**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF ILLINOIS**

KENNETH LLYOD DRAVLAND, JR.,

Plaintiff,

v.

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

Defendants.

**COMPLAINT AND DEMAND FOR JURY TRIAL**

Case No. 3:17-cv-133

## COMPLAINT

PLAINTIFF, **KENNETH LLYOD DRAVLAND, JR. (alternatively referred to herein as "Plaintiff")**, domiciled in **SWANSEA (SAINT CLAIR COUNTY)** within the State of **ILLINOIS**, by and through the undersigned attorneys, files this Complaint against Defendants AstraZeneca Pharmaceuticals LP; ("AstraZeneca Pharmaceuticals"); AstraZeneca LP; Procter & Gamble Manufacturing Company; and The Procter & Gamble Company (collectively "Defendants") and for his Complaint states, upon information and belief and based upon investigation to date of counsel, as follows:

## NATURE OF ACTION

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. Nexium, Prilosec, and Prilosec OTC are herein collectively referred to as "PPIs."

3. 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.

4. As set forth more fully herein, Plaintiff Kenneth Lloyd Dravland, Jr., ingested Prilosec, Nexium and Prilosec OTC as early as May 8, 2007 and through to June 15, 2016, which, upon information and belief, resulted in injuries to his kidneys, including acute kidney injury, on or around March 31, 2016 and acute kidney failure beginning on or around June 14, 2016. He continues to experience reduced kidney function to the present day.

**PLAINTIFF**

5. Plaintiff, Kenneth Lloyd Dravland, Jr., a natural person and domiciliary of Swansea, Illinois, located in St. Clair County, ingested PPIs, including Prilosec, Nexium, and Prilosec OTC between approximately 2005 to 2016, and therefore seeks damages for pain and suffering, ascertainable economic losses, attorneys' fees, recovery of costs of obtaining PPIs, including Nexium, Prilosec and Prilosec OTC, and recovery of all past, present, and future health and medical care costs related to his kidney related injuries and sequelae, including but not limited to Acute Kidney Injury and Renal Failure caused by his ingestion of PPIs, including Prilosec, Nexium, and Prilosec OTC.

**DEFENDANTS**

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

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

8. 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 (hereinafter, ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA LP are collectively referred to as "ASTRAZENECA").

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

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

11. 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").

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

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

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

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

## JURISDICTION AND VENUE

16. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds $75,000.00, 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 Illinois.

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

18. Further, because a substantial part of the events or omissions giving rise to the claim occurred in this District, Defendants transacts a substantial amount of business in this District, or Defendants otherwise have sufficient contacts with this District to justify it being fairly brought into this District. Moreover, a substantial part of the events and omissions giving

rise to Plaintiff's causes of action occurred in this district. Accordingly, pursuant to 28 U.S.C. § 1391, venue is proper in this district.

**SUMMARY OF THE CASE**

19. This action is for damages brought on behalf of Plaintiff, Kenneth Lloyd Dravland, Jr., who was prescribed and took the over the counter and prescription PPIs manufactured by Defendants. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff suffering severe and life threatening events including, but not limited to, Acute Kidney Injury and Renal Failure caused by PPIs including, Nexium, Prilosec, and Prilosec OTC.

20. As a result of the defective nature of PPIs, persons who ingested this product 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").

21. Defendants concealed and continue to conceal their knowledge of PPIs' unreasonably dangerous risks from Plaintiff, his 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.

22. As a result of Defendants' actions and inactions, Plaintiff was injured due to his 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.

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

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

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

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

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

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

29. 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.

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

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

b. Delayed-Release Oral Suspension Packets (2.5MG, 5MG, 20MG, 40MG),

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

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

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

32. 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.

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

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

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

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

a. Delayed-Release Capsule Pellets (20 mg), with NDA #019810, approved on 9/14/1989;

b. Delayed-Release Capsule Pellets (10mg), with NDA #019810, approved on 10/5/1995;

c. Delayed-Release Capsule Pellets (40mg), with NDA #019810, approved on 1/15/1998;

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

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

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

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

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

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

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

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

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

45. Defendants knew or should have known of the risks of AKI, Renal Failure 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.

46. As discussed more fully below, there are a multitude of studies that have been published linking the danger of PPI use with AIN, Acute Kidney Injury, Renal Failure, and Chronic Kidney Disease including:

a. Lazarus et al., Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease, Jama International Medicine, at http://archinte.jamanetwork.com. (2016).

b. Xie et al., Proton Pump Inhibitors and Risk of Incident CKD and Progression to ESRD, Journal of the American Society of Nephrology. (2016)

c. Klepser et al., Proton pump inhibitors and acute kidney injury: a nested case–control study, BMC Nephrology, 14:150 (2014).

47. Despite Defendants' knowledge of data indicating that PPI use is causally related to the development of Acute Kidney Injury, Defendants promoted and marketed PPIs as safe and effective for persons, such as Kenneth Lloyd Dravland, Jr., throughout the United States, including Illinois.

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

49. 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.

50. Consumers, including Kenneth Lloyd Dravland, Jr., have several alternative safer methods for treating GERD, including home remedies and other medication, including H2 antagonists.

51. As a result of the defective nature of PPIs, persons who ingested these products 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.

52. Defendants concealed and continue to conceal their knowledge of PPIs' unreasonably dangerous risks from Plaintiff, his physicians, other consumers, and the medical community. Specifically, Defendants failed and continue to fail to adequately inform and warn consumers and the prescribing medical community about the magnified risk of kidney injuries related to the use of PPIs, including Nexium, Prilosec and Prilosec OTC.

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

## FACTUAL ALLEGATIONS

54. 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.

55. 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.

56. 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.

57. 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.

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

59. 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]

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

60. 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.

61. 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.

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

63. 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 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]

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

65. 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]

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

"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 Renal Failure," and 26 cases of "renal impairment" were also identified. "All 5 commercially available PPIs were implicated in these cases."

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

67. 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."

68. 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.

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

70. 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

[6] Ian J. Simpson, Mark R. Marshall, Helen Pilmore, Paul Manley, Laurie Williams, Hla Thein, David Voss, *Proton pump inhibitors and acute interstitial nephritis: Report and analysis of 15 cases*, (September 29, 2006).
[7] Klepser, D., et al. Proton Pump Inhibitors and Acute Kidney Injury: A Nested Case-Control Study, BMC NEPHROLOGY (2013) 14:150.

increased recognition of patient complaints or clinical manifestations of renal disease in order to prevent further injury.

71. 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."

72. 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.

73. 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.

74. 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."

75. 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.*

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

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[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.

77. 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).

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

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

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

79. 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).

80. 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.

81. 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

[12] Xie, Y., et al. *Proton Pump Inhibitors and Risk of Incident CKD and Progression to ESRD*, J. AM. SOC. NEPHROL. (2016) 27: ccc–ccc.
[13] Brewster, UC and MA Perazella. *Acute Kidney Injury Following Proton Pump Inhibitor Therapy*, KIDNEY INTERNATIONAL (2007) 71, 589–593.

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]

82. To date, over-the-counter PPIs, including Prilosec OTC, lack detailed risk information for AIN, Acute Kidney Disease, or Renal Failure.

83. To date, prescription and over-the-counter PPIs lack detailed risk information for CKD, Acute Kidney Disease, or Renal Failure, including those manufactured by Defendants, specifically Nexium, Prilosec, and Prilosec OTC that were taken by Plaintiff.

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

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

86. 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.

87. 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.

88. 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.

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

89. 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.

90. 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.

91. 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.

92. 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.

93. 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.

94. 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.

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

96. 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.

97. As a result of Defendants' actions and inactions, Plaintiff was injured due to his ingestion of PPIs, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

98. As a result of Defendants' actions, Plaintiff and his 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.

99. 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.

100. 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 his new lifestyle.

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

## FEDERAL REQUIREMENTS

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

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

104. 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 Defendants' PPIs 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 because they failed to identify specific tests needed for selection or monitoring of patients who took Proton Pump Inhibitors.

k. 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.

l. 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.

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

n. 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.

o. Proton Pump Inhibitors violate 21 CFR § 211.165 in that Defendants' Proton Pump Inhibitors fail to meet established standards or specifications and any other relevant quality control criteria.

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

q. Defendants violate 21 CFR § 310.303 in that Proton Pump Inhibitors are not safe and effective for its intended use.

r. 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.

s. 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.

t. 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.

u. 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.

v. 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.

w. 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).

105. 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 Illinois law.

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

106. 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.

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

108. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPIs. The Defendants were under a duty to disclose the true character, quality and nature of PPIs because this was non-public information that the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers, and/or to their health facilities.

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

110. Plaintiff was not aware of the connection between the use of Proton Pump Inhibitors and Acute Kidney Injury or Kidney Failure until he saw a television commercial identifying the possible link between Proton Pump Inhibitors (including the Proton Pump Inhibitors prescribed and taken by Plaintiff) and kidney disease on or around August 30, 2016.

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

112. 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

### COUNT I
### NEGLIGENCE

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

114. 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.

115. Defendants owed a duty to manufacture, compound, label, market, distribute, and supply and/or sell their PPI in such a way as to avoid harm to persons upon whom they are used, such as Plaintiff, Kenneth Lloyd Dravland, Jr., or to refrain from such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

116. Defendants owed a duty to warn of the hazards and dangers associated with the use of its products for patients such as, Plaintiff, Kenneth Lloyd Dravland, Jr. herein, so as to avoid harm.

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

a. failing to conduct adequate and appropriate testing of their PPI products;

b. putting proton pump inhibitor products on the market without first conducting adequate testing to determine possible side effects;

c. putting proton pump inhibitor products on the market without adequate testing their dangers to humans;

d. failing to recognize the significance of their own and other testing of, and information regarding proton pump inhibitor products, which testing evidenced such products are potentially harmful to humans;

e. failing to respond promptly and appropriately to their own and other testing of, and information regarding proton pump inhibitor products, which indicated such products are potentially harmful to human;

f. failing to promptly and adequately warn of the potential of proton pump inhibitor products to be harmful to humans;

g. failing to promptly and adequately warn of the potential for kidney injuries including acute interstitial nephritis, acute kidney injuries, and chronic kidney disease when using proton pump inhibitor products;

h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom these products were used in light of such products potential harm to humans;

i. failing to properly, appropriately, and adequately monitor the post-market performance of proton pump inhibitors and such products effects on patients;

j. concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that proton pump inhibitors are harmful to humans;

k. promoting, marketing, advertising and/or selling PPIs for use on patients given their knowledge and experience of such products' potential harmful effects;

l. failing to withdraw PPIs from the market, restrict their use and/or warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;

m. failing to fulfill the standard of care required of a reasonable, prudent, products manufacturer engaged in the manufacture of PPIs;

n. placing and/or permitting the placement of PPIs into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;

o. failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of PPIs to be harmful to humans;

p. failing to respond or react promptly and appropriately to reports of PPIs causing harm to patients;

q. disregarding the safety of users and consumers of PPIs, including Plaintiff, Kenneth Lloyd Dravland, Jr., under the circumstances by failing adequately to warn of said products' potential harm to humans;

r. disregarding the safety of users and consumers of PPIs, including Plaintiff, Kenneth Lloyd Dravland, Jr., and/or his physicians' and/or hospital, under the circumstances by failing to withdraw said products from the market and/or restrict their usage;

s. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of PPIs and their potential harm to humans;

t. failing to exercise reasonable care in informing physicians and/or hospitals using PPIs about their own knowledge regarding said products' potential harm to humans;

u. failing to remove PPIs products from the stream of commerce;

v. failing to test PPIs properly and/or adequately so as to determine their safety for use;

w. promoting PPIs on websites aimed at creating user and consumer demand;

x. failing to conduct and/or respond to post-marketing surveillance of complications and injuries;

y. failing to use due care under the circumstances; and,

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

118. As a direct and proximate result of Defendants' negligent acts and omissions, Plaintiff, Kenneth Lloyd Dravland, Jr. suffered kidney injuries, including acute kidney injury and renal failure.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

## COUNT II
## STRICT PRODUCTS LIABILITY

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

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

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

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

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

123. Kenneth Lloyd Dravland, Jr. was prescribed and used PPIs for their intended purposes and for purposes that Defendants expected and could foresee.

124. Defendants expected and intended PPIs to reach, and did in fact reach, Kenneth Lloyd Dravland, Jr. without any substantial change in the condition of the product from when it was initially manufactured by Defendants.

125. Kenneth Lloyd Dravland, Jr. could not have discovered the unwarned risks of using PPIs through the exercise of reasonable care.

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

127. Kenneth Lloyd Dravland, Jr. did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Kenneth Lloyd Dravland, Jr. or to his treating physicians. The warnings that were given by Defendants were not accurate and were incomplete.

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

129. Defendants knew or should have known that the limited warnings disseminated with PPIs were inadequate, but they failed to communicate adequate information on the dangers

and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of GERD.

130. As a direct and proximate cause of Defendants manufacture, sale and promotion of the defectively designed drug and failure to warn Kenneth Lloyd Dravland, Jr. and his physicians about the significant risks inherent in PPI therapy, Kenneth Lloyd Dravland, Jr. sustained severe injuries.

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

a. failing to provide adequate warnings with their proton pump inhibitor; and

b. failing to properly and adequately design their product.

132. Because of Defendants' failures, Plaintiff, Kenneth Lloyd Dravland, Jr. used the PPIs, which the Defendants manufactured, designed, sold, supplied, marketed or otherwise introduced into the stream of commerce.

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

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

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

135. As a direct and proximate result of Defendants' PPIs, Plaintiff, Kenneth Lloyd Dravland, Jr. suffered kidney injuries.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

## COUNT III
## BREACH OF EXPRESS WARRANTY

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

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

138. Defendants expressly warranted to Plaintiff's physicians and Plaintiff by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, marketing, and other written materials intended for

physicians and the public that PPIs are safe, effective, fit and proper for its intended use, of merchantable quality, had been adequately tested, contained adequate warnings, and was effective.

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

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

141. Defendants knew or should have known Kenneth Lloyd Dravland, Jr. would rely on their warranties.

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

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

144. None of the PPIs consumed by Kenneth Lloyd Dravland, Jr. conformed to Defendants express representations; therefore, Defendants have breached their express warranties.

145. The breach of express warranties by Defendants was a foreseeable, direct, and proximate cause of Kenneth Lloyd Dravland, Jr.'s injuries and damages.

146. Defendants expressly warranted to the market, including Plaintiff, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, advertisements and other materials to the health care and general community, that Proton Pump Inhibitors were safe, effective, fit and proper for its intended use.

147. As a direct and proximate result of Defendants' breach of warranty as described herein, Plaintiff, Kenneth Lloyd Dravland, Jr. suffered the injuries and damages as set forth above.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

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

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

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

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

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

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the products were safe, and withheld and concealed information about the substantial risks of serious injury associated with long term use of PPIs;

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

152. In reliance upon Defendants' implied warranty, Plaintiff, Kenneth Lloyd Dravland, Jr. used said PPIs and in the foreseeable manner promoted, instructed, and marketed by Defendants.

153. Defendants breached their implied warranty to, Plaintiff, Kenneth Lloyd Dravland, Jr. in that PPIs are not of merchantable quality, safe and fit for their intended use, or adequately tested.

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

155. As a direct and proximate result of Defendants' breach of warranty as described herein, Plaintiff, Kenneth Lloyd Dravland, Jr. suffered the injuries and damages as set forth above.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred,

attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

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

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

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

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

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

160. Defendants made representations and failed to disclose material facts with the intent to induce consumers, including Plaintiff, Kenneth Lloyd Dravland, Jr. and the medical community to act in reliance by purchasing and using the proton pump inhibitor sold by Defendants.

161. Plaintiff, Kenneth Lloyd Dravland, Jr. and the medical community justifiably relied on Defendants' representations and omissions by purchasing and taking proton pump inhibitors.

162. As a direct and proximate result of Defendants' representations and omissions as described herein, Plaintiff, Kenneth Lloyd Dravland, Jr. suffered the injuries and damages as set forth above.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

**COUNT VI**
**VIOLATION OF ILLINOIS' CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT (815 ILCS 505, et seq.)**

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

164. The Consumer Fraud and Deceptive Business Practices Act prohibits fraudulent or deceptive conduct that creates a probability of confusion or misunderstanding in the course of a consumer transaction.

165. At all relevant times, Defendants were aware of the use for which their PPI products was intended and impliedly warranted its respective drug was of merchantable quality and safe and fit for such use.

166. Their PPIs were not of merchantable quality, nor fit for the products' intended uses, because the products cause increased risk of serious injury and death, including AIN, CKD, Acute Kidney Injury, and Renal Failure, and other serious and harmful adverse health effects.

167. Defendants breached the implied warranty that their PPIs were of merchantable quality and fit for such use in violation of applicable Illinois consumer protection laws.

168. Defendants were aware that consumers, including Plaintiff, would use their PPIs.

169. Plaintiff and the medical community reasonably relied upon Defendants' judgment and expertise to only sell them or allow them to use their PPIs only if the drugs were indeed of merchantable quality and safe and fit for the product's intended use.

170. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendants' implied warranty for their PPIs.

171. The PPIs reached consumers, including Plaintiff, without substantial change in the condition in which the products were manufactured and sold by Defendants.

172. Defendants breached their implied warranty to consumers, including Plaintiff, as their PPIs were not of merchantable quality or safe and fit for the products' intended uses.

173. Defendants failed to disclose and misrepresented material facts about the risks and benefits associated with PPIs, which was known by Defendants.

174. The omissions and/or misrepresentations regarding the risks and benefits associated with PPIs use were made by Defendants with scienter and/or reckless indifference to the truth. Defendants were either the direct manufacturer or seller of PPIs or were part of the chain of production that ultimately led to the manufacture, sale, merchandizing and post-sale analysis of PPIs.

175. Plaintiff and his physicians justifiably relied upon the material omissions and/or misrepresentations of Defendants, so that exercise of common prudence or diligence would not have revealed the truth.

176. As a direct and proximate result of Defendants' wrongful acts described herein, Plaintiff has suffered profound, permanent injuries; required medical treatment and hospitalization; become liable for medical and hospital expenses; and lost financial gain; and were kept from ordinary activities and duties and will continue to experience said damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred,

attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

**PUNITIVE DAMAGES ALLEGATIONS**

177. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Kenneth Lloyd Dravland, Jr. and other PPI users and for the primary purpose of increasing Defendants' profits from the sale and distribution of PPIs. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

178. Prior to the manufacturing, sale, and distribution of Nexium, Prilosec, and Prilosec OTC, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Kenneth Lloyd Dravland, Jr. and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or kidney failure from using PPIs.

179. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Nexium, Prilosec, and Prilosec OTC, and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Nexium, Prilosec, and Prilosec OTC. Defendants and their agents, officers, and directors

intentionally proceeded with the manufacturing, sale, and distribution and marketing of Nexium, Prilosec, and Prilosec OTC knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

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

**PRAYER FOR RELIEF**

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

a. compensatory, restitution and general damages in an amount that is fair and reasonable and just;

b. punitive damages, against Defendants as appropriate, in the amount set forth above;

c. reasonable and/or statutory attorneys' fees under state laws;

d. costs of suit;

e. prejudgment and post judgment interest thereon at 8% or other appropriate rate as provided for by statute; and

f. such other and further relief as the Court deems just, appropriate and equitable.

**DEMAND FOR JURY TRIAL**

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

Date: February 8, 2017

Respectfully submitted,

/s/ Roger C. Denton
Roger C. Denton
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Pensacola, Florida 32502
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*Pro Hac Vice to be filed*

*ATTORNEYS FOR PLAINTIFF*

JS 44 (Rev. 07/16)

# CIVIL COVER SHEET

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

**I. (a) PLAINTIFFS** KENNETH LLOYD DRAVLAND, JR.

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

**(c)** Attorneys *(Firm Name, Address, and Telephone Number)*
Roger C. Denton / Schlichter, Bogard & Denton
100 South 4th Street, Suite 1200
St. Louis, MO 63102 - TEL NO. (314) 621-6115

**DEFENDANTS**
ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; PROCTER & GAMBLE MANUFACTURING CO.; et al.

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)*

**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:
Products Liability Litigation

## VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

## VIII. RELATED CASE(S) IF ANY

*(See instructions):* JUDGE _____ DOCKET NUMBER _____

DATE
02/08/2017

SIGNATURE OF ATTORNEY OF RECORD
/s/ Roger C. Denton

**FOR OFFICE USE ONLY**

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

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

# UNITED STATES DISTRICT COURT

for the

Southern District of Illinois

KENNETH LLOYD DRAVLAND, JR.

*Plaintiff(s)*

v.

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

*Defendant(s)*

Civil Action No. 3:17-cv-133

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

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

A lawsuit has been filed against you.

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

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

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

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

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

# UNITED STATES DISTRICT COURT

for the

Southern District of Illinois

KENNETH LLOYD DRAVLAND, JR.

*Plaintiff(s)*

v.

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

*Defendant(s)*

Civil Action No. 3:17-cv-133

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

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

A lawsuit has been filed against you.

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

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

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

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

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

# UNITED STATES DISTRICT COURT

for the

Southern District of Illinois

KENNETH LLOYD DRAVLAND, JR.

*Plaintiff(s)*

v.

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

*Defendant(s)*

Civil Action No. 3:17-cv-133

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

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

A lawsuit has been filed against you.

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

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

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

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

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

# UNITED STATES DISTRICT COURT

for the

Southern District of Illinois

KENNETH LLOYD DRAVLAND, JR.

*Plaintiff(s)*

v.

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

*Defendant(s)*

Civil Action No. 3:17-cv-133

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Proctor & Gamble Manufacturing Company
1 Proctor & Gamble Plaza
Cincinnati, OH 45202

A lawsuit has been filed against you.

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

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

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

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*