

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE**

**AUBREY MCCULLOUGH, Individually
and as Representative of the Estate of
MARTHA MCCULLOUGH, Deceased,**

Plaintiff,

v.

**ASTRAZENECA PHARMACEUTICALS
LP and ASTRAZENECA LP,**

Defendants.

Civil Action No.:

JURY TRIAL DEMANDED

COMPLAINT

COMES NOW Plaintiff Aubrey McCullough, Individually, and as Representative of the Estate of Martha McCullough, Deceased (hereinafter “Plaintiff”), by and through the undersigned counsel, and brings this action against Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (hereinafter “Defendants”), and alleges as follows:

PARTIES

1. Plaintiff Aubrey McCullough is the surviving child of Martha McCullough, deceased, and the Representative of the Estate of Martha McCullough, deceased. Plaintiff Aubrey McCullough is a citizen and resident of the State of Tennessee and both he and Decedent Martha McCullough (hereinafter “Decedent”) were, at all relevant times, citizens and residents of the State of Tennessee and the United States.

2. Defendant AstraZeneca Pharmaceuticals LP is a corporation incorporated in Delaware with its principal place of business located at 1800 Concord Pike, Wilmington, DE 19897. Defendant AstraZeneca Pharmaceuticals LP is a citizen of Delaware.

3. Defendant AstraZeneca LP is a corporation incorporated in Delaware with its principal place of business located at 1800 Concord Pike, Wilmington, DE 19897. Defendant AstraZeneca LP is a citizen of Delaware.

4. Defendants are pharmaceutical companies involved in the developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, of pharmaceuticals including Nexium®.

5. Defendants are individually, jointly, and severally liable to Plaintiff for damages suffered by Plaintiff arising from Defendants' design, manufacture, marketing, labeling, distribution, sale and place of its defective pharmaceuticals at issue in the instant action, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments, and/or ownership.

6. Defendants are vicariously liable for the acts and/or omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of Defendants and within the scope of their employment or agency with Defendants.

JURISDICTION AND VENUE

7. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds \$75,000, exclusive of interests and costs.

8. This Court has personal jurisdiction over each of the Defendants pursuant to the Tennessee Long-Arm Statute, T.C.A. § 20-2-214(A). Defendants transact business within the State of Tennessee, and Defendants committed tortious acts and omissions in the State of Tennessee and elsewhere. Defendants' tortious acts and omissions caused injury to Plaintiff in the State of

Tennessee. Defendants have purposefully and persistently engaged in a course of conduct in the State of Tennessee including developing, manufacturing, publishing information, marketing, distributing, promoting and/or selling, either directly or indirectly, pharmaceuticals including Nexium® in the State of Tennessee, for which they derived significant and regular income. The Defendants reasonably expected that their defective pharmaceuticals, including Nexium®, would be sold, prescribed and/or purchased, and ingested in the State of Tennessee.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2).

10. This action may have potentially related actions pending in this Court. See Notice to Clerk of Court, attached hereto as Exhibit A.

FACTS COMMON TO ALL COUNTS

11. Decedent Martha McCullough took Nexium® for the treatment of heartburn and other related conditions and symptoms. Decedent was prescribed Nexium® by her physician and/or purchased the Nexium® over the counter at a local pharmacy without a prescription. As a result, on or about June 23, 2016, Decedent died in the State of Tennessee with the cause of death being kidney disease.

12. Defendants manufactured, sold, and/or distributed the Nexium® to Decedent through her physicians and/or directly to Decedent.

13. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution, and sale of Nexium®, including providing the warnings and instructions concerning the drug.

14. Among the intended purposes for which Defendants designed, manufactured, and sold Nexium® was use by individual consumers for the treatment of heartburn, the purpose for which Decedent used Nexium®.

15. Defendants represented to Decedent that Nexium® was a safe and effective product for the treatment of heartburn and related conditions and symptoms.

16. Defendants' Nexium® was defectively designed, was not reasonably safe for its intended use in treating heartburn and other related conditions and symptoms, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design of Nexium®, there was an unreasonable risk of severe kidney injuries, including but not limited to acute interstitial nephritis (hereinafter "AIN"), acute kidney injuries (hereinafter "AKI"), chronic kidney disease (hereinafter "CKD"), renal failure, also known as end-stage renal disease (hereinafter "ESRD"), and death.

17. Defendants concealed and continue to conceal their knowledge of Nexium®'s unreasonably dangerous risks from Plaintiff, Decedent, Decedent's physicians, other consumers, and the medical community. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the magnified risk of kidney injuries, kidney failure, and/or death related to the use of Nexium®.

18. As a result of Defendants' actions and inactions, Plaintiff was injured due to Decedent's ingestion of Nexium®, which caused Decedent's injuries, including kidney failure, and death and will continue to cause Plaintiff's injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

19. Over 60 million Americans experience heartburn, a major symptom of gastroesophageal reflux disease ("GERD"), at least once a month and some studies have suggested more than 15 million Americans experience heartburn on a daily basis. About 21 million Americans used one or more prescription or over the counter proton pump inhibitors (hereinafter

“PPIs”), including Nexium®, in 2009, accounting for nearly 20% of the drugs’ global sales and earning an estimated \$11 billion annually.

20. Upon information and belief, from 2003 to the present, Nexium® have been some of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

21. PPIs are one of the most commercially successful groups of medication in the United States. Upon information and belief, between 2008 and 2013, prescription PPIs had sales of over \$50 billion with approximately 240 million units dispensed.

22. Defendants, directly or through their agents, apparent agents, servants, or employees, designed, manufactured, marketed, advertised, distributed, promoted, and sold Nexium®.

23. In October of 1992, three years after the FDA’s initial approval of PPIs, researchers from the University of Arizona Health Sciences Center, led by Stephen Ruffenach, published the first article associating PPI usage with kidney injuries in *The American Journal of Medicine*, followed by years of reports from national adverse drug registries describing this association.

24. In 2006, researchers at Yale School of Medicine conducted a case series published in the International Society of Nephrology’s *Kidney International*, finding that PPI use, by way of AIN, left most patients “with some level of chronic kidney disease.” On August 23, 2011, Public Citizen, a consumer advocacy group, filed a petition with the FDA to add black box warnings and other safety information concerning several risks associated with PPIs, including AIN. According to the petition, at the time of its filing there was “no detailed risk information on any PPI for this adverse effect.”

25. On October 31, 2014, more than three years after Public Citizen's petition, the FDA responded by requiring consistent labeling regarding risk of AIN on all prescription PPIs. The FDA noted "that the prescription PPI labeling should be consistent with regard to this risk" and that "there is reasonable evidence of a causal association." In December 2014, the labels of prescription PPIs were updated to read:

Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [Brand] if acute interstitial nephritis develops.

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

27. In January 2016, a study published in the *Journal of the American Medical Association* found that PPI use was independently associated with a 20 - 50% higher risk of CKD.

28. In February 2016, a study published in the *Journal of the American Society of Nephrology* found that "exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of GERD."

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

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

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

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

33. PPIs, including Nexium®, irreversibly block the acidic hydrogen/potassium ATPase enzyme system (H⁺/K⁺ ATPase) of the gastric parietal cells, thereby halting the production of most hydrochloric acid.

34. In spite of their commercial success and global popularity, up to 70% of PPIs, including Nexium®, may be used inappropriately for indications or durations that were never tested or approved.

35. As a result of the defective nature of PPIs, including Nexium®, even if used as directed by a physician or healthcare professional, persons who ingested PPIs have been exposed to significant risks stemming from unindicated and/or long-term usage.

36. From these findings, PPIs, including Nexium®, and/or their metabolites - substances formed via metabolism - have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate acute interstitial nephritis (“AIN”), a sudden kidney inflammation that can result in mild to severe problems.

37. PPI-induced AIN is difficult to diagnose with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea, and weakness.

38. In April 2016, a study published in the *Journal of Nephrology* suggested that the development of and failure to treat AIN could lead to chronic kidney disease and end-stage renal disease, which requires dialysis or kidney transplant to manage.

39. CKD describes a slow and progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, waste can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

40. Prompt diagnosis and rapid withdrawal of the offending agent are key in order to preserve kidney function. While AIN can be treated completely, once it has progressed to CKD it is incurable and can only be managed, which, combined with the lack of numerous early-onset symptoms, highlighting the need for screening of at-risk individuals.

41. Consumers, including Decedent, who have used PPIs, including Nexium®, for the treatment of increased gastric acid had several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with PPI, including Nexium® therapy.

42. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Decedent and/or her physicians the true and significant risks, including kidney failure and death, associated with PPI, including Nexium®, use.

43. Defendants concealed and continue to conceal their knowledge that PPIs, including Nexium® can cause kidney injuries, kidney failure, and/or death from Decedent, other consumers, and the medical community. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community against the serious risks associated with PPIs and have completely failed to warn against the risk of CKD, ESRD, and death.

44. As a result of Defendants' actions and inactions, Decedent was injured due to her ingestion of Nexium®, which caused Decedent's injuries, including kidney failure, and death and will continue to cause Plaintiff various damages. Plaintiff accordingly seeks damages associated with these injuries.

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

Decedent had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

46. As a direct result of ingesting Nexium®, Decedent suffered kidney injuries, including kidney failure, and died as a result. Plaintiff has been permanently injured by the loss of her spouse, having suffered serious consequences from Decedent's Nexium® use.

47. Plaintiff and Decedent, as a direct and proximate result of Nexium® use, suffered severe mental and physical pain and suffering and Plaintiff has and will sustain permanent emotional distress, along with economic loss due to Decedent's death.

48. Decedent would not have used Nexium® had Defendants properly disclosed the risks associated with long-term Nexium® use.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

49. The running of any statute of limitation has been tolled by reason of the Defendants' conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff, Decedent, and Decedents' treating physicians the true risks associated with Nexium®.

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

51. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of Nexium®. Defendants were under a duty to disclose the true character, quality and nature of Nexium® because this was non-public information that Defendants had and continue to have exclusive control and Defendants knew that

this information was not available to the Decedent and/or her medical providers, and/or to their health facilities.

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

COUNT I
NEGLIGENT FAILURE TO WARN

53. Plaintiff incorporates herein by reference the allegations in the proceeding paragraphs.

54. Defendants had a duty to Plaintiff to exercise reasonable care in the researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale, warnings, and/or distribution of Nexium® into the stream of commerce, including a duty to assure that Nexium® would not cause users to suffer unreasonable, dangerous side effects such as kidney injuries, kidney failure, and/or death and to warn consumers of the consequences of ingesting Nexium®.

55. Defendants failed to exercise ordinary care and/or were reckless in researching, marketing, promoting, packaging, selling, testing, and warning of the risks which Defendant knew or should have known, and Defendants knew or should have known that using Nexium® caused a risk of unreasonable, dangerous side effects, including kidney injuries such as kidney failure and death, and failed to warn of those risks.

56. Defendants continued to market, manufacture, distribute and/or sell Nexium® to consumers, including Decedent, without adequately warning of the risks of kidney injuries, kidney failure, and/or death that Defendants knew, or should have known, about.

57. Defendants knew or should have known that consumers such as Plaintiff and Decedent would foreseeably suffer injuries, such as kidney injuries, kidney failure, and/or death, as a result of Defendants' failure to exercise ordinary care, as set forth above.

58. Defendants' negligence and/or recklessness were the proximate cause of Plaintiff and Decedent's injuries and harm of which Plaintiff and Decedent suffered and/or will continue to suffer.

59. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff and Decedent were caused to suffer from the aforementioned injury, including death, and damages. Defendants acted with conscious disregard for the serious injuries the Plaintiff and Decedent were caused to suffer, as well as other severe and personal injuries, including death, which are permanent and lasting in nature, physical pain and mental anguish, any and all life complications caused by Decedent's kidney injuries, including kidney failure, and death, justifying an award of punitive damages.

COUNT II
NEGLIGENCE

60. Plaintiff incorporates herein by reference the allegations in the proceeding paragraphs.

61. Defendants had a duty to Plaintiff and to Decedent to exercise reasonable care in the design researching, testing, manufacturing, marketing, supplying, promoting, packaging, sale, and/or distribution of Nexium® into the stream of commerce, including a duty to assure that Nexium® would not cause users to suffer unreasonable, dangerous side effects such as kidney injuries, including kidney failure, and death.

62. Upon information and belief, Defendants failed to use reasonable care in its design, manufacture, and marketing of Nexium®, including the provision of appropriate warnings concerning the use thereof, in that Defendants:

- a. failed to properly and thoroughly test Nexium® before releasing the drug to the market;
- b. failed to properly and thoroughly analyze the data resulting from the premarketing tests of Nexium®;
- c. failed to conduct sufficient post-market testing and surveillance of Nexium®;
- d. designed, manufactured, marketed, advertised, distributed, and sold Nexium® to consumers, including Decedent, without adequate warning of the significant and dangerous risks of Nexium® and without proper instructions to avoid the harm which could foreseeably occur as a result of extended use of the drug;
- e. failed to exercise due care when advertising and promoting Nexium®;
- f. negligently manufactured Nexium® in a fashion that included several manufacturing defects; and,
- g. negligently continued to manufacture, market, advertise, and distribute Nexium® after Defendants knew or should have known of its adverse effects.

63. A reasonable manufacturer would or should have known that the risks created by Nexium® are unreasonably greater than that of other medications for the treatment of heartburn

and that Nexium® has no clinical benefit over such other similar products that compensate in whole or in part for the increased risk.

64. Defendants failed to exercise ordinary care and/or were reckless in researching, marketing, promoting, packaging, selling, testing, and warning of the risks which Defendant knew or should have known, and Defendants knew or should have known that using Nexium® caused a risk of unreasonable, dangerous side effects, including kidney injuries and death, and failed to warn of those risks.

65. Despite the fact that Defendants knew or should have known that Nexium® was associated with and/or caused kidney injuries including kidney failure, and death, Defendants continued to market, manufacture, distribute and/or sell Nexium® to consumers, including Decedent.

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

67. Defendants' negligence and/or recklessness were the proximate cause of Decedent's injuries and death as well as Plaintiff's injuries and harm, of which she suffered and/or will continue to suffer.

68. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff and Decedent were caused to suffer from the aforementioned injury, including death, and damages. Defendants acted with conscious disregard for the serious injuries the Plaintiff and Decedent were caused to suffer, as well as other severe and personal injuries, including death, which are permanent and lasting in nature, physical pain and mental

anguish, any and all life complications caused by Decedent's kidney injuries, including kidney failure, and death, justifying an award of punitive damages.

COUNT III
STRICT PRODUCT LIABILITY

69. Plaintiff incorporates herein by reference the allegations in the proceeding paragraphs.

70. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, marketed, and/or introduced Nexium® into the stream of commerce, and in the course of same, directly advertised or marketed Nexium® to consumers or persons responsible for consumers, and therefore, had a duty to both the Plaintiff and Decedent directly and Decedent's physicians to warn of risks associated with the use of Nexium®.

71. Defendants had a duty to warn of adverse drug reactions, which they know or have reason to know can be caused by the use of Nexium® and/or are associated with the use of Nexium®.

72. The Nexium® manufactured and/or supplied by the Defendants was defective due to inadequate post-marketing warnings and/or instructions because, after the Defendants knew or should have known of the risks of kidney injuries, including kidney failure, and/or death from Nexium® use, they failed to provide adequate warnings to consumers of the Nexium®, including Decedent and Decedent's physicians, and continued to aggressively promote Nexium®.

73. Due to the inadequate warning regarding kidney injuries, including kidney failure, and/or death, Nexium® was in a defective condition and unreasonably dangerous at the time that it left the control of Defendants.

74. Defendants' failure to adequately warn Decedent and/or Decedent's physicians of the risk of kidney injury, including kidney failure, and/or death and prevented Decedent and/or Decedent's physicians from correctly and fully evaluating the risks and benefits of Nexium®.

75. Had Decedent been adequately warned of the potential life-threatening side effects of the Nexium®, Decedent would not have purchased or taken Nexium® and could have chosen to request other treatments or prescription medications.

76. Upon information and belief, had Decedent and/or Decedent's physicians been adequately warned of the potential life-threatening side effects of Nexium®, Decedent's physicians would have discussed the risks of kidney injuries, including kidney failure, and/or death of Nexium® use with Decedent and/or Plaintiff and/or would not have recommended its use.

77. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff and Decedent were caused to suffer from the aforementioned injuries, including death, and damages. Defendants acted with conscious disregard for the serious injuries the Plaintiff and Decedent were caused to suffer, as well as other severe and personal injuries, including death, which are permanent and lasting in nature, physical pain and mental anguish, any and all life complications caused by Decedent's kidney injuries, including kidney failure, and death, justifying an award of punitive damages.

COUNT IV
STRICT PRODUCTS LIABILITY- DEFECTIVE DESIGN

78. Plaintiff incorporates herein by reference the allegations in the proceeding paragraphs.

79. Nexium® was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the drug without substantial change in the condition in which it was produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

80. At all times relevant, Nexium® was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Decedent.

81. Nexium® as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants was defective in design and formulation because when it left the hands of the manufacturers and/or suppliers the foreseeable risks exceeded the alleged benefits associated with the design and formulation of Nexium®.

82. Nexium® as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants was defective in design and formulation because when it left the hands of Defendants' manufacturers and suppliers it was unreasonably dangerous and was more dangerous than the ordinary consumer would expect.

83. At all times herein mentioned, Nexium® was in a defective condition and was unsafe. Defendants knew and had reason to know that Nexium® was defective and inherently unsafe, especially when Nexium® was used in a form and manner instructed and provided by Defendants.

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

85. At the time of Decedent's use of Nexium®, it was being used for its intended purpose, and in a manner which was normally intended.

86. Defendants researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold and marketed a defective product, which caused an unreasonable risk to the health of consumers, and to Decedent in particular. Defendants are

therefore strictly liable for the injuries, including death, and damages sustained by Plaintiff and/or Decedent.

87. At the time Nexium® left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Nexium®. This was demonstrated by the existence of other heartburn treatments, which had a more established safety profile and a considerably lower risk profile.

88. Plaintiff and Decedent could not, by the reasonable exercise of care, have discovered Nexium®'s defects and perceived Nexium®'s danger.

89. The defects in Nexium® were substantial and contributing factors in causing Plaintiff's injuries.

90. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Decedent was caused to suffer a kidney injury, including kidney failure, and death and Plaintiff was caused to suffer from the aforementioned injuries and damages.

91. Due to the unreasonably dangerous condition of Nexium®, Defendants are strictly liable to Plaintiff.

92. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff and Decedent were caused to suffer from the aforementioned injuries and damages. Defendants acted with conscious disregard for the serious injuries the Plaintiff and Decedent were caused to suffer, as well as other severe and personal injuries, including death, which are permanent and lasting in nature, physical pain and mental anguish, any and all life complications caused by Decedent's kidney injuries, including kidney failure, and death, justifying an award of punitive damages.

COUNT V
BREACH OF EXPRESS WARRANTY

93. Plaintiff incorporates herein by reference the allegations in the proceeding paragraphs.

94. Defendants expressly warranted that Nexium® was safe for its intended use and as otherwise described in this Complaint. Nexium® did not conform to these express representations, including, but not limited to, the representation that it was safe and the representation that it did not have high and/or unacceptable levels of side effects such as kidney injuries, including kidney failure, and/or death.

95. The express warranties represented by Defendants were a part of the basis for Decedent's use of Nexium® and Decedent relied on these warranties in deciding to use Nexium®.

96. At the time of making the aforementioned express warranties, Defendants had knowledge of the purpose for which Nexium® was to be used and warranted Nexium® to be in all respects safe, effective, and proper for such purpose.

97. Nexium® does not conform to these express representations because Nexium® is not safe or effective and may produce serious side effects, including kidney injuries and kidney failure, and/or death, degrading Decedent's health and leading to Decedent's death.

98. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff and Decedent were caused to suffer from the aforementioned injuries and damages. Defendants acted with conscious disregard for the serious injuries the Plaintiff and Decedent were caused to suffer, as well as other severe and personal injuries, including death, which are permanent and lasting in nature, physical pain and mental anguish, any and all life complications caused by Decedent's kidney injuries, including kidney failure, and death, justifying an award of punitive damages.

COUNT VI
BREACH OF IMPLIED WARRANTY FOR A PARTICULAR PURPOSE

99. Plaintiff incorporates herein by reference the allegations in the proceeding paragraphs.

100. At all times herein mentioned, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, marketed, promoted and sold Nexium®.

101. Defendants impliedly represented and warranted to the users of Nexium® that Nexium® was safe and fit for the particular purpose for which Nexium® was to be used.

102. These representations and warranties aforementioned were false, misleading, and inaccurate in that Nexium® was unsafe, and degraded Decedent's health and caused her death.

103. Decedent relied on the implied warranty of fitness for a particular use and purpose in choosing to use Nexium®.

104. Decedent reasonably relied upon the skill and judgment of Defendants as to whether Nexium® was safe and fit for its intended use.

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

106. Defendants breached the aforementioned implied warranty, as Nexium® was not fit for its intended purpose and use.

107. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff and Decedent were caused to suffer from the aforementioned injuries and damages. Defendants acted with conscious disregard for the serious injuries the Plaintiff and Decedent were caused to suffer, as well as other severe and personal injuries,

including death, which are permanent and lasting in nature, physical pain and mental anguish, any and all life complications caused by Decedent's kidney injuries, including kidney failure, and death, justifying an award of punitive damages.

COUNT VII
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

108. Plaintiff incorporates herein by reference the allegations in the proceeding paragraphs.

109. Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, marketed, promoted and sold Nexium®.

110. Defendants marketed, sold and distributed Nexium® and knew and promoted the use for which Nexium® was being used by Decedent and impliedly warranted to Decedent that Nexium® was of merchantable quality and fit for the ordinary purpose for which it was intended.

111. These representations and warranties aforementioned were false, misleading, and inaccurate in that Nexium® was unsafe, and degraded Decedent's health and caused her death.

112. Decedent reasonably relied on the skill, expertise and judgment of Defendants and its representations as to the fact that Nexium® were of merchantable quality.

113. Nexium® as manufactured and supplied by Defendants was not of merchantable quality, as warranted by Defendants in that Nexium® had dangerous and life threatening side effects and was therefore not fit for the ordinary purpose for which it was intended.

114. As a direct and proximate result of the foregoing, Plaintiff, on behalf of Decedent, suffered bodily injury, pain and suffering, and economic loss.

115. As a foreseeable and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiff and Decedent were caused to suffer from the aforementioned injuries and damages. Defendants acted with conscious disregard for the serious injuries the

Plaintiff and Decedent were caused to suffer, as well as other severe and personal injuries, including death, which are permanent and lasting in nature, physical pain and mental anguish, any and all life complications caused by Decedent's kidney injuries, including kidney failure, and death, justifying an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment in her favor and seeks the following relief against Defendants:

- A. Compensatory damages in excess of \$75,000, exclusive of interest and costs;
- B. Costs of suit'
- C. Pre-judgment and post-judgment interest;
- D. Punitive damages; and
- E. Such other relief as this Court deems just and proper under the circumstances.

DEMAND FOR JURY TRIAL

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

Respectfully submitted,

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

/s/Mark P. Chalos

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Tennessee

AUBREY MCCULLOUGH, Individually and as
Representative of the Estate of MARTH
MCCULLOUGH, Deceased

Plaintiff(s)

v.

ASTRAZENECA PHARMACEUTICALS LP, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* ASTRAZENECA PHARMACEUTICALS LP
CT CORPORATION SYSTEM
800 S. Gay Street
Suite 2021
Knoxville, TN 37929-9710
USA

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: LIEFF, CABRASER, HEIMAN, BERNSTEIN, LLP
One Nashville Place
150 Fourth Avenue North, Suite 1650
Nashville, TN 37219

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

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

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)* _____
 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:

Print

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

UNITED STATES DISTRICT COURT

for the

Eastern District of Tennessee

AUBREY MCCULLOUGH, Individually and as
Representative of the Estate of MARTH
MCCULLOUGH, Deceased

Plaintiff(s)

V.

ASTRAZENECA PHARMACEUTICALS LP, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* ASTRAZENECA LP
CT CORPORATION SYSTEM
800 S. Gay Street
Suite 2021
Knoxville, TN 37929-9710
USA

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: LIEFF, CABRASER, HEIMAN, BERNSTEIN, LLP
One Nashville Place
150 Fourth Avenue North, Suite 1650
Nashville, TN 37219

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

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

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)* _____
 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

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