IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
NEWARK DIVISION

SANDRA J. HUNTER, INDIVIDUALLY AND AS THE REPRESENTATIVE OF THE ESTATE OF LARRY J. HUNTER, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP, and PFIZER INC., Defendants.	)	CASE NO.: **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff, Sandra J. Hunter, for her Complaint alleges as follows:

NATURE OF THE ACTION

1. This is an action for personal injuries and economic damages suffered by Plaintiff Sandra J. Hunter ("Plaintiff") and Decedent Larry J. Hunter ("Decedent") 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 drug ("PPI") known as Nexium (esomeprazole magnesium) and/or other Nexium-branded products with the same active ingredient (herein collectively referred to as "Nexium").

2. During the period in which Nexium has been sold in the United States, 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 kidney

injuries in patients that had ingested Nexium and other PPIs by as early as 2004.

3. Despite being on notice as to the excessive risks of kidney injuries related to the use of Nexium, Defendants took no action to inform Decedent or Decedent's physicians of this known risk. Rather, Defendants continued to represent that Nexium did not pose any risks of kidney injuries.

4. By omitting, concealing, and inadequately providing critical safety information regarding the use of Nexium in order to induce its purchase and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers, including Plaintiff and Decedent, resulting in the Decedent developing kidney injuries.

PARTIES

Plaintiff and Decedent, use of Nexium and Resulting Harm

5. At all times referenced herein, Plaintiff and Decedent are and were citizens of the Commonwealth of Pennsylvania.

6. Decedent was born on October 5, 1948.

7. Decedent was prescribed Nexium on numerous occasions, including but not limited to, March 1, 2006 through March 12, 2016. Decedent ingested Nexium as prescribed by his doctor.

8. Decedent read and followed the directions regarding the use of Nexium and would not have used Nexium had he been properly appraised of the risks associated with the use of Nexium.

9. Decedent was diagnosed with chronic kidney disease on or about December 1, 2014 while taking Nexium as prescribed.

10. Additionally, Decedent was diagnosed with Acute Kidney Injury on or about

September 1, 2015 while taking Nexium as prescribed.

Defendants

AstraZeneca Pharmaceuticals LP

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

12. 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.

13. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in Plaintiff's and Decedent's state of residency.

14. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited, and conducted business throughout the United States, including in Plaintiff's and Decedent's state of residency, and derived substantial revenue from such business.

15. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP expected or should have expected that its acts would have consequences within the United States, including in Plaintiff's and Decedent's state of residency.

16. 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

17. 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.

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

19. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business throughout the United States, including in Plaintiff's and Decedent's state of residency.

20. At all relevant times, Defendant AstraZeneca LP transacted, solicited, and conducted business throughout the United States, including in Plaintiff's and Decedent's state of residency, and derived substantial revenue from such business.

21. At all times relevant hereto, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences within the United States, including in Plaintiff's and Decedent's state of residency.

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

AstraZeneca Pharmaceuticals LP & AstraZeneca LP's Unity of Interest

23. Upon information and belief, at all relevant times, each of the Defendants

and their directors and officers acted within the scope of their authority. During the relevant times, Defendants possessed a unity of interest between themselves and exercised control over their respective subsidiaries and affiliates.

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

Pfizer Inc.

25. Defendant Pfizer Inc. is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in New York, New York.

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

27. Upon information and belief, at all relevant times, Defendant Pfizer Inc. was present and doing business in Plaintiff's and Decedent's state of residency.

28. At all relevant times, Defendant Pfizer Inc. transacted, solicited, and conducted business in Plaintiff's and Decedent's state of residency and derived substantial revenue from such business.

29. At all times relevant hereto, Defendant Pfizer Inc. expected or should have expected that its acts would have consequences within the United States, and Plaintiff's and Decedent's state of residency in particular.

30. Defendant Pfizer Inc. acquired global over-the-counter rights to NEXIUM

products from AstraZeneca in August 2012 and made NEXIUM 24HR available for purchase in the United States on or about May 27, 2014.

31. Defendant Pfizer Inc. is also the holder of an approved NDA for Nexium 24HR Delayed-Release Tablets (20 mg), with NDA # 207920, approved on November 23, 2015.

32. Defendants AstraZeneca LP, AstraZeneca Pharmaceuticals LP and Pfizer Inc. shall herein be collectively referred to as "Defendants."

JURISDICTION AND VENUE

33. 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 $150,000, exclusive of interest and costs, and is between citizens of different States.

34. Venue is properly set in this District pursuant to 28 U.S.C. §1391(b) because Defendants transact business within this judicial district. Likewise, a substantial part of the events giving rise to the claim occurred within this judicial district.

35. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, the Court has personal jurisdiction over Defendants, because Defendants are present in this District, such that requiring an appearance does not offend traditional notions of fair play and substantial justice. Further, Defendants have maintained registered agents in this District.

36. 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.

37. Requiring Defendants to litigate these claims in this District does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution. On information and belief, Defendants' Nexium products are sold at hundreds of local and national pharmacies, including, but not limited to Wal-Mart, Target, CVS, and Walgreens throughout this District.

38. On information and belief, Defendants avail themselves of numerous advertising and promotional materials regarding their defective Nexium products specifically intended to reach consumers throughout the United States, including, but not limited to, advertisements in this District on local television programs, advertisements on local radio broadcasts, advertisements on billboards in this District and advertisements in print publications delivered to consumers in this District.

39. Defendants regularly conduct or solicit business and derive substantial revenue from goods used or consumed in, *inter alia*, this District.

40. Upon information and belief, at all relevant times, Defendants were present and doing business in this District.

41. At all relevant times, Defendants transacted, solicited, and conducted business in this District and derived substantial revenue from such business.

42. At all times relevant hereto, Defendants expected or should have expected that its acts would have consequences within the United States, including in this District.

43. At all relevant times, Defendants placed Nexium products ingested by Decedent into the stream of interstate commerce.

44. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States, including in this District.

FACTUAL BACKGROUND

Proton Pump Inhibitors Generally

45. 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.

46. 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.

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

48. 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.

49. Pfizer Inc. sold NEXIUM 24HR with NDC numbers 0573-2450-14, 0573-2450-15, 0573-2450-17, 0573-2450-28, 0573-2450-42, 0573-2450-43, 0573-2450-44, 0573-2450-56, 0573-2451-14, and 0573-2451-42.

50. 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

51. 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.

52. 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 have received numerous case reports of several types of kidney and related injuries in patients that had ingested Nexium, including but not limited to:

a. Acute Interstitial Nephritis (AIN),
b. Chronic Kidney Disease (CKD),
c. Renal/Kidney Failure,
d. Acute Kidney Injury (AKI), and
e. Clostridium difficile.

53. 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.

Increased Risk of Acute Interstitial Nephritis (AIN) with PPIs

54. 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.

55. 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.

56. 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.

57. 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. *See* FDA Letter, dated December 19, 2014, to Laura Garcia-Davenport, Director of Regulatory Affairs at AstraZeneca Pharmaceuticals ("We also refer to our letter dated October 30, 2014, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Nexium."), available at http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/021153Orig1s050,021957Orig1s017,022101Orig1s014ltr.pdf.

58. In December 2014, the labeling for PPIs was updated to include a warning about Acute Interstitial Nephritis (AIN). *See* December 2014 revised label, available at http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm290945.htm.

59. Various medical studies and journals support the fact that there is an association between PPIs, including Nexium, and AIN. *See, e.g.*, Blank M-L, Parkin L, Paul C, et al., *A nationwide nested case-control study indicates an increased risk of acute interstitial nephritis with proton pump inhibitor use*, Kidney Int'l (Published online Mar. 19, 2014); 86:837–44;

available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4184187/. *See also Proton Pump Inhibitors: When is enough, enough?*, Best Practice Journal, Issue 61 (June 2014), available at http://www.bpac.org.nz/BPJ/2014/June/ppi.aspx, updated in *Proton Pump Inhibitors and the risk of acute kidney injury*, Best Practice Journal, Issue 76 (July 2016), available at http://www.bpac.org.nz/BPJ/2016/July/update.aspx.

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

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

Association between Chronic Kidney Disease (CKD) and PPIs

62. 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.

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

64. 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 key to avoiding the most negative outcomes.

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

66. 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.

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

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

69. Various medical studies support the fact that there is an association between PPIs, including Nexium, and CKD. *See, e.g.*, *JAMA Intern Med*. 2016; 176(2): pp. 238-246, "Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease," Published online January 11, 2016, Corrected on February 29, 2016.

70. Currently, Nexium lacks any warning of CKD.

Acute Kidney Injury (AKI) Dangers Associated with PPIs

71. Studies indicate that patients taking PPIs, such as Nexium, are at greater than a 2.5 times greater risk than the general population to suffer AKI.

72. Studies also indicate that those who develop AIN are at a significant risk of developing AKI even though there may not be obvious case kidney dysfunction.

73. Various medical studies support the fact that there is an association between PPIs, including Nexium, and AKI. *See, e.g.*, Klepser DG, Collier DS, Cochran GL. *Proton pump inhibitors and acute kidney injury: a nested case–control study*, BMC Nephrol 2013; 14:150; available at http://bmcnephrol.biomedcentral.com/articles/10.1186/1471-2369-14-150; Antoniou T, Macdonald EM, Hollands S, et al. *Proton pump inhibitors and the risk of acute kidney injury in older patients: a population-based cohort study*. CMAJ 2015;3: E166–71; available at

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4571830/.

74. Currently, Nexium lacks any warning of AKI.

Availability of Safer Alternatives to PPIs

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

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

a. the use of over-the-counter calcium carbonate remedies tablets, such as Maalox and Tums, that have been available since the 1930s, 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 H2 blockers are Zantac, Pepcid, and Tagamet.

77. Even though these safer alternatives at all relevant times existed, the sale of PPIs such as Nexium skyrocketed at the same time that the safer alternatives, namely the H2 blockers, plummeted.

78. This is true despite the fact that higher kidney injury risks are specific to PPI medications. The use of H2 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

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

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

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

TOLLING OF THE STATUTE OF LIMITATIONS

82. 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 Decedent and the public of such defects.

83. 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.

CASE- SPECIFIC INFORMATION

84. Upon information and belief, on approximately March 1, 2006, Dr. Robert Swansiger discussed prescribing Nexium to Decedent. Dr. Swansiger discussed the risks and benefits of Nexium. Because Defendants did not disclose the true risks of acute and chronic kidney injuries associated with the use of Nexium to Dr. Swansiger, nor did Defendants disclose the true risks of acute and chronic kidney injuries in the information given to Decedent, it was impossible for Dr. Swansiger to adequately discuss the true risks and benefits of Nexium with Decedent. Consequently, it was impossible for Decedent to learn of the true risks associated with Nexium.

85. Decedent, after consultation with Dr. Swansiger, began using Nexium on or about March 1, 2006. The Nexium used by Decedent remained in substantially the same condition between when it left Defendants' control and used by Decedent. Dr. Swansiger would not have prescribed Nexium to Decedent if Dr. Swansiger knew of the true risks associated with the use of Nexium. In other words, Dr. Swansiger would not have prescribed Nexium to Decedent if he knew the true risks associated with the use of Nexium.

86. Decedent would not have elected to use Nexium if he knew of the true risks associated with the use of Nexium. In other words, Decedent would not have elected to use Nexium if he knew the true risk of acute and chronic kidney injuries associated with the use of Nexium.

87. Upon information and belief, on or about December 1, 2014, Decedent suffered chronic kidney disease and on or about September 1, 2015, Decedent suffered Acute Kidney Injury and was hospitalized. Decedent suffered CKD and AKI because Nexium was negligently and defectively designed. Defendants knew that Nexium was negligently and defectively designed when it left Defendants' control, and Defendants knew that it caused CKD and AKI at a higher rate than other similar medications on the market. Defendants did not disclose these facts to Dr. Swansiger or Decedent.

88. Through no fault of his own, and no fault of his health care providers, on or about December 1, 2014, Decedent suffered chronic kidney disease and on or about September 1, 2015, Decedent suffered an Acute Kidney Injury. The CKD and AKI caused pain and suffering, financial loss and caused permanent injury to Decedent and Plaintiff.

CAUSES OF ACTION

COUNT I
NEGLIGENCE

89. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

90. Defendants owed Plaintiff and Decedent legal duties in connection with its development, manufacture, and distribution of Nexium. Defendants breached those duties, proximately causing Decedent'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 Decedent and Decedent's physicians of the known or reasonably foreseeable danger that Decedent would suffer a serious injury or death by ingesting Nexium;

b. Failure to adequately warn Decedent and Decedent's physicians of the known or reasonably foreseeable danger that Decedent 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 Decedent and Decedent'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.

91. 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 Decedent and Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT II
NEGLIGENT MISREPRESENTATION

92. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

93. Defendants failed to communicate to Decedent and/or the general public that the ingestion of Nexium could cause serious injuries after it became aware of such risks. Instead, Defendants represented in its marketing that Nexium was safe and effective.

94. Plaintiff brings this cause of action against Defendants under the theory of negligent misrepresentation for the following reasons:

a. Defendants, individually, and through their agents, representatives, distributors and/or employees, negligently misrepresented material facts about Nexium in that it made such misrepresentations when it knew or reasonably should have known of the falsity of such

misrepresentations. Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;

b. The above misrepresentations were made to Decedent as well as the general public;

c. Decedent and Decedent's healthcare providers justifiably relied on Defendants' misrepresentations; and

d. Consequently, Decedent ingested Nexium to Decedent's detriment. Defendants' negligent misrepresentations proximately caused Decedent's and Plaintiff's injuries and monetary losses.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT III
FRAUDULENT MISREPRESENTATION

95. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

96. Defendants are engaged in the business of selling Nexium. By their advertising, labels, or other information provided, Defendants made misrepresentations of material fact concerning the character or quality of Nexium to Decedent and the public.

97. Decedent justifiably relied on Defendants' misrepresentations in purchasing Nexium. Decedent and Plaintiff have suffered physical harm proximately caused by Defendants' misrepresentations regarding the character and/or quality of Nexium.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and

compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT IV
EXPRESS WARRANTY

98. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

99. Defendants are merchants and/or sellers of Nexium. Defendants sold Nexium to consumers, including Decedent, for the ordinary purpose for which such drugs are used by consumers. Defendants made representations to Decedent about the quality or characteristics of Nexium by affirmation of fact, promise and/or description. The representations by Defendants became part of the basis of the bargain between Defendants and Decedent. Nexium did not comport with the representations made by Defendants in that it was not safe for the use for which it was marketed. This breach of duty by Defendants was a proximate cause of the injuries and monetary loss suffered by Decedent and Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT V
IMPLIED WARRANTY

100. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

WARRANTY OF MERCHANTABILITY

101. Defendants are merchants and/or sellers of Nexium. Decedent purchased Nexium from Defendants and used Nexium for the ordinary purpose for which it is used by

consumers. At the time it was purchased by Decedent, Nexium was not fit for the ordinary purpose for which such drugs are used. Nexium was not fit for the ordinary purpose for which such drugs are used because it was not manufactured, designed or marketed in a manner to safely accomplish its purpose. Defendants' breach of their implied warranty of merchantability caused Decedent's and Plaintiff's injuries and monetary losses.

WARRANTY OF FITNESS

102. Defendants sold Nexium to Decedent with the knowledge that Decedent was purchasing Nexium for a particular purpose. Defendants knew, or should have known, that Decedent was relying on Defendants' skill or judgment to select goods fit for Decedent's purpose.

103. Defendants delivered goods that were unfit for Decedent's particular purpose and thus breached their implied warranty of fitness. Defendants' failure to select and sell a product which was reasonably safe for its intended use proximately caused Plaintiff's and Decedent's injuries and monetary losses.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT VI
FRAUD

104. Plaintiff incorporates by this reference the allegations set forth in the paragraphs above as if fully set forth herein.

105. Defendants made material representations that were false and that were either known to be false when made or were asserted without knowledge of their truth.

Defendants had in their possession adverse drug event reports, drug studies, and other documentation about Nexium and yet made the following misrepresentations:

a. Misrepresentations regarding the frequency of Nexium-related adverse event reports or occurrences in the Nexium label, package insert or PDR label;

b. Misrepresentations as to the existence, occurrence and frequency of occurrences, severity and extent of the overall risks of Nexium;

c. Misrepresentations as to the efficacy of Nexium;

d. Misrepresentations as to the number of adverse events and deaths reported with the use of Nexium; and

e. Misrepresentations regarding the nature, seriousness, and severity of adverse events reported with the use of Nexium.

106. Defendants intended that these misrepresentations be relied upon by physicians, including Decedent's physicians, healthcare providers and consumers. Decedent did rely upon the misrepresentations that caused Decedent's and Plaintiff's injuries.

107. Defendants' misrepresentations were the proximate and/or producing cause of Decedent's and Plaintiff's injuries.

WHEREFORE, Plaintiff demands judgment against Defendants for actual and compensatory damages; for punitive or exemplary damages; for costs herein incurred; and for such other and further relief as this Court deems just and proper.

COUNT VII
LOSS OF CONSORTIUM

108. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth, and further alleges as follows:

109. Plaintiff Sandra J. Hunter was the wife of Decedent.

110. As a result of the medical conditions developed by her husband and the medical treatment and hospitalizations that he endured, Plaintiff:

a. lost a substantial measure of her husband's household services;

b. lost, and will continue to lose in the future, a substantial measure of her husband's consortium; and

c. suffered the loss of services, loss of financial support, loss of society including loss of companionship, care, assistance, and attention, and mental anguish entitling her to compensatory damages and attorney's fees.

111. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff Sandra J. Hunter suffered injuries.

WHEREFORE, Plaintiff respectfully requests an award of compensatory damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

COUNT VIII
SURVIVAL

112. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth herein and further allege as follows.

113. Defendants' conduct was reckless and willful, wanton and outrageous disregard for the interests, safety and rights of others, including Decedent.

114. As a result of Defendants' unlawful conduct and reckless disregard for others as averred above, Decedent suffered actual and substantial loss, for which he possessed rights of action at the time of his death and for which his estate is entitled to recover, as follows:

(a) damages for severe pain, suffering and distress;

(b) loss of earning power less personal maintenance expenses from the time of death through his estimated working lifespan;

(c) punitive damages; and

(d) any and all other damages recoverable under the applicable survival statutes.

WHEREFORE, Plaintiff respectfully requests an award of compensatory and punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

PUNITIVE DAMAGES ALLEGATIONS

115. Plaintiff incorporates by reference each of the allegations set forth in this Complaint as though set forth fully herein and further alleges as follows.

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

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

118. Despite its knowledge, Defendants, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately

failed to remedy the known defects in Nexium and failed to warn the public, including Decedent, of the extreme risk of injury occasioned by said defects inherent in Nexium. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Nexium knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

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

WHEREFORE, Plaintiff respectfully requests an award of punitive damages, in addition to all costs, interest and fees, including attorneys' fees, to which she is entitled under law and such other relief as this Honorable Court deems appropriate.

RELIEF REQUESTED

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

1. Economic and non-economic damages, special damages and general damages, including pain and suffering, in an amount to be determined at trial;
2. For compensatory damages for the acts complained of herein in an amount to be determined by a jury;
3. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;

4. Punitive damages for the acts complained of herein in an amount to be determined by a jury;

5. For an award of attorneys' fees and costs;

6. For prejudgment interest;

7. For the costs of suit;

8. For post-judgment interest; and

9. For such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiff demands a jury trial as to all claims and issues triable of right by a jury.

Respectfully submitted,

Dated: November 30, 2016

/s/ *Dianne M. Nast*

NASTLAW LLC
Dianne M. Nast
Daniel N. Gallucci
Joanne E. Matusko
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Attorneys for Plaintiff

JS 44 (Rev. 07/16)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Sandra J. Hunter, Individually and as the Representative of the Estate of Larry J. Hunter

(b) County of Residence of First Listed Plaintiff Washington Cty., PA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, Email and Telephone Number)*
Dianne M. Nast, Esq. dnast@nastlaw.com
NASTLAW LLC (215) 923-9300
1101 Market Street, Suite 2801 / Philadelphia, PA 19107

DEFENDANTS

AstraZeneca Pharmaceuticals LP, AstraZeneca LP, and Pfizer, Inc.

County of Residence of First Listed Defendant New Castle County, 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

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

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

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

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

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

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

VI. CAUSE OF ACTION

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

Brief description of cause:
Product Liability Litigation

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 75,001.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Claire C. Cecchi DOCKET NUMBER 16-CV-05143

DATE 11/30/2016

SIGNATURE OF ATTORNEY OF RECORD /s Dianne M. Nast

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

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

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

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

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

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

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

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

UNITED STATES DISTRICT COURT

for the

District of New Jersey

SANDRA J. HUNTER, INDIVIDUALLY AND AS THE REPRESENTATIVE OF THE ESTATE OF LARRY J. HUNTER,

Plaintiff(s)

v.

ASTRAZENECA PHARMACEUTICALS LP; ASTRAZENECA LP, AND PFIZER, INC.,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* ASTRAZENECA LP; AGENT: THE CORPORATION TRUST COMPANY
1209 ORANGE STREET
WILMINGTON, DE 19801

PFIZER, INC.
235 EAST 42ND STREET
NEW YORK, NY 10017

A lawsuit has been filed against you.

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

DIANNE M. NAST
NASTLAW LLC
1101 MARKET STREET, SUITE 2801
PHILADELPHIA, PA 19107

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

CLERK OF COURT

Date: 11/30/2016

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* SANDRA J. HUNTER

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

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