UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

DENISE CRANDELL,

Plaintiff,

v.

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; ASTRA USA INC.; ASTRAZENECA AB; ASTRAZENECA UK LTD; ASTRAZENECA, PLC; TAKEDA PHARMACEUTICALS USA, INC; TAKEDA PHARMACEUTICALS AMERICA, INC.; TAKEDA PHARMECUETICALS INTERNATIONAL, INC.; TAKEDA DEVELOPMENT CENTER AMERICAS, INC.; TAKEDA PHARMACEUTICAL COMPANY LIMITED; PROCTER & GAMBLE MANUFACTURING COMPANY; and THE PROCTER & GAMBLE COMPANY,

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

Case No. _____

COMPLAINT

Plaintiff, Denise Crandell, (alternatively referred to herein as "Plaintiff"), residing in St. Mary Parish, within the State of Louisiana, by and through the undersigned attorneys, files this Complaint against Defendants AstraZeneca Pharmaceuticals LP; ("AstraZeneca Pharmaceuticals"); AstraZeneca LP; AstraZeneca PLC; Takeda Pharmaceuticals USA, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc.; Takeda Pharmaceutical Company Limited; 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 Denise Crandell ingested Defendants' respective 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 Louisiana.

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, Denise Crandell, a natural person and resident of Franklin, Louisiana, ingested PPIs, including Prevacid, Prilosec, and Nexium between approximately 2013 to 2016, and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, recovery of costs of obtaining PPIs, including Prevacid, Prilosec, and 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 PPIs, including Prevacid, Prilosec, and Nexium.

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 TAKEDA PHARMACEUTICALS USA, INC. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

17. Defendant TAKEDA PHARMACEUTICALS AMERICA, INC. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

18. Defendant TAKEDA DEVELOPMENT CENTER AMERICAS, INC. is an Illinois corporation which has its principal place of business at 208 South LaSalle Street, Chicago, IL 60604.

19. Defendant TAKEDA PHARMECUETICALS INTERNATIONAL, INC. is an Illinois corporation which has its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

20. Defendant TAKEDA PHARMACEUTICAL COMPANY LIMITED is a foreign corporation with its principal place of business located at 1-1, Doshomachi 4-chrome, Chuo-ku, Osaka 540-8645.

21. On information and belief, TAKEDA PHARMACEUTICALS USA INC is either the direct or indirect owner of substantially all the stock or other ownership interests of TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA DEVELOPMENT CENTER AMERICAS,

INC., TAKEDA PHARMECUETICALS INTERNATIONAL, INC., and TAKEDA PHARMACEUTICAL COMPANY LIMITED.

22. In doing the acts alleged herein, said Takeda Defendants (including TAKEDA PHARMACEUTICALS USA INC, TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC., TAKEDA PHARMECUETICALS INTERNATIONAL, INC., and TAKEDA PHARMACEUTICAL COMPANY LIMITED) 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 TAKEDA PHARMACEUTICALS USA INC, TAKEDA PHARMACEUTICALS AMERICA, INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC., TAKEDA PHARMECUETICALS INTERNATIONAL, INC., and TAKEDA PHARMACEUTICAL COMPANY LIMITED are collectively referred to as "TAKEDA").

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

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

25. 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").

26. 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.

27. 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.

28. 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.

29. 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

30. As a result of the defective nature of PPIs, persons who ingested Defendants' respective PPI products, 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").

31. 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.

32. 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

33. 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.

34. 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.

35. 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.

36. 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.

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

38. 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]

39. 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.

40. 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.

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

42. 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]

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

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

[3] *Id*.

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

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

44. 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 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."

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

46. 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."

47. 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.

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

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

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

49. 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.

50. Also in 2013, Sampathkumar, et al. followed four cases of PPI users, finding that AIN developed after an average period of four weeks of PPI therapy.[8] Researchers further noted that "a high index of suspicion about this condition should prompt the physician to stop the drug, perform a renal biopsy if needed and start steroid therapy for halting a progressive renal disease."

51. 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.

52. 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.

53. 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."

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

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

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

54. 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.*

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

56. In a study conducted by Benjamin Lazarus, et al., published in JAMA, PPI use was associated with a higher risk of incident CKD.[10] The authors leveraged longitudinal data from two large patient cohorts in the United States, the Atherosclerosis Risk in Communities study (n ¼ 10,482) and the Geisinger Health System (n ¼ 248,751), in order to evaluate the relationship between PPI use and the development of 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).

57. "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

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

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]

58. In quantifying the association between PPI use and CKD, Lazarus found that PPI use was associated with incident CKD in unadjusted analysis (hazard ratio [HR], 1.45; 95% CI, 1.11-1.90); in analysis adjusted for demographic, socioeconomic, and clinical variables (HR, 1.50; 95% CI, 1.14-1.96); and in analysis with PPI ever use modeled as a time-varying variable (adjusted HR, 1.35; 95% CI, 1.17-1.55). The association persisted when baseline PPI users were compared directly with H2 receptor antagonist users (adjusted HR, 1.39; 95% CI, 1.01-1.91) and with propensity score–matched nonusers (HR, 1.76; 95% CI, 1.13-2.74). In the Geisinger Health System replication cohort, PPI use was associated with CKD in all analyses, including a time-varying new-user design (adjusted HR, 1.24; 95% CI, 1.20-1.28). Twice-daily PPI dosing (adjusted HR, 1.46; 95% CI, 1.28-1.67) was associated with a higher risk than once-daily dosing (adjusted HR, 1.15; 95% CI, 1.09-1.21).

59. 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.

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

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

60. 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]

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

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

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

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

65. 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.

66. 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.

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

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

67. 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.

68. 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.

69. 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.

70. 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.

71. 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.

72. 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.

73. 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.

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

75. 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.

76. 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.

77. 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.

78. 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.

79. 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.

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

FEDERAL REQUIREMENTS

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

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

83. 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).

84. 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 Louisiana law.

FRAUDULENT CONCEALMENT

85. 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.

86. 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
VIOLATION OF THE LOUISIANA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW, La. R.S. § 51:1401, et seq.

87. 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.

88. 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.

89. 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.

90. The Defendants 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.

91. 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.

92. 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.

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

94. 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.

95. 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.

96. 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.

97. 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.

98. 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.

99. 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.

100. 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

101. 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.

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

103. 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.

c. 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.

104. 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.

105. 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:

a. There existed an alternate design for the product that was capable of preventing the Plaintiff's damages; and

b. 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.

106. For all of the reasons alleged herein, Proton Pump Inhibitors were unreasonably dangerous because an adequate warning about the product had not been provided and at the time the product left the manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide adequate warning that such characteristic and its dangers to users of the product.

107. Further, Defendants, 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, Defendants would have acquired such knowledge if it had acted as reasonable prudent manufacturers), and thus are liable for damages suffered by Plaintiff which arose as a consequence of Defendants' failure to use reasonable care to provide an adequate warning of such characteristic and its dangers to users.

108. Defendants expressly warranted to the market, including Plaintiff, by and through statements made by Defendants 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.

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

THIRD CAUSE OF ACTION
REDHIBITION

110. 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.

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

112. Defendants sold and promoted Proton Pump Inhibitors, which defendants 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 Defendants, 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.

113. 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.

114. Defendants are 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, Defendants 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

115. 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.

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

117. 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").

118. 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 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 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, Denise Crandell, hereby demands a trial by jury on all counts and as to all issues.

Date: October 19, 2016

/s/ Derriel C. McCorvey

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PRO HAC VICE TO BE SUBMITTED

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.)*

I. (a) PLAINTIFFS

DENISE CRANDELL

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Derriel C. McCorvey (L.A. 26083), McCORVEY LAW, LLC, 102 Versailles Blvd #620, Lafayette, LA 70501. (337) 291-2431
Neil D. Overholtz (FL 0188761) PRO HAC VICE TO BE SUBMITTED

DEFENDANTS

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

County of Residence of First Listed Defendant NEW CASTLE, DE
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

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

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

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

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

Click here for: Nature of Suit Code Descriptions.

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

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

TORTS

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

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

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

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

PRISONER PETITIONS

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

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

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

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

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

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

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

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

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

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

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. § 1332 (a)(1)

Brief description of cause:
Product liability litigation

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Judge Rebecca F. Doherty DOCKET NUMBER 6:16-cv-01455-RFD-CBW

DATE
10/19/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/ Derriel C. McCorvey

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE