UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

GEORGE MULLEN, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; and ASTRAZENECA LP, Defendants.	CASE NO. 1:16-cv-4801 **COMPLAINT AND DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiff, George Mullen, by and through the undersigned counsel, hereby brings this Complaint for damages against the Defendants, and alleges the following:

NATURE OF THE CASE

1. This is an action for personal injuries and economic damages suffered by Plaintiff George Mullen ("MR. MULLEN" or "Plaintiff") as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and/or sale of the proton pump inhibiting ("PPI") drug known as Nexium (esomeprazole magnesium) and/or other Nexium-branded products with the same active ingredient herein collectively referred to as "NEXIUM".

PARTIES

Plaintiff

2. At all times referenced herein, Plaintiff MR. MULLEN was and is a citizen of the State of Illinois.

Defendants

AstraZeneca Pharmaceuticals LP

3. AstraZeneca Pharmaceuticals LP Defendant AstraZeneca Pharmaceuticals LP is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

4. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling NEXIUM products.

5. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in the State of Delaware, Illinois and New York.

6. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited, and conducted business in the State of Delaware, Illinois and New York and derived substantial revenue from such business.

7. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP expected or should have expected that its acts would have consequences within the United States of America, State of Delaware, Illinois, and New York.

8. Defendant AstraZeneca Pharmaceuticals 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), with NDA # 021957, approved on 10/20/2006;

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 022101, approved on 03/31/2005.

AstraZeneca LP

9. At all times relevant hereto, Defendant AstraZeneca LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling NEXIUM products.

10. Defendant AstraZeneca LP is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

11. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in the State of Delaware, Illinois and New York.

12. At all relevant times, Defendant AstraZeneca LP transacted, solicited, and conducted business in the State of Delaware, Illinois and New York and derived substantial revenue from such business.

13. At all times relevant hereto, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences within the United States of America, State of Delaware, Illinois, and New York.

AstraZeneca Pharmaceuticals LP & AstraZeneca LP's Unity of Interest

14. Defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP shall herein be collectively referred to as "Defendants" or "AstraZeneca."

15. On information and belief, at all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority of each other Defendant and on

behalf of each other Defendant. During the relevant times, Defendants possessed a unity of interest between themselves and exercised control over their respective subsidiaries and affiliates.

16. Moreover, each Defendant was the agent and employee of each other Defendant, and in doing the things alleged was acting within the course and scope of such agency and employment and with each other Defendant's actual and implied permission, consent, authorization, and approval. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's injuries, losses and damages.

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332(a)(1) because this case is a civil action where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between citizens of different States.

18. This court has personal jurisdiction over Defendants pursuant to and consistent with the Constitutional requirements of Due Process in that Defendants, acting through their agents or apparent agents, committed one or more of the following:

a. The transaction of any business within the state;

b. The making of any contract within the state;

c. The commission of a tortious act within this state; and

d. The ownership, use, or possession of any real estate situated within this state.

FACTUAL BACKGROUND

Proton Pump Inhibitors Generally

19. Proton pump inhibitors ("PPI") are one of the most commonly prescribed medications in the United States to treat conditions such as:

a. Gastroesophageal reflux disease (GERD)

b. Dyspepsia

c. Acid peptic disease

d. Zollinger-Ellison syndrome

e. Acid reflux, and

f. Peptic or stomach ulcers.

20. In 2013, more than 15 million Americans used prescription PPIs, costing more than $10 billion. Of these prescriptions, however, it has been estimated that between 25% and 70% of them have no appropriate indication.

21. AstraZeneca sold NEXIUM with National Drug Code (NDC) numbers 0186-5020, 0186-5022, 0186-5040, 0186-5042, 0186-40100186-4020, and 0186-4040.

22. NEXIUM is AstraZeneca's largest-selling drug and, in the world market, the third largest selling drug overall. In 2005, AstraZeneca's sales of Nexium exceeded $5.7 billion dollars. In 2008, Nexium sales exceeded $5.2 billion dollars.

23. NEXIUM (esomeprazole magnesium) is a PPI that works by inhibiting the secretion of stomach acid. It shuts down acid production of the active acid pumps in the stomach, reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

Dangers Associated with PPIs

24. Even if used as directed, Defendants failed to adequately warn against the negative effects and risks associated with this product including, but not necessarily limited to, long term usage and the cumulative effects of long term usage.

25. During the period in which Nexium has been sold in the United States, hundreds of reports of injury have been submitted to the FDA in association with ingestion of Nexium and other PPIs. Defendants have had notice of serious adverse health outcomes through case reports,

clinical studies and post-market surveillance. Specifically, Defendants had received numerous case reports of several types of kidney and related injuries in patients that had ingested NEXIUM, including:

a. Acute Interstitial Nephritis (AIN),

b. Chronic Kidney Disease (CKD),

c. Renal/Kidney Failure,

d. Acute Kidney Injury (AKI), and

e. Clostridium difficile.

26. These reports of numerous injuries put Defendants on notice as to the excessive risks of injuries related to the use of Nexium. However, Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Nexium did not pose any risks of kidney injuries.

Acute Interstitial Nephritis (AIN) Dangers Associated with PPIs

27. Acute Interstitial Nephritis (AIN) is the Inflammation of the Tubes and Tissues of the Kidneys. The most common symptoms are fatigue, nausea and weakness. AIN-related symptoms can begin as early as one week following PPI ingestion.

28. The risk of AIN among PPI users was first raised in 1992. Five years later, an additional study raised concerns. By 2011, the World Health organization adverse drug reaction report included nearly 500 cases of AIN as of July 2011.

29. Between 2004 and 2007 at least three additional studies confirmed AIN related to PPI usage. More recent studies indicate that those using PPIs such as Nexium are at a three times greater risk than the general population to suffer AIN.

30. On or about October 30, 2014, the FDA notified Defendants that the FDA determined that PPIs (and all forms for NEXIUM, specifically) pose additional risks not previously disclosed.[1]

31. On December 19, 2014, the labeling for PPIs was updated to include a warning about AIN. The new label added a (never-before-included) section about AIN that read, in the relevant part, that AIN "may occur at any point during PPI therapy."[2]

32. Among others, the following medical studies support the fact that there is an association between PPIs, including NEXIUM, and AIN:

a. Ruffenach, Stephen J., Mark S. Siskind, and Yeong-Hau H. Lien, *Acute interstitial nephritis due to omeprazole*. The American journal of medicine 93, no. 4 (1992): 472-473.

b. Badov, David, Greg Perry, John Lambert, and John Dowling, *Acute interstitial nephritis secondary to omeprazole*, Nephrology Dialysis Transplantation 12, no. 11 (1997): 2414-2416, *available at* http://ndt.oxfordjournals.org/content/12/11/2414.short .

c. Torpey, Nicholas, Tim Barker, and Calum Ross, *Drug-induced tubulo-interstitial nephritis secondary to proton pump inhibitors: experience from a single UK renal unit*, Nephrology Dialysis Transplantation 19, no. 6 (2004): 1441-1446, *available at* http://ndt.oxfordjournals.org/content/19/6/1441.short .

d. Geevasinga, Nimeshan et al., *Proton Pump Inhibitors and Acute Interstitial Nephritis*, Clinical Gastroenterology and Hepatology , Volume 4 , Issue 5 , 597 – 604, *available at* http://www.cghjournal.org/article/S1542-3565(05)01092-X/abstract?cc=y=.

e. Harmark, Linda, Hans E. Van Der Wiel, Mark C. H. De Groot, and A. C. Van Grootheest, 2007, *Proton Pump Inhibitor-Induced Acute Interstitial Nephritis*,

[1] *See* http://www.accessdata.fda.gov/drugsatfda docs/appletter/2014/021153Orig1s050,021957Orig1s017,022101Orig1s014ltr.pdf

[2] *See* December 19, 2014 label at 1 & 6, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022101s014021957s017021153s050lbl.pdf.

British Journal Of Clinical Pharmacology 64 (6): 819-823, available at http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2125.2007.02927.x/full.

f. K. Sampathkumar, A. Abraham. 2013, *Acute Interstitial Nephritis Due To Proton Pump Inhibitors*, Indian Journal Of Nephrology 23 (4): 304, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3741979/.

33. Even the current warning of AIN is far from complete, lacking the necessary force to give patients and theaters the proper information needed to make an informed decision about whether to start a drug regimen with such potential dire consequences.

34. If left untreated, AIN can lead to Chronic Kidney Disease (CKD) and kidney failure.

Chronic Kidney Disease (CKD) Dangers Associated with PPIs

35. CKD is the gradual loss of kidney function. Kidneys filter wastes and excess fluids from the blood, which are then excreted. When chronic kidney disease reaches an advanced stage, dangerous levels of fluid, electrolytes and wastes can build up in the body.

36. In the early stages of CKD, patients may have few signs or symptoms. CKD may not become apparent until kidney function is significantly impaired.

37. Treatment for CKD focuses on slowing the progression of the kidney damage, usually by attempting to control the underlying cause. CKD can progress to end-stage kidney failure, which is fatal without artificial filtering, dialysis or a kidney transplant. Early treatment is often the key to avoiding the most negative outcomes.

38. CKD is associated with a substantially increased risk of death and cardiovascular events.

39. Studies have shown the *long term* use of PPIs was independently associated with a 20% to 50% higher risk of CKD, after adjusting for several potential confounding variables,

including demographics, socioeconomic status, clinical measurements, prevalent comorbidities, and concomitant use of medications.

40. In at least one study, the use of PPIs for *any period of time* was shown to increase the risk of CKD by 10%.

41. As a whole, patients with renal disease are nearly twice as likely to have been exposed to PPIs compared to those without renal disease.

42. Among others, the following medical studies support the fact that there is an association between PPIs, including NEXIUM, and CKD:

a. Brewster, U. C., and M. A. Perazella, *Proton pump inhibitors and the kidney: critical*, Clinical Nephrology 68, no. 2 (2007): 65-72, *available at* https://www.researchgate.net/profile/Mark_Perazella/publication/6117052_Proton_pump_inhibitors_and_the_kidney_Critical_review/links/5540b3b40cf2b7904369ac54.pdf.

b. Tony Antoniou, David N. Juurlink. 2015, *Proton Pump Inhibitors And The Risk Of Acute Kidney Injury In Older Patients: A Population-Based Cohort Study*, CMAJ Open 3 (2): E166, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4571830/ (three times Greater Risk of AIN with PPI).

c. Lazarus B, Chen Y, Wilson FP, et al., *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease.*, JAMA Intern Med. 2016;176(2):.doi:10.1001/jamainternmed.2015.7193, *available at* https://archinte.jamanetwork.com/article.aspx?articleid=2481157&version=meter+at+null&module=meter-Links&pgtype=Blogs&contentId=&mediaId=%25%25ADID%25%25&referrer=&priority=true&action=click&contentCollection=meter-links-click 20-50% increased risk of Chronic Kidney Disease).

43. Currently, NEXIUM lacks any warning of CKD.

Acute Kidney Injury (AKI) Dangers Associated with PPIs

44. Studies indicate that those using PPIs such as Nexium are at greater than a 2.5 times greater risk than the general population to suffer AKI. The AKIs occurred with 120 days of the patients staring the PPIs.

45. Studies also indicated that those who develop AIN are at significant risk of AKI even though they may not be an obvious case kidney dysfunction.

46. Among others, the following medical studies support the fact that there is an association between PPIs, including NEXIUM, and AKI:

a. Brewster, U. C., and M. A. Perazella, *Proton pump inhibitors and the kidney: critical*, Clinical Nephrology 68, no. 2 (2007): 65-72, *available at* https://www.researchgate.net/profile/Mark_Perazella/publication/6117052_Proton pump inhibitors and the kidney_Critical_review/links/5540b3b40cf2b7904369ac54.pdf.

b. Klepser, Donald, Dean Collier, and Gary Cochran. 2013, *Proton Pump Inhibitors and Acute Kidney Injury: A Nested Case–Control Study*, BMC Nephrology 14 (1): 1, *available at* http://bmcnephrol.biomedcentral.com/articles/10.1186/1471-2369-14-150.

c. Tony Antoniou, David N. Juurlink. 2015, *Proton Pump Inhibitors And The Risk Of Acute Kidney Injury In Older Patients: A Population-Based Cohort Study*, CMAJ Open 3 (2): E166, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4571830/ (three times Greater Risk of AIN with PPI).

d. Yen-Chun Peng, Chia-Hung Kao. 2016, *Association Between The Use Of Proton Pump Inhibitors And The Risk Of ESRD In Renal Diseases: A Population-Based, Case-Control Study*, Medicine 95 (15), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4839840/.

47. Currently, NEXIUM lacks any warning of AKI.

Safer Alternatives

48. Despite the fact that Nexium and other PPIs lead to an increased risk of the numerous injuries outlined herein, numerous safer alternatives are available.

49. Such safer alternative treatments include but are not limited to:

a. the use of over-the-counter calcium carbonate remedies tablets that have been available since the 1930s, such as Maalox and Tums, and/or

b. the use of histamine H2-receptor antagonists (also known as H2 blockers) that were developed in the late 1960s. H2 blockers act to prevent the production of stomach acid, and work more quickly than PPI. Examples of 112 blockers are Zantac, Pepcid, and Tagamet.

50. Even though these safer alternatives at all relevant times existed, the sale of PPIs such as Nexium skyrocketed as the same time that the safer alternatives, namely the as 112 blockers, plummeted.

51. This is true despite the fact that higher kidney injury risks are specific to PPI medications. The use of 112 receptor antagonists, which are prescribed for the same indication as PPIs, is not associated with such renal injuries.

Allegations Common to All Causes of Action

52. Defendants knew or should have known about the correlation between the use of Nexium and the significantly increased risk of CKD, AKI, and renal impairment. Yet Defendants failed to adequately warn against these negative effects and risks associated with NEXIUM.

53. In omitting, concealing, and inadequately providing critical safety information regarding the use of NEXIUM to Plaintiff and Plaintiff's doctors in order to induce its purchase, prescription and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiff and Plaintiff's doctors. This conduct is fraudulent, unfair, and unlawful.

54. Despite clear knowledge that NEXIUM causes a significantly increased risk of CKD, AKI, and renal impairment, Defendants continue to market and sell NEXIUM without warning consumers or healthcare providers of these significant risks.

Plaintiff's Use of Nexium and Resulting Harm

55. Plaintiff MR. MULLEN is and was at all times alleged herein a citizen of the State of Illinois.

56. Plaintiff MR. MULLEN was prescribed Nexium on numerous occasions, including but not limited to, in or about September 2006 through September of 2013. Plaintiff MR. MULLEN ingested Nexium as prescribed by his doctor.

57. Plaintiff MR. MULLEN read and followed the directions regarding the use of Nexium and would not have used Nexium had she been properly appraised of the risks associated with the use of Nexium.

58. Plaintiff MR. MULLEN suffered Chronic Kidney Disease (CKD) while taking Nexium as prescribed in or about 2008.

TOLLING OF THE STATUTE OF LIMITATIONS

59. Defendants, at all relevant times, knew or should have known of the problems and defects with Nexium products, and the falsity and misleading nature of Defendants' statements, representations and warranties with respect to Nexium products. Defendants concealed and failed to notify Plaintiff and the public of such defects.

60. Any applicable statute of limitation has therefore been tolled by Defendants' knowledge, active concealment and denial of the facts alleged herein, which behavior is ongoing.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

61. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

62. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Nexium into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

63. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Nexium into interstate commerce in that Defendants knew

or should have known that using Nexium could proximately cause Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Nexium. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

(a) Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Nexium;

(b) Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Nexium in unsafe doses;

(c) Failure to use reasonable care in testing and inspecting Nexium so as to ascertain whether or not it was safe for the purpose for which it was designed, manufactured and sold;

(d) Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Nexium;

(e) Failure to use reasonable care in the process of manufacturing Nexium in a reasonably safe condition for the use for which it was intended;

(f) Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using Nexium in unsafe doses; and

(g) Such further acts and/or omissions that may be proven at trial.

64. The above-described acts and/or omissions of Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff.

65. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing Nexium without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing Nexium without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not Nexium was safe for use; in that Defendants herein knew or should have known that Nexium was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling Nexium without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Nexium;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Nexium;

(g) Failing to test Nexium and/or failing to adequately, sufficiently and properly test Nexium;

(h) Negligently advertising and recommending the use of Nexium without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that Nexium was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently designing Nexium in a manner which was dangerous to its users;

(k) Negligently manufacturing Nexium in a manner which was dangerous to its users;

(l) Negligently producing Nexium in a manner which was dangerous to its users;

(m) Negligently assembling Nexium in a manner which was dangerous to its users; and

(n) Concealing information from the Plaintiff in knowing that Nexium was unsafe, dangerous, and/or non-conforming with FDA regulations.

66. Defendants under-reported, underestimated and downplayed the serious dangers of Nexium.

67. Defendants negligently compared the safety risk and/or dangers of Nexium with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

68. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Nexium in that they:

(a) Failed to use due care in designing and manufacturing Nexium so as to avoid the aforementioned risks to individuals when Nexium was used for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug-induced gastropathy;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Nexium;

(c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Nexium;

(d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Nexium;

(e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Nexium;

(g) Failed to warn Plaintiff, prior to actively encouraging the sale of Nexium, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

(h) Were otherwise careless and/or negligent.

69. Despite the fact that Defendants knew or should have known that Nexium caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell Nexium to consumers, including the Plaintiff.

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

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

72. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

74. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY)

75. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

76. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Nexium as hereinabove described that was used by the Plaintiff.

77. That Nexium was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

78. At those times, Nexium was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

79. The Nexium designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Nexium.

80. The Nexium designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

81. At all times herein mentioned, Nexium was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

82. Defendants knew, or should have known that at all times herein mentioned its Nexium was in a defective condition, and was and is inherently dangerous and unsafe.

83. At the time of the Plaintiff's use of Nexium, it was being used for the purposes and in a manner normally intended for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

84. Defendants with this knowledge voluntarily designed its Nexium in a dangerous condition for use by the public, and in particular the Plaintiff.

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

86. Defendants created a product unreasonably dangerous for its normal, intended use.

87. The Nexium designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Nexium left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

88. The Nexium designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Nexium was manufactured.

89. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

90. The Plaintiff could not, by the exercise of reasonable care, have discovered Nexium's defects herein mentioned and perceived its danger.

91. Nexium was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, kidney injuries, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

92. Nexium was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

93. Nexium was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, kidney injuries, as well as other severe and permanent health consequences from Nexium was, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Nexium.

94. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Nexium.

95. Defendants' defective design, manufacturing defect, and inadequate warnings of Nexium were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

96. That said defects in Defendants' drug Nexium were a substantial factor in causing Plaintiff's injuries.

97. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

99. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

100. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

101. Defendants expressly warranted that Nexium was safe and well accepted by users.

102. Nexium does not conform to these express representations because Nexium is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

103. Plaintiff did rely on the express warranties of the Defendants herein.

104. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Nexium in recommending, prescribing, and/or dispensing Nexium.

105. The Defendants herein breached the aforesaid express warranties, as their drug Nexium was defective.

106. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers, and/or the FDA that Nexium was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

107. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Nexium was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

108. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

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

111. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

112. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

113. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Nexium and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Nexium, for the

treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

114. At the time Defendants marketed, sold, and distributed Nexium for use by Plaintiff, Defendants knew of the use for which Nexium was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

115. The Defendants impliedly represented and warranted to the users of Nexium and their physicians, healthcare providers, and/or the FDA that Nexium was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

116. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Nexium was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

117. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

118. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Nexium was of merchantable quality and safe and fit for its intended use.

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

120. The Defendants herein breached the aforesaid implied warranties, as their drug Nexium was not fit for its intended purposes and uses.

121. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

123. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT MISREPRESENTATION)

124. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

125. The Defendants falsely and fraudulently represented to the medical and healthcare community, and/or the Plaintiff, and/or the FDA and the public in general, that said product, Nexium had been tested and was found to be safe and/or effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

126. That representations made by Defendants were, in fact, false.

127. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

128. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community it particular, to recommend, prescribe, dispense and/or purchase said product, Nexium, for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

129. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used Nexium, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

130. In reliance upon said representations, the Plaintiff was induced to and did use Nexium, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

131. Defendants knew and were aware or should have been aware that Nexium had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

132. Defendants knew or should have known that Nexium had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was

inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

133. Defendants brought Nexium to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

134. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

136. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT CONCEALMENT)

137. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

138. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Nexium for its intended use.

139. Defendants knew or were reckless in not knowing that its representations were false.

140. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

(a) that Nexium was not as safe as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug - induced gastropathy;

(b) that the risks of adverse events with Nexium were higher than those with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

(c) that the risks of adverse events with Nexium were not adequately tested and/or known by Defendants;

(d) that Defendants were aware of dangers in Nexium, in addition to and above and beyond those associated with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;

(e) that Nexium was defective, and that it caused dangerous side effects, including but not limited to kidney injuries;

(f) that patients needed to be monitored more regularly than normal while using Nexium;

(g) that Nexium was manufactured negligently;

(h) that Nexium was manufactured defectively;

(i) that Nexium was manufactured improperly;

(j) that Nexium was designed negligently;

(k) that Nexium was designed defectively; and

(l) that Nexium was designed improperly.

141. Defendants were under a duty to disclose to Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Nexium, including but not limited to the heightened risks of kidney injuries.

142. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Nexium, including the Plaintiff, in particular.

143. Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of Nexium was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and Plaintiff's physicians, hospitals and healthcare providers into reliance, continued use of Nexium, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Nexium and/or use the product.

144. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Nexium, as set forth herein.

145. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

146. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

148. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENT MISREPRESENTATION)

149. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

150. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, Nexium, had been tested and found to be safe and effective for treatment of peptic disorders which include gastroesophageal

reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

151. The representations made by Defendants were, in fact, false.

152. Defendants failed to exercise ordinary care in the representation of Nexium, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented Nexium's high risk of unreasonable, dangerous side effects.

153. Defendants breached their duty in representing Nexium's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

154. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

156. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUD AND DECEIT)

157. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

158. Defendants conducted research and used Nexium as part of their research.

159. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that Nexium was safe and effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

160. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

161. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.

162. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

163. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug Nexium was safe and

effective for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

164. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug Nexium carried the same risks, hazards, and/or dangers as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug-induced gastropathy.

165. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Nexium was not injurious to the health and/or safety of its intended users.

166. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Nexium was as potentially injurious to the health and/or safety of its intended as other forms of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

167. These representations were all false and misleading.

168. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Nexium was not safe as a means of treatment for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

169. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Nexium,

specifically but not limited to Nexium not having dangerous and serious health and/or safety concerns.

170. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff, regarding the safety of Nexium, specifically but not limited to Nexium being a safe means for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

171. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Nexium and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Nexium.

172. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Nexium was fit and safe for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

173. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Nexium was fit and safe for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

174. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Nexium did not present serious health and/or safety risks.

175. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Nexium did not present health and/or safety risks greater than other oral forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug-induced gastropathy.

176. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

177. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including the Plaintiff's respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or the Plaintiff's respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Nexium.

178. That Defendants, recklessly, intentionally, and falsely represented the dangerous and serious health and/or safety concerns of Nexium to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug-induced gastropathy.

179. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Nexium by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Nexium.

180. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as the Plaintiff's respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Nexium and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

181. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's respective healthcare professionals would rely upon the information being disseminated.

182. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Nexium.

183. That the Plaintiff and/or the Plaintiff's respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug-induced gastropathy.

184. That at the time the representations were made, the Plaintiff and/or the Plaintiff's respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Nexium.

185. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.

186. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Nexium, Plaintiff would not have purchased, used and/or relied on Defendants' drug Nexium.

187. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

188. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

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

190. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding Plaintiff reasonable attorneys' fees;

4. Awarding Plaintiff the costs of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

DATED: August 26, 2016

Respectfully submitted,

/s/ *Daniel C. Burke*

Daniel C. Burke
BERNSTEIN LIEBHARD LLP
10 East 40th Street
New York, New York 10016
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Email: dlee@bernlieb.com

Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

DATED: August 26, 2016

Respectfully submitted,

/s/ *Daniel. C. Burke*
Daniel C. Burke

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

GEORGE MULLEN

(b) County of Residence of First Listed Plaintiff Tazewell Co., IL
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Bernstein Liebhard LLP, 10 East 40th Street, New York, New York 10016; (212) 779-1414

DEFENDANTS

ASTRAZENECA PHARMACEUTICALS LP; and ASTRAZENECA LP

County of Residence of First Listed Defendant New Castle Co., 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 USC Section 1332

Brief description of cause:
Products Liability Litigation involving Proton Pump Inhibitor (Nexium®)

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
08/26/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/Daniel C. Burke

FOR OFFICE USE ONLY

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

CERTIFICATION OF ARBITRATION ELIGIBILITY

Local Arbitration Rule 83.10 provides that with certain exceptions, actions seeking money damages only in an amount not in excess of $150,000, exclusive of interest and costs, are eligible for compulsory arbitration. The amount of damages is presumed to be below the threshold amount unless a certification to the contrary is filed.

I, Daniel C. Burke, counsel for Plaintiff, do hereby certify that the above captioned civil action is ineligible for compulsory arbitration for the following reason(s):

☒ monetary damages sought are in excess of $150,000, exclusive of interest and costs,

☐ the complaint seeks injunctive relief,

☐ the matter is otherwise ineligible for the following reason

DISCLOSURE STATEMENT - FEDERAL RULES CIVIL PROCEDURE 7.1

Identify any parent corporation and any publicly held corporation that owns 10% or more or its stocks:

RELATED CASE STATEMENT (Section VIII on the Front of this Form)

Please list all cases that are arguably related pursuant to Division of Business Rule 50.3.1 in Section VIII on the front of this form. Rule 50.3.1 (a) provides that "A civil case is "related" to another civil case for purposes of this guideline when, because of the similarity of facts and legal issues or because the cases arise from the same transactions or events, a substantial saving of judicial resources is likely to result from assigning both cases to the same judge and magistrate judge." Rule 50.3.1 (b) provides that " A civil case shall not be deemed "related" to another civil case merely because the civil case: (A) involves identical legal issues, or (B) involves the same parties." Rule 50.3.1 (c) further provides that "Presumptively, and subject to the power of a judge to determine otherwise pursuant to paragraph (d), civil cases shall not be deemed to be "related" unless both cases are still pending before the court."

NY-E DIVISION OF BUSINESS RULE 50.1(d)(2)

1.) Is the civil action being filed in the Eastern District removed from a New York State Court located in Nassau or Suffolk County: No

2.) If you answered "no" above:
a) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in Nassau or Suffolk County? No

b) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in the Eastern District? No

If your answer to question 2 (b) is "No," does the defendant (or a majority of the defendants, if there is more than one) reside in Nassau or Suffolk County, or, in an interpleader action, does the claimant (or a majority of the claimants, if there is more than one) reside in Nassau or Suffolk County? No

(Note: A corporation shall be considered a resident of the County in which it has the most significant contacts).

BAR ADMISSION

I am currently admitted in the Eastern District of New York and currently a member in good standing of the bar of this court.

☒ Yes ☐ No

Are you currently the subject of any disciplinary action (s) in this or any other state or federal court?

☐ Yes (If yes, please explain) ☒ No

I certify the accuracy of all information provided above.

Signature: /s/Daniel C. Burke