UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

BETTE KOWALCZYK, Plaintiff, vs. EZRICARE LLC; EZRIRX LLC; DELSAM PHARMA LLC; GLOBAL PHARMA HEALTHCARE PRIVATE LTD.; ARU PHARMA INC.; and AMAZON, INC. Defendants.	)	**Civil Action No. 1:23-cv-7733** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff BETTE KOWALCZYK ("Plaintiff"), by and through her attorneys of record, Zane D. Smith & Associates, Ltd., and for their causes of action against EZRICARE, LLC, EZRIRX, LLC, ARU PHARMA INC., DELSAM PHARMA LLC, GLOBAL PHARMA HEALTHCARE PRIVATE LTD., and AMAZON ("Defendants"), and in support state the following:

NATURE OF THE ACTION

1. This action arises out of Plaintiff's purchase and use of EzriCare Artificial Tears (hereinafter, the "Product" and "Artificial Tears") that were manufactured, imported, sold, marketed, labeled, and distributed by Defendants. Defendants manufacture, design, import, advertise, label, distribute, market, and sell several over-the-counter pharmaceutical products, including the above-named Product, which contains a solution of Carboxymethylcellulose Sodium 10 MG in 1 ml.

2. Due to Defendants' negligent, reckless and/or intentional misconduct, consumers, like Plaintiff, purchased and used Defendants' Product which was adulterated and contaminated with "a rare, extensively drug-resistant strain of *Pseudomonas aeruginosa* bacteria."[1]

3. The presence of the *Pseudomonas Aeruginosa* bacteria in Defendants' EzriCare and Delsam Pharma Artificial Tear products is due to, *Inter alia*, Defendants' violation of Current Good Manufacturing Processes (as identified by the Food and Drug Administration), including "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."[2]

4. These violations, along with the presence of this rare and, in some cases, deadly, bacteria pose a significant and severe health risk to consumers, such as Plaintiff, who purchased and used Defendants' artificial tear products.

5. As a result of Plaintiff's use of Defendants' Product, Plaintiff was exposed to the Pseudomonas Aeruginosa bacteria and suffered from a severe corneal ulcer and scarring in her right eye and continues to suffer from serious and permanent injury to her right eye and vision.

6. Plaintiff has suffered, and continues to suffer, physical and economic damages due to Defendants' misconduct (as set forth below). Plaintiff alleges the following based upon personal knowledge as well as investigation by counsel, and as to all other matters, upon information and belief.

7. Plaintiff further believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

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[1] *See 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-warnsconsumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination.

[2] *Id.*

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 USC §1332(a) because the matter in controversy exceeds $75,000, exclusive of costs and Plaintiff and Defendants are citizens of different states.

9. This Court has jurisdiction over each Defendant because Defendants are authorized to conduct and do business in Illinois. Defendants have marketed, promoted, distributed, and sold EzriCare Artificial Tears and Delsam Pharma's Artificial Tears in Illinois, and Defendants have sufficient minimum contacts with this State and/or have sufficiently availed themselves of the markets in this State through promotion, sales, distribution, and marketing within this State to render the exercise of jurisdiction by this Court permissible.

10. Venue is proper under 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to this claim, namely Plaintiff's purchase of the EzriCare Artificial Tears at issue, as well as the injuries stemming from the use of it, occurred in this judicial district.

11. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants transact substantial business in this District.

12. Alternatively, venue is proper in this Court under 28 U.S.C. § 1391(b)(3) because all Defendants have sufficient minimum contacts with the State of Illinois and have intentionally availed themselves of the markets within Illinois through the promotion, sale, marketing, and distribution of their products, including the EzriCare Artificial Tears at issue.

13. This Court has specific personal jurisdiction over EzriCare because EzriCare committed a tort in whole or in part in Illinois. Specifically, EzriCare sold, supplied, distributed, shipped, advertised, and/or marketing artificial tears to Illinois residents and/or Illinois businesses, including the artificial tears that harmed Plaintiff.

14. This Court has general personal jurisdiction over Aru because Aru committed a tort in whole or in part in Illinois. Specifically, Aru sold, supplied, distributed, shipped, advertised, and/or marketing artificial tears to Illinois residents and/or Illinois businesses, including the artificial tears that harmed Plaintiff.

15. Upon information and belief, from their principal places of business located in New Jersey, Defendants EzriCare and EzriRx are engaged in the business of packaging, labeling, importing, selling, supplying, distributing, advertising, and/or marketing the Product throughout the United States, including to and in Illinois.

16. This court has specific personal jurisdiction over Amazon because Amazon committed a tort in whole or in part in Illinois. Specifically, Amazon sold, supplied, distributed, shipped, advertised, and/or marketing artificial tears to Illinois residents and/or Illinois businesses, including the artificial tears that harmed Plaintiff.

17. Further, this Court has jurisdiction over each Defendant because Defendants are authorized to conduct and do business in Illinois.

18. Further, this Court has jurisdiction over each Defendant because each Defendant engages in substantial, continuous, and systematic contacts with the State of Illinois, purposefully directing their activities towards Illinois, including the placement of their goods into the stream of commerce with the intent and expectation that they will likely be purchased and used by consumers in Illinois. This litigation arises out of those activities.

THE PARTIES

Plaintiff

19. Plaintiff, BETTE KOWALCZYK ("BETTE") is a citizen and resident of Illinois, and at all times relevant hereto has been a resident of Kane County.

20. Plaintiff was legally blind in her left eye and relied on her right eye to see.

21. On April 17, 2022, Plaintiff purchased EzriCare Artificial Tears online via Amazon.com, which she began to use after it was delivered by Amazon.

22. Mrs. Kowalczyk (through the assistance of his son) purchased EzriCare Artificial Tears from Amazon in Kane County.

23. Plaintiff's proof of purchase is as follows:

amazon.com

Final Details for Order #111-7293006-4172217
Print this page for your records.

Order Placed: April 17, 2022
Amazon.com order number: 111-7293006-4172217
Order Total: $7.06

Shipped on April 18, 2022

Items Ordered	**Price**
1 of: *2 PK Artificial Tears Eye Drops for Dry Eyes - Extra Strong Moisturizing Lubricating Eye Drops - Potent Concentration for Fast Acting Dry Eye Relief - 30mL by EzriCare* Sold by: EzriCare (seller profile) Condition: New	$6.99

Shipping Address:
Bette Kowalczyk
242 GREENBRIAR DR APT 139
YORKVILLE, IL 60560-3802
United States

24. During that time, based on the false and misleading claims by Defendants, Plaintiff was unaware that Defendants' artificial tear product(s) may be adulterated and contaminated with the dangerous *Pseudomonas Aeruginosa* bacteria. Mrs. Kowalczyk purchased Defendants' artificial tear product(s) on the assumption that the labeling of Defendants' artificial tears was accurate and that the products were unadulterated, safe, and effective and, most importantly, were not contaminated with this deadly bacterium. Mrs. Kowalczyk would not have purchased Defendants' artificial tear product(s) had she known there was a risk the product may contain the

Pseudomonas Aeruginosa bacteria and cause severe infection. As a result, Plaintiff suffered severe injury, including loss of vision, as alleged herein.

Defendants

25. Defendant Global Pharma Private Ltd. ("Global Pharma") is, and at all times relevant to this action was, a foreign corporation organized and existing under the laws of the Country of India, with its principal place of business at No. 2A, 3rd F, 4th Street, Ganga Nagar, Chennai – 600 024, Tamilnadu, India. Global Pharma Healthcare Private Ltd. manufactures, designs, tests, markets, advertises, labels, distributes, and sells the EzriCare Artificial Tears product (NDC# 79503-0101-15) at issue in this litigation. This includes marketing and selling the product in the State of Illinois, where Plaintiff purchased the product.

26. Defendant EzriCare, LLC ("EzriCare") is a limited liability company organized, incorporated, and existing under the laws of the State of New Jersey with its principal place of business in New Jersey. EzriCare is thus a citizen of the state of New Jersey. EzriCare's principal place of business is located in New Jersey at 1525 Prospect St., Ste. 204, Lakewood, NJ 08701 in Ocean County. "EzriCare" is a trademark registered and licensed to Defendant EzriRx LLC. EzriCare is engaged in the business of importing, selling, supplying, packaging, distributing, and marketing artificial tears products throughout the United States, including Illinois. EzriCare may be served with process at its registered agent Ezriel Green located at 1525 Prospect St., Ste. 204, Lakewood, NJ 08701.

27. Defendant EzriRx LLC ("ExriRx") is, and at all times relevant to this action was, a company incorporated under the laws of Delaware with its principal place of business located at 1525 Prospect Street, Suite 204, Lakewood, New Jersey 08701. Process may be served upon its registered agent: Registered Agent Solutions, Inc., 838 Walker Road, Suite 21-2, Dover, Delaware

19904. EzriRx LLC markets, advertises, labels, distributes, and sells the EzriCare Artificial Tears product at issue in this litigation. This includes marketing and selling the product in the State of Illinois, where Plaintiff purchased the product.

28. Defendant Aru Pharma, Inc. ("Aru") is, and at all relevant times to this action was, a corporation organized, incorporated, and existing under the laws of the State of New York with its principal place of business in New York. Aru is thus a citizen of the state of New York. Aru's principal place of business is located in New York at 925 Protano Lane, Mamaroneck, NY 10543 and/or 696 Locust Street, Mount Vernon 10552, both in Westchester County. Aru is engaged in the business of importing, selling, supplying, distributing, packaging, and marketing artificial tears products throughout the United States, including the State of Illinois. Aru may be served with process at its principal place of business at 925 Protano Lane, Mamaroneck, NY 10543.

29. Defendant Amazon, Inc. ("Amazon") is, and at all time relevant to this action was, a worldwide seller and distributor of products. Amazon is a Delaware corporation with its principal place of business located at 410 Terry Avenue North, Seattle, WA 98109. Amazon regularly does business in Illinois either online or through its stores. Amazon has sufficient contacts with the State of Illinois by regularly selling and distributing products in Illinois, including artificial tears, and by serving a market for artificial tears in Illinois. Amazon sold, distributed, advertised, and/or marketed the artificial tears which are the subject of this Complaint to Plaintiff. Amazon's contacts with Illinois are sufficient that Amazon should reasonably expect to be brought into court in Illinois. Amazon may be served with process through its registered agent Corporation Service Company 300 Deschutes Way SW, Suite 208 MC-CSC1, Tumwater, WA 98501.

FACTS

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

30. On January 31, 2023, the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) announced the multi-state outbreak of VIM-GES-CRPA, a rare strain of extensively drug-resistant *Pseudomonas Aeruginosa,* eye infections linked to the use of artificial tears products, EzriCare Artificial Tears.

31. Defendants EzriCare, EzriRx, and Aru imported, packaged, labeled, sold, supplied, distributed, and/or marketed the contaminated artificial tears products. Defendants EzriCare, EzriRx, and Aru then sold these products through retailers, such as Walmart, Amazon, and eBay.

32. According to the CDC, as of May 15, 2023, a total of 81 people infected with the outbreak strain were reported from 18 states, including: California, Colorado, Connecticut, Delaware, Florida, Illinois, North Carolina, New Jersey, Nevada, New Mexico, New York, Ohio, Pennsylvania, South Dekota, Texas, Utah, Washington, and Wisconsin.[3]

33. Four people have died, and there have been 14 reports of vision loss.[4]

34. The epidemiologic evidence available to investigators at this time indicates that artificial tears was the source of the outbreak.

35. EzriCare Artificial Tears, a preservative-free, over-the-counter product packaged in multidose bottles, was the brand most commonly reported.

36. Laboratory testing by CDC and FDA identified the presence of VIM-GES-CRPA in opened EzriCare bottles from multiple lots. These bottles were collected from patients with and

[3] https://www.cdc.gov/hai/outbreaks/CRPA-artificial-tears.html#anchor_1674746879046
[4] Id.

without eye infections and from two states. VIM-GES-CRPA recovered from opened products match the outbreak strain.

37. The FDA and CDC alerted that patients should stop using EzriCare Artificial Tears pending additional information and guidance from CDC and FDA.

38. Further, since the initial announcement, the FDA recommended this recall due to Defendants' current good manufacturing practice (CGMP) violations, including 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.

39. As such, multiple retailers and distributors have recalled or removed Defendants' artificial tears products.

40. In late February through early March of 2023, the FDA conducted an inspection of the Global Pharma's plant in India, and subsequently released a report of its preliminary findings.[5]

41. Among the most concerning problems identified in the report are as follows:

- The facility lacked adequate validation of its sterilization processes to prevent microbiological contamination;
- The facility used below-industry-standard filtration testing;
- The facility failed to perform container closure testing to ensure product protection had not been compromised or adulterated;
- The facility used deficient manufacturing processes that lack product sterility assurance to manufactured products;

[5] https://www.fda.gov/media/166739/download

- Drug production and control records were not properly reviewed by the facilities' quality control unit to ensure compliance.

42. As of filing this complaint, the CDC and FDA's investigations are ongoing.

B. VIM-GES-CRPA (*Pseudomonas Aeruginosa)*

43. VIM-GES-CRPA is a rare strain of *Pseudomonas Aeruginosa*. *Pseudomonas Aeruginosa* is a common encapsulated, gram-negative, aerobic–facultatively anaerobic, rod-shaped bacterium that can cause disease in plants and animals, including humans. It is a multidrug resistant pathogen recognized for its ubiquity, its intrinsically advanced antibiotic resistance mechanisms, and its association with serious illnesses.

44. What makes *Pseudomonas aeruginosa* remarkably dangerous is due to its natural resistance to antibiotics and its ability to grow extensive colonies in conditions of partial or total oxygen depletion. Advanced antibiotic drug regimens are often required for treatment, which can lead to other serious adverse effects.

45. Per the CDC, VIM-GES-CRPA isolates associated with this outbreak have been extensively drug-resistant (XDR)[6]. Isolates that underwent testing at public health laboratories were not susceptible to cefepime, ceftazidime, piperacillin-tazobactam, aztreonam, carbapenems, ceftazidime-avibactam, ceftolozane-tazobactam, fluoroquinolones, polymyxins, amikacin, gentamicin, and tobramycin. A subset of 3 isolates that underwent antimicrobial susceptibility testing for cefiderocol were susceptible to this agent.

C. Pseudomonas aeruginosa and Eye Infection

46. Studies showing the severity of *Pseudomonas aeruginosa* eye infections go as far back as the 1950s.

[6] https://www.cdc.gov/hai/outbreaks/crpa-artificial-tears.html#anchor_1674748630706

47. *Pseudomonas aeruginosa* eye infections can lead to a severe infection.

48. What can be said for certain is that infections with *Pseudomonas aeruginosa* can cause long-term complications, can lead to sepsis or bacteremia (blood stream infections), and permanent injury, including vision loss.

D. Bette Kowalczyk's ***Pseudomonas Aeruginosa*** **Infection**

49. BETTE KOWALCZYK purchased EzriCare Artificial tears in the weeks before her *Pseudomonas aeruginosa* infection.

50. On or about January 20, 2023, BETTE experienced decreased and blurry vision, discharge, and discomfort in her right eye.

51. On January 23, 2023, BETTE was admitted to the University of Illinois Hospital's Emergency Department due to increased symptoms of infection in her right eye.

52. The attending physician ordered culture testing. On January 24, 2023, BETTE tested positive for *Pseudomonas aeruginosa.*

53. Bette was admitted to University of Chicago Hospital, where she received inpatient treatment for her severe eye infection from January 23, 2023, to March 12, 2023.

54. Plaintiff continues to receive treatment for her right and left eye.

55. Plaintiff is now legally blind in both eyes.

CAUSES OF ACTION

COUNT I
STRICT PRODUCT LIABILITY – MANUFACTURING DEFECT

56. Plaintiff incorporates the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

57. Defendants are the manufacturers or apparent manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product

Artificial Tears. Global Pharma manufactured, designed, packaged, supplied, distributed, and sold the product; EzriCare and EzriRx were apparent manufacturers, packaged, labeled, marketed, advertised, supplied, distributed, and sold the product, and EzriRx owned the EzriCare trademark; Amazon marketed, advertised, distributed, and sold the product. Each Defendant received direct financial benefit from its activities and the sale of the product at issue. Each Defendant was integral to the business enterprise such that Defendants' conduct was a substantial and/or necessary factor in bringing the product to the customer market. Each Defendant had control over or a substantial ability to influence the distribution and marketing process.

58. The product was defective in that it was contaminated with Pseudomonas aeruginosa. Because it was contaminated, it differed from the manufacturer's design or specifications or from other typical units of the same product line.

59. The product was defective when it left Defendants' possession.

60. BETTE used Artificial Tears in a reasonably foreseeable manner. She believed EzriCare was the manufacturer. BETTE suffered harm, and the defect in the product was a substantial factor in causing that harm.

61. On information and belief, certain Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to: Global Pharma, EzriCare, and EzriRx failed to implement protocols to ensure that the product was safe and sterile, while simultaneously representing that the product was safe and in compliance with FDA regulations. These Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

62. The products that Defendants, manufactured, distributed packaged, labeled, supplied, marketed, advertised, and/or sold, and that Plaintiff purchased and used, as described previously, was expected to reach Plaintiff, and be used by her, without substantial change. Plaintiff used the products in the manner expected and intended, including when she used it.

63. Plaintiff suffered the aforementioned injuries as a direct and proximate result of their use of the contaminated, defective products manufactured, distributed, and sold by the Defendants.

64. Defendants are strictly liable to Plaintiff for the harm proximately caused by the manufacture and sale of an unsafe and defective product.

65. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future for the following: pain and suffering, mental anguish, emotional distress, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, punitive and/or exemplary damages and attorneys' fees (to the extent recoverable) and other general, special, ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances.

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. That the Court award Plaintiff judgment against Defendants for past and future economic and non-economic damages;

2. That the Court award all such other sums as shall be determined to fully and fairly compensate Plaintiff for all general, special, incidental and consequential damages incurred, or to be incurred, by Plaintiff as the direct and proximate result of the acts and omissions of Defendants;

3. That the Court award Plaintiff costs, disbursements and reasonable attorneys' fees incurred (to the extent recoverable);

4. Pre- and post-judgment interest at the highest rate allowed by law; and

5. That the Court award such other and further relief as it deems necessary and proper.

Count II
Strict Liability – Design Defect

66. Plaintiff incorporates the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

67. Defendants are the manufacturers or apparent manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears.

68. Global Pharma manufactured, designed, packaged, supplied, distributed, and sold the product; EzriCare and EzriRx were apparent manufacturers, packaged, labeled, marketed, advertised, supplied, distributed, and sold the product, and EzriRx owned the EzriCare trademark; Amazon marketed, advertised, distributed, and sold the product.

69. Each Defendant received direct financial benefit from its activities and the sale of the product at issue.

70. Each Defendant was integral to the business enterprise such that Defendants' conduct was a substantial and/or necessary factor in bringing the product to the customer market. Each Defendant had control over or a substantial ability to influence the distribution and marketing process.

71. The product's design was defective because it enabled the product to be contaminated with Pseudomonas aeruginosa and, thus, did not perform as safely as an ordinary

consumer would have expected it to perform when used or misused in an intended or reasonably foreseeable way.

72. Alternatively, the design was defective because it enabled the product to be contaminated with Pseudomonas aeruginosa and the risks associated with the product's design outweighed its benefits.

73. BETTE believed that EzriCare manufactured the product. BETTE was harmed. The product's design or failure to perform safely was a substantial factor in causing the harm suffered by BETTE.

74. On information and belief, certain Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to: Global Pharma, EzriCare, and EzriRx failed to implement protocols to ensure that the product was safe and sterile, while simultaneously representing that the product was safe and in compliance with FDA regulations.

75. These Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

76. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future for the following: pain and suffering, mental anguish, emotional distress, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, punitive and/or exemplary damages and attorneys' fees (to the extent recoverable) and other general, special, ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances.

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. That the Court award Plaintiff judgment against Defendants for past and future economic and non-economic damages;

2. That the Court award all such other sums as shall be determined to fully and fairly compensate Plaintiff for all general, special, incidental and consequential damages incurred, or to be incurred, by Plaintiff as the direct and proximate result of the acts and omissions of Defendants;

3. That the Court award Plaintiff costs, disbursements and reasonable attorneys' fees incurred (to the extent recoverable);

4. Pre- and post-judgment interest at the highest rate allowed by law; and

5. That the Court award such other and further relief as it deems necessary and proper.

Count III
Strict Liability – Failure to Warn

77. Plaintiff incorporates the preceding paragraphs by reference as though set forth here in their entirety.

78. Defendants are the manufacturers or apparent manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. Global Pharma manufactured, designed, packaged, supplied, distributed, and sold the product; EzriCare and EzriRx were apparent manufacturers, packaged, labeled, marketed, advertised, supplied, distributed, and sold the product, and EzriRx owned the EzriCare trademark; Amazon marketed, advertised, distributed, and sold the product.

79. Each Defendant received direct financial benefit from its activities and the sale of the product at issue.

80. Each Defendant was integral to the business enterprise such that Defendants' conduct was a substantial and/or necessary factor in bringing the product to the customer market. Each Defendant had control over or a substantial ability to influence the distribution and marketing process.

81. The product had potential risks, side effects, or adverse reactions that were known or knowable in light of the scientific and/or medical knowledge at the time of the product's manufacture, distribution, packaging, labeling, supplying, marketing, advertising, and/or selling – for example, that it may be contaminated with a potentially-deadly bacteria.

82. The potential risks, side effects, and/or adverse reactions presented a substantial danger when the product was used or misused in an intended or reasonably foreseeable way. Ordinary consumers would not have recognized the potential risks, side effects, or adverse reactions. Defendants had a duty to warn and to continually update warnings.

83. Defendants failed to adequately warn or instruct or update the potential risks, side effects, or adverse reactions.

84. BETTE believed that EzriCare manufactured the product. BETTE was harmed. The lack of sufficient instructions or warnings was a substantial factor in causing the harm that BETTE suffered.

85. On information and belief, certain Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example: Global Pharma, EzriCare, and EzriRx failed to implement protocols to ensure that the product was safe and sterile, while simultaneously representing that the product was safe and in compliance with FDA regulations.

86. These Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

87. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future for the following: pain and suffering, mental anguish, emotional distress, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, punitive and/or exemplary damages and attorneys' fees (to the extent recoverable) and other general, special, ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances.

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. That the Court award Plaintiff judgment against Defendants for past and future economic and non-economic damages;

2. That the Court award all such other sums as shall be determined to fully and fairly compensate Plaintiff for all general, special, incidental and consequential damages incurred, or to be incurred, by Plaintiff as the direct and proximate result of the acts and omissions of Defendants;

3. That the Court award Plaintiff costs, disbursements and reasonable attorneys' fees incurred (to the extent recoverable);

4. Pre- and post-judgment interest at the highest rate allowed by law; and

5. That the Court award such other and further relief as it deems necessary and proper.

Count IV
Negligent Failure to Warn

88. Plaintiff incorporates the preceding paragraphs by reference as though set forth here in their entirety.

89. Global Pharma, EzriCare, and EzriRx are manufacturers or apparent manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. Global Pharma manufactured, designed, packaged, supplied, distributed, and sold the product; EzriCare and EzriRx were apparent manufacturers, packaged, labeled, marketed, advertised, supplied, distributed, and sold the product, and EzriRx owned the EzriCare trademark. As such, Defendants owed Plaintiff a duty of care and a duty to assist and protect, including but not limited to a duty of reasonable care to manufacture, test, design, distribute, package, label, supply, market, advertise, and/or sell a product that was not unreasonably safe for human use.

90. Defendants owed a duty to Plaintiff to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, testing, distribution, storage, labeling, and sale of its products, including all applicable local, state, and federal health and safety regulations. Defendants failed to conform to this duty.

91. Defendants knew or reasonably should have known that the product was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner. The product was or became contaminated with Pseudomonas aeruginosa. Defendants knew or reasonably should have known that users would not realize the danger.

92. Defendants failed to adequately warn of the danger or instruct on the safe use of the product. A reasonable manufacturer, designer, distributor, packager, labeler, supplier,

marketer, advertiser, and/or seller under the same or similar circumstances would have warned of the danger or instructed on the safe use of the product.

93. Alternatively, Defendants failed to use any care or made an extreme departure from what a reasonably careful person would do in the same situation to prevent harm to oneself or to others.

94. BETTE believed that EzriCare was the manufacturer of the product. BETTE was harmed. Defendants' negligent failure to warn or instruct was a substantial factor in causing the harm suffered by BETTE.

95. On information and belief, certain Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others: Global Pharma, EzriCare, and EzriRx failed to implement protocols to ensure that the product was safe and sterile, while simultaneously representing that the product was safe and in compliance with FDA regulations.

96. These Defendants had awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid those consequences.

97. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future for the following: pain and suffering, mental anguish, emotional distress, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, punitive and/or exemplary damages and attorneys' fees (to the extent recoverable) and other general, special, ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances.

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. That the Court award Plaintiff judgment against Defendants for past and future economic and non-economic damages;

2. That the Court award all such other sums as shall be determined to fully and fairly compensate Plaintiff for all general, special, incidental and consequential damages incurred, or to be incurred, by Plaintiff as the direct and proximate result of the acts and omissions of Defendants;

3. That the Court award Plaintiff costs, disbursements and reasonable attorneys' fees incurred (to the extent recoverable);

4. Pre- and post-judgment interest at the highest rate allowed by law; and

5. That the Court award such other and further relief as it deems necessary and proper.

COUNT V
BREACH OF WARRANTY

98. Plaintiff incorporates the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

99. Plaintiff is a consumer.

100. Defendants are manufacturers, packagers, labelers, retailers, producers, distributors, suppliers, and/or merchants who sell products.

101. By offering products for sale to the public, Defendants impliedly and expressly warranted that such products were safe to use, that it was not adulterated with a deadly pathogen, and that the products had been safely prepared under sanitary conditions.

102. Defendants breached the implied warranties about the products they manufactured,

distributed packaged, labeled, supplied, marketed, advertised, and/or sold, which were used by Plaintiff, causing Plaintiff's injuries and losses.

103. Plaintiff's injuries proximately and directly resulted from Defendants' breach of implied and express warranties, and Plaintiff is thus entitled to recover for all actual, consequential, and incidental damages that flow directly and in a foreseeable fashion from these breaches.

104. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future for the following: pain and suffering, mental anguish, emotional distress, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, punitive and/or exemplary damages and attorneys' fees (to the extent recoverable) and other general, special, ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances.

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. That the Court award Plaintiff judgment against Defendants for past and future economic and non-economic damages;

2. That the Court award all such other sums as shall be determined to fully and fairly compensate Plaintiff for all general, special, incidental and consequential damages incurred, or to be incurred, by Plaintiff as the direct and proximate result of the acts and omissions of Defendants;

3. That the Court award Plaintiff costs, disbursements and reasonable attorneys' fees incurred (to the extent recoverable);;

4. Pre- and post-judgment interest at the highest rate allowed by law; and

5. That the Court award such other and further relief as it deems necessary and proper.

COUNT VI
NEGLIGENCE

105. Plaintiff incorporates the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

106. Defendants, as the manufacturer and/or seller of artificial tears products, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, distribute, and sell products free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

107. Defendants manufactured, prepared, distributed, and sold products that were adulterated with *Pseudomonas aeruginosa*, contaminated with *Pseudomonas aeruginosa*, and that were not reasonably safe as designed, manufactured, or sold.

108. Defendants manufactured, distributed packaged, labeled, supplied, marketed, advertised, and/or sold products that were adulterated with *Pseudomonas aeruginosa*, contaminated with *Pseudomonas aeruginosa*, and that were not reasonably safe as designed, manufactured, or sold.

109. Defendants were negligent in how they manufactured, distributed packaged, labeled, supplied, marketed, advertised, and/or sold products that were adulterated with *Pseudomonas aeruginosa*, contaminated with *Pseudomonas aeruginosa*, and not reasonably safe because they were contaminated with *Pseudomonas aeruginosa* and because adequate warnings or instructions were not provided, including but not limited to the warning that its products may contain *Pseudomonas aeruginosa*, and thus should not be given to, or used by humans.

110. Defendants had a duty to properly supervise, train, and monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of its products, to ensure

compliance with Defendants' operating standards and to ensure compliance with all applicable health regulations. Defendants failed to properly supervise, train, and monitor these employees, or the employees of its agents or subcontractors engaged in the import, manufacture, preparation and delivery of the products, and thus breached that duty.

111. Defendants owed a duty to Plaintiff to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling, and sale of its products, including all applicable local, state, and federal health and safety regulations. Defendants, by their manufacture, distribution, storage, labeling, and sale of adulterated and unsafe products, failed to conform to this duty.

112. Defendants owed Plaintiff the duty to exercise reasonable care in the preparation and sale of its products, as it was reasonably foreseeable that the defendant's manufacture, distribution and sale of products contaminated with *Pseudomonas aeruginosa* would cause injury and harm to all persons potentially exposed to *Pseudomonas aeruginosa* as a result. Defendants breached that duty, thereby causing injury to Plaintiff.

113. Defendants were negligent in manufacturing, preparing, distributing and selling products adulterated and/or contaminated with *Pseudomonas aeruginosa*, a dangerous pathogen. Defendants' negligent acts and omissions included, but were not limited to the following: Defendants' current good manufacturing practice (CGMP) violations, including 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.

114. Defendants owed Plaintiff a duty to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling and sale of its products, including the applicable provisions of the federal U.S. Food, Drug and Cosmetic Act.

115. The products that Defendants manufactured, distributed and sold, and that the consumers purchased and consumed, was "adulterated" within the meaning of the federal Food, Drug and Cosmetic Act.

116. Defendants violated federal, state, and local safety regulations by its manufacture, distribution, and sale of adulterated products.

117. The federal, state, and local product safety regulations applicable here, and as set forth above, establish a positive and definite standard of care in the manufacture, distribution and sale of products, and the violation of these regulations constitutes negligence per se.

118. Plaintiff was in the class of persons intended to be protected by these statutes and regulations and was injured as the direct and proximate result of Defendants' violation of applicable federal, state, and local safety regulations.

119. Plaintiff's injuries proximately and directly resulted from the negligence of Defendants, and from Defendants' violations of statutes, laws, regulations, and safety codes pertaining to the manufacture, production, supply, distribution, storage, and sale of products.

120. Defendants breached the aforementioned duties as alleged herein, which breach constituted the proximate cause of Plaintiff's injuries.

121. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future for the following: pain and suffering, mental anguish, emotional distress, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, punitive and/or

exemplary damages and attorneys' fees (to the extent recoverable) and other general, special, ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances.

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. That the Court award Plaintiff judgment against Defendants for past and future economic and non-economic damages;

2. That the Court award all such other sums as shall be determined to fully and fairly compensate Plaintiff for all general, special, incidental and consequential damages incurred, or to be incurred, by Plaintiff as the direct and proximate result of the acts and omissions of Defendants;

3. That the Court award Plaintiff costs, disbursements and reasonable attorneys' fees incurred (to the extent recoverable);

4. Pre- and post-judgment interest at the highest rate allowed by law; and

5. That the Court award such other and further relief as it deems necessary and proper.

COUNT VII
NEGLIGENCE *PER SE*

122. Plaintiff incorporates the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

123. Defendants had a duty to comply with all applicable state and federal regulations intended to ensure the purity and safety of their products, including, but not limited to, the requirements of the Federal Food, Drug and Cosmetics Act.

124. Defendants failed to comply with the provisions of the health and safety acts identified above and, as a result, were negligent per se in their manufacture, distribution, and/or sale of products adulterated with *Pseudomonas aeruginosa*, a dangerous and deadly pathogen.

125. Defendants violated federal, state, and local safety regulations by its manufacture, distribution, and sale of adulterated products.

126. The federal, state, and local product safety regulations applicable here, and as set forth above, establish a positive and definite standard of care in the manufacture, distribution and sale of products, and the violation of these regulations constitutes negligence per se.

127. Plaintiff was in the class of persons intended to be protected by these statutes and regulations and was injured as the direct and proximate result of Defendants' violation of applicable federal, state, and local safety regulations.

128. Plaintiff's injuries proximately and directly resulted from the negligence of Defendants, and from Defendants' violations of statutes, laws, regulations, and safety codes pertaining to the manufacture, production, supply, distribution, storage, and sale of products.

129. As a direct and proximate result of conduct by Defendants that was negligent *per se*, Plaintiff weas harmed.

130. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future for the following: pain and suffering, mental anguish, emotional distress, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, punitive and/or exemplary damages and attorneys' fees (to the extent recoverable) and other general, special, ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances.

131. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future for the following: pain and suffering, mental anguish, emotional distress, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, punitive and/or exemplary damages and attorneys' fees (to the extent recoverable) and other general, special, ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances.

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. That the Court award Plaintiff judgment against Defendants for past and future economic and non-economic damages;

2. That the Court award all such other sums as shall be determined to fully and fairly compensate Plaintiff for all general, special, incidental and consequential damages incurred, or to be incurred, by Plaintiff as the direct and proximate result of the acts and omissions of Defendants;

3. That the Court award Plaintiff costs, disbursements and reasonable attorneys' fees incurred (to the extent recoverable);

4. Pre- and post-judgment interest at the highest rate allowed by law; and

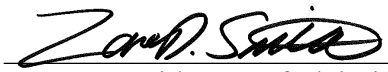
5. That the Court award such other and further relief as it deems necessary and proper.

JURY TRIAL DEMAND

Plaintiff demands trial by jury on all issues raised herein.

Dated: September 7, 2023.

Respectfully submitted,
BETTE KOWALCZYK, *Plaintiff*



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