UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

CAROLYN WINTERS,

Plaintiff,

v.

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; ASTRA USA INC.; ASTRAZENECA AB; ASTRAZENECA UK LTD; ASTRAZENECA, PLC; PROCTER & GAMBLE MANUFACTURING COMPANY; and THE PROCTER & GAMBLE COMPANY,

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

Case No. 1:16cv412 HSO-JCG

COMPLAINT

Plaintiff, Carolyn Winters (alternatively referred to herein as "Plaintiff"), residing in Jackson County, within the State of Mississippi, by and through the undersigned attorneys, files this Complaint against Defendants AstraZeneca Pharmaceuticals LP; ("AstraZeneca Pharmaceuticals"); AstraZeneca LP; AstraZeneca PLC; Procter & Gamble Manufacturing Company; The Procter & Gamble Company (collectively "Defendants") and for her Complaint states, upon information and belief and based upon investigation of counsel, as follows:

INTRODUCTION

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

2. PPIs are used to reduce acid production in order to lower the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as gastroesophageal reflux disease (GERD), dyspepsia, acid peptic disease, and other hypersecretory conditions, including Zollinger-Ellison Syndrome.

3. As set forth more fully herein, Plaintiff Carolyn Winters ingested PPIs, which resulted in serious injuries to her kidneys.

JURSIDICTION AND VALUE

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and the Defendants as Defendants are all incorporated and have their principal place of business in states other Plaintiff's home state of Mississippi.

5. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

6. Further, a substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in this district. Pursuant to 28 U.S.C. § 1391, venue is proper in this district.

PLAINTIFF

7. Plaintiff, Carolyn Winters, a natural person and resident of Vancleave, Mississippi, ingested PPIs, including Nexium and Nexium OTC between approximately 2009 to 2012, and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, recovery of costs of obtaining PPIs , including Nexium and Nexium OTC, and recovery of all past, present, and future health and medical care costs related to her kidney related injuries and sequelae caused by her ingestion of PPIs, including Nexium and Nexium OTC.

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

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

10. Defendant ASTRA USA INC. is a Delaware corporation, which has its principal place of business at 1800 Concord Pike, P.O. Box 15437, Wilmington, DE 19850-5437.

11. Defendant ASTRAZENECA AB is a foreign corporation, which has its principal place of business at Västra Mälarehamnen, 9 Södertälje SE-151 85, Sweden.

12. Defendant ASTRAZENECA UK LTD is a foreign corporation with its principal place of business located at 2 Kingdom Street, London W2 6BD, United Kingdom.

13. Defendant ASTRAZENECA PLC is a foreign corporation with its principal place of business located at 2 Kingdom Street, London W2 6BD, United Kingdom.

14. On information and belief, ASTRAZENECA PLC is either the direct or indirect owner of substantially all the stock or other ownership interests of ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA LP.

15. In doing the acts alleged herein, said AstraZeneca Defendants (including ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA LP, ASTRA USA INC, ASTRAZENECA AB, ASTRAZENECA UK LTD, and ASTRAZENECA PLC) 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 PLC,

ASTRAZENECAPHARMACEUTICALS LP, and ASTRAZENECA LP are collectively referred to as "ASTRAZENECA").

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

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

18. In doing the acts alleged herein, said Procter & Gamble Defendants (including PROCTER & GAMBLE MANUFACTURING COMPANY and THE PROCTER & GAMBLE COMPANY) 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 PROCTER & GAMBLE MANUFACTURING COMPANY and THE PROCTER & GAMBLE COMPANY are collectively referred to as "PROCTER & GAMBLE").

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

20. 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 Mississippi.

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

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

SUMMARY OF THE CASE

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

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 and sequelae.

FACTUAL ALLEGATIONS

26. 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.

27. 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.

28. 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.

29. 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.

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

31. 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]

32. 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.

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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.

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

34. In 2004, Defendants knew or should have known of 8 biopsy-proven cases report from Norwich University Hospital in the United Kingdom.[3]

35. International organizations also recognized the danger posed by PPIs to kidney health, finding both AIN and insidious renal failure resulting from PPIs. In 2006, Professor Ian Simpson and his team at the University of Auckland published an analysis of the clinical features of 15 patients with AIN and acute renal failure from PPI over three years. In all patients, the tie-course of drug exposure and improvement of renal function on withdrawal suggested the PPI were causal. "Although four patients presented with an acute systemic allergic reaction, 11 were asymptomatic with an insidious development of renal failure."[4]

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

37. 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." This study was the largest hospital-based case series on this issue and involved a retrospective case review of potential cases as two teaching hospitals as well as a review of registry data from the Therapeutic Goods Administration of Australia. The team identified 18 cases of biopsy-proven PPI-induced AIN. The TGA registry data identified an additional 31 cases

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[3] *Id.*

[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.

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."

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

39. 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."

40. 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.

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

42. 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.

43. 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 note

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[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).

[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.

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."

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

45. 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.

46. 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."

47. 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.*

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

49. 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

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[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.

[10] Lazarus, B., et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*,

large patient cohorts in the United States, the Atherosclerosis Risk in Communities study (n ¼ 10,482) and the Geisinger Health System (n ¼ 248,751), in order to evaluate the relationship between PPI use and the development of chronic kidney disease (CKD). Over a median of 13.9 years of follow-up in the Atherosclerosis Risk in Communities study, the incidence of documented CKD or end-stage renal disease was significantly higher in patients with self-reported use of prescription PPIs at baseline (adjusted hazard ratio 1.50, 95% confidence interval 1.14–1.96).

50. "Consistent with prior studies, the authors also observed a significant association between baseline PPI use and acute kidney injury as defined by diagnostic codes (adjusted hazard ratio 1.64, 95% confidence interval 1.22–2.21). The results were then validated in the Geisenger Health System cohort using prescription data to define baseline PPI use and laboratory data to define the CKD outcome, defined as sustained outpatient estimated glomerular filtration rate the validation cohort also suggest a possible dose-response relationship between PPI use and CKD risk, with higher risk observed in patients prescribed a PPI twice daily at baseline (adjusted hazard ratio 1.46, 95% confidence interval 1.28–1.67). Despite the limitations inherent in observational studies, the robustness of the observations in this large study suggests a true association between PPI use and increased CKD risk."[11]

51. 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

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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.

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).

52. 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 study patients over 5 years to ascertain renal outcomes. In adjusted Cox survival models, the PPI group, compared with the H2 blockers group, had an increased risk of CKD, doubling of serum creatinine level, and end-stage renal disease.

53. However, evidence of the connection of PPI's 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]

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

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[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.
[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.

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

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

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

58. 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.

59. 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.

60. 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.

61. 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.

62. 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.

63. 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.

64. 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.

65. 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.

66. 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.

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

68. 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.

69. 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.

70. 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.

71. 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.

72. 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.

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

FEDERAL REQUIREMENTS

74. Defendants had an obligation to comply with the law in the manufacture, design, and sale of Proton Pump Inhibitors.

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

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

a. Proton Pump Inhibitors are adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

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

c. Proton Pump Inhibitors are misbranded pursuant to 21 U.S.C. §352 because, among other things, it's labeling is false or misleading.

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

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

f. Proton Pump Inhibitors are misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

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

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

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

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of Proton Pump Inhibitors to cause and the need for regular and/or consistent

cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

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

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

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

n. Proton Pump Inhibitors violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

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

p. Proton Pump Inhibitors violate 21 CFR § 211.165 in that Nexium fails to meet established standards or specifications and any other relevant quality control criteria.

q. Proton Pump Inhibitors violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding Proton Pump Inhibitors were not followed.

r. Proton Pump Inhibitors violates 21 CFR § 310.303 in that Proton Pump Inhibitors are not safe and effective for its intended use.

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

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

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

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

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

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

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

FRAUDULENT CONCEALMENT

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

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

CAUSES OF ACTION

FIRST CAUSE OF ACTION
NEGLIGENCE

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

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

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

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

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

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

86. As a result Defendants' negligence and/or recklessness the Plaintiff was caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff's kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above.

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

88. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY - FAILURE TO WARN

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

90. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced PPIs into the stream of commerce, and in the course of same, directly advertised or marketed PPIs to consumers or

persons responsible for consumers, and therefore, had a duty to both the Plaintiff directly and Plaintiff's physician to warn of risks associated with the use of the Product.

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

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

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

94. Defendants' failure to adequately warn Plaintiff and Plaintiffs prescribing physicians of a bladder cancer risk prevented Plaintiff's prescribing physicians and Plaintiff from correctly and fully evaluating the risks and benefits of PPIs.

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

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

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

98. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN

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

100. Actos was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

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

102. PPIs as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants was defective in design and formulation in that when it left the hands of the manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of PPIs.

103. PPIs as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants was defective in design and

formulation, because when it left the hands of Defendants' manufacturers and suppliers it was unreasonably dangerous and was also more dangerous than the ordinary consumer would expect.

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

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

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

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

108. At the time Defendants' product left their control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of their product. This was demonstrated by the existence of other PPI's which had a more established safety profile and a considerably lower risk profile.

109. Plaintiff could not, by the reasonable exercise of care, have discovered PPIs defects and perceived its danger.

110. The defects in Defendants' product were substantial and contributing factors

in causing Plaintiffs injuries.

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

112. Due to the unreasonably dangerous condition of PPIs, Defendants are strictly liable to Plaintiff.

113. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

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

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

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

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

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

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

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

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

122. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
FOR A PARTICULAR PURPOSE

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

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

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

126. These representations and warranties aforementioned were false, misleading, and inaccurate in that PPIs were unsafe, and degraded Plaintiff's health.

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

128. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether PPIs were safe and fit for its intended use.

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

130. Defendants breached the aforesaid implied warranty, as their drug PPIs and Nexium was not fit for its intended purposes and uses.

131. As a result of the foregoing breach of warranty, the Plaintiff was caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiffs kidney injuries, as well as the need

for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

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

133. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

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

135. Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold PPIs.

136. Defendants marketed, sold and distributed PPIs and knew and promoted the use for which PPIs were being used by Plaintiff and impliedly warranted to Plaintiff that PPIs were of merchantable quality and fit for the ordinary purpose for which it was intended.

137. These representations and warranties aforementioned were false, misleading, and inaccurate in that PPIs were unsafe, and degraded Plaintiff's health.

138. Plaintiff reasonably relied on the skill, expertise and judgment of the Defendants and its representations as to the fact that PPIs were of merchantable quality.

139. The PPIs manufactured and supplied by the Defendants was not of merchantable quality, as warranted by the Defendants in that the drug had dangerous and life threatening side effects and was thus not fit for the ordinary purpose for which it was intended.

140. As a direct and proximate result of the foregoing, Plaintiff was caused bodily injury, pain and suffering and economic loss.

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

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

143. By reason of the foregoing, Plaintiff demands judgment against each Defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court deem proper.

144. By reason of the foregoing, Plaintiff is entitled to compensatory and punitive damages in a sum that exceeds the jurisdictional limits of all lower courts that might otherwise have jurisdiction.

SEVENTH CAUSE OF ACTION
VIOLATION OF THE MISSISSIPPI UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, MISS. CODE ANN. §§75-24-1, et seq.

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

146. 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.

147. The Plaintiff used Defendants' Proton Pump Inhibitors and suffered ascertainable losses as a result of the Defendants' actions in violation of the aforementioned consumer protection laws.

148. The Defendants violated the Mississippi Unfair Trade Practices and Consumer Protection Law, Miss. Code Ann. §§75-24-1, et seq, through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Proton Pump Inhibitors.

149. The Defendants uniformly communicated the purported benefits of Proton Pump Inhibitors while failing to disclose the serious and dangerous side effects related to the use of Proton Pump Inhibitors and of the true state of Proton Pump Inhibitor's regulatory status, its safety, its efficacy, and its usefulness. The Defendants made these representations to physicians, the medical community at large, and to patients and consumers, such as the Plaintiff, in the marketing and advertising campaign described herein.

150. The Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits, or qualities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and,

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

151. The Defendants have a statutory duty to refrain from unfair trade practices in the design, development, manufacture, promotion and sale of Proton Pump Inhibitors.

152. Had the Defendants not engaged in the deceptive conduct described herein, the Plaintiff would not have purchased and/or paid for Proton Pump Inhibitors, and would not have incurred related medical costs. Specifically, the Plaintiff, the Plaintiff's physicians and other Healthcare Professionals were misled by the deceptive conduct described herein.

153. The Defendants' deceptive, unconscionable, false, misleading and/or fraudulent representations and material omissions to patients, physicians and consumers, including the Plaintiff, of material facts relating to the safety of Proton Pump Inhibitors constituted unfair trade practices in violation of the state consumer protection statutes listed above.

154. The Defendants uniformly communicated the purported benefits of Proton Pump Inhibitors while failing to disclose the serious and dangerous side effects related to the use of Proton Pump Inhibitors and the true state of Proton Pump Inhibitor's regulatory status, its safety, its efficacy, and its usefulness. The Defendants made these representations to physicians, the medical community at large, and to patients and consumers, such as the Plaintiff, in the marketing and advertising campaign described herein.

155. The Defendants' conduct in connection with Proton Pump Inhibitors was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding because

the Defendants misleadingly, falsely and/or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy, and advantages of Proton Pump Inhibitors.

156. By reason of wrongful acts engaged in by the Defendants, the Plaintiff suffered ascertainable loss and damages for which the Plaintiff is now entitled to recover.

157. As a direct and proximate result of the Defendants' wrongful conduct, the Plaintiff was damaged by paying in whole or in part for Proton Pump Inhibitors and for the Plaintiff's medical treatment. Plaintiff is now entitled to recover those damages.

158. As a direct and proximate result of the Defendants' violations of unfair trade practices, the Plaintiff sustained economic losses and other damages for which the Plaintiff is entitled to statutory and compensatory damages and attorneys' fees, in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION
PUNITIVE DAMAGES

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

160. 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 Proton Pump Inhibitor users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Proton Pump Inhibitors. 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.

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, as follows:

a. Awarding actual damages to the Plaintiff incidental to her purchase and use of Proton Pump Inhibitors in an amount to be determined at trial;

b. Awarding past and future mental and emotional distress, according to proof;

c. Awarding punitive or exemplary damages according to proof;

d. Awarding pre-judgment and post-judgment interest to the Plaintiff;

e. Awarding the costs and the expenses of this litigation to the Plaintiff;

f. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and

g. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, Carolyn Winters, hereby demands a trial by jury on all counts and as to all issues.

Dated: 11/16/16

Respectfully submitted,

MARTIN D. CRUMP (MSB #10652)
ROBERT D. CAIN, JR. (MSB #104283)
DAVIS & CRUMP, P.C.
Post Office Drawer 6829
Gulfport, MS 39506
(228) 863-6000 Telephone
(228) 864-0907 Facsimile
martincrump@daviscrump.com
robert.cain@daviscrump.com

Attorneys for Plaintiff

JS 44 (Rev. 08/16)

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.)*

1:16cv412 HSO-JCG

I. (a) PLAINTIFFS

CAROLYN WINTERS

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Martin D. Crump, Robert D. Cain, Jr., Davis & Crump, P. O. Drawer 6829, Gulfport, MS 39506 (228-863-6000)

DEFENDANTS
Astrazeneca Pharmaceuticals LP, Astrazeneca LP, Astra USA Inc., Astrazeneca AB, Astrazeneca UK LTD, Astrazeneca, PLC, Procter & Gamble Manufacturing Company & The Procter & Gamble Company

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

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

Attorneys *(If Known)*

SOUTHERN DISTRICT OF MISSISSIPPI
FILED
NOV 16 2016
ARTHUR JOHNSTON
BY _____ DEPUTY

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)*
Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☒ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 376 Qui Tam (31 USC 3729(a))
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 400 State Reapportionment
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 410 Antitrust
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	☐ 830 Patent	☐ 430 Banks and Banking
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 840 Trademark	☐ 450 Commerce
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 720 Labor/Management Relations	SOCIAL SECURITY	☐ 460 Deportation
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	☐ 861 HIA (1395ff)	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	☐ 862 Black Lung (923)	☐ 480 Consumer Credit
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 790 Other Labor Litigation	☐ 863 DIWC/DIWW (405(g))	☐ 490 Cable/Sat TV
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 791 Employee Retirement Income Security Act	☐ 864 SSID Title XVI	☐ 850 Securities/Commodities/ Exchange
☐ 196 Franchise				☐ 865 RSI (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION	FEDERAL TAX SUITS	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	Habeas Corpus:	☐ 462 Naturalization Application	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 893 Environmental Matters
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 465 Other Immigration Actions	☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence			☐ 896 Arbitration
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General			☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 535 Death Penalty			☐ 950 Constitutionality of State Statutes
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	Other:			
	☐ 448 Education	☐ 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. Section 1332

Brief description of cause:
Plaintiff alleges injury as a result of ingestion of prescription and OTC drugs manufactured by defendants

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 MDL 2757

DATE 11/16/16 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT $400.00 APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

14643008675