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

GINGER K. BRADY-BUNCH, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; PFIZER INC.; PROCTER & GAMBLE MANUFACTURING COMPANY; and THE PROCTER & GAMBLE COMPANY, Defendants.	)	CASE NO.: **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff, Ginger K. Brady-Bunch, by and through the undersigned counsel, hereby submits this Complaint against AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Pfizer Inc., Proctor & Gamble Manufacturing Company and The Proctor and Gamble Company for equitable relief, monetary restitution and compensatory and punitive damages arising from the injuries she suffered as a result of her use of the medications Nexium and Prilosec, and further alleges as follows.

NATURE OF THE ACTION

1. This is an action for personal injuries and economic damages suffered by Plaintiff Ginger K. Brady-Bunch ("Plaintiff") as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and sale of the proton pump-inhibiting

drugs ("PPIs") known as Nexium and Prilosec.

2. During the period in which Nexium and Prilosec have been sold in the United States, Defendants have had notice of serious adverse health outcomes through case reports, clinical studies and post-market surveillance. Specifically, Defendants received numerous case reports by as early as 2004 of kidney injuries in patients who had ingested Nexium, Prilosec and other PPIs.

3. Despite being on notice as to the excessive risks of kidney injuries related to the use of Nexium and Prilosec, Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Rather, Defendants continued to represent that Nexium and Prilosec did not pose any risk of kidney injuries.

4. In omitting, concealing and inadequately providing critical safety information regarding the use of Nexium and Prilosec in order to induce their purchase and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers, including Plaintiff, resulting in the development of kidney injuries.

PARTIES

Plaintiff

5. At all times referenced herein, Plaintiff Ginger K. Brady-Bunch ("Plaintiff") was and is a citizen of the State of Oklahoma.

6. Plaintiff was prescribed Nexium and Prilosec on numerous occasions, including but not limited to, January 2008 through present. Plaintiff ingested Nexium and Prilosec as prescribed by her doctor.

Defendants

AstraZeneca Pharmaceuticals LP

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

8. 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 selling Nexium products.

9. Upon information and belief, at all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in Plaintiff's state of residency.

10. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited and conducted business throughout the United States, including in Plaintiff's state of residency, and derived substantial revenue from such business.

11. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP expected or should have expected that its acts would have consequences within the United States of America, including in Plaintiff's state of residency.

12. Defendant AstraZeneca Pharmaceuticals LP is the holder of approved New Drug Applications ("NDAs") for the following forms of Nexium:

a. Delayed-Release Capsule Pellets (20 mg and 40 mg), with NDA # 021153, approved on 2/20/2001;

b. Delayed-Release Oral Suspension Packets (2.5MG, 5MG, 20MG, 40MG), with NDA # 021957, approved on 10/20/2006;

c. Delayed-Release Oral Suspension Packets (10MG), with NDA # 022101, approved on 02/27/2008; and

d. Injection (20MG VIAL, 40MG VIAL), with NDA # 021689, approved on 03/31/2005.

AstraZeneca LP

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

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

15. Upon information and belief, at all times relevant hereto, Defendant AstraZeneca LP was present and doing business throughout the United States, including in Plaintiff's state of residency.

16. At all times relevant hereto, Defendant AstraZeneca LP transacted, solicited and conducted business throughout the United States, including in Plaintiff's state of residency, and derived substantial revenue from such business.

17. At all times relevant hereto, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences within the United States, including in Plaintiff's state of residency.

AstraZeneca Pharmaceuticals LP & AstraZeneca LP's Unity of Interest

18. Defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP shall herein be collectively referred to as "Defendants" or "AstraZeneca."

19. Upon information and belief, at all times relevant hereto, each of the Defendants and their directors and officers acted within the scope of their authority. During the relevant times, Defendants possessed a unity of interest between themselves and exercised

control over their respective subsidiaries and affiliates.

20. Moreover, each Defendant was the agent and employee of each other and in doing the things alleged was acting within the course and scope of such agency and employment and with each other Defendant's 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 injuries, losses and damages.

Pfizer Inc.

21. Defendant Pfizer Inc. is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in New York, New York.

22. At all times relevant hereto, Defendant Pfizer Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and selling Nexium products.

23. Upon information and belief, at all relevant times, Defendant Pfizer Inc. was present and doing business in Plaintiff's state of residency.

24. At all relevant times, Defendant Pfizer Inc. transacted, solicited, and conducted business in Plaintiff's state of residency and derived substantial revenue from such business.

25. At all times relevant hereto, Defendant Pfizer Inc. expected or should have expected that its acts would have consequences within the United States and Plaintiff's state of residency in particular.

26. Defendant Pfizer Inc. acquired global over-the-counter rights to Nexium products from AstraZeneca in August 2012 and made Nexium 24HR available for purchase in the United States on or about May 27, 2014.

27. Defendant Pfizer Inc. is also the holder of an approved NDA for Nexium

24HR Delayed-Release Tablets (20 mg), with NDA # 207920, approved on November 23, 2015.

The Procter & Gamble Company

28. At all times relevant hereto, Defendant The Procter & Gamble Company was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and selling Prilosec products.

29. Defendant The Procter & Gamble Company is, and at all times relevant to this action was, an Ohio corporation with its corporate headquarters in Cincinnati, Ohio.

30. Upon information and belief, at all times relevant hereto, Defendant The Procter & Gamble Company was present and doing business throughout the United States, including in Plaintiff's state of residency.

31. At all times relevant hereto, Defendant The Procter & Gamble Company transacted, solicited and conducted business throughout the United States, including in Plaintiff's state of residency, and derived substantial revenue from such business.

32. At all times relevant hereto, Defendant The Procter & Gamble Company expected or should have expected that its acts would have consequences within the United States, including in Plaintiff's state of residency.

Procter & Gamble Manufacturing Company

33. At all times relevant hereto, Defendant Procter & Gamble Manufacturing Company was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and selling Prilosec products.

34. Defendant Procter & Gamble Manufacturing Company is, and at all times relevant to this action was, an Ohio corporation with its corporate headquarters in Cincinnati,

Ohio.

35. Upon information and belief, The Procter & Gamble Company is either the direct or indirect owner of substantially all of the stock or other ownership interests of Procter & Gamble Manufacturing Company.

36. Upon information and belief, at all times relevant hereto, Defendant Procter & Gamble Manufacturing Company was present and doing business throughout the United States, including in Plaintiff's state of residency.

37. At all times relevant hereto, Defendant Procter & Gamble Manufacturing Company transacted, solicited and conducted business throughout the United States, including in Plaintiff's state of residency, and derived substantial revenue from such business.

38. At all times relevant hereto, Defendant Procter & Gamble Manufacturing Company expected or should have expected that its acts would have consequences within the United States, including in Plaintiff's state of residency.

39. Defendants AstraZeneca LP, AstraZeneca Pharmaceuticals LP, Pfizer Inc., The Procter & Gamble Company, and Procter & Gamble Manufacturing Company shall herein be collectively referred to as "Defendants."

JURISDICTION AND VENUE

40. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $150,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as Plaintiff is a citizen of Oklahoma, which is different from the states where Defendants are incorporated and have their principal places of business.

41. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

42. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants are subject to personal jurisdiction and because a substantial part of the events giving rise to Plaintiff's claims occurred in this jurisdiction.

43. Venue is also proper in this Court pursuant to the August 2, 2017 Order entered by the United States Judicial Panel on Multidistrict Litigation centralizing cases in *In Re: Proton-Pump Inhibitor Products Liability Litigation* (No. II), MDL 2789, before the Honorable Claire C. Cecchi in this district.

FACTUAL BACKGROUND

Proton Pump Inhibitors Generally

44. Proton pump inhibitors are among the most commonly prescribed medications in the United States to treat conditions such as:

a. Gastroesophageal reflux disease ("GERD")
b. Dyspepsia
c. Acid peptic disease
d. Zollinger-Ellison syndrome
e. Acid reflux, and
f. Peptic or stomach ulcers.

45. In 2013, more than 15 million Americans used prescription PPIs, costing more than $10 billion. Of these prescriptions, however, it has been estimated that between 25% and 70% of them have no appropriate indication.

46. AstraZeneca sold Nexium with National Drug Code (NDC) numbers 0186-5020, 0186-5022, 0186-5040, 0186-5042, 0186-40100186-4020 and 0186-4040.

47. 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

dollars. In 2008, Nexium sales exceeded $5.2 billion dollars.

48. Nexium (esomeprazole magnesium) is a PPI that works by inhibiting the secretion of stomach acid. It shuts down acid production of the active acid pumps in the stomach, reducing hydrochloric acid in the stomach. The drug binds with the proton pump, which inhibits the ability of the gastric parietal cell to secrete gastric acid.

Dangers Associated with PPIs

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

50. During the period in which Nexium and Prilosec have been sold in the United States, hundreds of reports of injury have been submitted to the Food and Drug Administration ("FDA") in association with ingestion of Nexium, Prilosec 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 and related injuries in patients that had ingested Nexium and Prilosec, including but not limited to:

a. Acute Interstitial Nephritis ("AIN"),
b. Chronic Kidney Disease ("CKD"),
c. Renal/Kidney Failure,
d. Acute Kidney Injury ("AKI"), and
e. Clostridium difficile.

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

Increased Risk of Acute Interstitial Nephritis with PPIs

52. 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.[1]

53. 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").[2] Acute AIN was identified in 24 (8.1%) biopsies. Eight out of 14 cases with presumed drug-related AIN could be attributed to the proton pump inhibitors omeprazole and lansoprazole.

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

55. In 2004, Defendants knew or should have known of eight biopsy-proven cases reported from Norwich University Hospital in the United Kingdom.[3]

56. 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 the use of PPI over three

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

[2] 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.

[3] *Id*.

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.[4]

57. Furthermore, in the New Zealand study, Defendants knew or should have known that 12 of the reported cases were biopsy-proven.

58. 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.[5] "Failure to recognize this entity might have catastrophic long-term consequences including chronic kidney disease." The study was the largest hospital-based case series on this issue and involved a retrospective case review of potential cases at two teaching hospitals as well as a review of registry data from the Therapeutic Goods Administration of Australia. The team identified 18 cases of biopsy-proven PPI-induced AIN. The Therapeutic Goods Administration ("TGA") registry data identified an additional 31 cases of "biopsy proven interstitial nephritis." An additional 10 cases of "suspected interstitial nephritis," 20 cases of "unclassified acute renal failure," and 26 cases of "renal impairment" were also identified. "All 5 commercially available PPIs were implicated in these cases."

59. In 2006, the Center for Adverse Reaction Monitoring ("CARM") in New Zealand, found that PPI products were the number one cause of AIN.[6]

60. In 2006, researchers at the Yale School of Medicine conducted a case series

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

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

[6] 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).

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."

61. 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.

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

63. 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."[7] Klepser's study called for increased recognition of patient complaints or clinical manifestations of renal disease in order to prevent further injury.

64. 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.[8] 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."

65. In 2014, New Zealand researchers conducted a nested case-control study using routinely collected national health and drug dispensing data to estimate the relative and absolute risks of AIN resulting in hospitalization or death in users of PPIs.[9] The study compared past use with current and ongoing use of PPIs, finding a significantly increased risk of AIN for

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

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

[9] 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.

patients currently taking PPIs.

66. 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.

67. 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."

68. 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.*

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

70. In a study conducted by Benjamin Lazarus, et al., published in JAMA, PPI use was associated with a higher risk of incident CKD.[10] 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 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).

71. "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

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

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 suggests 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."[11]

72. 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, 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).

73. Lazarus's data was confirmed and expanded by Yan Xie, et al.[12] 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

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

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

study tracked 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.

74. However, evidence of the connection of PPIs with AIN and CKD existed as early as 2007.[13] 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, pantoprazole, and rabeprazole, demonstrating that "AIN is a complication associated with all PPIs."[14]

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

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

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

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

79. 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.

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

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

80. 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.

81. 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 non-indicated or long-term usage.

82. From these findings, PPIs and 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 AIN, a sudden kidney inflammation that can result in mild to severe problems.

83. 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.

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

85. CKD describes a slow and progressive decline in kidney function that may result in End-Stage Renal Disease ("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.

86. 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.

87. 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.

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

89. 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.

90. 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.

91. 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.

92. 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.

93. 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.

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

Association between Chronic Kidney Disease and PPIs

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

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

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

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

99. 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 comorbidities and concomitant use of medications.

100. In at least one study, the use of PPIs for *any period of time* was shown to

increase the risk of CKD by 10%.

101. As a group, patients with renal disease are nearly twice as likely to have been exposed to PPIs compared to those without renal disease.

102. Various medical studies support the fact that there is an association between PPIs, including Nexium and Prilosec, and CKD. *See, e.g.*, *JAMA Intern Med*. 2016; 176(2): pp. 238-246, "Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease," Published online January 11, 2016, Corrected on February 29, 2016.

103. Currently, Nexium and Prilosec lack any warning of CKD.

Acute Kidney Injury Dangers Associated with PPIs

104. Studies indicate that patients taking PPIs, such as Nexium and Prilosec, are at a 2.5 times greater risk than the general population to suffer AKI.

105. Studies also indicate that those who develop AIN are at a significant risk of developing AKI even though there may not be obvious kidney dysfunction.

106. Various medical studies support the fact that there is an association between PPIs, including Nexium and Prilosec, and AKI. *See, e.g.*, Klepser DG, Collier DS, Cochran GL. *Proton pump inhibitors and acute kidney injury: a nested case–control study*, BMC Nephrol 2013; 14:150; available at http://bmcnephrol.biomedcentral.com/articles/10.1186/1471-2369-14-150; Antoniou T, Macdonald EM, Hollands S, et al. *Proton pump inhibitors and the risk of acute kidney injury in older patients: a population-based cohort study*. CMAJ 2015;3: E166–71; available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4571830/.

107. Currently, Nexium and Prilosec lack any warning of AKI.

Availability of Safer Alternatives to PPIs

108. Nexium, Prilosec and other PPIs lead to an increased risk of the injuries

outlined herein, but numerous safer alternatives are available.

109. Such safer alternative treatments include but are not limited to:

a. the use of over-the-counter calcium carbonate remedies, such as Maalox and Tums, which have been available since the 1930s, and

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. Examples of H2 blockers are Zantac, Pepcid and Tagamet.

110. Even though these safer alternatives at all relevant times existed, the sale of PPIs such as Nexium and Prilosec skyrocketed at the same time that the safer alternatives, namely the H2 blockers, plummeted.

111. This is true despite the fact that higher kidney injury risks are specific to PPI medications. The use of H2-receptor antagonists, which are prescribed for the same indication as PPIs, is not associated with such renal injuries.

Allegations Common to All Causes of Action

112. Defendants knew or should have known about the correlation between the use of Nexium and Prilosec and the significantly increased risk of AIN, CKD, AKI and renal impairment. Yet Defendants failed to adequately warn against these negative effects and risks associated with Nexium and Prilosec.

113. In omitting, concealing and inadequately providing critical safety information regarding the use of Nexium and Prilosec to Plaintiff and Plaintiff's doctors in order to induce its purchase, prescription and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiff and Plaintiff's doctors. This conduct is

fraudulent, unfair and unlawful.

114. Despite clear knowledge that Nexium and Prilosec cause a significantly increased risk of AIN, CKD, AKI and renal impairment, Defendants continue to market and sell Nexium and Prilosec without warning consumers or healthcare providers of these significant risks.

TOLLING OF THE STATUTE OF LIMITATIONS

115. Defendants, at all relevant times, knew or should have known of the problems and defects with Nexium and Prilosec products and the falsity and misleading nature of Defendants' statements, representations and warranties with respect to Nexium and Prilosec products. Defendants concealed and failed to notify Plaintiff and the public of such defects.

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

CASE-SPECIFIC INFORMATION

117. Upon information and belief, in or before January 2007, Dr. Barry Troutman discussed prescribing PPIs to Plaintiff. Dr. Troutman discussed the risks and benefits of Nexium and Prilosec. Because Defendants did not disclose the true risks of acute and chronic kidney injuries associated with the use of Nexium and Prilosec to Dr. Troutman, nor did Defendants disclose the true risks of acute and chronic kidney injuries in the information given to Plaintiff, it was impossible for Dr. Troutman to adequately discuss the true risks and benefits of Nexium and Prilosec with Plaintiff. Consequently, it was impossible for Plaintiff to learn of the true risks associated with Nexium.

118. Plaintiff, after a consultation with Dr. Troutman, began using Nexium on or about February 23, 2007. Dr. Troutman would not have prescribed Nexium and Prilosec to

Plaintiff if Dr. Troutman knew of the true risks associated with the use of Nexium and Prilosec. In other words, Dr. Troutman would not have prescribed Nexium and Prilosec to Plaintiff if he knew the true risks associated with the use of Nexium and Prilosec.

119. The Nexium and Prilosec used by Plaintiff remained in substantially the same condition between when it left Defendants' control and used by Plaintiff.

120. Plaintiff would not have elected to use Nexium and Prilosec if she knew of the true risks associated with the use of Nexium and Prilosec. In other words, Plaintiff would not have elected to use Nexium and Prilosec if she knew the true risk of acute and chronic kidney injuries associated with the use of Nexium and Prilosec.

121. Upon information and belief, on October 8, 2015, Plaintiff suffered AKI and was hospitalized. Plaintiff suffered AKI because Nexium and Prilosec were negligently and defectively designed. Defendants knew that Nexium and Prilosec were negligently and defectively designed when they left Defendants' control, and Defendants knew that they caused AKI at a higher rate than other similar medications on the market. Defendants did not disclose these facts to Dr. Troutman or Plaintiff.

122. Through no fault of her own, and no fault of her health care providers, on October 8, 2015, Plaintiff suffered AKI. The AKI caused pain and suffering, financial loss and permanent injury to Plaintiff.

CAUSES OF ACTION

COUNT I
STRICT PRODUCT LIABILITY

123. Plaintiff incorporates by reference the allegations set forth in the paragraphs above as if fully set forth herein.

124. The Nexium and Prilosec manufactured and supplied by Defendants were unaccompanied by proper warnings regarding all possible adverse side effects and the comparative severity and duration of such adverse effects; the warnings given did not accurately reflect the severity or duration of the adverse side effects or the true potential and likelihood or rate of the side effects. Defendants failed to perform adequate testing in that adequate testing would have shown that Nexium and Prilosec possessed serious potential side effects about which full and proper warnings accurately and fully reflecting symptoms, scope and severity of potential side effects should have been made. Had the testing been adequately performed, the product would have been allowed to enter the market, if at all, only with warnings that would have clearly and completely identified the risks and dangers of the drug.

125. The Nexium and Prilosec manufactured, distributed and supplied by Defendants were defective due to inadequate post-marketing warnings or instructions because Defendants failed to provide adequate warnings to users or consumers of Nexium and Prilosec and continued to aggressively promote Nexium and Prilosec.

126. As the proximate cause and legal result of the defective condition of Nexium and Prilosec as manufactured, supplied and distributed by Defendants, and as a direct and legal result of the conduct of Defendants described herein, Plaintiff has been harmed.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT II
DEFECTIVE DESIGN

127. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

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

129. At all times material to this action, Nexium and Prilosec were expected to reach, and did reach, consumers, including Plaintiff, in Plaintiff's home state and throughout the United States without substantial change in the condition in which they were sold.

130. At all times material to this action, Nexium and Prilosec were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and 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 Prilosec contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the 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 Prilosec were defective in design and formulation, making the use of Nexium and Prilosec 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 defects of Nexium and Prilosec existed before they left the control of Defendants;

d. Nexium and Prilosec were insufficiently and inadequately tested;

e. Nexium and Prilosec caused harmful side effects that outweighed any potential utility; and

f. Nexium and Prilosec were not accompanied by adequate instructions and 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.

131. In addition, at the time the product left the control of Defendants, there were practical and feasible alternative designs that would have prevented and significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. 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 product's utility.

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 and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

COUNT III
FAILURE TO WARN

132. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

133. Nexium and Prilosec 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 products, including but not limited to their propensity to cause 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 products were unreasonably dangerous because an adequate warning was not provided.

134. The products manufactured and supplied by Defendants were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the products, Defendants failed to provide adequate warnings to consumers and their health care providers of the defects of the products or alternatively failed to conform to federal and state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury or death.

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

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

137. Defendants, as manufacturers and distributors of the products, are held to the level of knowledge of an expert in the field.

138. Defendants, the manufacturers and distributors of the 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.

139. The warnings that were given by Defendants were ambiguous and not

accurate.

140. 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: AIN, CKD, Renal/Kidney Failure, AKI, and Clostridium difficile.

141. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

142. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Nexium and Prilosec.

143. Had Plaintiff received adequate warnings regarding the risks of Nexium, she would not have used them or would have chosen a different course of treatment.

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 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
NEGLIGENCE

144. Plaintiff incorporates by reference the allegations set forth in the paragraphs above as if fully set forth herein.

145. Defendants owed Plaintiff legal duties in connection with their development, manufacture and distribution of Nexium and Prilosec. Defendants breached those duties, proximately causing Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling and warning of Nexium and Prilosec. Defendants are liable for acts and

omissions amounting to negligence, gross negligence and malice including, but not limited to the following:

a. Failure to adequately warn Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Nexium and Prilosec;

b. Failure to adequately warn Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintif would suffer a serious injury or death by ingesting Nexium and Prilosec in unsafe doses;

c. Failure to use reasonable care in testing and inspecting Nexium and Prilosec so as to ascertain whether or not they were safe for the purpose for which they were designed, manufactured and sold;

d. Failure to use reasonable care in implementing and utilizing a reasonably safe design in the manufacture of Nexium and Prilosec;

e. Failure to use reasonable care in the process of manufacturing Nexium and Prilosec in a reasonably safe condition for the use for which they were intended;

f. Failure to use reasonable care in the manner and method of warning Plaintiff's physicians as to the danger and risks of using Nexium and Prilosec in unsafe doses; and

g. Such further acts and omissions that may be proven at trial.

146. The above-described acts and omissions of Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT V
FALSE MISREPRESENTATION

147. Plaintiff incorporates by reference the allegations set forth in the paragraphs above as if fully set forth herein.

148. Defendants failed to communicate to Plaintiff and the general public that the ingestion of Nexium or Prilosec could cause serious injuries after they became aware of such risks. Instead, Defendants represented in their marketing that Nexium and Prilosec were safe and effective.

149. Plaintiff brings this cause of action against Defendants under the theory of false misrepresentation for the following reasons:

a. Defendants individually, and through their agents, representatives, distributors and employees, negligently misrepresented material facts about Nexium and Prilosec in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;

b. The above misrepresentations were made to Plaintiff as well as the general public;

c. Plaintiff and Plaintiff's healthcare providers justifiably relied on Defendants' misrepresentations; and

d. Consequently, Plaintiff ingested Nexium and Prilosec to Plaintiff's detriment.

e. Defendants' negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT VI
EXPRESS WARRANTY

150. Plaintiff incorporates by reference the allegations set forth in the paragraphs above as if fully set forth herein.

151. Defendants are merchants and sellers of Nexium and Prilosec. Defendants sold Nexium and Prilosec to consumers, including Plaintiff, for the ordinary purpose for which such drugs are used by consumers. Defendants made representations to Plaintiff about the quality or characteristics of Nexium and Prilosec by affirmation of fact, promise or description. The representations by Defendants became part of the basis of the bargain between Defendants and Plaintiff. Nexium and Prilosec did not comport with the representations made by Defendants in that they were not safe for the use for which they were marketed. This breach of duty by Defendants was a proximate cause of the injuries and monetary loss suffered by Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT VII
FRAUD

152. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

153. Defendants made material representations that were false and that were either known to be false when made or were asserted without knowledge of their truth. Defendants had in their possession adverse drug event reports, drug studies and other documentation about Nexium and Prilosec and yet made the following misrepresentations:

a. Misrepresentations regarding the frequency of Nexium and Prilosec-related adverse event reports or occurrences in the Nexium and Prilosec labels, package inserts or Physicians' Desk Reference ("PDR") labels;

b. Misrepresentations as to the existence, occurrence and frequency of occurrences, severity and extent of the overall risks of Nexium and Prilosec;

c. Misrepresentations as to the efficacy of Nexium and Prilosec;

d. Misrepresentations as to the number of adverse events and deaths reported with the use of Nexium and Prilosec; and

e. Misrepresentations regarding the nature, seriousness and severity of adverse events reported with the use of Nexium and Prilosec.

154. Defendants intended that these misrepresentations be relied upon by physicians, including Plaintiff's physicians, healthcare providers and consumers. Plaintiff did rely upon the misrepresentations that caused Plaintiff's injuries.

155. Defendants' misrepresentations were the proximate or producing cause of Plaintiff's injuries.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

PUNITIVE DAMAGES ALLEGATIONS

156. Plaintiff incorporates by reference each of the allegations set forth in this Complaint as though set forth fully herein and further alleges as follows.

157. 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 Nexium and Prilosec users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Nexium and Prilosec. 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.

158. Prior to the manufacturing, sale and distribution of Nexium and Prilosec, Defendants knew that Nexium was in a defective condition as previously described herein 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 medications presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers to risk of injury or death from using Nexium and Prilosec.

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

160. 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 her to exemplary damages.

WHEREFORE, Plaintiff respectfully requests an award of punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for judgment against all Defendants and award of 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 trial as to all claims and issues triable of right by a jury.

Respectfully submitted,

Dated: August 4, 2017

/s/ *Dianne M. Nast*

Dianne M. Nast (N.J. Atty. ID No. 012611976)
Daniel N. Gallucci (PA Atty. ID No. 81995)
Joanne E. Matusko (PA Atty. ID No. 91059)
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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

Ginger K. Brady-Bunch

(b) County of Residence of First Listed Plaintiff Tulsa County, OK
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, Email and Telephone Number)*
Dianne M. Nast, Esq. dnast@nastlaw.com
NASTLAW LLC (215) 923-9300
1101 Market Street, Suite 2801 / Philadelphia, PA 19107

DEFENDANTS

AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Pfizer, Inc., The Procter & Gamble Company, and Procter & Gamble Manufacturing Co

County of Residence of First Listed Defendant New Castle County, 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

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

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

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

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

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)(1)

Brief description of cause:
Product Liability Litigation

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 75,001.00

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 MDL No. 2789

DATE 08/04/2017

SIGNATURE OF ATTORNEY OF RECORD /s Dianne M. Nast

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Print Save As... Reset

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

GINGER K. BRADY-BUNCH

Plaintiff

v.

ASTRAZENECA PHARMACEUTICALS LP, et. al

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* ASTRAZENECA LP
AGENT: THE CORPORATION TRUST COMPANY
1209 ORANGE STREET
WILMINGTON, DE 19801

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Dianne M. Nast, Esq.
NastLaw LLC
1101 Market Street, Suite 2801
Philadelphia, PA 19107

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* GINGER K. BRADY-BUNCH was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

GINGER K. BRADY-BUNCH

Plaintiff

v.

ASTRAZENECA PHARMACEUTICALS LP, et. al

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* ASTRAZENECA PHARMACEUTICALS LP
AGENT: THE CORPORATION TRUST COMPANY
1209 ORANGE STREET
WILMINGTON, DE 19801

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Dianne M. Nast, Esq.
NastLaw LLC
1101 Market Street, Suite 2801
Philadelphia, PA 19107

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* GINGER K. BRADY-BUNCH was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

GINGER K. BRADY-BUNCH

Plaintiff

v.

ASTRAZENECA PHARMACEUTICALS LP, et. al

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* PFIZER, INC.
235 EAST 42ND STREET
NEW YORK, NY 10017

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Dianne M. Nast, Esq.
NastLaw LLC
1101 Market Street, Suite 2801
Philadelphia, PA 19107

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* GINGER K. BRADY-BUNCH was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

GINGER K. BRADY-BUNCH

Plaintiff

v.

ASTRAZENECA PHARMACEUTICALS LP, et. al

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* PROCTER & GAMBLE MANUFACTURING COMPANY
1 PROCTER & GAMBLE PLAZA
CINCINNATI, OH 45202

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Dianne M. Nast, Esq.
NastLaw LLC
1101 Market Street, Suite 2801
Philadelphia, PA 19107

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* GINGER K. BRADY-BUNCH was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of New Jersey

GINGER K. BRADY-BUNCH

Plaintiff

v.

ASTRAZENECA PHARMACEUTICALS LP, et. al

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* THE PROCTER & GAMBLE COMPANY
1 PROCTER & GAMBLE PLAZA
CINCINNATI, OH 45202

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Dianne M. Nast, Esq.
NastLaw LLC
1101 Market Street, Suite 2801
Philadelphia, PA 19107

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CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

.

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: