UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
AT COVINGTON
CIVIL ACTION NO. _____

JUDITH GREGORY **PLAINTIFFS**

AND

DONALD GREGORY

V.

EZRICARE LLC

EZRIRX LLC

GLOBAL PHARMA HEALTHCARE PRIVATE LTD;

AND

ARU PHARMA INC. **DEFENDANTS**

COMPLAINT WITH JURY DEMAND

The Plaintiffs, Judith Gregory and Donald Gregory, by and through counsel, for their Complaint with Jury Demand ("Complaint") against Defendants, EzriCare LLC, EzriRx LLC, Global Pharma Healthcare Private Ltd., and Aru Pharma Inc. ("Defendants"), state as follows:

PARTIES, JURISDICTION, AND VENUE

1. The Plaintiff, Judith Gregory ("Judith"), is a citizen and resident of the Commonwealth of Kentucky, residing at 209 Caldwell Drive, Elsmere, Kenton County, Kentucky 41018. Judith Gregory purchased EzriCare Artificial Tears ("Product") over the counter. She was not aware the Product may be contaminated with a dangerous, and potentially life-threatening, bacteria, *Pseudomonas Aeruginosa*. Ms. Gregory made the purchase assuming the contents of the Product's labelling were accurate and that the

Product was untainted, safe, effective, and not contaminated by bacteria. Ms. Gregory would not have purchased or utilized the Product had she known of the risk and dangers associated with the use of the Product and the potential contaminate bacteria contained therein. As a result of purchasing and using the Product, Ms. Gregory suffered financial and personal injury.

2. The Plaintiff, Donald Gregory ("Donald"), is the husband of Plaintiff Judith Gregory. He is a citizen and resident of the Commonwealth of Kentucky, residing at 209 Caldwell Drive, Elsmere, Kenton County, Kentucky 41018.

3. Defendant, EzriCare LLC ("EzriCare"), is, and was at all times relevant herein, a New Jersey Limited Liability Company with its principal place of business being located at 1525 Prospect Street, Suite 204, Lakewood, New Jersey 08701. The Product is a trademark registered and licensed to EzriCare with the serial number 90629770. Service of process may be had pursuant to KRS §454.210 by serving the Secretary of State of the Commonwealth of Kentucky. EzriCare markets, advertises, labels, distributes, and sells the Product at issue herein.

4. Defendant, EzriRX LLC ("EzriRX"), is, and was at all times relevant herein, a company incorporated under the laws of Delaware with its principal place of business being located at 1525 Prospect Street, Suite 204, Lakewood, New Jersey 08701. Service of process may be had pursuant to KRS §454.210 by serving the Secretary of State of the Commonwealth of Kentucky. EzriRx markets, advertises, labels, distributes, and sells the Product at issue herein.

5. Defendant, Global Pharma Healthcare Private Limited ("Global Pharma") is, and was at all times relevant herein, a corporation organized and existing under the laws of

the country of India with its principal place of business being located at No. 2A, #rd F, 4th Street, Ganga Nagar, Chennai 500 024, Tamil Nadu, India. Service of process may be had pursuant to KRS §454.210 by serving the Secretary of State of the Commonwealth of Kentucky. Global Pharma manufactures, markets, advertises, labels, distributes, and sells the Product at issue herein.

6. Defendant, Aru Pharma Inc. ("Aru Pharma") is, and was at all times relevant herein, a New York Limited Liability Company with its principal place of business being located at 7 Wingate Place, Yonkers, New York 10705. Service of process may be had pursuant to KRS §454.210 by serving the Secretary of State of the Commonwealth of Kentucky. Aru Pharma imports, markets, and distributes the Product at issue herein.

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 as the matter in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs, and as between Plaintiffs, citizens of Kentucky, and Defendants, citizens of differing states, both foreign and domestic.

8. This Court has personal jurisdiction over each Defendant because Defendants conducted and do business, caused injury, and/or induced acts in the Commonwealth of Kentucky ("Commonwealth"). Defendants have also directed business in the Commonwealth by marketing, promoting, distributing, and selling the Product. Further, Defendants have sufficient minimum contacts with the Commonwealth and/or have availed themselves of the markets in the Commonwealth through its promotion, sales, distribution, and marketing within the Commonwealth.

9. Venue is proper with this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions that give rise to the claims asserted herein occurred in this judicial district.

FACTUAL ALLEGATIONS

10. Plaintiffs reiterate and incorporate the foregoing numerical paragraphs as if fully rewritten herein.

11. The Product's NDC number is 79503-101-15.

12. EzriCare began labeling, advertising, marketing, and selling the Product in November 2022.

13. The Product is a preservative-free, over the counter multidose ophthalmic solution. *Outbreak of Extensive Drug-resistant Pseudomonas aeruginosa Associated with Artificial Tears,* CDC.gov, https://emergency.cdc.gov/han/2023/han00485.asp (last visited May 2, 2023)

14. The Product is intended to be used as 1) a protectant against further irritation or to relieve dryness of the eye; and 2) temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun. *Artificial Tears Lubricant Eye Drops*, NIH.gov, https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=ac1ea23c-f1c6-418f-921e-58553ee919cb&type=display (last visited May 2, 2023)

15. The Product contains the active ingredient Carboxymethylcellulose Sodium, 10 mg in 1 mL. The inactive ingredients are as follows: Boric Acid, Potassium Chloride, Sodium Chloride, Calcium Chloride, Magnesium Chloride, Sodium Chlorite, Sodium Hydroxide, and Water. *Id.*

16. The Product used by Judith contained the pathogenic bacterium *Pseudomonas aeruginosa*.

17. In 2017, the World Health Organization ("WHO") categorized *Pseudomonas aeruginosa*, a multidrug resistant bacterium, as "Priority 1: Critical" for research and development of new antibiotics, the highest priority designated. *WHO Publishes List of Bacteria for which New Antibiotics are Urgently Needed,* WHO.int, https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed (last visited May 2, 2023)

18. *Pseudomonas aeruginosa* is known to cause infections of the blood, lungs, and other body parts in humans. *Pseudomonas aeruginosa in Healthcare Settings*, CDC.gov, https://www.cdc.gov/hai/organisms/pseudomonas.html#:~:text=Top%20of%20Page-,How%20is%20it%20spread%3F,is%20contaminated%20with%20these%20germs. (Last visited May 2, 2023)

19. The Centers for Disease Control and Protection ("CDC") found the presence of *Pseudomonas aeruginosa* in open Product bottles from multiple lot numbers. *Outbreak of Extensive Drug-resistant Pseudomonas aeruginosa Associated with Artificial Tears,* CDC.gov, https://emergency.cdc.gov/han/2023/han00485.asp (last visited May 2, 2023)

20. On February 1, 2023, the CDC issued a health alert recommending healthcare providers immediately discontinue using the Product pending further instruction from the CDC and Food and Drug Administration ("FDA"). *Id.*

21. On February 2, 2023, the FDA issued a similar warning to both consumers and healthcare providers to not purchase and immediately stop using the Product. *FDA Warns Consumers Not to Purchase or Use EzriCare Artificial Tears Due to Potential Contamination,*

FDA.gov, https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination#:~:text=Associated%20adverse%20events%20include%20hospitalization,guidance%20from%20CDC%20and%20FDA (last visited May 3, 2022)

22. The FDA recommended Global Pharma recall all unexpired lots of the Product because Global Pharma's violations of current good manufacturing practices ("CGMP") which include "lack of appropriate microbial testing, formulation issues" (lack of adequate preservatives for multi-use bottles of the Product), and "lack of proper controls concerning tamper-evident packaging." *Id.*

23. Global Pharma was also placed on import alert by the FDA, preventing importation of the Product, for providing inadequate responses to a records request and by not complying with CGMP. *Id.*

24. The FDA performed an inspection at Global Pharma's facilities from February 20, 2023 to March 2, 2023, and on March 2, 2023, issued a redacted report on its inspectional observations ("Report"). A copy of the Report is attached hereto and marked as Exhibit A.

25. Per the Report, the FDA's observations include, but are not limited to, the following:

a. the sterilization process is not validated;

b. the "manufacturing process lacked assurance of product sterility";

c. the testing methods lacked "accuracy, sensitivity, specificity, and reproducibility;

d. the "equipment used in the manufacture, processing, packing, or holding of drug products" was not appropriately designed "to facilitate operations for its intended use";

e. the system for cleaning and disinfecting aseptic processing areas is inadequate;

f. there are no written procedures for "cleaning and maintaining equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product";

g. bottle caps were not tested before releasing for manufacturing; and

h. various issues with quality control and quality assurance.

26. The FDA has linked the contaminated Product to an outbreak of *Pseudomonas aeruginosa* infections in the United States spanning across 16 states and affecting 68 people as of March 2023. *Eye Experts Weigh in on Artificial Tears in Midst of Infectious Outbreak,* NIH.gov, https://www.nei.nih.gov/about/news-and-events/news/eye-experts-weigh-artificial-tears-midst-infectious-outbreak (last visited May 2, 2023)

27. Judith reported to her ophthalmologist that she suffered from left eye pain, decreased vision and photophobia. She was diagnosed with episcleritis and iridocyclitis by her ophthalmologist and given medication to relieve her symptoms.

28. Despite the medication, Judith continued to have eye pain and decreased vision as well as redness of the eye. Upon returning to her ophthalmologist, she was then diagnosed with necrotizing, scleritis, scleromalacia, pseudophakia, anterior blepharitis, and posterior vitreous detachment.

29. On or about May 31, 2022, Judith reported to her ophthalmologist that she was using the Product.

30. On June 1, 2022, Judith returned to her ophthalmologist with eye pain, discharge, redness, and blurry vision. She was then diagnosed with necrotizing scleritis, suspected to be due to an infectious etiology.

31. Due to concerns, Judith was admitted to the medical intensive care unit ("ICU"), and on June 2, 2022, she was diagnosed with sepsis. She remained in the ICU continuing treatment until her discharge on June 10, 2022.

32. Judith continued to seek outpatient treatment for her eye, and by July 18, 2022, she has a notable increase in discharge with a worsening appearance of the eye.

33. Cultures from Judith's eye were collected and grew pan-resistant *Pseudomonas aeruginosa.*

34. Unfortunately, Judith's condition worsened further to the point she required a revision procedure on January 9, 2023.

35. Over the course of her treatment, Judith required multiple surgical interventions, hospitalizations, weekly ophthalmologist visits, and prolonged antibiotics.

36. Judith's ophthalmologist noted that Judith had been using the Product prior to the development of her infection and her case was reported to the CDC.

COUNT I
Strict Liability – Manufacturing Defect

37. Plaintiffs reiterate and incorporate the foregoing numerical paragraphs as if fully rewritten herein.

38. Defendants manufactured and sold the Product in the course of business and placed it in the stream of commerce.

39. The Product contained a manufacturing defect when it left the Defendants' facilities contaminated with *Pseudomonas aeruginosa.*

40. The purchase and use of the Product by Judith and other similarly situated individuals was foreseeable to Defendants.

41. Judith's use of the Product was the direct and proximate cause of her injury.

42. As a result of the manufacturing defect of the Product, Judith has suffered damages in an amount to be proven at trial.

COUNT II
Strict Liability - Failure to Warn

43. Plaintiffs reiterate and incorporate the foregoing numerical paragraphs as if fully rewritten herein.

44. Defendants sold the Product in the course of business and placed it in the stream of commerce

45. Defendants knew or should have known the Product was contaminated with *Pseudomonas aeruginosa.*

46. Defendants had a duty to warn Judith and other similarly situated individuals about the presence of *Pseudomonas aeruginosa* in the Product.

47. The use of the Product by ordinary consumers including Judith was foreseeable to Defendants.

48. Defendants knew or should have known of the dangers of *Pseudomonas aeruginosa* in light of the CGMP and other prevailing standards available at the time regarding the manufacture, assembly, inspection and testing of the Product.

49. Defendants failed to warn or give adequate notice of the contamination and risk of exposure.

50. Judith purchased and used the Product in a manner intended, reasonably anticipated, and promoted by the Defendants.

51. Judith and other similarly situated individuals relied upon the Defendants' manufacturing, labeling, packaging, marketing, and advertising of the Product for its purchase and use. Her reliance and use of the Product was the direct and proximate cause of her injury.

52. As a result of the Defendants' conduct, Judith has suffered damages in an amount to be proven at trial.

COUNT III
Negligence – Manufacturing

53. Plaintiffs reiterate and incorporate the foregoing numerical paragraphs as if fully rewritten herein.

54. Defendants owed Judith and other similarly situated individuals a duty to use reasonable care in manufacturing, assembling, inspecting, and/or testing the Product to ensure it was safe for the intended use.

55. Defendants breached their duty by manufacturing, assembling, inspecting, and/or testing the Product in a negligent or reckless manner such that it was likely the Product would cause infections due to contamination of *Pseudomonas aeruginosa*.

56. Defendants' negligent or reckless conduct is the direct and proximate cause of the injury to Judith, and as a result, Judith has suffered damages in an amount to be proven at trial.

COUNT IV
Negligence – Failure to Warn

57. Plaintiffs reiterate and incorporate the foregoing numerical paragraphs as if fully rewritten herein.

58. The use of the Product in its intended manner was foreseeable by the Defendants.

59. Defendants had a duty to warn Judith and other similarly situated individuals about the presence of *Pseudomonas aeruginosa* in the Product.

60. The presence of *Pseudomonas aeruginosa* in the Product is not readily ascertainable or recognizable by an ordinary consumer including Judith.

61. Defendants knew or should have known of the dangers of *Pseudomonas aeruginosa* in light of the CGMP and other prevailing standards available at the time regarding the manufacture, assembly, inspection and testing of the Product.

62. Defendants owed a duty to Judith and other similarly situated individuals to provide adequate warning to intended and foreseeable users such as Judith, on how to use, recognize, and appreciate the dangers associated with the Product.

63. The lack of and/or negligent warnings on the Product and/or its packaging were the direct and proximate cause of Judith's injuries, and as a result, Judith has suffered damages in an amount to be proven at trial.

COUNT V
Breach of Express Warranty

64. Plaintiffs reiterate and incorporate the foregoing numerical paragraphs as if fully rewritten herein.

65. Defendants expressly warranted through marketing, advertising, and packaging that the Product was safe and fit for its intended purposes; that the Product was of merchantable quality; and that they did not pose a risk of danger or contamination.

66. The labeling represents the use of the Product is to assist with eye dryness or irritation and as such, implies that it is safe for use.

67. Defendants knew or should have known the Product was contaminated with *Pseudomonas aeruginosa.*

68. Defendants breached the expressed warranties because the Product was not safe for use and was contaminated.

69. Judith relied upon the warranties prior to purchasing and using the Product and was induced to purchase and use the same. Her reliance and use of the Product was the direct and proximate cause of her injury.

70. As a result of Defendants' breach, Judith has suffered damages in an amount to be proven at trial.

COUNT VI
Breach of Implied Warranty

71. Plaintiffs reiterate and incorporate the foregoing numerical paragraphs as if fully rewritten herein.

72. Defendants impliedly warranted the Product was safe and fit for its ordinary purpose.

73. Judith purchased and used the Product relying on Defendants' implied warranty. Her reliance and use of the Product was the direct and proximate cause of her injury.

74. Defendants breached the implied warranty because the Product was not safe, not fit for its ordinary purpose, and was not of generally accepted quality because it was contaminated with *Pseudomonas aeruginosa*.

75. As a result of Defendants' breach, Judith has suffered damages in an amount to be proven at trial.

COUNT VII
Negligent Representation/Omission

76. Plaintiffs reiterate and incorporate the foregoing numerical paragraphs as if fully rewritten herein.

77. Defendants represented the Product's active and inactive ingredients on its packaging and labeling.

78. Defendants intended Judith and other similarly situated individuals to rely on the representations, and Judith relied upon the same.

79. The representations were material to Judith's purchasing and use of the product.

80. Defendants had a duty to accurately disclose the contents of the Product and to not make false representations.

81. Defendants breached their duties by making false representations regarding the safety and quality of the Product.

82. As a result of Defendants' breach, Judith has suffered damages in an amount to be proven at trial.

COUNT VIII
Loss of Consortium

83. Plaintiffs reiterate and incorporate the foregoing numerical paragraphs as if fully rewritten herein.

84. As a result of the negligent or reckless acts and/or omissions of Defendants, Donald has incurred damages for the loss of Judith's services, assistance, aid, and companionship as is between husband and wife.

85. Donald is entitled to recover his damages against Defendants for their negligent or reckless acts and/or omissions in an amount to be proven at trial.

WHEREFORE, the Plaintiffs, Judith Gregory and Donald Gregory, pray as follows:

A. For a trial by jury on all triable issues;
B. For judgment against the Defendants to compensate Plaintiffs for their injuries and all damages recoverable by law;
C. For an award of costs and attorney's fees;
D. For pre and post judgment interest;
E. For an award of punitive damages; and
F. For any other relief to which the Plaintiffs may be entitled.

Respectfully submitted,

/s/ Stacey L. Graus

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