

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

DIANE MORRISON,)	
)	
Plaintiff,)	
)	
v.)	
)	
ASTRAZENECA PHARMACEUTICALS)	
LP; and ASTRAZENECA LP,)	
)	
Defendants.)	
)	

CASE NO.: _____

**COMPLAINT AND DEMAND
FOR JURY TRIAL**

COMPLAINT

Plaintiff, DIANE MORRISON, for her Complaint alleges as follows:

NATURE OF THE ACTION

1. This is an action for personal injuries and economic damages suffered by Plaintiff DIANE MORRISON (“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 DIANE MORRISON was and is a citizen of the State of Michigan.

Defendants

AstraZeneca Pharmaceuticals LP

3. 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 Plaintiffs' state of residency.

6. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited, and conducted business in Plaintiffs' state of residency 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, and Plaintiffs' state of residency in particular.

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 Plaintiffs' state of residency.

12. At all relevant times, Defendant AstraZeneca LP transacted, solicited, and conducted business in Plaintiffs' state of residency 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, and Plaintiffs' state of residency in particular.

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 jurisdiction pursuant to 28 U.S.C. §1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds \$75,000 exclusive of interest and costs.

18. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. §1391(b) because, at all times material hereto, Defendants conducted substantial business in this district.

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 tubulointerstitial 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](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*, *British Journal Of Clinical Pharmacology* 64 (6): 819-823,

¹ See

http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/021153Orig1s050,021957Orig1s017,022101Orig1s014ltr.pdf

² See December 19, 2014 label at 1 & 6, available at

http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022101s014021957s017021153s050bl.pdf.

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 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 within 120 days of the patients starting 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 H2 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 at the same time that the safer alternatives, namely the H2 blockers, plummeted.

51. 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

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.

Plaintiffs' Use of Nexium and Resulting Harm

55. Plaintiff DIANE MORRISON is and was at all times alleged herein a citizen of the State of Michigan.

56. Plaintiff DIANE MORRISON was prescribed Nexium on numerous occasions, including but not limited to, in or about December 2003 through February 2015. Plaintiff DIANE MORRISON ingested Nexium as prescribed by her doctor.

57. Plaintiff DIANE MORRISON 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 DIANE MORRISON suffered Chronic Kidney Disease (CKD) while taking Nexium as prescribed in or about November 2014.

59. Plaintiff DIANE MORRISON also suffered Acute Interstitial Nephritis (AIN) while taking Nexium as prescribed in or about February 2015.

TOLLING OF THE STATUTE OF LIMITATIONS

60. 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.

61. 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.

COUNT I **PRODUCT LIABILITY ACT — DEFECTIVE DESIGN** **(N.J.S.A. 2A:58C-1, *et seq.*)**

62. Plaintiff restates the allegations set forth above as if fully rewritten herein.

63. NEXIUM is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

64. At all times material to this action, NEXIUM was expected to reach, and did reach, consumers in Plaintiff's home state and throughout the United States, including receive by Plaintiff, without substantial change in the condition in which it was sold.

65. At all times material to this action, NEXIUM was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

- a. When placed in the stream of commerce, NEXIUM contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject product, including, but not limited to, permanent personal injuries including, but not limited to, developing CKD and other serious injuries and side effects;
- b. When placed in the stream of commerce, NEXIUM was defective in design and formulation, making the use of NEXIUM more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat GERD and other stomach-acid-related ailments;
- c. The design defects of NEXIUM existed before it left the control of Defendants;
- d. NEXIUM was insufficiently and inadequately tested;
- e. NEXIUM caused harmful side effects that outweighed any potential utility; and

- f. NEXIUM was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

66. In addition, at the time the subject product left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible – indeed they were already on the market – and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

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

COUNT II
PRODUCT LIABILITY ACT — FAILURE TO WARN
(N.J.S.A. 2A:58C-1, *et seq.*)

67. Plaintiff restates the allegations set forth above as if fully rewritten herein.

68. NEXIUM was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, developing CKD and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for

GERD and other stomach-acid-related ailments. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided as required pursuant to N.J.S.A. 2A:58C-1, *et seq.*

69. The subject product manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the product could cause serious injury and/or death.

70. Plaintiff was prescribed and used the subject product for its intended purpose.

71. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

72. Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

73. Defendants, the manufacturers and/or distributors of the subject prescription product, are held to a level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

74. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

75. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to: Acute Interstitial Nephritis (AIN), Chronic Kidney Disease (CKD), Renal/Kidney Failure, Acute Kidney Injury

(AKI), and *Clostridium difficile*.

76. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants

77. Defendants had a continuing duty to warn Plaintiff of the dangers associated with NEXIUM.

78. Had Plaintiff received adequate warnings regarding the risks of NEXIUM, she would not have used it and/or chosen a different course of treatment.

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

COUNT III
BREACH OF EXPRESS WARRANTY

79. Plaintiff restates the allegations set forth above as if fully rewritten herein.

80. Defendants expressly represented to Plaintiff, other consumers, and the medical community that NEXIUM was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

81. NEXIUM does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries, including, but not limited to, developing CKD and other serious injuries and side effects.

82. At the time of the making of the express warranties, Defendants knew, or in the exercise of reasonable care should have known, of the purpose for which the subject product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject product was unreasonably dangerous because it failed to conform to

an express warranty of Defendants.

83. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

84. At all relevant times NEXIUM did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

85. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

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

COUNT IV
PUNITIVE DAMAGES ALLEGATIONS
(N.J.S.A. 2A:58C-5c)

86. Plaintiff restates the allegations set forth above as if fully rewritten herein.

87. Despite the holding of *McDarby v. Merck & Co.*, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008), numerous courts around the country, and in this District specifically, have found that punitive damages are appropriate under N.J. Stat. Ann. § 2A:58C-5c subsequent to *Wyeth v. Levine*, 555 U.S. 555 (2009). See, e.g., *Sullivan v. Novartis Pharms. Corp.*, 602 F. Supp. 2d 527, 534 n.8 (D.N.J. 2009) (“The vitality of *McDarby* was subsequently cast into some doubt by the Supreme Court's decision in *Wyeth*.”).

88. The wrongs done by Defendants were aggravated by malice, fraud, and grossly

negligent disregard for the rights of others, the public, and Plaintiff, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, Defendants' conduct involved an extreme degree of risk. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious disregard for to the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff and her healthcare providers.

89. Plaintiff relied on Defendants' representations and suffered injuries as a proximate result of this reliance.

90. Plaintiff therefore asserts claims for exemplary damages.

91. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff.

92. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety of NEXIUM. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of NEXIUM, and intentionally downplayed the type, nature, and extent of the adverse side effects

of ingesting NEXIUM, despite their knowledge and awareness of these serious side effects and risks.

93. Defendants had knowledge of, and were in possession of evidence demonstrating that NEXIUM caused serious side effects. Notwithstanding Defendants' knowledge, Defendants continued to market the drug by providing false and misleading information with regard to the product's safety to regulatory agencies, the medical community, and consumers of NEXIUM.

94. Although Defendants knew or recklessly disregarded the fact that NEXIUM causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute NEXIUM to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating diabetes.

95. Defendants failed to provide adequate warnings that would have dissuaded health care professionals from prescribing NEXIUM and consumers from purchasing and ingesting NEXIUM, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming NEXIUM.

96. Defendants knew of NEXIUM's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote the drug to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by NEXIUM.

97. Defendants' acts, conduct, and omissions were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff 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 out of Defendants.

98. Prior to the manufacture, sale, and distribution of NEXIUM, Defendants knew that the drug was in a defective condition 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 drug presented a substantial and unreasonable risk of harm to the public, including Plaintiff. As such, Defendants unreasonably subjected consumers of NEXIUM to risk of injury or death.

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

100. Defendants' conduct was committed with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

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

RELIEF REQUESTED

WHEREFORE, Plaintiffs pray 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 supported by the evidence 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 pursuant to Title 6 Delaware Code;
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

Plaintiffs demand a jury trial as to all claims and issues triable of right by a jury.

Respectfully submitted,

SEEGER WEISS LLP

By: /s/ Christopher A. Seeger

Christopher A. Seeger

Asim M. Badaruzzaman

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Attorneys for Plaintiff

Dated: November 10, 2017

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

DIANE MORRISON

DEFENDANTS

ASTRAZENECA PHARMACEUTICALS LP; and ASTRAZENECA LP

(b) County of Residence of First Listed Plaintiff Saginaw County, MI
(EXCEPT IN U.S. PLAINTIFF CASES)

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)

(c) Attorneys (Firm Name, Address, and Telephone Number)
Christopher A. Seeger cseeger@seegerweiss.com
SEEGER WEISS LLP, 550 Broad Street, Suite 920, Newark, NJ 07102
Tel. (973) 639-9100, Fax (973) 639-9393

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

- 1 U.S. Government Plaintiff
- 2 U.S. Government Defendant
- 3 Federal Question (U.S. Government Not a Party)
- 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)

- | | | | | | |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| | PTF | DEF | | PTF | DEF |
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input checked="" type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

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

Click here for:

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer w/Disabilities - Employment <input type="checkbox"/> 446 Amer w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 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)

Brief description of cause:
Products liability litigation

VII. REQUESTED IN COMPLAINT:

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

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

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE Honorable Claire C. Cecchi

DOCKET NUMBER 2:17-md-02789-CCC

DATE 11/10/2017 SIGNATURE OF ATTORNEY OF RECORD /s Christopher A. Seeger

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 there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [. . .](#)
- 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 statute.
- 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.