

IN THE CIRCUIT COURT OF THE 11TH
JUDICIAL CIRCUIT IN AND FOR MIAMI-
DADE COUNTY, FLORIDA

CIRCUIT CIVIL DIVISION

CASE NO.

CLARA ELVIRA OLIVA,

Plaintiff,

v.

GLOBAL PHARMA HEALTHCARE
PRIVATE LTD., EZRICARE, LLC,
EZRIRX, LLC, ARU PHARMA, INC.,
LEON MEDICAL CENTERS, LLC; and
HEALTHSPRING OF FLORIDA, INC.,

Defendants.

_____ /

COMPLAINT FOR DAMAGES

The Plaintiff, Clara Elvira Oliva, sues the Defendants Global Pharma Healthcare Private Ltd., EzriCare, LLC, EzriRx, LLC, Leon Medical Centers, LLC, and HealthSpring of Florida, Inc., and alleges:

JURISDICTIONAL STATEMENT AND IDENTIFICATION OF PARTIES

1. This is an action for damages in excess of this Court's minimum jurisdictional limits, exclusive of interest and costs.

2. This case arises out of a defective artificial tear product that was designed, manufactured, distributed, imported, sold, and/or supplied by the Defendants. The name of this defective artificial tear product is EzriCare Artificial Tears (hereinafter referred to as "EzriCare Artificial Tears," "Artificial Tears" or "Product"). The Defendants were responsible for the Artificial Tears entering Florida's stream of commerce, which, as the Defendants intended, were

purchased and used by Florida consumers, including the Plaintiff. As a result of the Artificial Tears' defects, numerous consumers, including the Plaintiff, suffered catastrophic permanent injuries from using the Artificial Tears.

3. The Plaintiff, Clara Elvira Oliva, is a resident of Broward County, Florida.

4. Defendant Global Pharma Healthcare Private Ltd. ("Global") was and is a foreign corporation operating as a manufacturer of pharmaceutical products. It manufactures tablets, capsules, liquid orals, dry syrup, ointments, sachets, parenterals, eye care products, and antibiotics to customers across the globe. Defendant Global manufactured the contaminated Product at issue in this litigation that caused Plaintiff's significant injuries. This Court has specific personal jurisdiction over Defendant Global, under Florida's long-arm statute, §48.193(1)(a)(6)(b), because the Product processed, serviced and/or manufactured by Global was consumed within the state of Florida in the ordinary course of commerce, injuring Mrs. Oliva. Moreover, Global is engaged in substantial and not isolated activity within the state of Florida because it purposefully established minimum contacts within the forum by contracting with the other Defendant entities, identified below, knowing that the Product it manufactured would be distributed, imported, sold, promoted, and consumed in the United States, including Florida. *Id.* at (2). Such activity was substantial, continuous and planned so that Defendant Global, within the Product's supply chain, would profit from local consumers. Global's sufficient minimum contacts with Florida support the exercise of this Court's jurisdiction, which does not offend traditional notions of fair play and substantial justice.

5. Defendant EzriCare, LLC ("EzriCare"), was and is a New Jersey limited liability company that was at all times material engaged in the business of importing, selling, supplying, packaging, distributing, and marketing the Artificial Tears throughout the United States, including Florida. This Court has specific personal jurisdiction over Defendant EzriCare, under Florida's

long-arm statute, §48.193(1)(a)(6)(b), because the Product processed, serviced and/or manufactured by EzriCare was consumed within the state of Florida in the ordinary course of commerce, injuring Mrs. Oliva. Moreover, EzriCare is engaged in substantial and not isolated activity within the state of Florida because it purposefully established minimum contacts within the forum by contracting with the other Defendant entities, identified in this Complaint, knowing that its Product would be distributed, imported, sold, promoted, and consumed in the United States, including Florida. *Id.* at (2). Such activity was substantial, continuous and planned so that Defendant EzriCare, within the Product’s supply chain, would profit from local consumers. EzriCare’s sufficient minimum contacts with Florida support the exercise of this Court’s jurisdiction, which does not offend traditional notions of fair play and substantial justice.

6. Defendant EzriRx, LLC (“EzriRx”), was and is a Delaware limited liability company that was at all times material engaged in the business of importing, selling, supplying, packaging, distributing, and marketing the Artificial Tears throughout the United States, including Florida. EzriRx operates an online platform that allows pharmacies to purchase over tens of thousands of medications and over-the-counter products from wholesalers throughout the United States. This Court has specific personal jurisdiction over Defendant EzriRx, under Florida’s long-arm statute, §48.193(1)(a)(6)(b), because the Product processed, serviced and/or manufactured by EzriRx was consumed within the state of Florida in the ordinary course of commerce, injuring Mrs. Oliva. EzriRx is engaged in substantial and not isolated activity within the state of Florida because it purposefully established minimum contacts within the forum by contracting with the other Defendant entities, identified in this Complaint, knowing that its Product would be distributed, imported, sold, promoted, and consumed in the United States, including Florida. *Id.* at (2). Such activity was substantial, continuous and planned so that Defendant EzriRx, within the Product’s supply chain, would profit from local consumers. EzriRx’s sufficient minimum contacts

with Florida support the exercise of this Court’s jurisdiction, which does not offend traditional notions of fair play and substantial justice.

7. Defendant Aru Pharma, Inc. (“Aru”), was and is a New York corporation that was at all times material engaged in the business of importing, marketing, and distributing the Artificial Tears throughout the United States, including Florida. Upon information and belief, Defendant Aru formulated, designed, and imported the Artificial Tears into the United States. Nevertheless, this Court has specific personal jurisdiction over Defendant Aru, under Florida’s long-arm statute, §48.193(1)(a)(6)(b), because the Product processed, serviced and/or manufactured by Aru was consumed within the state of Florida in the ordinary course of commerce, injuring Mrs. Oliva. Aru is engaged in substantial and not isolated activity within the state of Florida because it purposefully established minimum contacts within the forum by contracting with the other Defendant entities, identified in this Complaint, knowing that the Product it manufactured would be distributed, imported, sold, promoted, and consumed in the United States, including Florida. *Id.* at (2). Such activity was substantial, continuous and planned so that Defendant Aru, within the Product’s supply chain, would profit from local consumers. Aru’s sufficient minimum contacts with Florida support the exercise of this Court’s jurisdiction, which does not offend traditional notions of fair play and substantial justice.

8. Defendant Leon Medical Centers, LLC (“Leon”), was and is a Florida limited liability company, with its principal place of business located in Miami-Dade County, Florida. Leon has three managers, all of whom are in Miami-Dade County, Florida. At all times material, Leon operated medical clinics and provides pharmaceutical services.

9. Defendant HealthSpring of Florida, Inc., d/b/a Leon Medical Centers Health Plans (“HealthSpring”), is a Florida corporation, with its principal place of business located in Miami-Dade County, Florida. At all times material, HealthSpring operated as an insurance company,

offering healthcare and disability insurance services to customers internationally.

10. Venue is proper in Miami-Dade County, Florida, where one or more of the Defendants reside and the events giving rise to this lawsuit occurred.

FACTS GIVING RISE TO CAUSE OF ACTION

a. EzriCare Artificial Tears

11. The Artificial Tears are a preservative-free lubricant eye drop available for over-the-counter purchase.

12. The Artificial Tears have been marketed and advertised to the public (1) as a protectant against further irritation or to relieve dryness of the eye; and (2) for the temporary relief of discomfort due to minor irritations of the eye, or to wind or sun exposure.

13. The active ingredient in Artificial Tears is a solution of Carboxymethylcellulose Sodium 10 MG in 1 ml, and the inactive ingredients include Boric Acid, Potassium Chloride, Sodium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride, Sodium Chlorite, Sodium Hydroxide, and Water for injection. Notably, because the Product is “preservative free,” chemicals used to prevent the growth of bacteria have been removed and are not present in the Product.

14. The National Drug Code (NDC) number for the Artificial Tears is 79503-101-15.

15. At all times material, the Artificial Tears eye drops were manufactured in India and then imported, distributed, marketed, supplied and ultimately sold to consumers throughout the United States, including Florida, by the Defendants.

16. At all times material, each Defendant was part of the Artificial Tear “supply chain” and had the responsibility to prevent this defective Product from reaching the end consumer, including the Plaintiff.

b. The 2023 Outbreak of VIM-GES-CRPA (*Pseudomonas Aeruginosa*) Linked to Artificial Tears

17. On January 24, 2023, Defendant EzriCare issued a statement regarding the

contamination of its Artificial Tears Product, stating that it was made aware of the Centers for Disease Control’s (“CDC”) ongoing investigation related to adverse events implicating various over-the-counter eye drops.

18. On February 1, 2023, about a week later, the CDC issued a Health Alert Network Health Advisory announcing a multi-state outbreak of VIM-GES-CRPA, a rare strain of extensively drug-resistant *Pseudomonas Aeruginosa*, identifying 55 infected patients in 12 states: California, Colorado, Florida, New Jersey, New Mexico, Nevada, Texas, Utah, Washington and Wisconsin.

19. Notably, the outbreak strain, carbapenem-resistant *Pseudomonas aeruginosa* with Verona integron-mediated metallo- β -lactamase and Guiana extended-spectrum- β -lactamase (VIM-GES-CRPA), had never been reported in the United States prior to this outbreak. The CDC noted that the outbreak is associated with multiple types of infections, including eye infections.

20. That same day, Defendant EzriCare issued another statement: “EzriCare, LLC first received notice of the CDC's ongoing investigation into a multistate cluster of *Pseudomonas aeruginosa* infections on January 20, 2023. As of today, we are not aware of any testing that definitively links the *Pseudomonas aeruginosa* outbreak to EzriCare Artificial Tears. Nonetheless, we immediately took action to stop any further distribution or sale of EzriCare Artificial Tears. To the greatest extent possible, we have been contacting customers to advise them against continued use of the product. We also immediately reached out to both CDC and FDA and indicated our willingness to cooperate with any requests they may have of us.”¹

21. On February 2, 2023, the U.S. Food and Drug Administration (“FDA”) then issued a statement “warning consumers and health care practitioners not to purchase and to immediately

¹ *EzriCare Artificial Tears – Discontinue Use*, located at <https://ezricare-info.com/>

stop using the contaminated EzriCare Artificial Tears ... due to potential bacterial contamination.”²

22. The FDA also urged Global Pharma to initiate a recall due to the company’s “current good manufacturing practice (CGMP) violations,” which included a “lack of appropriate microbial testing, formulation issues (the company manufactures and distributes ophthalmic drugs in multi-use bottles, without an adequate preservative), and lack of proper controls concerning tamper-evident packaging.” *Id.*

23. Accordingly, Global Pharma voluntarily recalled all unexpired lots of EzriCare Artificial Tears and acknowledged the 55 reported adverse events including eye infections, permanent loss of vision, and a death with a blood stream infection.³ The included “Risk Statement” further acknowledged that the “[u]se of contaminated artificial tears can result in the risk of eye infection that could result in blindness.”⁴

24. The FDA also placed Global Pharma on import alert for providing an inadequate response to a records request and for not complying with CGMP requirements. The import alert currently prevents their products from entering the United States.⁵

25. The epidemiologic evidence investigated by the CDC indicates that contaminated

² *FDA warns consumers not to purchase or use EzriCare Artificial Tears due to potential contamination*, Food & Drug Admin. (Feb. 2, 2023), located at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination>.

³ *See Global Pharma Healthcare Issues Voluntary Nationwide Recall of Artificial Tears Lubricant Eye Drops Due to Possible Contamination*, located at <https://global-pharma.com/otc.pdf>.

⁴ *Id.*

⁵ *FDA warns consumers not to purchase or use EzriCare Artificial Tears due to potential contamination*, Food & Drug Admin. (Feb. 2, 2023), located at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination>.

Artificial Tears were the source of the outbreak. Further, most infected patients reported using Artificial Tears. Most infected patients specifically reported using EzriCare Artificial Tears, and CDC laboratory testing identified the presence of the outbreak strain, VIM-GES-CRPA, in multiple lots of opened EzriCare Artificial Tear bottles, involving specimens collected from May 2022 to January 2023.

26. Exposed consumers have developed a variety of complications, including keratitis, endophthalmitis, respiratory infections, urinary tract infections, sepsis, permanent vision loss and enucleation resulting from cornea infection, extensive hospitalization, and death due to systematic infection.

27. Since the CDC's initial Health Advisory, three additional adverse events have been reported. Currently, a total of 58 patients with infections have been identified in 13 states.

c. The *Pseudomonas Aeruginosa* Bacteria

28. *Pseudomonas Aeruginosa* is a bacterium notorious for being versatile and innately drug resistant. Specifically, it is a common encapsulated, gram-negative, aerobic-facultatively anaerobic, rod-shaped bacterium typically found in freshwater environments. It is a multidrug resistant pathogen recognized for its ubiquity, its intrinsically advanced antibiotic resistance mechanisms, and its wide range of dynamic defenses, which make it an extremely challenging organism to treat in modern day medicine.

29. In addition to plants and animals, the *Pseudomonas Aeruginosa* bacteria has been known to infect humans. This specific bacterium has been linked to serious skin, eye, lung and other severe infections throughout the body.

30. Infections caused by *Pseudomonas Aeruginosa* are remarkably dangerous because the bacterium has the ability to grow extensive colonies in conditions of partial or total oxygen depletion. As a result, advanced antibiotic regimens are often required for treatment and such

regimens often can lead to other serious adverse reactions or effects.

31. According to the CDC, VIM-GES-CRPA or *Pseudomonas Aeruginosa* isolates associated with this outbreak, tested at public health laboratories, were resistant to the following antibiotics: cefepime, ceftazidime, piperacillin-tazobactam, aztreonam, carbapenems, ceftazidime-avibactam, ceftolozane-tazobactam, fluoroquinolones, polymyxins, amikacin, gentamicin, and tobramycin.

d. Plaintiff Clara E. Oliva's *Pseudomonas Aeruginosa* Infection

32. Plaintiff Clara E. Oliva is a 68-year-old woman with a history of dry eyes related to her prescribed contact lenses, which she has been using for approximately 30 years.

33. Aside from diminished acuity in her left eye, she has no other significant ocular history or issues.

34. Over the years, Clara obtained her contact lenses from Leon Medical Center. To address the dryness of her eyes caused by the contact lenses, she uses eye drops. She has used such products for many years and obtains them with her contacts at Leon Medical Center through her insurance plan provided through Defendant HealthSpring.

35. Defendant HealthSpring contracts with certain product manufacturers and/or distributors, unilaterally deciding which products to supply its insureds with.

36. Defendant HealthSpring typically provided Mrs. Oliva with lubricant eye drops manufactured by a company known as Bausch + Lomb, Inc. However, in May 2022, Mrs. Oliva noticed that the eye drops authorized by her insurer had changed. This time she was provided with EzriCare Artificial Tears.

37. Mrs. Oliva began using the new brand of eye drops the Leon Defendants supplied her with. She used EzriCare Artificial Tears for the next few months.

38. On August 1, 2022, however, her right eye, with no prior issues and good vision,

was noticeably red, swollen, and abnormally watery. That day, she presented to Leon Medical Center to be evaluated by an ophthalmologist. She was seen by several different providers and was told that she had a corneal scratch. The doctors prescribed her polytime, vigamox, tobramycin, erythromycin ointment and cyclopentolate.

39. Despite Mrs. Oliva's adherence to the prescribed regimen of antimicrobial and antibiotic treatment, the symptoms in her right eye persisted and worsened. As a result, she went to Bascom Palmer Eye Institute's emergency room on August 4th.

40. The doctors at Bascom Palmer examined Mrs. Oliva and noted that the prescribed medicines were ineffective, so they escalated the dosages and frequency of her antimicrobial and antibiotic treatment. The doctors also performed a slit lamp and fundus exam of the right eye, determining that Mrs. Oliva had confluent peripheral corneal ulcer. Cultures were obtained via a cornea scraping diagnostic smear, and she was instructed to return in three days for re-evaluation.

41. On August 7, 2022, Mrs. Oliva returned to Bascom Palmer's Rapid Access Clinic as instructed. She was seen by an ophthalmology resident, who noted that her right eye still had not improved and that her visual acuity was deteriorating. A physical exam showed an increase in the size of her ulcer and the presence of fungus. Because the cultures from August 4th were still pending, the treaters decided to start Mrs. Oliva on empiric antifungal therapy. She was started on an antifungal and antiviral regimen, was instructed to taper the vancomycin and tobramycin, and again was told to return in three days.

42. Over the next three days, Mrs. Oliva's symptoms persisted, and she returned to Bascom Palmer's Rapid Access Clinic on August 10th as instructed. The results from the cultures taken on August 4th had now been analyzed, which showed moderate growth of *pseudomonas aeruginosa*. As a result, Mrs. Oliva was instructed to stop taking the antifungal medications and vancomycin. Instead, she started on steroids and moxifloxacin and instructed to continue taking

tobramycin and cyclopentolate and to return in two days.

43. From August 12th to August 27th, Mrs. Oliva returned to Bascom Palmer ten times. By August 27th it was clear to her Bascom providers that despite aggressive medical treatment the pain in her right eye continued to increase, her visual acuity continued to worsen, and the corneal ulcer continued to grow. The treaters modified her medications, but nothing attempted was effective.

44. Given Mrs. Oliva's deteriorating vision and chronic pain in her right eye, she was scheduled to undergo a Penetrating Keratoplasty on August 29th. This procedure involves a complete transplant of the damaged or diseased cornea with a donor cornea.

45. On August 29, 2022, Mrs. Oliva underwent the Penetrating Keratoplasty procedure for visual rehabilitation of the right eye. However, intraoperatively the surgeon observed and noted scleral abscesses that extended well beyond the capabilities of the trephine or tool used to remove the damaged cornea. As a result, the damaged portions of the cornea could not be safely removed, and the procedure was aborted.

46. Given the severity of the infection in Mrs. Oliva's right eye, the exhaustion of treatment methods, and the risk of the infection spreading systematically creating a life-threatening condition, it was determined that an enucleation of Mrs. Oliva's right eye was the best option to control the severe antibiotic resistant infection.

47. Mrs. Oliva consulted with two ophthalmic plastic and reconstructive surgery specialists in the immediate days following the abandoned procedure. Both recommended enucleation of the right eye as soon as possible.

48. On September 1, 2022, Mrs. Oliva's right eye was surgically removed and replaced with a plastic implant. Given her decreased visual acuity of 20/200 in her remaining left eye, Mrs. Oliva is now legally blind.

49. As a direct and proximate result of the conduct of the Defendants in manufacturing, importing, compounding, assembling, packaging, distributing, supplying and marketing of the contaminated EzriCare Artificial Tears, Mrs. Oliva has been permanently injured both physically and emotionally. She now leads a difficult life that is markedly differing from what she had been accustomed to.

COUNT 1

CLAIM AGAINST DEFENDANT GLOBAL PHARMA HEALTHCARE PRIVATE LTD. **STRICT LIABILITY – MANUFACTURING DEFECT**

50. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

51. Defendant Global researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the EzriCare Artificial Tears product and therefore had a duty to create a product that was not defective.

52. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant Global was defective because of a manufacturing defect.

53. The product reached Mrs. Oliva in an unreasonably dangerous condition.

54. The product reached Mrs. Oliva without substantial change affecting its condition.

55. The product was unreasonably dangerous because of a manufacturing defect because it was different from its intended design and failed to perform as safely as the intended design would have performed, since the intended design was intended to be sterile and not contaminated with *pseudomonas aeruginosa* bacteria that can cause severe infections, leading to life-threatening complications.

56. The Defendant's defective product directly and proximately caused Plaintiff Mrs. Oliva permanent damages as alleged in detail below.

COUNT 2

CLAIM AGAINST DEFENDANT EZRICARE, LLC
STRICT LIABILITY – MANUFACTURING DEFECT

57. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

58. Defendant EzriCare researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the EzriCare Artificial Tears product and therefore had a duty to create a product that was not defective.

59. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant EzriCare was defective because of a manufacturing defect.

60. The product reached Mrs. Oliva in an unreasonably dangerous condition.

61. The product reached Mrs. Oliva without substantial change affecting its condition.

62. The product was unreasonably dangerous because of a manufacturing defect because it was different from its intended design and failed to perform as safely as the intended design would have performed, since the intended design was intended to be sterile and not contaminated with *pseudomonas aeruginosa* bacteria that can cause severe infections, leading to life-threatening complications.

63. The Defendant's defective product directly and proximately caused Plaintiff Mrs. Oliva permanent damages as alleged in detail below.

COUNT 3

CLAIM AGAINST DEFENDANT EZRIRX, LLC
STRICT LIABILITY – MANUFACTURING DEFECT

64. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

65. Defendant EzriRx researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the EzriCare Artificial Tears product and therefore had a duty to create a product that

was not defective.

66. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant EzriRx was defective because of a manufacturing defect.

67. The product reached Mrs. Oliva in an unreasonably dangerous condition.

68. The product reached Mrs. Oliva without substantial change affecting its condition.

69. The product was unreasonably dangerous because of a manufacturing defect because it was different from its intended design and failed to perform as safely as the intended design would have performed, since the intended design was intended to be sterile and not contaminated with *pseudomonas aeruginosa* bacteria that can cause severe infections, leading to life-threatening complications.

70. The Defendant's defective product directly and proximately caused Plaintiff Mrs. Oliva permanent damages as alleged in detail below.

COUNT 4

CLAIM AGAINST DEFENDANT ARU PHARMA, INC. **STRICT LIABILITY – MANUFACTURING DEFECT**

71. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

72. Defendant Aru researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the EzriCare Artificial Tears product and therefore had a duty to create a product that was not defective.

73. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant Aru was defective because of a manufacturing defect.

74. The product reached Mrs. Oliva in an unreasonably dangerous condition.

75. The product reached Mrs. Oliva without substantial change affecting its condition.

76. The product was unreasonably dangerous because of a manufacturing defect

because it was different from its intended design and failed to perform as safely as the intended design would have performed, since the intended design was intended to be sterile and not contaminated with *pseudomonas aeruginosa* bacteria that can cause severe infections, leading to life-threatening complications.

77. The Defendant's defective product directly and proximately caused Plaintiff Mrs. Oliva permanent damages as alleged in detail below.

COUNT 5

CLAIM AGAINST DEFENDANT LEON MEDICAL CENTERS, LLC **STRICT LIABILITY – MANUFACTURING DEFECT**

78. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

79. Defendant Leon researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the EzriCare Artificial Tears product and therefore had a duty to create a product that was not defective.

80. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant Leon was defective because of a manufacturing defect.

81. The product reached Mrs. Oliva in an unreasonably dangerous condition.

82. The product reached Mrs. Oliva without substantial change affecting its condition.

83. The product was unreasonably dangerous because of a manufacturing defect because it was different from its intended design and failed to perform as safely as the intended design would have performed, since the intended design was intended to be sterile and not contaminated with *pseudomonas aeruginosa* bacteria that can cause severe infections, leading to life-threatening complications.

84. The Defendant's defective product directly and proximately caused Plaintiff Mrs. Oliva permanent damage as alleged in detail below.

COUNT 6

**CLAIM AGAINST DEFENDANT HEALTHSPRING OF FLORIDA, INC.,
d/b/a LEON MEDICAL CENTER HEALTH PLANS
STRICT LIABILITY – MANUFACTURING DEFECT**

85. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

86. Defendant HealthSpring researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the EzriCare Artificial Tears product and therefore had a duty to create a product that was not defective.

87. The product created, designed, manufactured, distributed, sold, and/or supplied by Defendant HealthSpring was defective because of a manufacturing defect.

88. The product reached Mrs. Oliva in an unreasonably dangerous condition.

89. The product reached Mrs. Oliva without substantial change affecting its condition.

90. The product was unreasonably dangerous because of a manufacturing defect because it was different from its intended design and failed to perform as safely as the intended design would have performed, since the intended design was intended to be sterile and not contaminated with *pseudomonas aeruginosa* bacteria that can cause severe infections, leading to life-threatening complications.

91. The Defendant's defective product directly and proximately caused Plaintiff Mrs. Oliva permanent damage as alleged in detail below.

COUNT 7

**CLAIM AGAINST DEFENDANT GLOBAL PHARMA HEALTHCARE PRIVATE LTD.
STRICT LIABILITY – DESIGN DEFECT**

92. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

93. Defendant Global researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream

of commerce the product, and directly advertised or marketed the product to Plaintiff Mrs. Oliva, and therefore had a duty to create a product that was not defective.

94. The product is defective because it was in a condition unreasonably dangerous to Plaintiff Mrs. Oliva when created, designed, manufactured, distributed, sold, and/or supplied by Defendant Global.

95. The product reached Mrs. Oliva without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Global.

96. The product had a design defect because it failed to perform as safely as an ordinary consumer would expect when used as intended, causing permanent damage to Mrs. Oliva.

97. The product's risk of danger in the design, by not including preservatives in multiuse bottles, which is discouraged by the FDA because it can enable bacteria growth, outweighs the potential benefits of exclusion.

98. Defendant Global, through the defective product, directly and proximately caused Plaintiff Mrs. Oliva serious permanent damage as set forth below.

COUNT 8

CLAIM AGAINST DEFENDANT EZRICARE, LLC **STRICT LIABILITY – DESIGN DEFECT**

99. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

100. Defendant EzriCare researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Plaintiff Mrs. Oliva, and therefore had a duty to create a product that was not defective.

101. The product is defective because it was in a condition unreasonably dangerous to Plaintiff Mrs. Oliva when created, designed, manufactured, distributed, sold, and/or supplied by Defendant EzriCare.

102. The product reached Mrs. Oliva without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant EzriCare.

103. The product had a design defect because it failed to perform as safely as an ordinary consumer would expect when used as intended, causing permanent damage to Mrs. Oliva.

104. The product's risk of danger in the design, by not including preservatives in multiuse bottles, which is discouraged by the FDA because it can enable bacteria growth, outweighs the potential benefits of exclusion.

105. Defendant EzriCare, through the defective product, directly and proximately caused Plaintiff Mrs. Oliva serious permanent damage and she claims the damages set forth below.

COUNT 9

CLAIM AGAINST DEFENDANT EZRIRX, LLC **STRICT LIABILITY – DESIGN DEFECT**

106. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

107. Defendant EzriRx researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Plaintiff Mrs. Oliva, and therefore had a duty to create a product that was not defective.

108. The product is defective because it was in a condition unreasonably dangerous to Plaintiff Mrs. Oliva when created, designed, manufactured, distributed, sold, and/or supplied by Defendant EzriRx.

109. The product reached Mrs. Oliva without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant EzriRx.

110. The product had a design defect because it failed to perform as safely as an ordinary consumer would expect when used as intended, causing permanent damage to Mrs. Oliva.

111. The product's risk of danger in the design, by not including preservatives in

multiuse bottles, which is discouraged by the FDA because it can enable bacteria growth, outweighs the potential benefits of exclusion.

112. Defendant EzriRx, through the defective product, directly and proximately caused Plaintiff Mrs. Oliva serious permanent damage and she claims the damages set forth below.

COUNT 10

CLAIM AGAINST DEFENDANT ARU PHARMA, INC. **STRICT LIABILITY – DESIGN DEFECT**

113. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

114. Defendant Aru researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Plaintiff Mrs. Oliva, and therefore had a duty to create a product that was not defective.

115. The product is defective because it was in a condition unreasonably dangerous to Plaintiff Mrs. Oliva when created, designed, manufactured, distributed, sold, and/or supplied by Defendant Aru.

116. The product reached Mrs. Oliva without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Aru.

117. The product had a design defect because it failed to perform as safely as an ordinary consumer would expect when used as intended, causing permanent damage to Mrs. Oliva.

118. The product's risk of danger in the design, by not including preservatives in multiuse bottles, which is discouraged by the FDA because it can enable bacteria growth, outweighs the potential benefits of exclusion.

119. Defendant Aru, through the defective product, directly and proximately caused Plaintiff Mrs. Oliva serious permanent damage and she claims the damages set forth below.

COUNT 11

CLAIM AGAINST DEFENDANT LEON MEDICAL CENTERS, LLC
STRICT LIABILITY – DESIGN DEFECT

120. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

121. Defendant Leon researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Plaintiff Mrs. Oliva, and therefore had a duty to create a product that was not defective.

122. The product is defective because it was in a condition unreasonably dangerous to Plaintiff Mrs. Oliva when created, designed, manufactured, distributed, sold, and/or supplied by Defendant Leon.

123. The product reached Mrs. Oliva without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant Leon.

124. The product had a design defect because it failed to perform as safely as an ordinary consumer would expect when used as intended, causing permanent damage to Mrs. Oliva.

125. The product's risk of danger in the design, by not including preservatives in multiuse bottles, which is discouraged by the FDA because it can enable bacteria growth, outweighs the potential benefits of exclusion.

126. Defendant Leon, through the defective product, directly and proximately caused Plaintiff Mrs. Oliva serious permanent damage and she claims the damages set forth below.

COUNT 12

CLAIM AGAINST DEFENDANT HEALTHSPRING OF FLORIDA, INC.
d/b/a LEON MEDICAL CENTERS HEALTH PLANS
STRICT LIABILITY – DESIGN DEFECT

127. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

128. Defendant HealthSpring researched, developed, designed, tested, manufactured,

inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Plaintiff Mrs. Oliva, and therefore had a duty to create a product that was not defective.

129. The product is defective because it was in a condition unreasonably dangerous to Plaintiff Mrs. Oliva when created, designed, manufactured, distributed, sold, and/or supplied by Defendant HealthSpring.

130. The product reached Mrs. Oliva without substantial change affecting that condition after creation, design, manufacture, distribution, sale, and/or supply by Defendant HealthSpring.

131. The product had a design defect because it failed to perform as safely as an ordinary consumer would expect when used as intended, causing permanent damage to Mrs. Oliva.

132. The product's risk of danger in the design, by not including preservatives in multiuse bottles, which is discouraged by the FDA because it can enable bacteria growth, outweighs the potential benefits of exclusion.

133. Defendant HealthSpring, through the defective product, directly and proximately caused Plaintiff Mrs. Oliva serious permanent damage and she claims the damages set forth below.

COUNT 13

CLAIM AGAINST DEFENDANT GLOBAL PHARMA HEALTHCARE PRIVATE LTD. STRICT LIABILITY – FAILURE TO WARN

134. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

135. Defendant Global researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty to warn of the risks associated with the use of the product.

136. The product was under the control of Defendant Global and was unaccompanied by appropriate warnings regarding the risk of developing severe infections. No warnings

accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to Mrs. Oliva.

137. Defendant Global had a duty to warn Plaintiff Mrs. Oliva about the dangers of the presence of *pseudomonas aeruginosa* bacteria in the contaminated EzriCare Artificial Tears product yet failed to do so.

138. Defendant Global downplayed the potential serious and dangerous side effects of the contaminated product to encourage the sale of the product.

139. The product was defective and unreasonably dangerous when it left the possession of Defendant Global in that it contained warnings insufficient to alert Mrs. Oliva to the dangerous risks and reactions associated with it, including, but not limited to severe infections. The particular risks were known, or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Even though the Defendant knew or should have known the risks associated with the product, specifically that their artificial tears were contaminated with a dangerous and deadly bacterium, Defendant Global still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

140. The product reached Mrs. Oliva without substantial change affecting that condition after creation design manufacture, distribution, sale, and/or supply by Defendant Global.

141. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant Global by providing reasonable instructions or warnings about the high likelihood of adverse events such as infections, pain, and damage to the eyes via the contaminated product and the failure to provide those instruction or warnings makes the product unreasonably dangerous.

142. Plaintiff Mrs. Oliva used the product in the manner as indicated by Defendant Global.

143. Plaintiff Mrs. Oliva did not have the same knowledge as Defendant Global, and no adequate warning was communicated to her.

144. As a direct and proximate consequence of Defendant Global's actions, omissions, and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage as alleged in detail below.

COUNT 14

CLAIM AGAINST DEFENDANT EZRICARE, LLC **STRICT LIABILITY – FAILURE TO WARN**

145. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

146. Defendant EzriCare researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty to warn of the risks associated with the use of the product.

147. The product was under the control of Defendant EzriCare and was unaccompanied by appropriate warnings regarding the risk of developing severe infections. No warnings accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to Mrs. Oliva.

148. Defendant EzriCare had a duty to warn Plaintiff Mrs. Oliva about the dangers of the presence of *pseudomonas aeruginosa* bacteria in the contaminated EzriCare Artificial Tears product yet failed to do so.

149. Defendant EzriCare downplayed the potential serious and dangerous side effects of the contaminated product to encourage the sale of the product.

150. The product was defective and unreasonably dangerous when it left the possession of Defendant EzriCare in that it contained warnings insufficient to alert Mrs. Oliva to the dangerous risks and reactions associated with it, including, but not limited to severe infections. The particular risks were known, or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Even

though the Defendant knew or should have known the risks associated with the product, specifically that their artificial tears were contaminated with a dangerous and deadly bacterium, Defendant EzriCare still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

151. The product reached Mrs. Oliva without substantial change affecting that condition after creation design manufacture, distribution, sale, and/or supply by Defendant EzriCare.

152. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant EzriCare by providing reasonable instructions or warnings about the high likelihood of adverse events such as infections, pain, and damage to the eyes via the contaminated product and the failure to provide those instruction or warnings makes the product unreasonably dangerous.

153. Plaintiff Mrs. Oliva used the product in the manner as indicated by Defendant EzriCare.

154. Plaintiff Mrs. Oliva did not have the same knowledge as Defendant EzriCare, and no adequate warning was communicated to her.

155. As a direct and proximate consequence of Defendant EzriCare's actions, omissions, and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage as alleged in detail below.

COUNT 15

CLAIM AGAINST DEFENDANT EZRIRX, LLC **STRICT LIABILITY – FAILURE TO WARN**

156. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

157. Defendant EzriRx researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty to warn of the risks associated with the use of the product.

158. The product was under the control of Defendant EzriRx and was unaccompanied by appropriate warnings regarding the risk of developing severe infections. No warnings accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to Mrs. Oliva.

159. Defendant EzriRx had a duty to warn Plaintiff Mrs. Oliva about the dangers of the presence of *pseudomonas aeruginosa* bacteria in the contaminated EzriCare Artificial Tears product yet failed to do so.

160. Defendant EzriRx downplayed the potential serious and dangerous side effects of the contaminated product to encourage the sale of the product.

161. The product was defective and unreasonably dangerous when it left the possession of Defendant EzriRx in that it contained warnings insufficient to alert Mrs. Oliva to the dangerous risks and reactions associated with it, including, but not limited to severe infections. The particular risks were known, or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Even though the Defendant knew or should have known the risks associated with the product, specifically that their artificial tears were contaminated with a dangerous and deadly bacterium, Defendant EzriRx still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

162. The product reached Mrs. Oliva without substantial change affecting that condition after creation design manufacture, distribution, sale, and/or supply by Defendant EzriRx.

163. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant EzriRx by providing reasonable instructions or warnings about the high likelihood of adverse events such as infections, pain, and damage to the eyes via the contaminated product and the failure to provide those instruction or warnings makes the product unreasonably dangerous.

164. Plaintiff Mrs. Oliva used the product in the manner as indicated by Defendant EzriRx.

165. Plaintiff Mrs. Oliva did not have the same knowledge as Defendant EzriRx, and no adequate warning was communicated to her.

166. As a direct and proximate consequence of Defendant EzriRx's actions, omissions, and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage as alleged in detail below.

COUNT 16

CLAIM AGAINST DEFENDANT ARU PHARMA, LLC **STRICT LIABILITY – FAILURE TO WARN**

167. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

168. Defendant Aru researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty to warn of the risks associated with the use of the product.

169. The product was under the control of Defendant Aru and was unaccompanied by appropriate warnings regarding the risk of developing severe infections. No warnings accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to Mrs. Oliva.

170. Defendant Aru had a duty to warn Plaintiff Mrs. Oliva about the dangers of the presence of *pseudomonas aeruginosa* bacteria in the contaminated EzriCare Artificial Tears product yet failed to do so.

171. Defendant Aru downplayed the potential serious and dangerous side effects of the contaminated product to encourage the sale of the product.

172. The product was defective and unreasonably dangerous when it left the possession of Defendant Aru in that it contained warnings insufficient to alert Mrs. Oliva to the dangerous risks and reactions associated with it, including, but not limited to severe infections. The particular

risks were known, or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Even though the Defendant knew or should have known the risks associated with the product, specifically that their artificial tears were contaminated with a dangerous and deadly bacterium, Defendant Aru still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

173. The product reached Mrs. Oliva without substantial change affecting that condition after creation design manufacture, distribution, sale, and/or supply by Defendant Aru.

174. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant Aru by providing reasonable instructions or warnings about the high likelihood of adverse events such as infections, pain, and damage to the eyes via the contaminated product and the failure to provide those instruction or warnings makes the product unreasonably dangerous.

175. Plaintiff Mrs. Oliva used the product in the manner as indicated by Defendant Aru.

176. Plaintiff Mrs. Oliva did not have the same knowledge as Defendant Aru, and no adequate warning was communicated to her.

177. As a direct and proximate consequence of Defendant Aru's actions, omissions, and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage as alleged in detail below.

COUNT 17

CLAIM AGAINST DEFENDANT LEON MEDICAL CENTERS, LLC **STRICT LIABILITY – FAILURE TO WARN**

178. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

179. Defendant Leon researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of

commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty to warn of the risks associated with the use of the product.

180. The product was under the control of Defendant Leon and was unaccompanied by appropriate warnings regarding the risk of developing severe infections. No warnings accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to Mrs. Oliva.

181. Defendant Leon had a duty to warn Plaintiff Mrs. Oliva about the dangers of the presence of *pseudomonas aeruginosa* bacteria in the contaminated EzriCare Artificial Tears product yet failed to do so.

182. Defendant Leon downplayed the potential serious and dangerous side effects of the contaminated product to encourage the sale of the product.

183. The product was defective and unreasonably dangerous when it left the possession of Defendant Leon in that it contained warnings insufficient to alert Mrs. Oliva to the dangerous risks and reactions associated with it, including, but not limited to severe infections. The particular risks were known, or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Even though the Defendant knew or should have known the risks associated with the product, specifically that their artificial tears were contaminated with a dangerous and deadly bacterium, Defendant Leon still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

184. The product reached Mrs. Oliva without substantial change affecting that condition after creation design manufacture, distribution, sale, and/or supply by Defendant Leon.

185. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant Leon by providing reasonable instructions or warnings about the high likelihood of adverse events such as infections, pain, and damage to the eyes via

the contaminated product and the failure to provide those instruction or warnings makes the product unreasonably dangerous.

186. Plaintiff Mrs. Oliva used the product in the manner as indicated by Defendant Leon.

187. Plaintiff Mrs. Oliva did not have the same knowledge as Defendant Leon, and no adequate warning was communicated to her.

188. As a direct and proximate consequence of Defendant Leon's actions, omissions, and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage as alleged in detail below.

COUNT 18

CLAIM AGAINST DEFENDANT HEALTHSPRING OF FLORIDA, INC. **d/b/a LEON MEDICAL CENTERS HEALTH PLANS** **STRICT LIABILITY – FAILURE TO WARN**

189. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

190. Defendant HealthSpring researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty to warn of the risks associated with the use of the product.

191. The product was under the control of Defendant HealthSpring and was unaccompanied by appropriate warnings regarding the risk of developing severe infections. No warnings accurately reflect the risk, incidence, symptoms, scope, or severity of such injuries to Mrs. Oliva.

192. Defendant HealthSpring had a duty to warn Plaintiff Mrs. Oliva about the dangers of the presence of *pseudomonas aeruginosa* bacteria in the contaminated EzriCare Artificial Tears product yet failed to do so.

193. Defendant HealthSpring downplayed the potential serious and dangerous side effects of the contaminated product to encourage the sale of the product.

194. The product was defective and unreasonably dangerous when it left the possession of Defendant HealthSpring in that it contained warnings insufficient to alert Mrs. Oliva to the dangerous risks and reactions associated with it, including, but not limited to severe infections. The particular risks were known, or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Even though the Defendant knew or should have known the risks associated with the product, specifically that their artificial tears were contaminated with a dangerous and deadly bacterium, Defendant HealthSpring still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

195. The product reached Mrs. Oliva without substantial change affecting that condition after creation design manufacture, distribution, sale, and/or supply by Defendant HealthSpring.

196. The product was defective because the foreseeable risks of harm from the product could have been avoided by Defendant HealthSpring by providing reasonable instructions or warnings about the high likelihood of adverse events such as infections, pain, and damage to the eyes via the contaminated product and the failure to provide those instruction or warnings makes the product unreasonably dangerous.

197. Plaintiff Mrs. Oliva used the product in the manner as indicated by Defendant HealthSpring.

198. Plaintiff Mrs. Oliva did not have the same knowledge as Defendant HealthSpring, and no adequate warning was communicated to her.

199. As a direct and proximate consequence of Defendant HealthSpring's actions, omissions, and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage as alleged in detail below.

COUNT 19

CLAIM AGAINST DEFENDANT GLOBAL PHARMA HEALTHCARE PRIVATE LTD.
NEGLIGENCE - PRODUCT LIABILITY

200. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

201. Defendant Global researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty of reasonable care to Mrs. Oliva, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and/or supplier would use under like circumstances.

202. Notwithstanding this duty of care, Defendant Global breached its duty of care to Mrs. Oliva in the following ways:

- a. Negligently failing to manufacture a product safe for consumers that was not adulterated or contaminated with, *pseudomonas aeruginosa*, a dangerous and rare pathogen;
- b. Negligently failing to properly supervise, train or monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with Defendant's operating standards;
- c. Negligently failing to properly supervise, train or monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with all applicable health and safety regulations;
- d. Negligently failing to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling and sale of the EzriCare Artificial Tears product, including all applicable local, state, and federal health and safety regulations;
- e. Negligently violating federal, state, and local safety regulations in its manufacturing, distribution and sale of the contaminated EzriCare Artificial Tears product;
- f. Negligently violating Defendant's current good manufacturing practices (CGMP), including the lack of appropriate microbial testing, formulation issues, and lack of proper controls concerning tamper-evident packaging;

- g. Negligently failing to thoroughly and regularly inspect its facility to determine whether it was reasonably safe and appropriate for manufacturing and preparing EzriCare Artificial Tears multidose bottles in bulk;
- h. Negligently failing to have inspections over a period of time to assure uniformity in the performance of the facility;
- i. Negligently failing to conduct appropriate due diligence on its sources for the product and the product's component parts;
- j. Negligently failing to implement and enforce appropriate controls to ensure the safety and sterility of the product;
- k. Negligently allowing the product to remain in the market and stream of commerce notwithstanding that it knew or should have known about adverse effects associated with the contaminated product;
- l. Negligently failing to conduct appropriate follow up research on patients to determine safety of the product;
- m. Negligently failing to warn Plaintiff Mrs. Oliva of the serious and dangerous side effects of the contaminated product to encourage sales of the product;
- n. Negligently failing to warn Plaintiff Mrs. Oliva of the risk, incidence, symptoms, scope, or severity of the injuries produced by the contaminated product to Mrs. Oliva;
- o. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as infections, vision loss, and death; and
- p. Other negligent failures as determined in discovery.

203. As a direct and proximate consequence of Defendant Global's actions, omissions, and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage, as described in detail below.

COUNT 20

CLAIM AGAINST DEFENDANT EZRICARE, LLC
NEGLIGENCE - PRODUCT LIABILITY

204. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

205. Defendant EzriCare researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream

of commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty of reasonable care to Mrs. Oliva, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and/or supplier would use under like circumstances.

206. Notwithstanding this duty of care, Defendant EzriCare breached its duty of care to Mrs. Oliva in the following ways:

- a. Negligently failing to manufacture a product safe for consumers that was not adulterated or contaminated with, *pseudomonas aeruginosa*, a dangerous and rare pathogen;
- b. Negligently failing to properly supervise, train or monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with Defendant's operating standards;
- c. Negligently failing to properly supervise, train or monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with all applicable health and safety regulations;
- d. Negligently failing to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling and sale of the EzriCare Artificial Tears product, including all applicable local, state, and federal health and safety regulations;
- e. Negligently violating federal, state, and local safety regulations in its manufacturing, distribution and sale of the contaminated EzriCare Artificial Tears product;
- f. Negligently violating Defendant's current good manufacturing practices (CGMP), including the lack of appropriate microbial testing, formulation issues, and lack of proper controls concerning tamper-evident packaging;
- g. Negligently failing to thoroughly and regularly inspect its facility to determine whether it was reasonably safe and appropriate for manufacturing and preparing EzriCare Artificial Tears multidose bottles in bulk;
- h. Negligently failing to have inspections over a period of time to assure uniformity in the performance of the facility;
- i. Negligently failing to conduct appropriate due diligence on its sources for the product and the product's component parts;

- j. Negligently failing to implement and enforce appropriate controls to ensure the safety and sterility of the product;
- k. Negligently allowing the product to remain in the market and stream of commerce notwithstanding that it knew or should have known about adverse effects associated with the contaminated product;
- l. Negligently failing to conduct appropriate follow up research on patients to determine safety of the product;
- m. Negligently failing to warn Plaintiff Mrs. Oliva of the serious and dangerous side effects of the contaminated product to encourage sales of the product;
- n. Negligently failing to warn Plaintiff Mrs. Oliva of the risk, incidence, symptoms, scope, or severity of the injuries produced by the contaminated product to Mrs. Oliva;
- o. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as infections, vision loss, and death; and
- p. Other negligent failures as determined in discovery.

207. As a direct and proximate consequence of Defendant EzriCare's actions, omissions, and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage, as described in detail below.

COUNT 21

CLAIM AGAINST DEFENDANT EZRIRX, LLC **NEGLIGENCE - PRODUCT LIABILITY**

208. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

209. Defendant EzriRx researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty of reasonable care to Mrs. Oliva, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and/or supplier would use under like circumstances.

210. Notwithstanding this duty of care, Defendant EzriRx breached its duty of care to Mrs. Oliva in the following ways:

- a. Negligently failing to manufacture a product safe for consumers that was not adulterated or contaminated with, *pseudomonas aeruginosa*, a dangerous and rare pathogen;
- b. Negligently failing to properly supervise, train or monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with Defendant's operating standards;
- c. Negligently failing to properly supervise, train or monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with all applicable health and safety regulations;
- d. Negligently failing to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling and sale of the EzriCare Artificial Tears product, including all applicable local, state, and federal health and safety regulations;
- e. Negligently violating federal, state, and local safety regulations in its manufacturing, distribution and sale of the contaminated EzriCare Artificial Tears product;
- f. Negligently violating Defendant's current good manufacturing practices (CGMP), including the lack of appropriate microbial testing, formulation issues, and lack of proper controls concerning tamper-evident packaging;
- g. Negligently failing to thoroughly and regularly inspect its facility to determine whether it was reasonably safe and appropriate for manufacturing and preparing EzriCare Artificial Tears multidose bottles in bulk;
- h. Negligently failing to have inspections over a period of time to assure uniformity in the performance of the facility;
- i. Negligently failing to conduct appropriate due diligence on its sources for the product and the product's component parts;
- j. Negligently failing to implement and enforce appropriate controls to ensure the safety and sterility of the product;
- k. Negligently allowing the product to remain in the market and stream of commerce notwithstanding that it knew or should have known about adverse effects associated with the contaminated product;

- l. Negligently failing to conduct appropriate follow up research on patients to determine safety of the product;
- m. Negligently failing to warn Plaintiff Mrs. Oliva of the serious and dangerous side effects of the contaminated product to encourage sales of the product;
- n. Negligently failing to warn Plaintiff Mrs. Oliva of the risk, incidence, symptoms, scope, or severity of the injuries produced by the contaminated product to Mrs. Oliva;
- o. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as infections, vision loss, and death; and
- p. Other negligent failures as determined in discovery.

211. As a direct and proximate consequence of Defendant EzriRx's actions, omissions, and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage as described in detail below.

COUNT 22

CLAIM AGAINST DEFENDANT ARU PHARMA, LLC **NEGLIGENCE - PRODUCT LIABILITY**

212. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

213. Defendant Aru researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty of reasonable care to Mrs. Oliva, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and/or supplier would use under like circumstances.

214. Notwithstanding this duty of care, Defendant Aru breached its duty of care to Mrs. Oliva in the following ways:

- a. Negligently failing to manufacture a product safe for consumers that was not adulterated or contaminated with, *pseudomonas aeruginosa*, a dangerous and rare pathogen;
- b. Negligently failing to properly supervise, train or monitor its employees, or the

employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with Defendant's operating standards;

- c. Negligently failing to properly supervise, train or monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with all applicable health and safety regulations;
- d. Negligently failing to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling and sale of the EzriCare Artificial Tears product, including all applicable local, state, and federal health and safety regulations;
- e. Negligently violating federal, state, and local safety regulations in its manufacturing, distribution and sale of the contaminated EzriCare Artificial Tears product;
- f. Negligently violating Defendant's current good manufacturing practices (CGMP), including the lack of appropriate microbial testing, formulation issues, and lack of proper controls concerning tamper-evident packaging;
- g. Negligently failing to thoroughly and regularly inspect its facility to determine whether it was reasonably safe and appropriate for manufacturing and preparing EzriCare Artificial Tears multidose bottles in bulk;
- h. Negligently failing to have inspections over a period of time to assure uniformity in the performance of the facility;
- i. Negligently failing to conduct appropriate due diligence on its sources for the product and the product's component parts;
- j. Negligently failing to implement and enforce appropriate controls to ensure the safety and sterility of the product;
- k. Negligently allowing the product to remain in the market and stream of commerce notwithstanding that it knew or should have known about adverse effects associated with the contaminated product;
- l. Negligently failing to conduct appropriate follow up research on patients to determine safety of the product;
- m. Negligently failing to warn Plaintiff Mrs. Oliva of the serious and dangerous side effects of the contaminated product to encourage sales of the product;
- n. Negligently failing to warn Plaintiff Mrs. Oliva of the risk, incidence, symptoms, scope, or severity of the injuries produced by the contaminated

product to Mrs. Oliva;

- o. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as infections, vision loss, and death; and
- p. Other negligent failures as determined in discovery.

215. As a direct and proximate consequence of Defendant Aru's actions, omissions, and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage, as described in detail below.

COUNT 23

CLAIM AGAINST DEFENDANT LEON MEDICAL CENTERS, LLC **NEGLIGENCE - PRODUCT LIABILITY**

216. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

217. Defendant Leon researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty of reasonable care to Mrs. Oliva, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and/or supplier would use under like circumstances.

218. Notwithstanding this duty of care, Defendant Leon breached its duty of care to Mrs. Oliva in the following ways:

- a. Negligently failing to manufacture a product safe for consumers that was not adulterated or contaminated with, *pseudomonas aeruginosa*, a dangerous and rare pathogen;
- b. Negligently failing to properly supervise, train or monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with Defendant's operating standards;
- c. Negligently failing to properly supervise, train or monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with all applicable health and safety regulations;

- d. Negligently failing to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling and sale of the EzriCare Artificial Tears product, including all applicable local, state, and federal health and safety regulations;
 - e. Negligently violating federal, state, and local safety regulations in its manufacturing, distribution and sale of the contaminated EzriCare Artificial Tears product;
 - f. Negligently violating Defendant's current good manufacturing practices (CGMP), including the lack of appropriate microbial testing, formulation issues, and lack of proper controls concerning tamper-evident packaging;
 - g. Negligently failing to thoroughly and regularly inspect its facility to determine whether it was reasonably safe and appropriate for manufacturing and preparing EzriCare Artificial Tears multidose bottles in bulk;
 - h. Negligently failing to have inspections over a period of time to assure uniformity in the performance of the facility;
 - i. Negligently failing to conduct appropriate due diligence on its sources for the product and the product's component parts;
 - j. Negligently failing to implement and enforce appropriate controls to ensure the safety and sterility of the product;
 - k. Negligently allowing the product to remain in the market and stream of commerce notwithstanding that it knew or should have known about adverse effects associated with the contaminated product;
 - l. Negligently failing to conduct appropriate follow up research on patients to determine safety of the product;
 - m. Negligently failing to warn Plaintiff Mrs. Oliva of the serious and dangerous side effects of the contaminated product to encourage sales of the product;
 - n. Negligently failing to warn Plaintiff Mrs. Oliva of the risk, incidence, symptoms, scope, or severity of the injuries produced by the contaminated product to Mrs. Oliva;
 - o. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as infections, vision loss, and death; and
 - p. Other negligent failures as determined in discovery.
219. As a direct and proximate consequence of Defendant Leon's actions, omissions,

and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage, as described in detail below.

COUNT 24

CLAIM AGAINST DEFENDANT HEALTHSPRING OF FLORIDA, INC.
d/b/a LEON MEDICAL CENTERS HEALTH PLANS
NEGLIGENCE - PRODUCT LIABILITY

220. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

221. Defendant HealthSpring researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and/or otherwise released into the stream of commerce the product, and directly advertised or marketed the product to Mrs. Oliva, and therefore had a duty of reasonable care to Mrs. Oliva, which is the care that a reasonably careful designer, manufacturer, seller, importer, distributor, and/or supplier would use under like circumstances.

222. Notwithstanding this duty of care, Defendant HealthSpring breached its duty of care to Mrs. Oliva in the following ways:

- a. Negligently failing to manufacture a product safe for consumers that was not adulterated or contaminated with, *pseudomonas aeruginosa*, a dangerous and rare pathogen;
- b. Negligently failing to properly supervise, train or monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with Defendant's operating standards;
- c. Negligently failing to properly supervise, train or monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of EzriCare Artificial Tears, to ensure compliance with all applicable health and safety regulations;
- d. Negligently failing to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling and sale of the EzriCare Artificial Tears product, including all applicable local, state, and federal health and safety regulations;

- e. Negligently violating federal, state, and local safety regulations in its manufacturing, distribution and sale of the contaminated EzriCare Artificial Tears product;
- f. Negligently violating Defendant's current good manufacturing practices (CGMP), including the lack of appropriate microbial testing, formulation issues, and lack of proper controls concerning tamper-evident packaging;
- g. Negligently failing to thoroughly and regularly inspect its facility to determine whether it was reasonably safe and appropriate for manufacturing and preparing EzriCare Artificial Tears multidose bottles in bulk;
- h. Negligently failing to have inspections over a period of time to assure uniformity in the performance of the facility;
- i. Negligently failing to conduct appropriate due diligence on its sources for the product and the product's component parts;
- j. Negligently failing to implement and enforce appropriate controls to ensure the safety and sterility of the product;
- k. Negligently allowing the product to remain in the market and stream of commerce notwithstanding that it knew or should have known about adverse effects associated with the contaminated product;
- l. Negligently failing to conduct appropriate follow up research on patients to determine safety of the product;
- m. Negligently failing to warn Plaintiff Mrs. Oliva of the serious and dangerous side effects of the contaminated product to encourage sales of the product;
- n. Negligently failing to warn Plaintiff Mrs. Oliva of the risk, incidence, symptoms, scope, or severity of the injuries produced by the contaminated product to Mrs. Oliva;
- o. Negligently failing to provide reasonable instructions and warnings about the high likelihood of adverse events such as infections, vision loss, and death; and
- p. Other negligent failures as determined in discovery.

223. As a direct and proximate consequence of Defendant HealthSpring's actions, omissions, and misrepresentations, Plaintiff Mrs. Oliva suffered permanent damage, as described in detail below.

COUNT 25

CLAIM AGAINST DEFENDANT GLOBAL PHARMA HEALTHCARE PRIVATE LTD.
EXPRESS WARRANTY

224. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

225. The product inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant Global was defective because it did not conform to representations of fact made by Defendant Global, orally and in writing, through its employees and agents, in connection with the transaction on which Plaintiff Mrs. Oliva relied in the use of the product.

226. Defendant Global represented the fact that the EzriCare Artificial Tears were safe, fit for the purposes intended, that they were of merchantable quality, and that they did not pose significant and dangerous health risks. Moreover, the labeling on the EzriCare Artificial Tears product represents that the use of these artificial tears serves to protect the eye from dryness and/or irritation and that the product is safe for use in the consumer's eye.

227. Such statements constitute an affirmation of fact or promise or a description of the product as being safe, sterile and not posing serious health risks.

228. Manufacturing, distributing, selling, and supplying a product with an express promise that the product is safe to be used in one's eyes requires safeguards not taken by Defendant Global and expertise not possessed by Defendant Global.

229. Defendant Global breached these express warranties because the EzriCare Artificial Tears product was not safe. Instead, the contaminated product poses serious and dangerous health risks because multiple lots across the country were contaminated with *pseudomonas aeruginosa*—a dangerous, drug resistant and deadly bacteria.

230. Defendant Global knew or should have known that the product did not conform to

its express warranties and representations and that, in fact, it was contaminated with a deadly pathogen known to cause severe human infection.

231. Defendant Global received notice of the breach of warranty when it became aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

232. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damage as alleged in detail below.

COUNT 26

CLAIM AGAINST DEFENDANT EZRICARE, LLC **EXPRESS WARRANTY**

233. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

234. The product inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant EzriCare was defective because it did not conform to representations of fact made by Defendant EzriCare, orally and in writing, through its employees and agents, in connection with the transaction on which Plaintiff Mrs. Oliva relied in the use of the product.

235. Defendant EzriCare represented the fact that the EzriCare Artificial Tears were safe, fit for the purposes intended, that they were of merchantable quality, and that they did not pose significant and dangerous health risks. Moreover, the labeling on the EzriCare Artificial Tears product represents that the use of these artificial tears serves to protect the eye from dryness and/or irritation and that the product is safe for use in the consumer's eye.

236. Such statements constitute an affirmation of fact or promise or a description of the product as being safe, sterile and not posing serious health risks.

237. Manufacturing, distributing, selling, and supplying a product with an express promise that the product is safe to be used in one's eyes requires safeguards not taken by Defendant

EzriCare and expertise not possessed by Defendant EzriCare.

238. Defendant EzriCare breached these express warranties because the EzriCare Artificial Tears product was not safe. Instead, the contaminated product poses serious and dangerous health risks because multiple lots across the country were contaminated with *pseudomonas aeruginosa*—a dangerous, drug resistant and deadly bacteria.

239. Defendant EzriCare knew or should have known that the product did not conform to its express warranties and representations and that, in fact, it was contaminated with a deadly pathogen known to cause severe human infection.

240. Defendant EzriCare received notice of the breach of warranty when it became aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

241. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 27

CLAIM AGAINST DEFENDANT EZRIRX, LLC **EXPRESS WARRANTY**

242. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

243. The product inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant EzriRx was defective because it did not conform to representations of fact made by Defendant EzriRx, orally and in writing, through its employees and agents, in connection with the transaction on which Plaintiff Mrs. Oliva relied in the use of the product.

244. Defendant EzriRx represented the fact that the EzriCare Artificial Tears were safe, fit for the purposes intended, that they were of merchantable quality, and that they did not pose significant and dangerous health risks. Moreover, the labeling on the EzriCare Artificial Tears

product represents that the use of these artificial tears serves to protect the eye from dryness and/or irritation and that the product is safe for use in the consumer's eye.

245. Such statements constitute an affirmation of fact or promise or a description of the product as being safe, sterile and not posing serious health risks.

246. Manufacturing, distributing, selling, and supplying a product with an express promise that the product is safe to be used in one's eyes requires safeguards not taken by Defendant EzriRx and expertise not possessed by Defendant EzriRx.

247. Defendant EzriRx breached these express warranties because the EzriCare Artificial Tears product was not safe. Instead, the contaminated product poses serious and dangerous health risks because multiple lots across the country were contaminated with *pseudomonas aeruginosa*—a dangerous, drug resistant and deadly bacteria.

248. Defendant EzriRx knew or should have known that the product did not conform to its express warranties and representations and that, in fact, it was contaminated with a deadly pathogen known to cause severe human infection.

249. Defendant EzriRx received notice of the breach of warranty when it became aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

250. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 28

CLAIM AGAINST DEFENDANT ARU PHARMA, LLC **EXPRESS WARRANTY**

251. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

252. The product inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant Aru was defective because it did

not conform to representations of fact made by Defendant Aru, orally and in writing, through its employees and agents, in connection with the transaction on which Plaintiff Mrs. Oliva relied in the use of the product.

253. Defendant Aru represented the fact that the EzriCare Artificial Tears were safe, fit for the purposes intended, that they were of merchantable quality, and that they did not pose significant and dangerous health risks. Moreover, the labeling on the EzriCare Artificial Tears product represents that the use of these artificial tears serves to protect the eye from dryness and/or irritation and that the product is safe for use in the consumer's eye.

254. Such statements constitute an affirmation of fact or promise or a description of the product as being safe, sterile and not posing serious health risks.

255. Manufacturing, distributing, selling, and supplying a product with an express promise that the product is safe to be used in one's eyes requires safeguards not taken by Defendant Aru and expertise not possessed by Defendant Aru.

256. Defendant Aru breached these express warranties because the EzriCare Artificial Tears product was not safe. Instead, the contaminated product poses serious and dangerous health risks because multiple lots across the country were contaminated with *pseudomonas aeruginosa*—a dangerous, drug resistant and deadly bacteria.

257. Defendant Aru knew or should have known that the product did not conform to its express warranties and representations and that, in fact, it was contaminated with a deadly pathogen known to cause severe human infection.

258. Defendant Aru received notice of the breach of warranty when it became aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

259. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs.

Oliva sustained serious permanent damages as alleged in detail below.

COUNT 29

CLAIM AGAINST DEFENDANT LEON COUNTY MEDICAL CENTERS, LLC
EXPRESS WARRANTY

260. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

261. The product inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant Leon was defective because it did not conform to representations of fact made by Defendant Leon, orally and in writing, through its employees and agents, in connection with the transaction on which Plaintiff Mrs. Oliva relied in the use of the product.

262. Defendant Leon represented the fact that the EzriCare Artificial Tears were safe, fit for the purposes intended, that they were of merchantable quality, and that they did not pose significant and dangerous health risks. Moreover, the labeling on the EzriCare Artificial Tears product represents that the use of these artificial tears serves to protect the eye from dryness and/or irritation and that the product is safe for use in the consumer's eye.

263. Such statements constitute an affirmation of fact or promise or a description of the product as being safe, sterile and not posing serious health risks.

264. Manufacturing, distributing, selling, and supplying a product with an express promise that the product is safe to be used in one's eyes requires safeguards not taken by Defendant Leon and expertise not possessed by Defendant Leon.

265. Defendant Leon breached these express warranties because the EzriCare Artificial Tears product was not safe. Instead, the contaminated product poses serious and dangerous health risks because multiple lots across the country were contaminated with *pseudomonas aeruginosa*—a dangerous, drug resistant and deadly bacteria.

266. Defendant Leon knew or should have known that the product did not conform to

its express warranties and representations and that, in fact, it was contaminated with a deadly pathogen known to cause severe human infection.

267. Defendant Leon received notice of the breach of warranty when it became aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

268. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 30

CLAIM AGAINST DEFENDANT HEALTHSPRING OF FLORIDA, INC. **d/b/a LEON MEDICAL CENTERS HEALTH PLANS** **EXPRESS WARRANTY**

269. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

270. The product inspected, distributed, marketed, promoted, sold, supplied, and otherwise released into the stream of commerce by Defendant HealthSpring was defective because it did not conform to representations of fact made by Defendant HealthSpring, orally and in writing, through its employees and agents, in connection with the transaction on which Plaintiff Mrs. Oliva relied in the use of the product.

271. Defendant HealthSpring represented the fact that the EzriCare Artificial Tears were safe, fit for the purposes intended, that they were of merchantable quality, and that they did not pose significant and dangerous health risks. Moreover, the labeling on the EzriCare Artificial Tears product represents that the use of these artificial tears serves to protect the eye from dryness and/or irritation and that the product is safe for use in the consumer's eye.

272. Such statements constitute an affirmation of fact or promise or a description of the product as being safe, sterile and not posing serious health risks.

273. Manufacturing, distributing, selling, and supplying a product with an express

promise that the product is safe to be used in one's eyes requires safeguards not taken by Defendant HealthSpring and expertise not possessed by Defendant HealthSpring.

274. Defendant HealthSpring breached these express warranties because the EzriCare Artificial Tears product was not safe. Instead, the contaminated product poses serious and dangerous health risks because multiple lots across the country were contaminated with *pseudomonas aeruginosa*—a dangerous, drug resistant and deadly bacteria.

275. Defendant HealthSpring knew or should have known that the product did not conform to its express warranties and representations and that, in fact, it was contaminated with a deadly pathogen known to cause severe human infection.

276. Defendant HealthSpring received notice of the breach of warranty when it became aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

277. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 31

CLAIM AGAINST DEFENDANT GLOBAL PHARMA HEALTHCARE PRIVATE LTD. IMPLIED WARRANTY OF MERCHANTABILITY

278. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

279. The product was defective because it was not reasonably fit for both the uses intended and the uses reasonably foreseeable by Defendant Global

280. As a matter of fact, the product is not fit for use as a product for any purpose.

281. The product was defective for the use intended by Defendant Global, namely, to protect the eye from dryness and/or irritation.

282. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant Global.

283. Plaintiff Mrs. Oliva justifiably relied on Defendant Global's representations about

the product when agreeing to use the product to treat her dry eyes.

284. Defendant Global received notice of the breach of warranty when it was made aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

285. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 32

CLAIM AGAINST DEFENDANT EZRICARE, LLC **IMPLIED WARRANTY OF MERCHANTABILITY**

286. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

287. The product was defective because it was not reasonably fit for both the uses intended and the uses reasonably foreseeable by Defendant EzriCare.

288. As a matter of fact, the product is not fit for use as a product for any purpose.

289. The product was defective for the use intended by Defendant EzriCare, namely, to protect the eye from dryness and/or irritation.

290. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant EzriCare.

291. Plaintiff Mrs. Oliva justifiably relied on Defendant EzriCare's representations about the product when agreeing to use the product to treat her dry eyes.

292. Defendant EzriCare received notice of the breach of warranty when it was made aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

293. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 33

CLAIM AGAINST DEFENDANT EZRIRX, LLC

IMPLIED WARRANTY OF MERCHANTABILITY

294. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

295. The product was defective because it was not reasonably fit for both the uses intended and the uses reasonably foreseeable by Defendant EzriRx.

296. As a matter of fact, the product is not fit for use as a product for any purpose.

297. The product was defective for the use intended by Defendant EzriRx, namely, to protect the eye from dryness and/or irritation.

298. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant EzriRx.

299. Plaintiff Mrs. Oliva justifiably relied on Defendant EzriRx's representations about the product when agreeing to use the product to treat her dry eyes.

300. Defendant EzriRx received notice of the breach of warranty when it was made aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

301. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 34

CLAIM AGAINST DEFENDANT ARU PHARMA, LLC
IMPLIED WARRANTY OF MERCHANTABILITY

302. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

303. The product was defective because it was not reasonably fit for both the uses intended and the uses reasonably foreseeable by Defendant Aru.

304. As a matter of fact, the product is not fit for use as a product for any purpose.

305. The product was defective for the use intended by Defendant Aru, namely, to protect the eye from dryness and/or irritation.

306. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant Aru.

307. Plaintiff Mrs. Oliva justifiably relied on Defendant Aru's representations about the product when agreeing to use the product to treat her dry eyes.

308. Defendant Aru received notice of the breach of warranty when it was made aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

309. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 35

CLAIM AGAINST DEFENDANT LEON MEDICAL CENTERS, LLC **IMPLIED WARRANTY OF MERCHANTABILITY**

310. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

311. The product was defective because it was not reasonably fit for both the uses intended and the uses reasonably foreseeable by Defendant Leon.

312. As a matter of fact, the product is not fit for use as a product for any purpose.

313. The product was defective for the use intended by Defendant Leon, namely, to protect the eye from dryness and/or irritation.

314. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant Leon.

315. Plaintiff Mrs. Oliva justifiably relied on Defendant Leon's representations about the product when agreeing to use the product to treat her dry eyes.

316. Defendant Leon received notice of the breach of warranty when it was made aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

317. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 36

CLAIM AGAINST DEFENDANT HEALTHSPRING OF FLORIDA, INC.
d/b/a LEON MEDICAL CENTERS HEALTH PLANS
IMPLIED WARRANTY OF MERCHANTABILITY

318. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

319. The product was defective because it was not reasonably fit for both the uses intended and the uses reasonably foreseeable by Defendant HealthSpring.

320. As a matter of fact, the product is not fit for use as a product for any purpose.

321. The product was defective for the use intended by Defendant HealthSpring, namely, to protect the eye from dryness and/or irritation.

322. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant HealthSpring.

323. Plaintiff Mrs. Oliva justifiably relied on Defendant HealthSpring's representations about the product when agreeing to use the product to treat her dry eyes.

324. Defendant HealthSpring received notice of the breach of warranty when it was made aware of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

325. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 37

CLAIM AGAINST DEFENDANT GLOBAL PHARMA HEALTHCARE PRIVATE LTD.
IMPLIED WARRANTY – FITNESS FOR A PARTICULAR PURPOSE

326. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

327. The product was defective because it was not reasonably fit for the specific purpose for which Defendant Global knowingly sold the product and for which, in reliance on the judgment of Defendant Global, the Plaintiff Mrs. Oliva purchased the product.

328. Defendant Global knowingly manufactured, distributed, supplied, sold and/or

promoted EzriCare Artificial Tears for the specific purpose of protecting and relieving consumers' eyes from dryness and/or irritation.

329. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant Global.

330. The product did not treat the Plaintiff's eye dryness or irritation. Rather, the product introduced a dangerous pathogen into Plaintiff's eyes and forced her to surgically remove an eye to avoid a life-threatening systematic infection.

331. Defendant Global received notice of the breach of warranty when it learned of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

332. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 38

CLAIM AGAINST DEFENDANT EZRICARE, LLC **IMPLIED WARRANTY – FITNESS FOR A PARTICULAR PURPOSE**

333. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

334. The product was defective because it was not reasonably fit for the specific purpose for which Defendant EzriCare knowingly sold the product and for which, in reliance on the judgment of Defendant EzriCare, the Plaintiff Mrs. Oliva purchased the product.

335. Defendant EzriCare knowingly manufactured, distributed, supplied, sold and/or promoted EzriCare Artificial Tears for the specific purpose of protecting and relieving consumers' eyes from dryness and/or irritation.

336. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant EzriCare.

337. The product did not treat the Plaintiff's eye dryness or irritation. Rather, the product introduced a dangerous pathogen into Plaintiff's eyes and forced her to surgically remove an eye

to avoid a life-threatening systematic infection.

338. Defendant EzriCare received notice of the breach of warranty when it learned of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

339. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 39

CLAIM AGAINST DEFENDANT EZRIRX, LLC **IMPLIED WARRANTY – FITNESS FOR A PARTICULAR PURPOSE**

340. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

341. The product was defective because it was not reasonably fit for the specific purpose for which Defendant EzriRx knowingly sold the product and for which, in reliance on the judgment of Defendant EzriRx, the Plaintiff Mrs. Oliva purchased the product.

342. Defendant EzriRx knowingly manufactured, distributed, supplied, sold and/or promoted EzriCare Artificial Tears for the specific purpose of protecting and relieving consumers' eyes from dryness and/or irritation.

343. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant EzriRx.

344. The product did not treat the Plaintiff's eye dryness or irritation. Rather, the product introduced a dangerous pathogen into Plaintiff's eyes and forced her to surgically remove an eye to avoid a life-threatening systematic infection.

345. Defendant EzriRx received notice of the breach of warranty when it learned of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

346. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 40

CLAIM AGAINST DEFENDANT ARU PHARMA, LLC
IMPLIED WARRANTY – FITNESS FOR A PARTICULAR PURPOSE

347. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

348. The product was defective because it was not reasonably fit for the specific purpose for which Defendant Aru knowingly sold the product and for which, in reliance on the judgment of Defendant Aru, the Plaintiff Mrs. Oliva purchased the product.

349. Defendant Aru knowingly manufactured, distributed, supplied, sold and/or promoted EzriCare Artificial Tears for the specific purpose of protecting and relieving consumers' eyes from dryness and/or irritation.

350. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant Aru.

351. The product did not treat the Plaintiff's eye dryness or irritation. Rather, the product introduced a dangerous pathogen into Plaintiff's eyes and forced her to surgically remove her remaining good eye to avoid a life-threatening systematic infection.

352. Defendant Aru received notice of the breach of warranty when it learned of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

353. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 41

CLAIM AGAINST DEFENDANT LEON MEDICAL CENTERS, LLC
IMPLIED WARRANTY – FITNESS FOR A PARTICULAR PURPOSE

354. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

355. The product was defective because it was not reasonably fit for the specific purpose for which Defendant Leon knowingly sold the product and for which, in reliance on the judgment

of Defendant Leon, the Plaintiff Mrs. Oliva purchased the product.

356. Defendant Leon knowingly manufactured, distributed, supplied, sold and/or promoted EzriCare Artificial Tears for the specific purpose of protecting and relieving consumers' eyes from dryness and/or irritation.

357. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant Leon.

358. The product did not treat the Plaintiff's eye dryness or irritation. Rather, the product introduced a dangerous pathogen into Plaintiff's eyes and forced her to surgically remove her remaining good eye to avoid a life-threatening systematic infection.

359. Defendant Leon received notice of the breach of warranty when it learned of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

360. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

COUNT 42

CLAIM AGAINST DEFENDANT HEALTHSPRING OF FLORIDA, INC. **d/b/a LEON MEDICAL CENTERS HEALTH PLANS** **IMPLIED WARRANTY – FITNESS FOR A PARTICULAR PURPOSE**

361. The Plaintiff adopts and realleges paragraphs 1 through 49 and further alleges:

362. The product was defective because it was not reasonably fit for the specific purpose for which Defendant HealthSpring knowingly sold the product and for which, in reliance on the judgment of Defendant HealthSpring, the Plaintiff Mrs. Oliva purchased the product.

363. Defendant HealthSpring knowingly manufactured, distributed, supplied, sold and/or promoted EzriCare Artificial Tears for the specific purpose of protecting and relieving consumers' eyes from dryness and/or irritation.

364. Privity of contract exists between Plaintiff Mrs. Oliva and Defendant HealthSpring.

365. The product did not treat the Plaintiff's eye dryness or irritation. Rather, the product introduced a dangerous pathogen into Plaintiff's eyes and forced her to surgically remove her remaining good eye to avoid a life-threatening systematic infection.

366. Defendant HealthSpring received notice of the breach of warranty when it learned of the CDC's ongoing investigation and the reported outbreak of *pseudomonas aeruginosa* associated with EzriCare Artificial Tears.

367. As a direct and proximate cause of the breach of warranty alleged, Plaintiff Mrs. Oliva sustained serious permanent damages as alleged in detail below.

DAMAGES CLAIMED BY PLAINTIFF CLARA ELVIRA OLIVA

368. The Plaintiff, as a direct and proximate result of the Defendants alleged above, has in the past and will in the future continue to suffer the following damages:

- a. Bodily injury;
- b. Pain and suffering;
- c. Disability;
- d. Disfigurement;
- e. Loss of the capacity for the enjoyment of life;
- f. Aggravation of pre-existing conditions;
- g. Medical and hospital care and expenses;
- h. Warranty damages;
- i. Out of pocket expenses;
- j. Rehabilitation expenses; and
- k. Mental distress.

WHEREFORE, Plaintiff Clara Elvira Oliva demands judgment against Defendants for damages in an amount in excess of the jurisdictional limits of this Court exclusive of interest and costs, and all such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

369. The Plaintiff demands trial by jury of all issues triable as of right.

Dated this 7th of March, 2023.

GROSSMAN ROTH YAFFA COHEN, P.A.

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