

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF ILLINOIS

**IRMA COLEMAN and JAMES B  
COLEMAN, h/w**

**Plaintiffs,**

**v.**

**ASTRAZENECA PHARMACEUTICALS  
LP; ASTRAZENECA LP; PROCTER &  
GAMBLE MANUFACTURING  
COMPANY; and THE PROCTER &  
GAMBLE COMPANY ABC  
CORPORATIONS, 1-10, the fictitious names  
for unknown companies and/or other  
business entities; JOHN DOES, 1-10, the  
fictitious names for unknown companies  
and/or other business entities; and JANE  
DOES, 1-10, the fictitious names for  
unknown companies and/or other business  
entities and/or other business entities**

**Defendants.**

**COMPLAINT AND  
DEMAND FOR JURY TRIAL**

**Case No. 3:17-cv-130**

**Division No.**

.....  
**COMPLAINT**

PLAINTIFFS, **IRMA COLEMAN**, (alternatively referred to as “Plaintiff) and **JAMES B. COLEMAN**, (hereinafter “Plaintiff-Spouse”), domiciled in **RAMSEY (FAYETTE COUNTY)** within the State of **ILLINOIS**, by and through the undersigned attorneys, hereby bring this cause of action against Defendants **AstraZeneca Pharmaceuticals LP (“AstraZeneca Pharmaceuticals”), AstraZeneca LP, Procter & Gamble Manufacturing Company (“Procter & Gamble Manufacturing”) and The Procter & Gamble Company (collectively “Defendants”)** and as for their Complaint alleges, upon information and belief and based on the investigation to date of counsel, as follows:

**NATURE OF ACTION**

1. This is a personal injury action against Defendants, AstraZeneca Pharmaceuticals LP AstraZeneca LP, Procter & Gamble Manufacturing Company and The Procter & Gamble Company and their affiliates, subsidiaries, alter-egos, and/or joint-venturers who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling proton pump inhibitors (“PPI”s), specifically, Nexium, Prilosec, and Prilosec OTC, respectively.

2. Nexium, Prilosec, and Prilosec OTC are herein collectively referred to as “PPIs.”

3. PPIs are used to reduce the production of acid in order to reduce the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as to treat gastroesophageal reflux disease (“GERD”) and certain pathological hypersecretory conditions including Zollinger-Ellison syndrome.

4. Plaintiff in this case, Irma Coleman, ingested Prilosec and Prilosec OTC from January 5, 2009 to February 18, 2013, and Nexium from February 18, 2013 to January 19, 2015 which, upon information and belief, resulted in injuries to her kidneys, including chronic kidney disease on July 14, 2014 and acute renal failure on May 10, 2015.

**PLAINTIFFS**

5. Plaintiff, Irma Coleman, is a natural person and a domiciliary of Ramsey, Illinois located in Fayette County. Plaintiff ingested Prilosec and Nexium, as prescribed and/or directed by her physician, as well as Prilosec OTC.

6. Plaintiff-Spouse, James B. Coleman, is a natural person and domiciliary of Ramsey, Illinois located in Fayette County.

7. Plaintiff, Irma Coleman was injured as a result of her use of Prilosec, Nexium and Prilosec OTC and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, reimbursement costs of obtaining PPIs, and reimbursement for all past, present, and future health and medical care costs related to PPIs.

**DEFENDANTS**

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

9. Defendant ASTRAZENECA LP is a limited partnership, which has its principal place of business at 1800 Concord Pike, Wilmington, DE 19897.

10. In doing the acts alleged herein, said Defendants 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 are collectively referred to as "ASTRAZENECA").

11. Defendant PROCTER & GAMBLE MANUFACTURING COMPANY is an Ohio corporation, which has its principal place of business at 1 Procter & Gamble Plaza, Cincinnati.

12. Defendant THE PROCTER & GAMBLE COMPANY is an Ohio corporation, which has its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, OH 45202.

13. On information and belief, THE PROCTER & GAMBLE COMPANY is either the direct or indirect owner of substantially all the stock or other ownership interests of PROCTER & GAMBLE MANUFACTURING COMPANY.

14. In doing the acts alleged herein, said Defendants 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 THE PROCTER & GAMBLE COMPANY and PROCTER & GAMBLE MANUFACTURING COMPANY are collectively referred to as “PROCTER & GAMBLE”).

15. On information and belief, Defendants have transacted and conducted business in the State of Illinois, and/or contracted to supply goods and services within the State of Illinois, and these causes of action have arisen from the same.

16. On information and belief, at all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States of America and the State of Illinois.

17. On information and belief, at all relevant times, Defendants derived and derive substantial revenue from goods and products used in the State of Illinois and from interstate commerce.

18. On information and belief, at all relevant times, Defendants committed tortious acts within the State of Illinois causing injury within the State of Illinois, out of which act(s) these causes of action arise.

#### **JURISDICTION AND VENUE**

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

20. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff’s claims occurred, in part, in the Southern District of Illinois.

21. Because a substantial part of the events or omissions giving rise to the claim occurred in this District, Defendants transacts a substantial amount of business in this District, or Defendants otherwise has sufficient contacts with this District to justify it being fairly brought into this District, and Plaintiff is domiciled in this District and was first injured in this District.

### **SUMMARY OF THE CASE**

22. This action is for damages brought on behalf of Plaintiff, Irma Coleman, who was prescribed and took the over the counter and prescription PPIs manufactured by Defendants. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff suffering severe and life threatening events of chronic kidney disease and acute renal failure caused by PPIs, including Nexium, Prilosec, and Prilosec OTC.

23. As a result of the defective nature of PPIs, persons who ingested this product, including Plaintiff, 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”).

24. 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.

25. 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.

26. Nexium, Prilosec, and Prilosec OTC are members of the proton pump inhibitor class of pharmaceuticals also known as PPIs.

27. PPIs, including Nexium, Prilosec and Prilosec OTC, irreversibly block the stomach's proton pump of acid producing parietal cells thereby suppressing gastrointestinal acid secretion.

28. In inhibiting the stomach's proton pump, PPIs, including Nexium, Prilosec and Prilosec OTC, cause inflammation of the kidneys' tubules resulting in an immunogenic injury to the kidney through haptimization, antigen mimicry, and/or neo-antigen formation.

29. The inflammation of the kidney tubules, also known as interstitial nephritis, is the cause of the vast majority of acute kidney injuries, and can lead to chronic kidney disease, the upstaging of chronic kidney disease, and end-stage renal disease requiring dialysis.

30. AstraZeneca LP, in collaboration with AstraZeneca Pharmaceuticals LP, designed and developed the proton pump inhibitor, Nexium.

31. In December, 1999, AstraZeneca Pharmaceutical LP submitted its first NDA for a Nexium product, NDA # 21-153, also known as esomeprazole magnesium to the FDA for approval to market Nexium in the United States.

32. In December, 2000, the FDA approved Nexium, NDA 21-153, and Nexium Delayed Release, NDA 21-154 for healing of erosive esophagitis, maintenance of healing erosive esophagitis, and treatment of GERD.

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

- d. Injection (20MG VIAL, 40MG VIAL), with NDA number 021689, approved on 03/31/2005.021689.

34. AstraZeneca entities market and sell Nexium with National Drug Code numbers 0186-5020, 0186-5040, and 0186-4040.

35. AstraZeneca employees hold key roles in the design, development, regulatory approval, manufacturing, distribution, and marketing of Nexium and direct these activities on behalf of AstraZeneca PLC.

36. AstraZeneca LP, in collaboration with AstraZeneca Pharmaceuticals LP, designed and developed the proton pump inhibitor, Prilosec.

37. In 1989, AstraZeneca Pharmaceutical LP submitted its first NDA for a Prilosec product, NDA # 019810, also known as omeprazole, to the FDA for approval to market Prilosec in the United States.

38. In September 1989, the FDA approved Prilosec, NDA #019810 for healing of erosive esophagitis, maintenance of healing erosive esophagitis, and treatment of GERD.

39. AstraZeneca Pharmaceutical LP is the holder of approved NDAs for the following forms of Prilosec:

- a. Delayed-Release Capsule Pellets (20 mg) , with NDA #019810, approved on 9/14/1989;
- b. Delayed-Release Capsule Pellets (10mg) , with NDA #019810, approved on 10/5/1995;
- c. Delayed-Release Capsule Pellets (40mg), with NDA #019810, approved on 1/15/1998;

d. Delayed-Release Oral Suspension (2.5 & 10mg) with NDA # 022056, approved on 3/20/2008.

40. AstraZeneca entities market and sell Prilosec with National Drug Code numbers 0186-0625, 0186-0610, 0186-0606, 0186-0742 and 0186-0743.

41. Procter & Gamble Co., in collaboration with Procter & Gamble Manufacturing Company and AstraZeneca Pharmaceuticals LP, designed and developed the proton pump inhibitor, Prilosec OTC.

42. In January 2000, Procter & Gamble Co. submitted its first NDA for a Prilosec OTC product, NDA # 021229, also known as omeprazole to the FDA for approval to market Prilosec OTC in the United States.

43. In June 2003, the FDA approved Prilosec OTC, NDA #021229, for healing of erosive esophagitis, maintenance of healing erosive esophagitis, and treatment of GERD.

44. Procter & Gamble Co. is the holder of NDAs for Prilosec OTC (20 mg; delayed-release tablets), with NDA # 021229, approved on 6/20/2003.

45. Procter & Gamble Co. entities market and sell Prilosec OTC with National Drug Code numbers 37000-459.

46. Materials including advertisements, press releases, web site publications, and other communications regarding all PPIs herein mentioned are part of the labeling of the drug, and could be altered by AstraZeneca and Procter & Gamble with respect to their corresponding PPIs without prior FDA approval.

47. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPIs and failed to warn about the risks of acute interstitial nephritis, acute kidney failure and other injuries.



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

49. There are a multitude of studies that have been published linking the danger of PPI use with AIN and Chronic Kidney Disease including:

- a. Lazarus et al., Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease, *Jama International Medicine*, at <http://archinte.jamanetwork.com>. (2016).
- b. Xie et al., Proton Pump Inhibitors and Risk of Incident CKD and Progression to ESRD, *Journal of the American Society of Nephrology*. (2016)
- c. Klepser et al., Proton pump inhibitors and acute kidney injury: a nested case–control study, *BMC Nephrology*, 14:150 (2014).

50. Despite Defendants' knowledge of data indicating that PPI use is causally related to the development of chronic kidney disease, Defendants promoted and marketed PPIs as safe and effective for persons, such as Irma Coleman, throughout the United States, including Illinois.

51. Despite Defendants' knowledge of the increased risk of severe injury among PPI users, Defendants did not warn patients but instead continued to defend PPIs, mislead physicians and the public and minimize unfavorable findings.

52. Consumers of PPIs and their physicians relied on Defendants' false representations and were misled as to the drug's safety, and as a result have suffered injuries, including acute kidney injury, chronic kidney disease, kidney failure, and life-threatening complications thereof.

53. Consumers, including Irma Coleman, have several alternative safer methods for treating GERD, including home remedies and other medication, including H2 antagonists.

54. As a result of the defective nature of PPIs, persons who ingested these products, including Plaintiff, have suffered and may continue to suffer from kidney injuries including acute interstitial nephritis, acute kidney injuries, chronic kidney disease (“CKD”) and renal failure, also known as end-stage renal disease.

55. 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 and continue to fail to adequately inform and warn consumers and the prescribing medical community about the magnified risk of kidney injuries related to the use of PPIs including Nexium, Prilosec and Prilosec OTC.

56. As a result of Defendants actions and inactions, Plaintiff was injured due to her ingestion of Nexium, Prilosec and Prilosec OTC, which caused and will continue to cause Plaintiff’s injuries and damages. Plaintiff accordingly seeks damages associated with these injuries and sequelae.

### **FACTUAL ALLEGATIONS**

57. 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.

58. 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.

59. 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.

60. 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 a sale of over \$50 billion with approximately 240 million units dispensed.

61. Defendants, directly or through their agents, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed, promoted, and sold PPIs, including Nexium, Prilosec, and Prilosec OTC.

62. 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.

63. 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."

64. In 2007, F. Sierra et al. published an article in the *Journal of Alimentary Pharmacology and Therapeutics*, titled, "Systematic review: proton pump inhibitor-associated acute interstitial nephritis." The researchers concluded that long term use of proton pump inhibitors is associated with interstitial nephritis.

65. In February 2007, Harmark et al. published an article in the British Journal of Clinical Pharmacology titled “Proton pump inhibitor-induced acute interstitial nephritis.” The article states:

*Our reports show that AIN can be induced by various PPIs. This assumption is supported by data from the World Health Organization Collaborating Centre for International Drug Monitoring in Uppsala, Sweden, where PPI-induced AIN is disproportionately present in the database. The reporting odds ratios are presented in Table 2. This databank contains more than 3.7 million spontaneous reports of adverse drug reactions from more than 80 countries worldwide. About 150 of these concern PPI-induced AIN, showing that this is a relatively rare condition.*

66. 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.

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

68. 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.

69. 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.”

70. 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 [PPI] if acute interstitial nephritis develops.*

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

72. In January of 2016, a study published in the Journal of the American Medical Association found that PPI use was independently associated with a 20-50% higher risk of CKD.

73. In February of 2016, a study published in the Journal of the American Society of Nephrology found that “exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD.”

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

75. To date, prescription and over-the-counter PPIs lack detailed risk information for CKD including those manufactured by Defendants, specifically Nexium, Prilosec, and Prilosec OTC that were taken by Plaintiff.

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

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

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

79. 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.

80. 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.

81. 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.

82. 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.

83. AIN’s slow presentation can cause significant damage over time without those affected exhibiting acute symptoms.

84. PPI-induced AIN exclusively affects the kidney’s interstitial tissue, rather than the kidney’s glomeruli, as seen in non-PPI induced kidney injury.

85. Unlike many forms of AIN, PPI-induced AIN results in an excess of white blood cells in the urine, indicating an immunological response.

86. 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.

87. Analyses of the study were adjusted for age, sex, race, baseline eGFR, cigarette smoking, BMI, systolic blood pressure, diabetes, a history of cardiovascular disease, antihypertensive medication use, anticoagulant medication use, statin, aspirin, NSAID use.

Across all groups, “each of these sensitivity analyses showed a consistent association between PPI use and a higher risk of CKD.

88. 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.

89. 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.

90. 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.

91. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with the use of Nexium, Prilosec, or Prilosec OTC use.

92. 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 completely failed to warn against the risk of CKD and ESRD to this day.

93. 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.

94. 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 First Amended Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

95. 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.

96. 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.

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

**ESTOPPEL FROM PLEADING AND  
TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

98. The running of any statute of limitation has been tolled by reason of the Defendants' conduct. The Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with PPIs.

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

100. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPIs. The Defendants were under a duty to disclose the true character, quality and nature of PPIs because this was non-



public information that the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers, and/or to their health facilities.

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

102. Plaintiff was not aware of the connection between the use of Proton Pump Inhibitors and chronic kidney disease until May of 2016, when Plaintiff saw a television commercial identifying the possible link between Proton pump inhibitors (including the Proton Pump Inhibitors prescribed and taken by Plaintiff) and kidney disease.

103. Prior to May of 2016, Plaintiff did not have access to, or actually receive any studies or information recognizing the increased risk of chronic kidney disease with Proton Pump Inhibitor use.

**COUNT I**  
**NEGLIGENCE**

104. The paragraphs above are incorporated by reference hereto as if set forth at length.

105. The Plaintiff pleads this Count in the broadest sense available under law to include pleading same pursuant to all substantive law that applies to this case as may be determined by choice of law principles, regardless of whether arising under statute and/or common law.

106. Defendants owed a duty to manufacture, compound, label, market, distribute, and supply and/or sell their PPI in such a way as to avoid harm to persons upon whom they are used,

such as Plaintiff, Irma Coleman, or to refrain from such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

107. Defendants owed a duty to warn of the hazards and dangers associated with the use of its products for patients such as, Plaintiff, Irma Coleman herein, so as to avoid harm.

108. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were guilty of carelessness, recklessness, negligence, gross negligence and willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their proton pump inhibitor products, including in the following particular respects:

- a. failing to conduct adequate and appropriate testing of its PPI products.
- b. putting proton pump inhibitor products on the market without first conducting adequate testing to determine possible side effects;
- c. putting proton pump inhibitor products on the market without adequate testing their dangers to humans;
- d. failing to recognize the significance of their own and other testing of, and information regarding proton pump inhibitor products, which testing evidenced such products are potentially harmful to humans;
- e. failing to respond promptly and appropriately to their own and other testing of, and information regarding proton pump inhibitor products, which indicated such products are potentially harmful to human;
- f. failing to promptly and adequately warn of the potential of proton pump inhibitor products to be harmful to humans;

- g. failing to promptly and adequately warn of the potential for kidney injuries including acute interstitial nephritis, acute kidney injuries, and chronic kidney disease when using proton pump inhibitor products;
- h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom these products were used in light of such products potential harm to humans;
- i. failing to properly, appropriately, and adequately monitor the post-market performance of proton pump inhibitors and such products effects on patients;
- j. concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that proton pump inhibitors are harmful to humans;
- k. promoting, marketing, advertising and/or selling PPIs for use on patients given their knowledge and experience of such products' potential harmful effects;
- l. failing to withdraw PPIs from the market, restrict their use and/or warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;
- m. failing to fulfill the standard of care required of a reasonable, prudent, products manufacturer engaged in the manufacture of PPIs
- n. placing and/or permitting the placement of PPIs into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;
- o. failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of PPIs to be harmful to humans;

- p. failing to respond or react promptly and appropriately to reports of PPIs causing harm to patients;
- q. disregarding the safety of users and consumers of PPIs, including Plaintiff, Irma Coleman, under the circumstances by failing adequately to warn of said products' potential harm to humans;
- r. disregarding the safety of users and consumers of PPIs, including Plaintiff, Irma Coleman, and/or her physicians' and/or hospital, under the circumstances by failing to withdraw said products from the market and/or restrict their usage;
- s. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of PPIs and their potential harm to humans;
- t. failing to exercise reasonable care in informing physicians and/or hospitals using PPIs about their own knowledge regarding said products' potential harm to humans;
- u. failing to remove PPIs products from the stream of commerce;
- v. failing to test PPIs properly and/or adequately so as to determine their safety for use;
- w. promoting PPIs on websites aimed at creating user and consumer demand;
- y. failing to conduct and/or respond to post-marketing surveillance of complications and injuries;
- z. failing to use due care under the circumstances; and,

aa. such other acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

109. As a direct and proximate result of Defendants' negligent acts and omissions, Plaintiff, Irma Coleman suffered kidney injuries including chronic kidney disease.

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 herein contained be tried by a jury.

**COUNT II**  
**STRICT PRODUCTS LIABILITY**

110. The paragraphs above are incorporated by reference hereto as if set forth at length.

111. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and distributed PPIs in a defective and unreasonably dangerous condition, including Nexium or other Nexium branded products and Prilosec or other Prilosec branded products used by Irma Coleman. The design defect made the PPIs more dangerous than an ordinary consumer would expect and more dangerous than other drugs used to treat GERD.

112. These PPIs' inadequate warnings rendered them unreasonably dangerous and defective.

113. Defendants' defective warnings for their respective PPIs were reckless, willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of PPIs. Defendants made conscious decisions not to adequately warn about risks they know or should have known about. Defendants' reckless conduct warrants an award of punitive damages.

Defendant's conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of PPIs.

114. Irma Coleman was prescribed and used PPIs for their intended purposes and for purposes that Defendants expected and could foresee.

115. Defendants expected and intended PPIs to reach, and did in fact reach, Irma Coleman without any substantial change in the condition of the product from when it was initially manufactured by Defendants.

116. Irma Coleman could not have discovered the unwarned risks of using PPIs through the exercise of reasonable care.

117. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that the warnings and other relevant information and data which they distributed regarding the risks of injuries and death associated with the use of PPIs were incomplete and inadequate.

118. Irma Coleman did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Irma Coleman or to her treating physicians. The warnings that were given by Defendants were not accurate and were incomplete.

119. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take other such steps as necessary to ensure that PPIs manufactured or distributed by them did not cause users to suffer from unreasonable and dangerous risks.

120. Defendants knew or should have known that the limited warnings disseminated with PPIs 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 GERD.

121. As a direct and proximate cause of Defendants manufacture, sale and promotion of the defectively designed drug and failure to warn Irma Coleman and her physicians about the significant risks inherent in PPI therapy, Irma Coleman sustained severe injuries.

122. As a result of the unreasonably dangerous and defective condition of PPIs, which Defendants manufactured, designed, labeled, marketed, distributed, supplied, sold and/or placed into the stream of commerce, they are strictly liable to the Plaintiff for her injuries that they directly and proximately caused, based on the following:

- a. failing to provide adequate warnings with their proton pump inhibitor; and
- b. failing to properly and adequately design their product.

123. Because of Defendants' failures, Plaintiff, Irma Coleman, used the PPIs, which the Defendants manufactured, designed, sold, supplied, marketed or otherwise introduced into the stream of commerce.

124. For all of the reasons alleged herein, the PPIs Nexium or other Nexium branded products and Prilosec or other Prilosec branded products, were unreasonably dangerous because an adequate warning about the product had not been provided and at the time the product left the manufacturer's control, the product possessed a characteristic that may cause damage and the

manufacturer failed to use reasonable care to provide adequate warnings that such characteristic and its dangers to users of the product.

125. Further, Defendants, before, during, and after these products left their control, acquired knowledge of the characteristic of the product that may cause damage and the danger of such characteristic (or, alternatively, Defendants would have acquired such knowledge if it had acted as reasonable prudent manufacturers), and thus are liable for damages suffered by Plaintiff which arose as a consequence of Defendants' failure to use reasonable care to provide an adequate warning of such characteristic and its dangers to users.

126. As a direct and proximate result of Defendants' PPIs, Plaintiff, Irma Coleman suffered kidney injuries.

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 herein contained be tried by a jury.

**COUNT III**  
**BREACH OF EXPRESS WARRANTY**

127. The paragraphs above are incorporated by reference hereto as if set forth at length.

128. In the advertising and marketing of PPIs, Defendants warranted that their products were safe for the use, which had the natural tendency to induce physicians and hospitals to use the same for patients and for patients to want to be treated with the same.

129. Defendants expressly warranted to Plaintiff's physicians and Plaintiff by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, marketing, and other written materials intended for physicians and the public that PPIs are safe, effective, fit and proper for its intended use, of



merchantable quality, had been adequately tested, contained adequate warnings, and was effective.

130. Nexium or other Nexium branded products and Prilosec or other Prilosec branded products' "Warnings and Precautions" sections prescribing information purports to expressly describe the relevant and material side-effects that Defendants knew or should have known about.

131. On information and belief, Irma Coleman consumed that drug reasonably relying on these warranties. Irma Coleman and her physician could not have learned independently that Defendants' representations, labels, warnings, direct to consumer marketing, express and implied warranties were false and misleading. The aforesaid warranties were breached by Defendants and constituted a serious danger to the user.

132. Defendants knew or should have known Irma Coleman would rely on their warranties.

133. Plaintiff reasonably relied on the skill, judgment, representations, and foregoing express warranties of Defendants.

134. The warranties and representations were false. PPIs can cause acute interstitial nephritis, chronic kidney disease, and end stage renal disease.

135. None of the PPIs consumed by Irma Coleman conformed to Defendants express representations; therefore, Defendants have breached their express warranties.

136. The breach of express warranties by Defendants was a foreseeable, direct, and proximate cause of Irma Coleman's injuries and damages.

137. Defendants expressly warranted to the market, including Plaintiff, by and through statements made by Defendants or their authorized agents or sales representatives, orally

and in publications, package inserts, advertisements and other materials to the health care and general community, that Proton Pump Inhibitors were safe, effective, fit and proper for its intended use.

138. As a direct and proximate result of Defendants' breach of warranty as described herein, Plaintiff, Irma Coleman suffered the injuries and damages as set forth above.

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 herein contained be tried by a jury.

**COUNT IV**  
**BREACH OF IMPLIED WARRANTY**

139. The paragraphs above are incorporated by reference hereto as if set forth at length.

140. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold their PPIs that block the production of stomach acid in order to reduce the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as to treat gastroesophageal reflux disease ("GERD") and certain pathological hypersecretory conditions including Zollinger-Ellison syndrome.

141. At all relevant times, Defendants intended that their PPIs be used in the manner that the Plaintiff used it and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

142. Defendants breached various implied warranties with respect to the products, including:

- a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice

letters, and regulatory submissions that the products were safe, and withheld and concealed information about the substantial risks of serious injury associated with long term use of PPIs;

b. Defendants represented that PPIs were safe to use every day;

143. In reliance upon Defendants' implied warranty, Plaintiff, Irma Coleman used said PPIs and in the foreseeable manner promoted, instructed, and marketed by Defendants.

144. Defendants breached their implied warranty to, Plaintiff, Irma Coleman in that PPIs are not of merchantable quality, safe and fit for their intended use, or adequately tested.

145. In using PPIs, Plaintiff and her physicians relied on the skill, judgment, representations, and foregoing express warranties of Defendants. These warranties and representations proved to be false because the product was not safe and was unfit for the uses for which it was intended.

146. As a direct and proximate result of Defendants' breach of warranty as described herein, Plaintiff, Irma Coleman suffered the injuries and damages as set forth above.

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 herein contained be tried by a jury.

**COUNT V**  
**FRAUDULENT MISREPRESENTATION AND OMISSION**

147. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

148. Defendant, having undertaken design, formulation, testing, manufacture, marketing, sale, and distribution of PPIs owed a duty to provide accurate and complete information regarding said drug.

149. Defendants fraudulently misrepresented that the daily use of their PPI was safe and effective.

150. Defendant had a duty to provide consumers with true and accurate information regarding the PPIs it manufactured, marketed, distributed and sold.

151. Defendants made representations and failed to disclose material facts with the intent to induce consumers, including Plaintiff, Irma Coleman and the medical community to act in reliance by purchasing and using the proton pump inhibitor sold by Defendants.

152. Plaintiff, Irma Coleman and the medical community justifiably relied on Defendants' representations and omissions by purchasing and taking proton pump inhibitors.

153. As a direct and proximate result of Defendants' representations and omissions as described herein, Plaintiff, Irma Coleman suffered the injuries and damages as set forth above.

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 herein contained be tried by a jury.

**COUNT VI**  
**LOSS OF CONSORTIUM**

154. Plaintiffs incorporate by reference each proceeding and succeeding paragraph as though set forth fully at length herein.

155. Plaintiff- Spouse is the husband of Irma Coleman, and was her lawful husband on all material and relevant dates.

156. As a direct and proximate result of the negligence and other acts omissions of Defendants, described within the previous Counts of this Complaint, Plaintiff -Spouse has suffered a loss of consortium, society, affections and services of his wife, Irma Coleman, as well as other economic damages.

WHEREFORE, Plaintiffs respectfully requests that this Court enter judgment in Plaintiffs' 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. Plaintiffs also demands that the issues herein contained be tried by a jury.

#### **PUNITIVE DAMAGES ALLEGATIONS**

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, health and safety of Irma Coleman 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.

158. Prior to the manufacturing, sale, and distribution of Nexium, Prilosec, and Prilosec OTC, 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 Irma Coleman and as such, Defendants

unreasonably subjected consumers of said drugs to risk of injury or kidney failure from using PPIs.

159. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Nexium, Prilosec, and Prilosec OTC, and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Nexium, Prilosec, and Prilosec OTC. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Nexium, Prilosec, and Prilosec OTC 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 Irma Coleman, entitling Plaintiff to exemplary damages.

#### **PRAYER FOR RELIEF**

WHEREFORE, for the foregoing reasons, Plaintiffs prays the Court for judgment against Defendants in an amount to be determined at trial, as appropriate for:

- a. compensatory, restitution and general damages in an amount that is fair and reasonable and just;
- b. punitive damages, against Defendants as appropriate, in the amount set forth above;
- c. reasonable and/or statutory attorneys' fees under state laws;
- d. costs of suit;

- e. prejudgment and post judgment interest thereon at 8% or other appropriate rate as provided for by statute; and
- f. such other and further relief as the Court deems just, appropriate and equitable.

**DEMAND FOR JURY TRIAL**

Plaintiffs hereby demand a trial by jury on all claims so triable.

Date: February 8, 2017

Respectfully submitted,

/s/ Roger C. Denton  
Roger C. Denton, Esq. (#6182610)  
Dana J. Hantack, Esq. (#6322567)  
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314-621-7151 (fax)  
[rdenton@uselaws.com](mailto:rdenton@uselaws.com)  
[dhantack@uselaws.com](mailto:dhantack@uselaws.com)

/s/ Paul J. Pennock  
Paul J. Pennock (PP3315)  
**WEITZ & LUXENBERG, P.C.**  
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Phone: (212) 558-5500  
Fax: (212) 363-2721  
[ppennock@weitzlux.com](mailto:ppennock@weitzlux.com)

*ATTORNEYS FOR PLAINTIFF*

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.)

<p><b>I. (a) PLAINTIFFS</b> IRMA COLEMAN and JAMES B COLEMAN</p> <p><b>(b) County of Residence of First Listed Plaintiff</b> <u>FAYETTE COUNTY</u> <i>(EXCEPT IN U.S. PLAINTIFF CASES)</i></p> <p><b>(c) Attorneys (Firm Name, Address, and Telephone Number)</b> ROGER C. DENTON / SCHLICHTER BOGARD &amp; DENTON 100 S 4TH ST #1200 ST. LOUIS, MO 63102 - TEL NO. (314) 621-6115</p>	<p><b>DEFENDANTS</b> ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; PROCTER &amp; GAMBLE MANUFACTURING COMPANY; PROCTER &amp; GAMBLE COMPANY</p> <p>County of Residence of First Listed Defendant <u>NEW CASTLE, DE</u> <i>(IN U.S. PLAINTIFF CASES ONLY)</i></p> <p>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.</p> <p>Attorneys (If Known)</p>
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<p><b>II. BASIS OF JURISDICTION</b> <i>(Place an "X" in One Box Only)</i></p> <p><input type="checkbox"/> 1 U.S. Government Plaintiff</p> <p><input type="checkbox"/> 2 U.S. Government Defendant</p> <p><input type="checkbox"/> 3 Federal Question <i>(U.S. Government Not a Party)</i></p> <p><input checked="" type="checkbox"/> 4 Diversity <i>(Indicate Citizenship of Parties in Item III)</i></p>	<p><b>III. CITIZENSHIP OF PRINCIPAL PARTIES</b> <i>(Place an "X" in One Box for Plaintiff and One Box for Defendant)</i></p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td></td> <td style="text-align: center;"><b>PTF</b></td> <td style="text-align: center;"><b>DEF</b></td> <td></td> <td style="text-align: center;"><b>PTF</b></td> <td style="text-align: center;"><b>DEF</b></td> </tr> <tr> <td>Citizen of This State</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 1</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> </tr> </table>		<b>PTF</b>	<b>DEF</b>		<b>PTF</b>	<b>DEF</b>	Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
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**IV. NATURE OF SUIT** *(Place an "X" in One Box Only)*

<p><b>CONTRACT</b></p> <p><input type="checkbox"/> 110 Insurance</p> <p><input type="checkbox"/> 120 Marine</p> <p><input type="checkbox"/> 130 Miller Act</p> <p><input type="checkbox"/> 140 Negotiable Instrument</p> <p><input type="checkbox"/> 150 Recovery of Overpayment &amp; Enforcement of Judgment</p> <p><input type="checkbox"/> 151 Medicare Act</p> <p><input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans)</p> <p><input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits</p> <p><input type="checkbox"/> 160 Stockholders' Suits</p> <p><input type="checkbox"/> 190 Other Contract</p> <p><input type="checkbox"/> 195 Contract Product Liability</p> <p><input type="checkbox"/> 196 Franchise</p>	<p><b>TORTS</b></p> <p><b>PERSONAL INJURY</b></p> <p><input type="checkbox"/> 310 Airplane</p> <p><input type="checkbox"/> 315 Airplane Product Liability</p> <p><input type="checkbox"/> 320 Assault, Libel &amp; Slander</p> <p><input type="checkbox"/> 330 Federal Employers' Liability</p> <p><input type="checkbox"/> 340 Marine</p> <p><input type="checkbox"/> 345 Marine Product Liability</p> <p><input type="checkbox"/> 350 Motor Vehicle</p> <p><input type="checkbox"/> 355 Motor Vehicle Product Liability</p> <p><input type="checkbox"/> 360 Other Personal Injury</p> <p><input type="checkbox"/> 362 Personal Injury - Medical Malpractice</p> <p><b>PERSONAL INJURY</b></p> <p><input type="checkbox"/> 365 Personal Injury - Product Liability</p> <p><input checked="" type="checkbox"/> 367 Health Care/ Pharmaceutical Personal Injury Product Liability</p> <p><input type="checkbox"/> 368 Asbestos Personal Injury Product Liability</p> <p><b>PERSONAL PROPERTY</b></p> <p><input type="checkbox"/> 370 Other Fraud</p> <p><input type="checkbox"/> 371 Truth in Lending</p> <p><input type="checkbox"/> 380 Other Personal Property Damage</p> <p><input type="checkbox"/> 385 Property Damage Product Liability</p>	<p><b>FORFEITURE/PENALTY</b></p> <p><input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881</p> <p><input type="checkbox"/> 690 Other</p> <p><b>LABOR</b></p> <p><input type="checkbox"/> 710 Fair Labor Standards Act</p> <p><input type="checkbox"/> 720 Labor/Management Relations</p> <p><input type="checkbox"/> 740 Railway Labor Act</p> <p><input type="checkbox"/> 751 Family and Medical Leave Act</p> <p><input type="checkbox"/> 790 Other Labor Litigation</p> <p><input type="checkbox"/> 791 Employee Retirement Income Security Act</p> <p><b>IMMIGRATION</b></p> <p><input type="checkbox"/> 462 Naturalization Application</p> <p><input type="checkbox"/> 465 Other Immigration Actions</p>	<p><b>BANKRUPTCY</b></p> <p><input type="checkbox"/> 422 Appeal 28 USC 158</p> <p><input type="checkbox"/> 423 Withdrawal 28 USC 157</p> <p><b>PROPERTY RIGHTS</b></p> <p><input type="checkbox"/> 820 Copyrights</p> <p><input type="checkbox"/> 830 Patent</p> <p><input type="checkbox"/> 840 Trademark</p> <p><b>SOCIAL SECURITY</b></p> <p><input type="checkbox"/> 861 HIA (1395ff)</p> <p><input type="checkbox"/> 862 Black Lung (923)</p> <p><input type="checkbox"/> 863 DIWC/DIWW (405(g))</p> <p><input type="checkbox"/> 864 SSID Title XVI</p> <p><input type="checkbox"/> 865 RSI (405(g))</p> <p><b>FEDERAL TAX SUITS</b></p> <p><input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant)</p> <p><input type="checkbox"/> 871 IRS—Third Party 26 USC 7609</p>	<p><b>OTHER STATUTES</b></p> <p><input type="checkbox"/> 375 False Claims Act</p> <p><input type="checkbox"/> 376 Qui Tam (31 USC 3729(a))</p> <p><input type="checkbox"/> 400 State Reapportionment</p> <p><input type="checkbox"/> 410 Antitrust</p> <p><input type="checkbox"/> 430 Banks and Banking</p> <p><input type="checkbox"/> 450 Commerce</p> <p><input type="checkbox"/> 460 Deportation</p> <p><input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations</p> <p><input type="checkbox"/> 480 Consumer Credit</p> <p><input type="checkbox"/> 490 Cable/Sat TV</p> <p><input type="checkbox"/> 850 Securities/Commodities/Exchange</p> <p><input type="checkbox"/> 890 Other Statutory Actions</p> <p><input type="checkbox"/> 891 Agricultural Acts</p> <p><input type="checkbox"/> 893 Environmental Matters</p> <p><input type="checkbox"/> 895 Freedom of Information Act</p> <p><input type="checkbox"/> 896 Arbitration</p> <p><input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision</p> <p><input type="checkbox"/> 950 Constitutionality of State Statutes</p>
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**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:  
Products liability litigation

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

**VIII. RELATED CASE(S) IF ANY**    *(See instructions):*    JUDGE \_\_\_\_\_    DOCKET NUMBER \_\_\_\_\_

DATE: 02/08/2017    SIGNATURE OF ATTORNEY OF RECORD: /s/ ROGER C. DENTON

**FOR OFFICE USE ONLY**

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_



AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Southern District of Illinois

IRMA COLEMAN and JAMES B. COLEMAN

Plaintiff(s)

v.

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

Defendant(s)

Civil Action No. 3:17-cv-130

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address)

Astrazeneca LP
c/o Corporation Trust
1209 Orange Street
Wilmington, DE 19806

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:

Roger C. Denton
Schlichter, Bogard & Denton, LLP
100 South 4th Street, Suite 1200
St. Louis, MO 63102

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

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT
for the
Southern District of Illinois

IRMA COLEMAN and JAMES B. COLEMAN

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ASTRAZENECA PHARMACEUTICALS LP,
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Roger C. Denton
Schlichter, Bogard & Denton, LLP
100 South 4th Street, Suite 1200
St. Louis, MO 63102

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AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT
for the
Southern District of Illinois

IRMA COLEMAN and JAMES B. COLEMAN

Plaintiff(s)

v.

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ASTRAZENECA LP, THE PROCTER & GAMBLE
MANUFACTURING COMPANY and THE PROCTOR
& GAMBLE COMPANY

Defendant(s)

Civil Action No. 3:17-cv-130

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address)

The Proctor & Gamble Manufacturing Company
1 Proctor & 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:

Roger C. Denton
Schlichter, Bogard & Denton, LLP
100 South 4th Street, Suite 1200
St. Louis, MO 63102

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

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Southern District of Illinois

IRMA COLEMAN and JAMES B. COLEMAN

Plaintiff(s)

v.

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

Defendant(s)

Civil Action No. 3:17-cv-130

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address)

The Proctor & Gamble Company
1 Proctor & gamble Plaza
Cincinnati, OH 45202

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Roger C. Denton
Schlichter, Bogard & Denton, LLP
100 South 4th Street, Suite 1200
St. Louis, MO 63102

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CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk