UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

SANDRA T. PERILLOUX

Plaintiff,

v.

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP;
Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

Case No. 17-cv-5505

COMPLAINT

Plaintiff, SANDRA T. PERILLOUX, (alternatively referred to herein as "Plaintiff"), residing in St. John The Baptist Parish, within the State of Louisiana, by and through the undersigned attorneys, files this Complaint against Defendants AstraZeneca Pharmaceuticals LP; and AstraZeneca LP (hereinafter referred to as "Defendants");

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 ("PPIs").

2. More specifically, AstraZeneca Pharmaceuticals LP and AstraZeneca LP were responsible for designing, developing, researching manufacturing, testing, packaging, promoting, marketing, advertising, distributing, labeling, and/or selling Nexium 40 mg, which is the AstraZeneca Pharmaceuticals LP and AstraZeneca LP prescription brand-name PPI medication ingested by Plaintiff and referred to as Nexium. As set forth more fully herein, Plaintiff Sandra Perilloux ingested AstraZeneca respective PPIs, which resulted in serious injuries to her kidneys.

JURSIDICTION AND VALUE

3. 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 than Plaintiff's home state of Louisiana.

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

5. 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.

PARTIES

6. Plaintiff, Sandra Perilloux, a natural person and resident of LaPlace, Louisiana, ingested PPIs, including Nexium between approximately 2007 to 2013, and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, recovery of costs of obtaining Nexium, 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 Nexium.

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

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

9. In doing the acts alleged herein, said AstraZeneca Defendants (including ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA LP, were acting in the

course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence, and ratification of each other.

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

11. 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 Louisiana.

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

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

SUMMARY OF THE CASE

14. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff suffering Chronic Kidney Disease and life threatening reduced kidney function caused by PPIs including Nexium.

15. As a result of the defective nature of Nexium, persons who ingested Defendants' respective PPI 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").

16. 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 Nexium.

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

18. Nexium is a member of the proton pump inhibitor class of pharmaceuticals also known as PPIs.

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

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

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

22. Defendants designed and developed the proton pump inhibitor, Nexium.

23. In December 1999, Defendants 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.

24. 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.

25. AstraZeneca Pharmaceutical LP is the holder of the approved new drug applications (NDAs") for the following forms of Nexium:

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

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

c. Delayed Release Oral Suspension Packets 910MG), 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.

26. Defendant AstraZeneca LP is the holder of an approved NDA for Nexium 24HR Delayed-Release Capsules (22.3 mg), with NDA #204655, approved on March 28, 2014.

27. AstraZeneca entities market and sell Nexium with National Drug Code numbers 0186-5020, 01860-5040, and 0186-4040.

28. 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.

29. Specifically, at her home in Houma, Louisiana, Plaintiff viewed AstraZeneca commercials for Nexium and relied on the information provided therein when deciding to begin

and continue ingesting Nexium, including that the product could be safely taken on a daily basis, indefinitely, when in actuality this could not be done without a serious risk of kidney injury.

30. Additionally, at her home in Houma, Louisiana, Plaintiff reviewed package insert and labeling provided and created by Defendant for Nexium at the time that she purchased it, and she relied on the information contained therein when deciding to begin ingesting the product.

31. Defendant 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.

32. There are a multitude of studies that have been published linking the danger of long term 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, 7,14:150 (2014).

33. Despite Defendants' knowledge of data indicating that PPI use is causally related to the development of chronic kidney disease, Defendant promoted and marketed Nexium as safe and effective for persons such as Plaintiff throughout the United States, including Louisiana.

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

35. 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.

36. Consumers, including Plaintiff, have several alternative safer methods for treating GERD, including home remedies and other medication, including H2 antagonists, ranitidine or TUMS antacid, all of which similarly reduce acid production but do not carry the same risk of Chronic Kidney Disease and other kidney injuries associated with Proton Pump Inhibitors sustained by Plaintiff.

37. Moreover, consumers, including Plaintiff, have additional safer methods for treating GERD, including modifying one's diet in addition to Defendant producing their respective Proton Pump Inhibitors without the products' current nephrotoxic properties.

38. Because of the defective nature of Nexium, Prilosec, and Prefaced, 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.

39. Defendant concealed and continues to conceal their knowledge of PPIs' unreasonably dangerous risks from Plaintiff, her physicians, other consumers, and the medical community. Specifically, Defendant failed and continues 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 Defendants' Nexium.

40. Moreover, AstraZeneca LP and AstraZeneca Pharmaceuticals LP were the agents and employees of each other, and in doing the things alleged was acting within the course and scope of such agency and employment and with each other Defendant's actual and implied permission, consent, authorization, and approval. As such, Astra Zeneca LP and AstraZeneca Pharmaceuticals LP are individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's injuries, losses and damages.

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

FACTUAL ALLEGATIONS

42. 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.

43. 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.

44. 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.

45. 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.

46. Defendant, directly or through their agent, apparent agents, servants, or employees designed, manufactured, marketed, advertised, distributed, promoted, and sold PPIs.

47. In October of 1992, three years after the FDA's initial PPI approval, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article associating PPI usage with kidney injuries in *The American Journal of Medicine,* followed by years of reports from national adverse drug registries describing this association. In 1997, David Badov, et al., described two further case studies documenting the causal connection between omeprazole and interstitial nephritis in the elderly.[2]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).[1] 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] 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.

49. In 2004, Defendant knew or should have known of 8 biopsy-proven cases report from Norwich University Hospital in the United Kingdom.[2]

50. 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."[3]

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

52. In 2006, Nimeshan Geevasinga, et al., found "evidence to incriminate all the commercially available PP's, suggesting there is a class effect" with regard to PPI-induced AIN.[4] "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 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

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2 *Id*.

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

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

impairment" were also identified. "All 5 commercially available PPIs were implicated in these cases."

53. In 2006, the Center for Adverse Reaction Monitoring (CARM) in New Zealand, found that PPI products were the number one cause of AIN.[5]

54. 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."

55. 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.

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

57. 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."[6] Klepser's study called for increased recognition of patient complaints or clinical manifestations of renal disease in order to prevent further injury.

58. 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.[7] Researchers further noted

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[5] 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).

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

[7] 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."

59. 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.[8] 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.

60. 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.

61. 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."

62. 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.*

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

64. In a study conducted by Benjamin Lazarus, et al., published in JAMA, PPI use was associated with a higher risk of incident CKD.[9] The authors leveraged longitudinal data from two large patient cohorts in the United States, the Atherosclerosis Risk in Communities study (n ¼

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[8] 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.

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

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).

65. "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."[10]

66. In quantifying the association between PPI use and CKD, Lazarus found that PPI use was associated with incident CKD in unadjusted analysis (hazard ratio [HR], 1.45; 95% CI, 1.11-1.90); in analysis adjusted for demographic, socioeconomic, and clinical variables (HR, 1.50; 95% CI, 1.14-1.96); and in analysis with PPI ever use modeled as a time-varying variable (adjusted HR, 1.35; 95% CI, 1.17-1.55). The association persisted when baseline PPI users were compared directly with H2 receptor antagonist users (adjusted HR, 1.39; 95% CI, 1.01-1.91) and with

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

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).

67. Lazarus's data was confirmed and expanded by Yan Xie, et al.[11] 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.

68. However, evidence of the connection of PPI's with AIN and CKD existed as early as 2007.[12] 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."[13]

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

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

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

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

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

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

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

73. 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.

74. 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.

75. 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.

76. 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.

77. 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.

78. 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.

79. 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.

80. 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.

81. 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.

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

83. Defendant concealed and continue to conceal their knowledge that PPIs can cause kidney injuries from Plaintiff, other consumers, and the medical community. Specifically, Defendant has 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.

84. 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.

85. 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.

86. 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.

87. 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.

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

FEDERAL REQUIREMENTS

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

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

91. With respect to Proton Pump Inhibitors, the Defendant, 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 Defendant 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 Defendant 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 Defendant 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 Defendant 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 Defendant violated 21 CFR § 310.303 because the Defendant 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 Defendant 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 Defendant 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 Defendant 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 Defendant 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 Defendant 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 Defendant 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).

92. Defendant 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 Defendant liable under Louisiana law.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

93. Plaintiff is within the applicable statutes of limitations for the claims presented herein because Plaintiff did not discover the defects and unreasonably dangerous condition of Defendants' PPIs and the risks associated with its use and could not reasonably have discovered the defects and unreasonably dangerous condition of Defendants' PPIs and the risks associated with its use, due to the Defendants' failure to warn, suppression of important information about the risks of the drug, including, but not limited to, the true risk benefit profile, and the risk of CKD and other damages known by Defendants to result from the use of PPIs, and other acts and omissions.

94. 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.

95. In addition, Defendants are estopped from relying on any statutes of limitations or repose by virtue of their acts of fraudulent concealment, affirmative misrepresentations and omissions, which include Defendants' intentional concealment from Plaintiff, Plaintiff's prescribing health care professionals and the general consuming public that Defendants' PPIs were defective, unreasonably dangerous and carried with it the serious risk of developing the injuries Plaintiff has suffered while aggressively and continually marketing and promoting PPIs as safe and effective. This includes, but is not limited to, Defendants' failure to disclose and warn of the risk of chronic kidney disease and other injuries known by Defendants to result from use of PPIs, for example, and not by way of limitation, suppression of information about these risks and injuries from physicians and patients, including Plaintiff; use of sales and marketing documents and information that contained information contrary to the internally held knowledge regarding the aforesaid risks and injuries; and overstatement of the efficacy and safety of PPIs.

96. Plaintiff, Plaintiff's prescribing health care professionals and the general consuming public, had no knowledge of, and no reasonable way of discovering, the defects found in Defendants' PPIs or the true risks associated with her use at the time she purchased and used Defendants' PPIs.

97. Defendants did not notify, inform, or disclose to Plaintiff, Plaintiff's prescribing health care professionals or the general consuming public that Defendants' PPIs were defective

and that its use carried with it the serious risk of developing the injuries Plaintiff has suffered and complained of herein.

98. Because Defendants failed in their duty to notify Plaintiff, Plaintiff's prescribing health care professionals and the general consuming public that their PPIs were defective and, further, actively attempted to conceal this fact, Defendants should be estopped from asserting defenses based on statutes of limitation or repose.

99. Accordingly, Plaintiff files this lawsuit within the applicable statutes of limitations, Plaintiff could not by exercise of reasonable diligence have discovered any wrongdoing, nor could have discovered the causes of her injuries at an earlier time, and when Plaintiff's injuries were discovered, their causes were not immediately known or knowable based on the lack of necessary information, which was suppressed by the Defendants. Further, the relationship of Plaintiff's injuries due to exposure through the Defendants' drug was inherently difficult to discover, in part due to the Defendants' knowing suppression of important safety information. Consequently, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff discovered, or by the exercise of reasonable diligence should have discovered, that Plaintiff may have a basis for an actionable claim.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
VIOLATION OF THE LOUISIANA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, La. R.S. § 51:1401, et seq.

100. 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.

101. 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.

102. The Defendant violated the Louisiana Unfair Trade Practices and Consumer Protection Law, La. R.S. §51:1401, et seq, through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Proton Pump Inhibitors.

103. The Defendant 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 Defendant 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.

104. The Defendant 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.

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

106. Had the Defendant 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.

107. 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.

108. The Defendant 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 Defendant 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.

109. 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 Defendant 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.

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

111. 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.

112. 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.

SECOND CAUSE OF ACTION
LOUISIANA PRODUCTS LIABILITY ACT

113. Plaintiff's damages were caused by characteristics of Proton Pump inhibitors manufactured by the Defendant that rendered the Proton Pump Inhibitors unreasonably dangerous after a reasonably anticipated use of the products by Plaintiff making Defendant liable to Plaintiff pursuant to LSA R.S. 9:2800.54.

114. Proton Pump Inhibitors are unreasonably dangerous under the following:

a. Proton Pump Inhibitors are unreasonably dangerous in construction or composition as per LSA R.S. 9:2800.55;

b. Proton Pump Inhibitors are unreasonably dangerous in design as per LSA R.S. 9:2800.56.

Proton Pump Inhibitors are unreasonably dangerous because an accurate warning about the product was not provided as required by LSA R.S. 9:2800.57.

d. Proton Pump Inhibitors are unreasonably dangerous because the products do not conform to an express warranty of the manufacturer about the product as per LSA R.S. 9:2800.58.

115. The characteristics of Proton Pump Inhibitors that render the products unreasonably dangerous under LSA R.S. 9:2800.55, LSA R.S. 9:2800.56, and LSA R.S. 9:2800.57 et seq. existed at the time the product left the control of the manufacturers.

116. For all of the reasons alleged herein, Proton Pump Inhibitors were unreasonably dangerous in design at the time the products left the manufacturers' control in that there existed an alternate design for the product that was capable of preventing the Plaintiff's damages; and The likelihood that the product's design would cause the Plaintiff's damages and the gravity of those damages outweigh the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

117. For all of the reasons alleged herein, Nexium was 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 warning that such characteristic and its dangers to users of the product.

118. Further, Defendant, before, during, and after the product left its control, acquired knowledge of the characteristic of the product that may cause damage and the danger of such characteristic (or, alternatively, Defendant 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.

119. Defendant expressly warranted to the market, including Plaintiff, by and through statements made by Defendant or its 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.

120. In using Proton Pump Inhibitors, Plaintiff and her physicians relied on the skill, judgment, representations, and foregoing express warranties of the Defendant. 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.

THIRD CAUSE OF ACTION
REDHIBITION

121. The subject product contains a vice or defect which renders it useless or its use so inconvenient that buyers would not have purchased it.

122. Defendant sold and promoted Proton Pump Inhibitors, which defendant placed into the stream of commerce. Under Louisiana law, the seller warrants the buyer against redhibitory defects, or vices, in the thing sold. La. C.C. art. 2520. The subject product sold and promoted by Defendant, possesses a redhibitory defect because it was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which renders the subject product useless or so inconvenient that it must be presumed that a buyer would not have bought the subject product had he known of the defect. Pursuant to La. C.C. art. 2520, Plaintiff is entitled to obtain a rescission of the sale of the subject product.

123. The subject product alternatively possesses a redhibitory defect because the subject product was not manufactured and marketed in accordance with industry standards and/or is unreasonably dangerous, as described above, which diminishes the value of the subject product so that it must be presumed that a buyer would still have bought it but for a lesser price. In this instance, Plaintiff is entitled to a reduction of the purchase price.

124. Defendant is liable as bad faith sellers for selling a defective product with knowledge of the defect, and thus, are liable to Plaintiff for the price of the subject product, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the subject product, and attorneys' fees. As the manufacturer of the subject product, under Louisiana law, Defendant are deemed to know that Proton Pump Inhibitors possessed a redhibitory defect. La. C.C. art. 2545.

FOURTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES UNDER LA. CC. ART. 2524

125. In addition to warranting against redhibitory defects, Defendant warrants that the subject product is reasonably fit for its ordinary and intended use. La. C.C. art. 2524.

126. The subject product is not safe, has numerous and serious side effects and causes severe and permanent injuries including, but not limited to, acute interstitial nephritis ("AIN"), acute kidney injuries ("AKI"), chronic kidney disease ("CKD") and renal failure, also known as end-stage renal disease ("ESRD").

127. As a direct and proximate result of Defendants' actions, Plaintiff has sustained serious, significant and permanent injuries including but not limited to Chronic Kidney Disease, Acute Kidney Injury, Kidney Failure and related sequelae. In addition, Plaintiff required and will continue to require healthcare and services as a result of her injury. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant, as follows:

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

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

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

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

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

DEMAND FOR JURY TRIAL

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

Date: June 2, 2017

Respectfully submitted,
/s/ Andrew J. Geiger
ANDREW J. GEIGER (BAR NO. 32467)
ALLAN BERGER (BAR NO. 2977)
ALLAN BERGER & ASSOCIATES PLC
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Fax: (504) 483-8130
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WAIVER OF SERVICE WILL BE FORWARDED TO DEFENDANTS

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
SANDRA T. PERILLOUX

(b) County of Residence of First Listed Plaintiff ST. JOHN THE BAPTIST
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
ANDREW GEIGER/4173 CANAL STREET/NEW ORLEANS, LA 70119
PHONE: 504-486-9481

DEFENDANTS
ASTRAZENECA PHARMACEUTICALS, ET AL

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

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

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

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

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

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

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

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Product Liability

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
06/02/2017

SIGNATURE OF ATTORNEY OF RECORD
s/Andrew Geiger

FOR OFFICE USE ONLY

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

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

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

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

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

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

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

V. **Origin.** Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

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

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

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

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