.

21. In 2004, Defendants knew or should have known of 8 biopsy-proven cases reported from Norwich University Hospital in the United Kingdom.[4]

22. International organizations also recognized the danger posed by PPIs to kidney health, finding both AIN and insidious renal failure resulting from PPIs. In 2006, Professor Ian Simpson and his team at the University of Auckland published an analysis of the clinical features of 15 patients with AIN and acute renal failure from PPI over three years. In all patients, the tie-course of drug exposure and improvement of renal function on withdrawal suggested the PPI were causal. "Although four patients presented with an acute systemic allergic reaction, 11 were asymptomatic with an insidious development of renal failure."[5]

23. Furthermore, in the New Zealand study, Defendants knew or should have known that twelve of the reported cases were biopsy-proven.

24. In 2006, Nimeshan Geevasinga, et al., found "evidence to incriminate all the commercially available PPIs, suggesting there is a class effect" with regard to PPI-induced AIN.[6] "Failure to recognize this entity might have catastrophic long-term consequences including chronic kidney disease." This study was the largest hospital-based case series on this issue and involved a retrospective case review of potential cases as two teaching hospitals as well as a review of registry data from the Therapeutic Goods Administration of Australia. The team

---

4 *Id*.

5 Simpson, I., et al., *PPI and Acute Interstitial Nephritis*, NEPHROLOGY (2006)11: 381-85.

6 Geevasinga, N., et al. *Proton Pump Inhibitors and Acute Interstitial Nephritis*, CLINICAL GASTROENTEROLOGY AND HEPATOLOGY, (2006)4:597-604.

identified eighteen cases of biopsy-proven PPI-induced AIN. The TGA registry data identified an additional thirty-one cases of "biopsy proven interstitial nephritis." An additional ten cases of "suspected interstitial nephritis," twenty cases of "unclassified acute renal failure," and twenty-six cases of "renal impairment" were also identified. "All Five commercially available PPIs were implicated in these cases."

25. In 2006, the Center for Adverse Reaction Monitoring (CARM) in New Zealand, found that PPI products were the number one cause of AIN.[7]

26. In 2006, researchers at the Yale School of Medicine conducted a case series published in the *International Society of Nephrology's Kidney International* finding that PPI use, by way of AIN, left most patients "with some level of chronic kidney disease."

27. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a petition with the FDA to add black box warnings and other safety information concerning several risks associated with PPIs including AIN.

28. According to the petition, at the time of its filing there was "no detailed risk information on any PPI for this adverse effect."

29. In 2013, Klepser, et al. found that "patients with a renal disease diagnosis were twice as likely to have used a previous prescription for a PPI."[8] Klepser's study called for increased recognition of patient complaints or clinical manifestations of renal disease in order to prevent further injury.

---

[7] Ian J. Simpson, Mark R. Marshall, Helen Pilmore, Paul Manley, Laurie Williams, Hla Thein, David Voss, *Proton pump inhibitors and acute interstitial nephritis: Report and analysis of 15 cases*, (September 29, 2006).

[8] Klepser, D., et al. Proton Pump Inhibitors and Acute Kidney Injury: A Nested Case-Control Study, BMC NEPHROLOGY (2013) 14:150.

30. Also in 2013, Sampathkumar, et al. followed four cases of PPI users, finding that AIN developed after an average period of four weeks of PPI therapy.[9] Researchers further noted that "a high index of suspicion about this condition should prompt the physician to stop the drug, perform a renal biopsy if needed and start steroid therapy for halting a progressive renal disease."

31. In 2014, New Zealand researchers conducted a nested case-control study using routinely collected national health and drug dispensing data in New Zealand to estimate the relative and absolute risks of acute interstitial nephritis resulting in hospitalization or death in users of PPIs.[10] The study compared past use with current and ongoing use of PPIs, finding a significantly increased risk of acute interstitial nephritis for patients currently taking PPIs.

32. On October 31, 2014, more than three years after Public Citizen's petition, the FDA responded by requiring consistent labeling regarding risk of AIN on all prescription PPIs.

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

34. In December of 2014, the labels of prescription PPIs were updated to read:

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

35. The FDA did not require the consistent labeling regarding risk of AIN on over-the-counter PPIs.

---

[9] Sampathkumar, K., et al. *Acute Interstitial Nephritis Due to Proton Pump Inhibitors*, INDIAN J. NEPHROLOGY (2013) 23(4): 304-07.

[10] Blank, M., et al. *A Nationwide Nested Case-Control Study Indicates an Increased Risk of Acute Interstitial Nephritis with Proton Pump Inhibitor Use*, KIDNEY INTERNATIONAL (2014) 86, 837–844.

36. In a study conducted by Benjamin Lazarus, et al., published in JAMA, PPI use was associated with a higher risk of incident CKD.[11] The authors leveraged longitudinal data from two large patient cohorts in the United States, the Atherosclerosis Risk in Communities study (n ¼ 10,482) and the Geisinger Health System (n ¼ 248,751), in order to evaluate the relationship between PPI use and the development of chronic kidney disease (CKD). Over a median of 13.9 years of follow-up in the Atherosclerosis Risk in Communities study, the incidence of documented CKD or end-stage renal disease was significantly higher in patients with self-reported use of prescription PPIs at baseline (adjusted hazard ratio 1.50, 95% confidence interval 1.14–1.96).

37. "Consistent with prior studies, the authors also observed a significant association between baseline PPI use and acute kidney injury as defined by diagnostic codes (adjusted hazard ratio 1.64, 95% confidence interval 1.22–2.21). The results were then validated in the Geisenger Health System cohort using prescription data to define baseline PPI use and laboratory data to define the CKD outcome, defined as sustained outpatient estimated glomerular filtration rate the validation cohort also suggest a possible dose-response relationship between PPI use and CKD risk, with higher risk observed in patients prescribed a PPI twice daily at baseline (adjusted hazard ratio 1.46, 95% confidence interval 1.28–1.67). Despite the limitations inherent in observational studies, the robustness of the observations in this large study suggests a true association between PPI use and increased CKD risk."[12]

38. In quantifying the association between PPI use and CKD, Lazarus found that PPI use was associated with incident CKD in unadjusted analysis (hazard ratio [HR], 1.45; 95% CI,

---

[11] Lazarus, B., et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*, JAMA INTERN. MED., published online 11 Jan. 2016.

[12] See Schoenfeld, A. and Deborah Grady. *Adverse Effects Associated with Proton Pump Inhibitors*, JAMA INTERNAL MEDICINE, published online 11 Jan. 2016.

1.11-1.90); in analysis adjusted for demographic, socioeconomic, and clinical variables (HR, 1.50; 95% CI, 1.14-1.96); and in analysis with PPI ever use modeled as a time-varying variable (adjusted HR, 1.35; 95% CI, 1.17-1.55). The association persisted when baseline PPI users were compared directly with H2 receptor antagonist users (adjusted HR, 1.39; 95% CI, 1.01-1.91) and with propensity score–matched nonusers (HR, 1.76; 95% CI, 1.13-2.74). In the Geisinger Health System replication cohort, PPI use was associated with CKD in all analyses, including a time-varying new-user design (adjusted HR, 1.24; 95% CI, 1.20-1.28). Twice-daily PPI dosing (adjusted HR, 1.46; 95% CI, 1.28-1.67) was associated with a higher risk than once-daily dosing (adjusted HR, 1.15; 95% CI, 1.09-1.21).

39. Lazarus's data was confirmed and expanded by Yan Xie, et al.[13] Using Department of Veterans Affairs national databases to build a primary cohort of new users of PPI (n=173,321) and new users of histamine H2-receptor antagonists (H2 blockers; n=20,270), this study patients over 5 years to ascertain renal outcomes. In adjusted Cox survival models, the PPI group, compared with the H2 blockers group, had an increased risk of CKD, doubling of serum creatinine level, and end-stage renal disease.

40. However, evidence of the connection of PPI's with AIN and CKD existed as early as 2007.[14] In Brewster and Perazella's review, they found that not only are PPIs "clearly associated with the development of AIN," most PPI patients they studied were "left with some level of chronic kidney disease." This CKD existed despite recovery of kidney function following PPI withdrawal.– Furthermore, Härmark, et al., noted that the Netherlands Pharmacovigilance Centre Lareb received reports of AIN with the use of omeprazole,

[13] Xie, Y., et al. *Proton Pump Inhibitors and Risk of Incident CKD and Progression to ESRD*, J. AM. SOC. NEPHROL. (2016) 27: ccc–ccc.

[14] Brewster, UC and MA Perazella. *Acute Kidney Injury Following Proton Pump Inhibitor Therapy*, KIDNEY INTERNATIONAL (2007) 71, 589–593.

pantoprazole, and rabeprazole, demonstrating that "AIN is a complication associated with all PPIs."[15]

41. To date, over-the-counter PPIs lack detailed risk information for AIN.

42. To date, prescription and over-the-counter PPIs lack detailed risk information for CKD.

43. Parietal cells in the stomach lining secrete gastric juices containing hydrochloric acid to catalyze the digestion of proteins.

44. Excess acid secretion results in the formation of most ulcers in the gastroesophageal system and symptoms of heartburn and acid reflux.

45. PPIs irreversibly block the acidic hydrogen/potassium ATPase enzyme system (H+/K+ ATPase) of the gastric parietal cells, thereby halting the production of most hydrochloric acid.

46. In spite of their commercial success and global popularity, up to 70% of PPIs may be used inappropriately for indications or durations that were never tested or approved.

47. As a result of the defective nature of PPIs, even if used as directed by a physician or healthcare professional, persons who ingested PPIs have been exposed to significant risks stemming from unindicated and/or long-term usage.

48. From these findings, PPIs and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate acute interstitial nephritis ("AIN"), a sudden kidney inflammation that can result in mild to severe problems.

---

[15] Härmark, L., et al. *Proton Pump Inhibitor-Induced Acute Interstitial Nephritis*, BRIT. J. OF CLIN. PHARMACOLOGY (2007) 64(6): 819-23.

49. PPI-induced AIN is difficult to diagnose with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea, and weakness.

50. In April 2016, a study published in the *Journal of Nephrology* suggested that the development of and failure to treat AIN could lead to chronic kidney disease and end-stage renal disease, which requires dialysis or kidney transplant to manage.

51. CKD describes a slow and progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

52. Prompt diagnosis and rapid withdrawal of the offending agent are key in order to preserve kidney function. While AIN can be treated completely, once it has progressed to CKD it is incurable and can only be managed, which, combined with the lack of numerous early-onset symptoms, highlights the need for screening of at-risk individuals.

53. Consumers, including the Plaintiff, who have used PPIs for the treatment of increased gastric acid have and had several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with PPI therapy.

54. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with PPI use.

55. Defendants concealed and continue to conceal their knowledge that PPIs can cause kidney injuries from Plaintiff, other consumers, and the medical community. Specifically, Defendants have failed to adequately inform consumers and the prescribing medical community

against the serious risks associated with PPIs and have completely failed to warn against the risk of CKD and ESRD.

56. As a result of Defendants' actions and inactions, Plaintiff was injured due to her ingestion of PPIs, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

57. As a result of Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

58. As a direct result of ingesting PPIs, Plaintiff has been permanently and severely injured, having suffered serious consequences from PPI use. Plaintiff requires and will in the future require ongoing medical care and treatment.

59. Plaintiff, as a direct and proximate result of PPI use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living related expenses due to her new lifestyle.

60. Plaintiff would not have used PPIs had Defendants properly disclosed the risks associated with long-term use.

61. Prior to March 2017, Plaintiff Clarice Armstrong did not know about the causal link between Plaintiff's kidney injuries and ingestion of Defendants' Nexium.

62. It was not until on or about March 2017 that Plaintiff Clarice Armstrong first learned of the possible causal link.

63. Prior to March 2017, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries associated with Nexium use.

Federal Requirements

64. Defendants had an obligation to comply with the law in the manufacture, design, and sale of PPIs.

65. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

66. With respect to PPIs, the Defendants, upon information and belief, have or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. PPIs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they fail to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation are not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. PPIs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, their strength differs from or their quality or purity falls below the standard set forth in the official compendium for the Subject Drug and such deviations are not plainly stated on their labels.

c. PPIs are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading.

d. PPIs are misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. PPIs are misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. PPIs are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. PPIs do not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which they are intended, including conditions, purposes, or uses for which they are prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which they are intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. PPIs are misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of PPIs to cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took PPIs.

l. PPIs are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

m. PPIs violate 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

n. PPIs violate 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

o. PPIs violate 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

p. PPIs violate 21 CFR § 211.165 in that the Subject Drug fails to meet established standards or specifications and any other relevant quality control criteria.

q. PPIs violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding PPIs were not followed.

r. PPIs violate 21 CFR § 310.303 in that PPIs are not safe and effective for their intended use.

s. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

t. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with PPIs as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drug experience.

u. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with PPIs, and evaluating the cause of the adverse event.

v. The Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

w. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of PPIs or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

x. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions

taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

67. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendants liable under State law.

Fraudulent Concealment

68. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through affirmative misrepresentations and omissions, actively concealed from Plaintiff, physicians, the medical community, and the general public the true risks associated with PPIs.

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

CAUSES OF ACTION - THEORIES OF RECOVERY

COUNT ONE -NEGLIGENCE
(As to All Defendants)

70. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

71. Defendants had a duty to Plaintiff to exercise reasonable care in the designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of PPIs into the stream of commerce, including a duty to assure that PPI's would not cause users to suffer unreasonable, dangerous side effects such as kidney injuries.

72. Defendants failed to exercise ordinary care and/or were reckless in designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of PPIs into interstate commerce in that Defendants knew or should have known that using PPIs caused a risk of unreasonable, dangerous side effects, including kidney injuries.

73. Despite the fact that Defendants knew or should have known that PPIs were associated with and/or caused kidney injuries, Defendants continued to market, manufacture, distribute and/or sell PPIs to consumers, including the Plaintiff.

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

75. Defendants' negligence and/or recklessness was the proximate cause of Plaintiff's injuries, harm and economic loss which she suffered and/or will continue to suffer.

76. As a result Defendants' negligence and/or recklessness, the Plaintiff was caused to suffer serious and dangerous side effects, 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, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff's kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above.

77. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related

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

COUNT TWO - STRICT PRODUCTS LIABILITY - FAILURE TO WARN
(As to All Defendants)

78. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

79. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced PPIs into the stream of commerce, and in the course of same, directly advertised or marketed PPIs to consumers or persons responsible for consumers, and therefore, had a duty to both the Plaintiff directly and Plaintiff's physician to warn of risks associated with the use of PPIs.

80. Defendants had a duty to warn of adverse drug reactions, which they know or have reason to know can be caused by the use of PPIs and/or are associated with the use of PPIs.

81. The PPIs manufactured and/or supplied by the Defendants were defective due to inadequate post-marketing warnings and/or instructions because, after the Defendants knew or should have known of the risks of kidney injuries from PPI use, they failed to provide adequate warnings to consumers of the product, including Plaintiff and Plaintiff's physicians, and continued to aggressively promote PPIs.

82. Due to the inadequate warning regarding kidney injuries, PPIs were in a defective condition and unreasonably dangerous at the time that they left the control of the Defendants.

83. Defendants' failure to adequately warn Plaintiff and Plaintiff’s prescribing physicians of kidney injuries risk prevented Plaintiff's prescribing physicians and Plaintiff from correctly and fully evaluating the risks and benefits of PPIs.

84. Had Plaintiff been adequately warned of the potential life-threatening side effects of the Defendants' PPI, Plaintiff would not have purchased or taken the PPI and could have chosen to request other treatments or prescription medications.

85. Upon information and belief, had Plaintiff's prescribing physicians been adequately warned of the potential life-threatening side effects of the Defendants' PPIs, Plaintiff's prescribing physicians would have discussed the risks of kidney injuries and PPIs with the Plaintiff and/or would not have prescribed them.

86. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages.

COUNT THREE – STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN
(As to All Defendants)

87. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

88. PPIs were expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

89. At all times relevant, PPIs were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff.

90. PPIs as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation because when they left the hands of the manufacturers and/or suppliers the

foreseeable risks exceeded the alleged benefits associated with the design and formulation of PPIs.

91. PPIs as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in design and formulation, because when they left the hands of Defendants' manufacturers and suppliers they were unreasonably dangerous and were also more dangerous than the ordinary consumer would expect.

92. At all times herein mentioned, the PPIs were in a defective condition and were unsafe, and Defendants knew and had reason to know that the product was defective and inherently unsafe, especially when PPIs were used in a form and manner instructed and provided by Defendants.

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

94. At the time of Plaintiff's use of PPIs, it was being used for its intended purpose, and in a manner that it was normally intended.

95. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed a defective product that caused an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore strictly liable for the injuries and damages sustained by Plaintiff.

96. At the time Defendants' product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of their product. This was

demonstrated by the existence of other PPIs which had a more established safety profile and a considerably lower risk profile.

97. Plaintiff could not, by the reasonable exercise of care, have discovered PPIs' defects and perceived their danger.

98. The defects in Defendants' product were substantial and contributing factors in causing Plaintiffs injuries.

99. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff was caused to suffer from the aforementioned injuries and damages. Due to the unreasonably dangerous condition of PPIs, Defendants are strictly liable to Plaintiff.

COUNT FOUR – BREACH OF EXPRESS WARRANTY
(As to All Defendants)

100. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

101. Defendants expressly warranted that PPIs were safe for their intended use and as otherwise described in this Complaint. PPIs did not conform to these express representations, including, but not limited to, the representation that they were safe and the representation that they did not have high and/or unacceptable levels of side effects like kidney injuries.

102. The express warranties made by the Defendants were a part of the basis for Plaintiff's use of PPIs and Plaintiff relied on these warranties in deciding to use PPIs.

103. At the time of making the express warranties, the Defendants had knowledge of the purpose for which the PPIs were to be used, and warranted same to be in all respects safe, effective and proper for such purpose.

104. PPIs do not conform to these express representations because PPIs are not safe or effective and may produce serious side effects, including kidney injuries, degrading Plaintiff's health.

105. As a result of the foregoing breaches of express warranties the Plaintiff was caused to suffer Acute Kidney Failure, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff's kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

106. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendants' PPI drug.

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

COUNT FIVE– BREACH OF IMPLIED WARRANTY
(As to All Defendants)

108. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

109. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold PPIs.

110. The Defendants impliedly represented and warranted to the users of PPIs that PPIs were safe and fit for the particular purpose for which said product was to be used.

111. These aforementioned representations and warranties were false, misleading, and inaccurate because PPIs were unsafe, and degraded Plaintiff's health.

112. Plaintiff relied on the implied warranty of fitness for a particular use and purpose.

113. Plaintiff reasonably relied upon the skill and judgment of Defendants with respect to whether PPIs were safe and fit for their intended use.

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

115. Defendants breached the aforesaid implied warranties as PPIs were not fit for their intended purposes and uses.

116. As a result of the foregoing breach of warranties, the Plaintiff was caused to suffer serious and dangerous side effects, 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, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff’s kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

117. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related

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

COUNT SIX- PUNITIVE DAMAGES
(As to All Defendants)

118. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

119. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint, were willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other PPI users and for the primary purpose of increasing Defendants' profits from the sale and distribution of PPIs. 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 of Defendants.

120. Prior to the manufacturing, sale, and distribution of PPIs, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of serious and permanent injury from using PPIs.

121. Despite their knowledge, Defendants, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and

deliberately failed to remedy the known defects in PPIs and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in PPIs. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of PPIs knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

122. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

COUNT SEVEN - VIOLATION OF THE NEW JERSEY CONSUMER FRAUD ACT (As to All Defendants)

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

124. At all times relevant, the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et. seq., prohibits "[the] act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise…" and declares such acts or practices as unlawful.

125. Defendants violated the New Jersey Consumer Fraud Act by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Nexium. Defendants communicated the purported benefits of Nexium

while failing to disclose the serious and dangerous side effects related to the use of Nexium with the intent that consumers, including Plaintiff and Plaintiff's healthcare providers rely upon the omissions and misrepresentations and purchase or prescribe Nexium, respectively.

126. As a result of violating the New Jersey Consumer Fraud Act, Defendants caused Plaintiff to be prescribed and to use Nexium, causing severe injuries and damages as previously described herein.

COUNT EIGHT - PRODUCT LIABILITY – DESIGN DEFECT
(N.J.S.A. 2A:58C-1 *et seq*))
(As to All Defendants)

127. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

128. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed Nexium, including the Nexium used by Plaintiff, was in a defective and unreasonably dangerous condition.

129. Defendants expected Nexium to reach, and it did in fact reach, Plaintiff without substantial change in the condition in which it was manufactured and sold by the Defendants.

130. At all times relevant hereto, Defendants' Nexium was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for use by the public and in particular by Plaintiff.

131. At all times relevant to this action, Nexium, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by the Defendants, was defective in design and formulation in one or more of the following particulars:

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

b. When placed in the stream of commerce, Nexium was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

c. Nexium was insufficiently tested;

d. Nexium caused harmful side effects that outweighed any potential utility;

e. Defendants were aware at the time Nexium was marketed that ingestion of Nexium would result in an increased risk of AKI, CKD, ESRD, and other injuries;

f. Inadequate post-marketing surveillance; and/or

g. There were safer alternative designs and formulations that were not utilized.

132. Nexium was defective, failed to perform safely, and was unreasonably dangerous when used by ordinary consumers, including Plaintiff, as intended and in a reasonably foreseeable manner.

133. Nexium, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in its design or formulation, in that it was unreasonably dangerous and its foreseeable risks exceeded the alleged benefits associated with Nexium's design or formulation.

134. Nexium, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in

design or formulation in that it posed a greater likelihood of injury than other proton-pump inhibitors and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

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

136. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and otherwise ensure that Nexium was not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

137. When Defendants placed Nexium into the stream of commerce, they knew it would be prescribed to treat peptic disorders, and they marketed and promoted Nexium as safe for treating peptic disorders.

138. Plaintiff was prescribed, purchased, and used Nexium. Plaintiff used Nexium for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

139. Neither Plaintiff nor Plaintiff's health care professionals, by the exercise of reasonable care, could have discovered the defects and risks associated with Nexium before Plaintiff's ingestion of Nexium.

140. The harm caused by Nexium far outweighed its benefit, rendering Nexium more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed Nexium to make it less

dangerous. When Defendants designed Nexium, the state of the industry's scientific knowledge was such that a less risky design was attainable.

141. At the time Nexium left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the reasonably anticipated or intended function of Nexium. This was demonstrated by the existence of other peptic disorder medications that had a more established safety profile and a considerably lower risk profile.

142. Defendants' defective design of Nexium was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Nexium. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of Nexium.

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

144. Due to the unreasonably dangerous condition of Nexium, Defendants are liable to Plaintiff.

145. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of Nexium, including Plaintiff, with knowledge of the safety problems associated with Nexium, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

146. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered an AKI, and other related health

complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

COUNT NINE - PRODUCTS LIABILITY – FAILURE TO WARN
(N.J.S.A. 2A:58C-1 *et seq.*))
(As to All Defendants)

147. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

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

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

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

151. Nexium, as manufactured and/or supplied by Defendants, was defective due to inadequate warnings or instructions. Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

152. Nexium was defective and unsafe such that it was unreasonably dangerous when it left Defendants' possession and/or control, was distributed by Defendants, and ingested by Plaintiff. Nexium contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with Nexium, including the development of Plaintiff's injuries.

153. This defect caused serious injury to Plaintiff, who used Nexium for its intended purpose and in a reasonably anticipated manner.

154. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as are necessary to ensure Nexium did not cause users to suffer from unreasonable and dangerous risks.

155. Defendants negligently and recklessly labeled, distributed, and promoted Nexium.

156. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Nexium.

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

158. Plaintiff could not have discovered any defects in Nexium through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

159. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that Nexium caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of Nexium, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

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

161. Each of the Defendants knew or should have known that the limited warnings disseminated with Nexium were inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for

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

162. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended. In particular, Defendants:

a. disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of Nexium;

b. continued to aggressively promote Nexium even after Defendants knew or should have known of the unreasonable risks from use;

c. failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of Nexium and the comparative severity of such adverse effects;

d. failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with Nexium's capacity to cause its users to suffer CKD;

e. failed to adequately warn users, consumers, and physicians about the need to monitor renal function in patients who do not already suffer from renal impairment; and

f. overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, the risks associated with the use of Nexium.

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

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

165. Had Defendants properly disclosed and disseminated the risks associated with Nexium, Plaintiff would have avoided the risk of developing injuries as alleged herein.

166. The Defendants are liable to Plaintiff for injuries caused by their negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of Nexium and the risks associated with its use.

167. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered CKD, and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

COUNT TEN - PRODUCT LIABILITY – MANUFACTURING DEFECT
(N.J.S.A. 2A:58C-1 *et seq.*))
(As to All Defendants)

168. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

169. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Nexium.

170. At all times material to this action, Nexium was expected to reach, and did reach, consumers in the States of Virginia, New Jersey, and throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

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

a. When placed in the stream of commerce, Nexium contained manufacturing defects which rendered the product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of Defendants;

c. The subject product was not made in accordance with Defendants' specifications or performance standards; and/or

d. The subject product's manufacturing defects existed before it left the control of Defendants.

172. As a direct and proximate result of the design defect and Defendants' misconduct set forth herein, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has expended and will continue to expend large sums of money for medical care and treatment, has suffered and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

COUNT ELEVEN - PUNITIVE DAMAGES
UNDER COMMON LAW, THE PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15 *et seq.*)
AND THE PRODUCTS LIABILITY ACT (N.J.S.A. 2A:58C-1 *et seq.*))
(As to All Defendants)

173. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

174. Plaintiff is entitled to punitive damages because Defendants misrepresented and/or withheld information and materials from the FDA, the medical community and the public at large, including the Plaintiff, concerning the safety profile, and, more specifically the serious side effects and/or complications associated with Nexium.

175. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of Nexium, despite available information that Nexium was likely to cause serious side effects and/or complications.

176. In respect to the FDA, physicians, and consumers, Defendant downplayed, understated or disregarded knowledge of the serious and permanent side effects and risks associated with the use of Nexium, despite available information that Nexium was likely to cause serious side effects and/or complications.

177. Defendants' failure to provide the necessary materials and information to the FDA, as well as their failure warn physicians and consumers of the serious side effects and/or complications, was reckless and without regard for the public's safety and welfare.

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

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

DAMAGES

180. Plaintiff respectfully requests the following damages be considered separately and individually for the purpose of determining the sum of money that will fairly and reasonably compensate plaintiff:

a. Medical Expenses;

b. Pain and Suffering;

c. Mental Anguish, Anxiety, and Discomfort;

d. Physical Impairment;

e. Loss of Enjoyment of Life;

f. Pre and post judgment interest;

g. Exemplary and Punitive Damages;

h. Treble damages and

i. Reasonable and necessary attorney's fees.

WHEREFORE, Plaintiff demands judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate the Plaintiff for the injuries suffered or will suffer. Plaintiff further demands judgment against each of the Defendants for punitive damages. Plaintiff further demands payment by each of the Defendants jointly and severally of the costs and attorney fees of this action. Plaintiff further demands payment by each Defendant jointly and severally of interest on the above and such other relief as the Court deems just.

DATED: September 22, 2017

Respectfully submitted,

/s/ *Dae Y. Lee*
Dae Y. Lee (NJS Bar No. 033702012)
BERNSTEIN LIEBHARD LLP
10 East 40th Street
New York, New York 10016
Tel: (212) 779-1414
Fax: (212) 779-3218
Email: dlee@bernlieb.com
Email: jkeller@bernlieb.com
Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

DATED: September 22, 2017

RESPECTFULLY SUBMITTED,

/s/ Dae Y. Lee
Dae Y. Lee

JS 44 (Rev. 07/16)

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

Clarice Armstrong

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

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

DEFENDANTS

AstraZeneca Pharmaceuticals LP and AstraZeneca LP

County of Residence of First Listed Defendant New Castle Co., DE
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	☒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

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

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 Qui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. 1332(a)

Brief description of cause:
Products Liability Litigation involving Proton Pump Inhibitors

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

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

DATE 09/22/2017

SIGNATURE OF ATTORNEY OF RECORD /s/ Dae Y. Lee

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE