UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

ALEJANDRO RODRIGUEZ, INDIVIDUALLY and SURVIVING HEIR OF FRANK RODRIGUEZ, DECEASED,

Plaintiff,

v.

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP; ASTRA USA INC.; ASTRAZENECA AB; ASTRAZENECA UK LTD; and ASTRAZENECA, PLC,

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

Case No. _____

COMPLAINT

COMES NOW the Plaintiff, Alejandro Rodriguez, individually and as Surviving Heir of Frank Rodriguez (alternatively referred to herein as "Plaintiffs"), residing in Franklin County, within the State of Kansas, by and through the undersigned attorneys, and files this Complaint against Defendants AstraZeneca Pharmaceuticals LP; ("AstraZeneca Pharmaceuticals"); AstraZeneca LP; AstraZeneca PLC; (collectively "Defendants") and for his Complaint states, upon information and belief and based upon investigation of counsel, as follows:

INTRODUCTION

1. This is a products liability 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, Decedent Frank Rodriguez ingested PPIs, which resulted in serious injuries to his kidneys and subsequent death on October 30, 2014.

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 Kansas.

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.

PLAINTIFFS

7. Plaintiff Alejandro Rodriguez is the son and a surviving heir of Frank Rodriguez, deceased ("Decedent"), and a natural person and resident of Ottawa, Kansas. Plaintiff Alejandro Rodriguez also brings this action as the Personal Representative of the Estate of Decedent.

8. Decedent Frank Rodriguez was a resident of Ottawa, Kansas and ingested PPIs, including Prilosec, from approximately 2006 until his death on October 30, 2014. Plaintiffs seek damages for pain and suffering, ascertainable economic losses, attorneys' fees, recovery of costs

of obtaining PPIs, including Prilosec, and recovery of all past, medical care costs related to his kidney related injuries and sequelae caused by his ingestion of PPIs, including Prilosec up to the time of Frank Rodriguez's death, and any and all other damages available under Kansas law.

9. Potential beneficiaries of recovery for Decedent's wrongful death include: Alejandro Rodriguez (son of Frank Rodriguez); Gina Olipari (daughter of Frank Rodriguez); and Salvatore Rodriguez (son of Frank Rodriguez). Plaintiff files this suit under applicable wrongful death and as a survival action under Kansas law.

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

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

12. 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.

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

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

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

16. 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.

17. 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").

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

19. 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 Kansas.

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

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

SUMMARY OF THE CASE

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

23. Defendants concealed and continue to conceal their knowledge of PPIs' unreasonably dangerous risks from Decedent, 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.

24. As a result of Defendants' actions and inactions, Decedent was injured due to his ingestion of Prilosec, which took his life on October 30, 2014 accordingly seeks damages associated with these injuries and sequelae.

FACTUAL ALLEGATIONS

25. 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.

26. 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.

27. 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.

28. 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.

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

30. 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]

31. 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.

32. 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.

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

34. 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

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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*.

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]

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

36. 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."

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

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[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.

[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).

38. 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."

39. 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.

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

41. 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.

42. 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."

43. 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

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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.

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.

44. 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.

45. 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."

46. 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.*

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

48. 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

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

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

with self-reported use of prescription PPIs at baseline (adjusted hazard ratio 1.50, 95% confidence interval 1.14–1.96).

49. "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]

50. 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

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

(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).

51. 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.

52. 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]

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

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

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

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

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

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

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

57. 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.

58. 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.

59. 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.

60. 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.

61. 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.

62. 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.

63. 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.

64. 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.

65. Consumers, including the Decedent, 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.

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

67. Defendants concealed and continue to conceal their knowledge that PPIs can cause kidney injuries from Decedent, 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.

68. As a direct and proximate result of Defendants' actions and inactions, Decedent was injured due to his ingestion of PPIs, which caused various injuries, pain and suffering, and death.

69. As a result of Defendants' actions, Decedent and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Decedent 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.

70. As a direct and proximate result of ingesting PPIs, Decedent was permanently and severely injured, having suffered serious consequences from PPI use, and resulting in his death.

71. Decedent, as a direct and proximate result of PPI use, suffered severe mental and physical pain and suffering and sustained permanent injuries and emotional distress, along with economic loss due to medical expenses, and living related expenses due to his new lifestyle.

72. As a direct and proximate result of PPI use, Decedent incurred pecuniary losses, including medical expenses, lost wages and other economic damages.

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

74. As a direct and proximate result of PPI use, Plaintiff has also incurred pecuniary losses, including medical and funeral expenses and other economic damages due to Decedent's death.

75. As a direct and proximate result of PPI use, Plaintiff also suffered damages by losing the consortium, services, companionship, instruction, guidance, counsel, training and support of Decedent.

76. Defendant's acts, conduct and omissions were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Decedent and other users of Defendants' products, and for the primary

purpose of increasing Defendants' profits. As such, Plaintiff is entitled to an award of punitive damages.

FEDERAL REQUIREMENTS

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

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

79. 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 Prilosec 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 Prilosec 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).

80. 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 Decedent, making the Defendants liable under Louisiana law.

FRAUDULENT CONCEALMENT

81. 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 Decedent, physicians, the medical community, and the general public the true risks associated with Proton Pump Inhibitors.

82. As a result of Defendants' actions, Decedent 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.

COUNT I

[Strict Liability]

83. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

84. The PPI products manufactured, marketed, supplied and/or distributed by Defendants was defective at the time of manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying such labels failed to warn of the dangerous risks they posed, including the risk of developing AIN, Chronic Kidney Disease, AKI, or Kidney Failure.

85. At all times alleged herein, the PPI products manufactured, marketed, supplied, and/or distributed by Defendants was defective, and Defendants knew that PPISs were to be used by consumers without inspection for defects. Moreover, Decedent, Decedent's prescribing physicians, and Decedent's healthcare providers neither knew nor had reason

to know at the time of Decedent's use of PPIs of the aforementioned defects. Decedent and ordinary consumers, like the Decedent, would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

86. At all times alleged herein, the PPI was prescribed to and used by Decedent as intended by Defendants and in a manner reasonably foreseeable to Defendants.

87. The design of PPI product was defective in that the risks associated with using the drugs for the duration and aggressively promoted therapies, such as heartburn or frequent heartburn did not dictate the use of PPIS and the risks of AIN, CKD, AKI and/or kidney/renal failure outweighed any benefits of their design. Any benefits associated with the use of PPIs in such situations were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results but without the increased risk of developing AIN, CKD, AKI, or kidney/renal failure.

88. The defect in design existed when the products left Defendants' possession.

89. At the time the PPI product left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting their drug.

90. As a result of the defective condition of the PPI products, Decedent and Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff respectfully request that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, medical monitoring, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT II

[Product Liability – Failure to Warn]

91. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

92. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting PPIs and, through that conduct, have knowingly and intentionally placed such drugs into the stream of commerce with full knowledge that their products reach consumers such as Decedent who ingested them.
93. Defendants did in fact sell, distribute, supply, manufacture, and/or promote PPIs to Decedent and to Decedent's prescribing physicians. Additionally, Defendants expected the drugs they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and they did in fact reach – prescribing physicians and consumers, including Decedent and Decedent's prescribing physicians, without any substantial change in the condition from when they were initially distributed by Defendants.
94. At all times herein mentioned, PPIs were defective and unsafe in manufacture such that they was unreasonably dangerous to the user, and were so at the time they were distributed by Defendants and ingested by Decedent. The defective condition of such drugs was due in part to the fact that they were not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially AIN, CKD, AKI, or kidney/renal failure as a result of their use.
95. This defect caused serious injuries to Decedent, who used Defendants' PPI products in its intended and foreseeable manner.
96. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that PPIs did not cause users to suffer from unreasonable and dangerous side effects.
97. Defendants so negligently and recklessly labeled, distributed, and promoted PPIs that it was dangerous and unsafe for the use and purpose for which it was intended.
98. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with PPIs, namely AIN, CKD, AKI, kidney/renal Failure, or death.
99. Defendants were aware of the probable consequences of the aforesaid conduct.

Despite the fact that Defendants knew or should have known that PPIs caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing AIN, CKD, AKI or kidney/renal failure from its use, even though this side effect was known or reasonably scientifically knowable at the time of their its marketing and distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Decedent.

100. Decedent could not have discovered any defect in PPIs through the exercise of reasonable care.

101. Defendants, as the manufacturers and/or distributors of PPIs, are held to the level of knowledge of experts in the field.

102. Decedent reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

103. Had Defendants properly disclosed the risks associated with PPIs, Decedent would have avoided the risk of AIN, CKD, AKI, kidney failure, or eventual death by not using the drug.

104. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Decedent and Plaintiff to sustain injuries as herein alleged.

WHEREFORE, Plaintiff respectfully request that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, medical monitoring, 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

[Negligence]

105. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

106. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Decedent herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of PPIs.

107. Defendants breached their duty of reasonable care to Decedent in that they negligently promoted, marketed, distributed, and/or labeled PPIs.

108. Decedent's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

a. In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of PPIs;

b. In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Decedent herein, of the dangerous and defective characteristics of PPIs;

c. In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for PPIs;

d. In promoting PPIs in an overly aggressive, deceitful, and fraudulent manner, including as a frequent and/or daily therapy for conditions for which it was not indicated, such as heartburn, despite evidence as to the drug's defective and dangerous characteristics due to its propensity to cause AIN, CKD, AKI or kidney/renal failure;

e. In representing that PPIs were safe for its intended use when, in fact, the products were unsafe for their intended use;

f. In failing to perform appropriate pre-market testing of PPIs;

g. In failing to perform appropriate post-market surveillance of PPIs;

h. In failing to continue to warn consumers and/or Decedent and Decedent's

physicians of the dangers of AIN, CDK, AKI and/or kidney/renal failure;

i. In failing to adequately and properly test PPIs before and after placing it on the market;

j. In failing to conduct sufficient testing on PPIs which, if properly performed, would have shown that it had the serious side effect of causing AIN, CKD, AKI and/or kidney/renal failure;

k. In failing to adequately warn Decedent and Decedent's healthcare providers that the use of PPI drugs carried a risk of developing AIN, CKD, AKI, or kidney/renal failure.

l. In failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risk of AIN, CKD, AKI, or kidney/renal failure associated with the use of PPIs; and

m. In failing to adequately and timely inform Decedent and the healthcare industry of the risk of serious personal injury, namely AIN, CKD, AKI, or kidney/renal failure, from PPIs ingestion as described herein.

109. Defendants knew or should have known that consumers, such as Decedent, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

110. As a direct and proximate result of Defendants' carelessness and negligence, Decedent and Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, AIN, CKD, AKI, or kidney/renal failure. Decedent and Plaintiff has endured pain and suffering, physical impairment, suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, medical monitoring, together with

interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT IV

[Breach of Express Warranty]

111. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

112. Before Decedent were first prescribed PPI and during the period in which Decedent used PPIs, Defendants expressly warranted that PPIs were safe.

113. Defendants' PPIs did not conform to these express representations because the PPI products were not safe and had an increased risk of serious side effects, including AIN, CKD, AKI, or kidney failure.

114. As a direct and proximate result of this wrongful conduct, Decedent and Plaintiffs was injured as described above.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, medical monitoring, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT V

[Breach of Implied Warranty]

115. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

116. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold PPIs, and before PPIs were prescribed to Decedent, Defendants impliedly warranted to Decedent that PPIs were of merchantable quality and safe and fit for the use for which it was intended.

117. Decedent, individually and through Decedent's prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

118. Decedent was prescribed, purchased, and used the subject products for its intended purpose.

119. Due to Defendants' wrongful conduct as alleged herein, Decedent could not have known about the nature of the risks and side effects associated with PPIs until after Decedent used it.

120. Contrary to the implied warranty for the subject products, PPIS were not of merchantable quality, and it was neither safe nor fit for its intended uses and purposes, as alleged herein.

121. As a direct and proximate result of Defendants' breach of implied warranty, Decedent suffered severe and permanent physical and emotional injuries, including, but not limited to, AIN, CKD, kidney failure, and/or death. Decedent and Plaintiff have endured pain and suffering, suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully request that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, medical monitoring, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VI

[Fraud]

122. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

123. Defendants, having undertaken to prepare, design, research, develop,

manufacture, inspect, label, market, promote, and sell PPIs, owed a duty to provide accurate and complete information regarding the drug.

124. Defendants' advertising, marketing and educational programs, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of PPIs were safe for human use, had no unacceptable side effects, and would not interfere with daily life.

125. Defendants did not properly study nor report accurately the results of their studies in terms of risks and benefits of PPIs.

126. Defendants purposefully concealed, failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of PPIs.

127. Thus, Defendants, through the publication of medical literature, deceived potential users and prescribers of PPIs by relaying only allegedly positive information, while concealing, misstating, and downplaying the known adverse and serious health effects, including AIN, CKD, or kidney/renal failure.

128. Defendants similarly used promotional practices to deceive potential users and prescribers of PPIs by relaying only allegedly positive information, while concealing, misstating, and downplaying the known adverse and serious health effects, including AIN, CKD, AKI, or kidney/renal failure.

129. Defendants also falsely and deceptively kept relevant information from potential PPI users and minimized prescriber concerns regarding the safety and efficacy of PPIs.

130. The scientific and medical communities were misled as to the true nature of the risk and benefits of PPIs in particular and in general as to the treatment needs and options for patients in need of acid reflux control.

131. The misconceptions as to the true risks and benefits of Defendants' PPI drugs were pervasive throughout the medical and scientific communities due to the marketing methods employed by Defendants that included the following:

a. The publication of fraudulent scientific papers in scientific

and medical literature;

b. Providing false and misleading information to doctors during sales and detailing calls at the doctors' offices or at medical or scientific conferences and meetings;

c. Funding and sponsoring physicians, consultants and/or Key Opinion Leaders to disseminate false and misleading scientific and medical information through medical journals and publications;

d. Funding third-party companies to disseminate false and misleading scientific and medical information through its publications and its members to physicians and patients;

e. Funding continuing medical education to disseminate false and misleading information to doctors;

f. Paying specialists in the field to meet with prescribing doctors for the purpose of disseminating false and misleading information about the risks and benefits of the PPI drugs;

g. Disseminating direct to consumers advertising to drive patients to their doctors' offices to ask for Prilosec based on false and misleading information regarding the risks and benefits of the drugs.

h. Disseminating false and misleading marketing materials directly to Consumers and Decedent such as television advertisements and print advertisements.

132. In particular, Defendants falsely and deceptively misrepresented material facts regarding the safety and effectiveness of PPIs and fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the

safety and effectiveness of their PPI products.

133. The misrepresentations and/or active concealments were perpetuated directly and/or indirectly by Defendants. Moreover, as a result of these efforts it was accepted by the medical and scientific communities that PPIs had a certain risk benefit profile that was shown to be completely false by independent studies, case series, Defendants own postmarketing experience, and individual reports.

134. Defendants were in possession of evidence demonstrating that PPIs caused serious and sometimes debilitating side effects, including AIN, CKD, AKI, and kidney/renal failure. Nevertheless, Defendants continued to market such products by providing false and misleading information with regard to its safety and efficacy to Decedent and Decedent's treating physicians.

135. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Decedent, Decedent's prescribing physicians and the healthcare industry generally.

136. Defendants made these false representations with the intent or purpose that Decedent, Decedent's prescribing physicians and the healthcare industry would rely on them, leading to the widespread use of PPIs by Decedent as well as the general public.

137. At all times herein mentioned neither Decedent nor Decedent's physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of these facts, Decedent's physicians would not have prescribed and Decedent would not have taken PPIs.

138. Decedent, Decedent's prescribing physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of PPIs that Defendants did suppress, conceal, or fail to disclose to Decedent's detriment. Decedent justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true dangers of Decedent. Based on the nature of

the physician-patient relationship, Defendants had reason to expect that Decedent would indirectly rely on Defendants' misrepresentations and/or active concealment.

139. As a result of the concealment and/or suppression of the material facts set forth above, Decedent ingested PPIs and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully request that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, medical monitoring, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VII

[Negligent Misrepresentation]

140. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

141. Defendants negligently and/or recklessly misrepresented to Consumers, Decedent, Decedent's prescribing physicians, and the healthcare industry the safety and effectiveness of PPI and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by PPIs.

142. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that PPIs had defects, dangers, and characteristics that were other than what Defendants had represented to Decedent, Decedent's physicians and the healthcare industry generally.

143. The negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

144. Defendants should have known through the exercise of due care that these representations were false, and they made the representations without the exercise of due

care leading to the deception of Decedent, Decedent's prescribing physicians, and the healthcare industry.

145. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Decedent, Decedent's prescribing physicians, and the healthcare industry would rely on them, leading to the use of PPIs by Decedent as well as the general public.

146. At all times herein mentioned neither Decedent nor Decedent's physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had Decedent been aware of said facts, Decedent's physicians would not have prescribed and Decedent would not have taken PPIs.

147. Decedent justifiably relied on and/or were induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of PPIs and relied on the absence of information regarding the dangers of PPIs which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Decedent's detriment.

148. Defendants had a post-sale duty to warn Decedent, Decedent's prescribing physicians, and the general public about the potential risks and complications associated with their PPI drugs in a timely manner.

149. Defendants made the representations and actively concealed information about the defects and dangers of PPIs with the absence of due care such that Decedent's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting PPIs.

150. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts as set forth above, Decedent ingested PPIs and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully request that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, medical monitoring, together with

interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VIII

[Fraudulent Concealment]

151. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

152. Defendants are estopped from asserting a statute of limitations defense because they fraudulently concealed their wrongful conduct from the Decedent with the intent that Decedent and Decedent's prescribing physicians would rely on such material representations**.** First, Defendants had actual knowledge of the defective and dangerous nature of PPIs. Second, Defendants failed to conduct adequate testing on PPIs to establish safety and efficacy. Third, Defendants had actual knowledge of their misrepresentations, negligence, breach of warranties, and false, misleading, deceptive, and unconscionable conduct. Yet, Defendants continued to perpetuate their wrongful conduct with the intent and fixed purpose of concealing their wrongs from the Decedent and the public at large.

153. Decedent and Decedent's prescribing physicians were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material misrepresentations, and Decedent were injured as a direct and proximate result.

154. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Decedent, Decedent's prescribing physicians, and the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact, with the intent that Decedent and Decedent's prescribing physicians would rely on Defendants' misrepresentations. Decedent and their prescribing physicians did, in fact, act in actual and justifiable reliance on Defendants' representations, and Decedent was injured as a result.

155. Defendants, as the manufacturer and/or distributor of PPIs, were in a position of superior knowledge and judgment regarding any potential risks associated with their drugs.

156. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Decedent relating to PPIs at issue in this lawsuit, said breach or breaches constituting fraud because of its propensity to deceive others or constitute an injury to public interests or public policy.

157. In breaching their duties to Decedent and Plaintiff, Defendants used their position of trust as the manufacturer and/or distributor of PPIs to increase sales of the drugs at the expense of informing Plaintiff that, by ingesting these drugs, they were placing themselves at a significantly-increased risk of developing AIN, CKD, AKI and/or renal/kidney failure.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff favor for compensatory and punitive damages, medical monitoring, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT IX

[Punitive Damages]

158. At all times material hereto, Defendants knew or should have known that Prilosec was inherently dangerous with respect to the risk of CKD, AIN, AKI, or renal/kidney failure.

159. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Prilosec.

160. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Decedent, concerning the safety of Prilosec.

161. At all times material hereto, Defendants knew and recklessly disregarded the fact that Prilosec cause AIN, CKD, AKI, or renal/kidney failure and/or injuries to multiple other body systems.

162. Notwithstanding the foregoing, Defendants continued to aggressively market Prilosec to consumers, including Decedent, without disclosing the aforesaid side effects.

163. Defendants knew of Prilosec's lack of warnings regarding the risk of developing AIN, CKD, AKI, and/or renal/kidney failure, and/or injuries to multiple other body systems, but they intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and/or sell Prilosec without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Decedent, in conscious and/or negligent disregard of the foreseeable harm caused by Prilosec.

164. Defendants' intentional and/or reckless failure to disclose information deprived Decedent of necessary information to enable Decedent to weigh the true risks of using Prilosec against its benefits.

165. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Decedent suffered severe and permanent physical and emotional injuries, including, but not limited to, renal/kidney failure, AIN, CKD, or AKI and/or injuries to multiple other body systems or death. Decedent and Plaintiff have endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiffs and Decedent's injuries and damages are prolonged and/or permanent and will continue into the future.

166. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Decedent, thereby entitling Plaintiff to punitive damages in an amount

appropriate to punish Defendants and deter them from similar conduct in the future.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

a. For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;
b. For medical, incidental, and hospital expenses according to proof;
c. For pre-judgment and post-judgment interest as provided by law;
d. For full refund of all purchase costs Decedent paid for Prilosec;
e. For compensatory damages in excess of the jurisdictional minimum of this Court;
f. For consequential damages in excess of the jurisdictional minimum of this Court;
g. For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;
h. For attorneys' fees, expenses, and costs of this action; and
i. For such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury at Kansas City Division on all issues so triable.

Date: October 28, 2016

Respectfully submitted,

/s/ Kirk J. Goza
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