UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHANNON URIOSTE,	)	
	)	
Plaintiff,	)	**Civil Action No.** 3:24-cv-07269
	)	
vs.	)	
	)	
EZRICARE LLC; EZRIRX LLC; and GLOBAL PHARMA HEALTHCARE PRIVATE LTD.;	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	
	)	
	)	
	)	

COMPLAINT

Plaintiff Shannon Urioste ("Plaintiff"), by and through the undersigned, files this Complaint against Defendants EzriCare LLC, EzriRx LLC, and Global Pharma Healthcare Private Ltd., ("Defendants"), and in support states the following:

NATURE OF THE ACTION

1. This action arises out of Plaintiff's purchase and use of EzriCare Artificial Tears (hereinafter, the "Product") that were designed, 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 artificial tears, which contain a solution of Carboxymethylcellulose Sodium 10 MG in 1 ml. Defendants EzriCare and EzriRx's artificial tears are adulterated and contaminated with "a rare, extensively drug-resistant strain of *Pseudomonas aeruginosa* bacteria."[1] The presence of the

[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-

Pseudomonas Aeruginosa bacteria in Defendants' Product renders it adulterated under the Food, Drug, and Cosmetic Act, and such contamination is due to Defendants' violation(s) 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] 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 EzriCare and EzriRx's Artificial Tears. The plaintiff suffered significant personal injury due to Defendants' misconduct (as set forth below) and seeks damages, both non-economic and economic, and any other relief this Court deems just and equitable.

2. Plaintiff purchased the Product in the State of California through Amazon.com.

3. As a result of Plaintiff's use of EzriCare Artificial Tears, Plaintiff was exposed to *Pseudomonas Aeruginosa* and other bacteria and suffered eye and vision damage—possibly permanent—as a result.

JURISDICTION AND VENUE

4. This Court has subject-matter jurisdiction over this case pursuant to 28 U.S.C. § 1332(a), because the amount in controversy exceeds $75,000, and Plaintiff and Defendants are residents of different states.

5. This Court has personal jurisdiction over Defendants because Defendants have sufficient minimum contacts with the State of New Jersey and regularly conducted (and still

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and-availability/fda-warns-consumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination.

[2] *Id.*

conduct) business in the State of New Jersey relating to the design, development, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the Product, such that exercising jurisdiction over Defendants would not offend due process or traditional notions of fair play and substantial justice.

6. Defendants' Product was sold either directly or indirectly to members of the general public within the State of New Jersey.

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(a) and (b)(2) and 1391(c)(2) because a substantial part of the events or omissions giving rise to the claims occurred in this judicial district, and the Defendants are subject to this Court's personal jurisdiction. Venue is also proper under 18 U.S.C. § 1965 (a) because Defendants transact substantial business in this district.

8. Upon information and belief, at all relevant times, Defendants were present and transacted, solicited, and conducted business in the State of New Jersey through their employees, agents, and/or sales representatives and derived substantial revenue from such business.

9. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States and the State of New Jersey.

THE PARTIES

A. Plaintiff

10. Plaintiff, Shannon Urioste, is a citizen and resident of Wrightwood, California, and at all times relevant hereto has been a resident of San Bernardino County, California.

11. On or about January 7, 2023, Plaintiff purchased two bottles of EzriCare Artificial Tears online via Amazon.com. Plaintiff paid $6.99, for the "2 PK Artificial Tears Eye Drops for Dry Eyes" sold by EzriCare. Plaintiff used the Product in January 2023 and discontinued its use

that same month after discovering that the product had been recalled.

12. On or about February 20, 2023 after Ms. Urioste used the EzriCare Artificial Tears, she visited her healthcare provider with a chief complaint of redness, irritation, and swelling in both of her eyes, as well as tearing and discharge in her right eye. Her optometrist noted that Ms. Urioste was using artificial tears that were recalled.

13. Ms. Urioste was diagnosed with acute bacterial conjunctivitis in both eyes and was started on Vigamox 0.5% TID to be used for 7 days.

14. As a result of Ms. Urioste's use of EzriCare Artificial Tears and the subsequent infection she was diagnosed with, Ms. Urioste suffered from injury to both her eyes and to her vision. Her eyes are potentially permanently affected by the infection, as she now suffers from light sensitivity, constant dryness, burning, and itching, and she also sees spots within her field of vision.

B. Defendants

15. Defendant EzriCare LLC is, and at all times relevant to this action was, a New Jersey Limited Liability Company with its principal place of business located at 1525 Prospect Street, Suite 204, Lakewood, NJ 08701. "EzriCare" is a trademark registered and licensed to Defendant EzriRx LLC with the serial number 90629770. EzriCare LLC markets, advertises, labels, distributes, and sells the EzriCare Artificial Tears product at issue in this litigation.

16. Defendant EzriRx LLC 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, and 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.

17. Defendant Global Pharma Healthcare Private Limited 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 located 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 at issue in this litigation.

18. Prior to the date that Plaintiff used the Product, Defendants possessed technical, medical, and/or scientific data from which Defendants knew or should have known through the exercise of reasonable diligence that the EzriCare Artificial Tears were contaminated with a dangerous and deadly bacteria and, thus, were hazardous to the life, health, and safety of persons who were exposed to them—*i.e.*, intended consumers of said product.

19. At all times relevant to this litigation, Defendants did business in New Jersey as manufacturers, distributors, packagers, marketers, suppliers, and/or sellers of the EzriCare Artificial Tears product at issue in this litigation.

20. At all pertinent times, Defendants were engaged in the research, development, manufacture, design, testing, packaging, labeling, sale, and marketing of the EzriCare Artificial Tears and introduced such products into interstate commerce with knowledge and intent that such products be sold in the State of New Jersey.

21. At all times material hereto, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the EzriCare Artificial Tears product.

22. Defendants placed the defective and contaminated EzriCare Artificial Tears

product into the stream of interstate commerce from approximately September 2, 2022—when Plaintiff began using the Product—until the Product was recalled.

FACTUAL ALLEGATIONS

EzriCare Artificial Tears

1. The NDC number for EzriCare Artificial Tears is 79503-101-15.

2. EzriCare LLC began packaging, labeling, advertising, marketing, and selling these artificial tears on or about November 22, 2020.

3. EzriCare Artificial Tears are intended to be used in the following manner: (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 exposure to wind or sun.[3]

4. These artificial tears are "preservative free," which removes any chemical used to prevent the growth of bacteria in the product.[4]

5. These artificial tears are also contained in a "multi-use" bottle that is meant to be re-used. However, because product/container is preservative-free, this could create a perfect storm for bacterial growth in the bottle/container.[5]

6. The active ingredient in the EzriCare Artificial Tears is a solution of Carboxymethylcellulose Sodium 10 MG in 1 ml. The inactive ingredients include Boric Acid,

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[3] *See* EzriCare Artificial Tears Product Monograph, located at https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=ac1ea23c-f1c6-418f-921e-58553ee919cb&type=display.

[4] *See Outbreak of Extensively Drug-resistant Pseudomonas aeruginosa Associated with Artificial Tears*, CDC HEALTH ALERT NETWORK, located at https://emergency.cdc.gov/han/2023/han00485.asp?ACSTrackingID=USCDC_511-DM98842&ACSTrackingLabel=HAN%20485%20-%20General%20Public&deliveryName=USCDC_511-DM98842.

[5] Amanda Holpuch, *Eye Drops Are Recalled After Being Linked to Vision Loss and 1 Death*, N.Y. TIMES (2/2/2023), located at https://www.nytimes.com/2023/02/02/business/eye-drops-ezricare-infections-cdc.html (article quoting Dr. Thomas L. Steinemann, an ophthalmologist at MetroHealth Medical Center in Cleveland, and a spokesperson for the American Academy of Ophthalmology).

Potassium Chloride, Sodium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride, Sodium Chlorite, Sodium Hydroxide, and Water for Injection.[6]

7. EzriCare Artificial Tears' packaging and labeling appears as follows:

Inner Package

Source: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=ac1ea23c-f1c6-418f-921e-58553ee919cb&type=display.

The *Pseudomonas Aeruginosa* Bacteria

[6] *Id.*

8. The *Pseudomonas Aeruginosa* bacteria is not a new bacteria, but it is notorious for being "versatile" and "innately drug resistant."[7] It is most frequently found in the environment, such as within the soil and/or freshwater.

9. The *Pseudomonas Aeruginosa* bacteria is also known to infect humans, and it can cause serious skin, eye, lung, and other infections throughout the body.

10. Currently, it is estimated that the *Pseudomonas Aeruginosa* bacteria is resistant to the following antibiotics: cefepime, ceftazidime, piperacillin-tazobactam, aztreonam, carbapenems, ceftazidime-avibactam, ceftolozane-tazobactam, fluoroquinolones, polymyxins, amikacin, gentamicin, and tobramycin.[8]

11. But, new therapies—known as "phage" therapies—may be utilized to treat antibiotic-resistant bacteria, like the *Pseudomonas Aeruginosa*. These therapies "work by deploying viruses that aim to attack bacteria, fending off infections that traditional antibiotic drugs fail to stamp out."[9]

Pseudomonas Aeruginosa and EzriCare Artificial Tears

12. The current outbreak of the *Pseudomonas Aeruginosa* bacteria resulting from the use of the EzriCare Artificial Tears was first detected by the U.S. Centers for Disease Control ("CDC") in May 2022 and has now been linked to 16 states.[10]

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[7] Beth Mole, *Extremely drug-resistant germ found in eye drops infects 55 in 12 states; 1 dead*, ARS TECHNICA (Feb. 2, 2023), located at https://arstechnica.com/science/2023/02/extremely-drug-resistant-germ-found-in-eye-drops-infects-55-in-12-states-1-dead/.

[8] Beth Mole, *Extremely drug-resistant germ found in eye drops infects 55 in 12 states; 1 dead*, ARS TECHNICA (Feb. 2, 2023), located at https://arstechnica.com/science/2023/02/extremely-drug-resistant-germ-found-in-eye-drops-infects-55-in-12-states-1-dead/.

[9] Alexander Tin, *Death toll climbs in outbreak linked to recalled eye drops as new treatment identified*, CBS NEWS (March 21, 2023 5:59pm), located at https://www.cbsnews.com/news/eye-drop-recall-death-toll-pseudomonas-aeruginosa-new-treatment.

[10] OUTBREAK OF EXTENSIVELY DRUG-RESISTANT PSEUDOMONAS AERUGINOSA ASSOCIATED WITH ARTIFICIAL TEARS, CENTERS FOR DISEASE CONTROL & PREVENTION (updated March 21, 2023), located at https://www.cdc.gov/hai/outbreaks/crpa-artificial-tears.html.

13. The CDC has isolated the specific strain of *Pseudomonas Aeruginosa* and identified it as Verona Integron-mediated Metallo-β-lactamase (VIM) and Guiana-Extended Spectrum-β-Lactamase (GES)-producing carbapenem-resistant Pseudomonas aeruginosa ("VIM-GES-CRPA").[11] This particular strand is incredibly drug-resistant and dangerous.

14. Prior to this outbreak, the CDC reported that this particular strain of *Pseudomonas Aeruginosa* "had never been reported in the United States."[12]

15. The CDC reported that its "laboratory testing identified the presence of the outbreak strain in opened EzriCare bottles with different lot numbers collected from two states."[13]

16. The CDC also reported that it was able to isolate the outbreak strain from 15 sputum or bronchial washes, 17 cornea swabs, 10 urine samples, two blood samples, 26 rectal swabs, and four other nonsterile sources.[14,15]

17. Out of the 68 individuals who have been identified as having been infected with the *Pseudomonas Aeruginosa* bacteria from use of the Product thus far, approximately eight (8) people

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[11] *See Outbreak of Extensively Drug-resistant Pseudomonas aeruginosa Associated with Artificial Tears*, CDC HEALTH ALERT NETWORK, located at https://emergency.cdc.gov/han/2023/han00485.asp?ACSTrackingID=USCDC_511-DM98842&ACSTrackingLabel=HAN%20485%20-%20General%20Public&deliveryName=USCDC_511-DM98842.

[12] OUTBREAK OF EXTENSIVELY DRUG-RESISTANT PSEUDOMONAS AERUGINOSA ASSOCIATED WITH ARTIFICIAL TEARS, CENTERS FOR DISEASE CONTROL & PREVENTION (updated March 21, 2023), located at https://www.cdc.gov/hai/outbreaks/crpa-artificial-tears.html.

[13] *See Outbreak of Extensively Drug-resistant Pseudomonas aeruginosa Associated with Artificial Tears*, CDC HEALTH ALERT NETWORK, located at https://emergency.cdc.gov/han/2023/han00485.asp?ACSTrackingID=USCDC_511-DM98842&ACSTrackingLabel=HAN%20485%20-%20General%20Public&deliveryName=USCDC_511-DM98842.

[14] OUTBREAK OF EXTENSIVELY DRUG-RESISTANT PSEUDOMONAS AERUGINOSA ASSOCIATED WITH ARTIFICIAL TEARS, CENTERS FOR DISEASE CONTROL & PREVENTION (updated March 21, 2023), located at https://www.cdc.gov/hai/outbreaks/crpa-artificial-tears.html.

[15] *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.

have suffered permanent vision loss, four (4) people have had their eyeballs removed, and three (3) people have died due to systemic infection.[16] Others have endured extensive treatment to treat their infections.

18. Further testing by the FDA has revealed that the EzriCare Artificial Tears "were contaminated with microorganisms . . . . includ[ing] but were not limited to Pseudomonas species."[17] As such, the *Pseudomonas Aerginosa* bacterium was only one of many bacterial contaminants present within Defendants' EzriCare Artificial Tears when Plaintiff used the Product.

Product Recall

19. On January 24, 2023, Defendant EzriCare LLC first issued a statement on the contamination of the Product, stating; "EzriCare became aware in the last few days that the Center for Disease Control (CDC) is conducting an ongoing investigation related to adverse events implicating various Over the Counter (OTC) eye drops."[18]

20. After development of this story, on February 1, 2023, Defendant EzriCare LLC 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

[16] Alexander Tin, *Death toll climbs in outbreak linked to recalled eye drops as new treatment identified*, CBS NEWS (March 21, 2023 5:59pm), located at https://www.cbsnews.com/news/eye-drop-recall-death-toll-pseudomonas-aeruginosa-new-treatment.

[17] *See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ezricare-llc-658390-02132024.

[18] EzriCare Artificial Tears - Discontinue Use (Feb. 2, 2023), located at https://ezricare-info.com.

to both CDC and FDA and indicated our willingness to cooperate with any requests they may have of us."[19]

21. Additionally, on February 1, 2023, Defendant Global Pharma Healthcare Private Ltd. initiated a voluntary recall of all unexpired lots of EzriCare Artificial Tears.[20]

22. Then, on February 2, 2023, the U.S. Food and Drug Administration ("FDA") issued a statement "warning consumers and health care practitioners not to purchase and to stop using EzriCare Artificial Tears or Delsam Pharma's Artificial Tears due to bacterial contamination."[21] The FDA highlighted that it recommended Defendant Global Pharma initiate a product recall due to "the company's 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-evidence packaging."[22]

23. Further, the FDA also "placed [Defendant] Global Pharma Healthcare Private Limited on import alert . . . for providing an inadequate response to a records request and for not complying with CGMP requirements."[23] According to the FDA, the import alert "prevents these products from entering the United States."[24]

24. Moreover, from February 20, 2023 to March 2, 2023, the FDA conducted an

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[19] *Id.*
[20] *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. At the same time, Global Pharma also issued a recall of the Delsam Pharma Artificial Tears—a similar product with the same active ingredient as EzriCare Artificial Tears and manufactured by Defendant Global Pharma Healthcare Private Ltd.
[21] *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.
[22] *Id.*
[23] *Id.*
[24] *Id.*

inspection of Defendant Global Pharma's manufacturing facility in Tamilnadu, India. Among the numerous CGMP violations cited in the FDA's report are findings of (1) a failure to include validation procedures for sterilization processes, (2) a failure to perform container closure integrity tests for certain [redacted] drug products, (3) use of manufacturing processes that lacked assurance of product sterility, (4) a failure to implement and use a clear and specific written procedure for aseptic interventions, (5) a failure to adhere to cleaning and disinfecting procedures related to aseptic processing areas, (6) a failure to conduct at least one test to verify the identity of each component of a drug product, and (7) a failure to adhere to procedures for monitoring environmental conditions related to aseptic processing areas.[25]

25. Finally, on February 13, 2024, the FDA issued a Warning Letter to EzriCare LLC (CMS # 658390) detailing the FDA's inspection of EzriCare LLC and citing EzriCare LLC for violating the FDCA. Specifically, the Warning Letter states:

> The inspection of your facility revealed that you operate as a distributor of EzriCare's Artificial Tears. Your receipt in interstate commerce of adulterated drugs, and the delivery or proffered delivery thereof, is a violation of section 301(c) of the FD&C Act, 21 U.S.C. 331(c), and your distribution of adulterated drugs violated section 301(a) of the FD&C Act, 21 U.S.C. 331(a).
>
> In addition, EZRICARE Artificial Tears is misbranded under section 502(j) of the FD&C ACT, 21 U.S.C. 352(j). Introduction or delivery for introduction of misbranded products into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).[26]

26. This Warning Letter also details how Defendant EzriCare LLC received and distributed "three shipments of EzriCare's Artificial Tears" that were imported by a third party from Global Pharma. The FDA cited Defendant EzriCare LLC for "fail[ing] to have adequate

[25] *See* DEP'T OF HEALTH AND HUMAN SERVICES, FOOD & DRUG ADMIN., located at https://www.fda.gov/media/166739/download.

[26] *See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ezricare-llc-658390-02132024.

procedures to ensure the ophthalmic drug products produced for [their] firm met appropriate quality attributes and were free of microbial contamination."[27]

27. The FDA also cited Defendant EzriCare LLC for "fail[ing] to have adequate supplier qualification procedures to ensure that the drug products received from Global Pharma Healthcare Private Limited were manufactured in compliance with CGMPs prior to being distributed in the United States," as well as being "unable to provide any written agreements or procedures that demonstrated you required your [contract manufacturing organization] to meet CGMP requirements or make suitable release decisions of drug products for distribution into the U.S. supply chain."[28]

28. The FDA emphasized that EzriCare LLC is "responsible for ensuring that the drugs [it] distribute[s] are not adulterated and are manufactured in accordance with CGMP requirements."[29]

TOLLING OF THE STATUTE OF LIMITATIONS, FRAUDULENT CONCEALMENT, EQUITABLE TOLLING, AND CONTINUING VIOLATIONS

29. Plaintiff did not discover and could not have discovered through the exercise of reasonable diligence, the existence of the claims sued upon herein until immediately prior to commencing this civil action.

30. Any applicable statutes of limitation have been tolled by Defendants' affirmative acts of fraudulent concealment and misrepresentations and/or violations of the CGMPs, as the facts alleged above reveal.

31. Because of the self-concealing nature of Defendants' actions and their affirmative

[27] *Id.*
[28] *Id.*
[29] *Id.*

acts of violating the requisite CGMPs, Plaintiff asserts the tolling of any applicable statutes of limitations affecting the claims raised herein.

32. Defendants are estopped from relying on any statute of limitations defense because of their unfair, negligent, and deceptive conduct.

33. By reason of the foregoing, the claims of Plaintiff are timely under any applicable statute of limitations, pursuant to the discovery rule, the equitable tolling doctrine, and/or fraudulent concealment.

COUNT ONE – Strict Liability (Failure to Warn)
(Against All Defendants)

34. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

35. Defendants sold the EzriCare Artificial Tears in the course of Defendants' business.

36. At all pertinent times, Plaintiff used the EzriCare Artificial Tears in her eyes, which is a reasonably foreseeable use.

37. Defendants knew or should have known that the EzriCare Artificial Tears were adulterated and/or contaminated with dangerous and deadly bacteria.

38. At all pertinent times, including the time(s) of sale and use, the EzriCare Artificial Tears, when put to the aforementioned reasonably foreseeable use, were in an unreasonably dangerous and defective condition because they failed to contain adequate and proper warnings and/or instructions regarding the presence of—and dangers of—*Pseudomonas Aeruginosa* and other bacteria within the bottles and/or packaging of EzriCare Artificial Tears. Defendants themselves failed to properly test and adequately warn and instruct Plaintiff as to the risks and benefits of the EzriCare Artificial Tears given her need for this information, thus breaching the duty owed by Defendants to Plaintiff.

39. Defendants knew that the risk of exposure to *Pseudomonas Aeruginosa* bacteria (and other bacteria) from use of its products was not readily recognizable to an ordinary consumer and that consumers would not inspect the product for bacteria.

40. Defendants did not adequately test and/or give adequate warnings to Plaintiff that the EzriCare Artificial Tears were contaminated with the *Pseudomonas Aaeruginosa* bacteria or about the dangers of the presence of *Pseudomonas Aeruginosa* bacteria (and other bacteria) in their artificial tear products.

41. Plaintiff was justified in her reliance on Defendants' manufacturing, labeling, packaging, marketing, and advertising of the product for use as artificial tears.

42. Had Plaintiff received notice or a warning that the EzriCare Artificial Tears were contaminated with the *Pseudomonas Aaeruginosa* bacteria (and other bacteria), she would not have used it and would not have suffered eye and vision damage that is possibly permanent.

43. Defendants' EzriCare Artificial Tears product was defective because Defendants failed to perform proper microbial testing on the Product, and it failed to contain warnings and/or instructions and breached express warranties and/or failed to conform to express factual representations upon which Plaintiff justifiably relied in electing to use EzriCare Artificial Tears. The defect or defects (*i.e.*, the *preventable*—or, at the very least, detectable before sale—contamination with the *Pseudomonas Aaeruginosa* and other bacteria) made EzriCare Artificial Tears unreasonably dangerous to persons, such as Plaintiff, who could reasonably be expected to use such product. As a result, the defect or defects were a producing cause of Plaintiff's injuries and damages.

44. Defendants' EzriCare Artificial Tears product failed to contain adequate warnings and/or instructions regarding the presence of—and dangers of—the *Pseudomonas Aaeruginosa*

bacteria (and other bacteria) with the use of the EzriCare Artificial Tears.

45. As a proximate result of Defendants' design, manufacture, packaging, labeling, marketing, sale, and distribution of EzriCare Artificial Tears, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT TWO – Strict Liability (Design and/or Manufacturing Defect)
(Against All Defendants)

46. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

47. Defendants engaged in the design, development, manufacture, marketing, packaging, labeling, sale, and distribution of EzriCare Artificial Tears in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

48. Defendants caused EzriCare Artificial Tears to enter the stream of commerce and to be sold through various retailers where Plaintiff purchased the EzriCare Artificial Tears, like Amazon.com.

49. EzriCare Artificial Tears were expected to, and did, reach consumers, including Plaintiff, without change in the condition in which it was manufactured and sold by Defendants and/or otherwise released into the stream of commerce.

50. Plaintiff used EzriCare Artificial Tears in a manner normally intended, recommended, promoted, and marketed by Defendants.

51. As found by the FDA, Defendants violated CGMPs and failed, among other things,

to properly test the Product for microbials before placing the Product into the stream of commerce for consumers, like Plaintiff, to purchase.

52. EzriCare Artificial Tears failed to perform safely when used by Plaintiff in a reasonably foreseeable manner; that is, the presence of the *Pseudomonas Aaeruginosa* and other bacteria rendered these tears unreasonably dangerous and exposed Plaintiff to a dangerous and deadly bacterium that caused her to suffer eye and vision damage that is possibly permanent.

53. The EzriCare Artificial Tears contained a manufacturing defect when they left the possession of Defendants. Specifically, the EzriCare Artificial Tears differ from Defendants' intended result or from (possibly) other lots of the same product line because they were contaminated with the *Pseudomonas Aeruginosa* and other bacteria, and Defendants failed to properly and adequately test the Product for the presence of bacteria before distributing it.

54. Importantly, EzriCare Artificial Tears is an inessential over-the-counter product that does not treat or cure any *serious* disease. Further, safer alternatives, including artificial tears products that contain preservatives to prevent the growth of bacteria, have been readily available for decades.

55. As a proximate result of Defendants' design, manufacture, packaging, labeling, marketing, sale, and distribution of EzriCare Artificial Tears, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT THREE – Products Liability (Negligence – Failure to Warn)

(Against All Defendants)

56. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

57. At all relevant times, Defendants engaged in the design, development, manufacture, marketing, sale, and distribution of the EzriCare Artificial Tears that were in in a defective and unreasonably dangerous condition and were nonetheless marketed and sold to consumers, including Plaintiff.

58. Defendants knew, or by the exercise of reasonable care should have known, use of EzriCare Artificial Tears was dangerous, harmful, and injurious when used by Plaintiff in a reasonably foreseeable manner.

59. Defendants knew, or by the exercise of reasonable care, should have known that ordinary consumers, such as Plaintiff, would not have realized the potential risks and dangers of EzriCare Artificial Tears, and that EzriCare Artificial Tears were likely to increase the risks of vision loss and/or significant damage to the eye, which renders it unreasonably dangerous when used in the manner it was intended and to an extent beyond what would be contemplated by the ordinary consumer.

60. Defendants owed a duty to all reasonably foreseeable consumers to disclose the risks associated with the use of EzriCare Artificial Tears.

61. Defendants breached their duty of care by failing to use reasonable care in providing adequate warnings on EzriCare Artificial Tears, including that EzriCare Artificial Tears were likely to increase the risks of vision loss and/or significant damage to the eye, which when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer.

62. The failure of Defendants to adequately warn about their defective EzriCare Artificial Tears, and their efforts to misleadingly advertise through conventional avenues, created a danger of injuries that were reasonably foreseeable at the time of design and/or manufacture and distribution.

63. At all relevant times, Defendants could have provided adequate warnings and instructions to prevent the harms and injuries set forth herein, such as providing full and accurate information about EzriCare Artificial Tears in advertising.

64. A reasonable actor under the same or similar circumstances would have warned and instructed of the dangers associated with the presence and contamination of the *Pseudomonas Aeruginosa* bacteria (and other bacteria).

65. Plaintiff was injured as a direct and proximate result of Defendants' failure to warn and instruct, because she would not have used the EzriCare Artificial Tears had she received adequate warnings and instructions that EzriCare Artificial Tears could increase the risks of vision loss and/or significant damage to the eye, which renders it unreasonably dangerous when used in the manner it was intended and to an extent beyond what would be contemplated by the ordinary consumer.

66. Defendants' lack of adequate and sufficient warnings and instructions, and their inadequate and misleading advertising, was a substantial contributing factor in causing harm to Plaintiff.

67. As a proximate result of Defendants' design, manufacture, marketing, packaging, labeling, sale, and distribution of EzriCare Artificial Tears, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT FOUR –Products Liability (Negligence – Design/Manufacturing Defect)
(Against All Defendants)

68. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

69. At all relevant times, Defendants engaged in the design, development, manufacture, packaging, labeling, marketing, sale, and distribution of EzriCare Artificial Tears in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

70. Defendants caused EzriCare Artificial Tears to enter the stream of commerce and to be sold through various retailers, such as Amazon.com, where Plaintiff purchased it.

71. EzriCare Artificial Tears were expected to, and did, reach consumers, including Plaintiff, without change in the condition in which it was manufactured and sold by Defendants and/or otherwise released into the stream of commerce.

72. Plaintiff used EzriCare Artificial Tears in a manner normally intended, recommended, promoted, and marketed by Defendants.

73. EzriCare Artificial Tears failed to perform safely when used by Plaintiff in a reasonably foreseeable manner, specifically increasing his risk of developing infection and resulting eye injury, significant damage to the eye, and/or vision loss.

74. The propensity to the exposure of *Pseudomonas Aeruginosa* and other bacteria from use of EzriCare Artificial Tears that can cause vision loss and/or significant damage to the eye renders EzriCare Artificial Tears unreasonably dangerous when used in the manner it was intended and to an extent beyond what would be contemplated by the ordinary consumer.

75. Safer alternatives, including products that contain a preservative to prevent contamination with bacteria, and/or single-use vials as opposed to multi-use bottles, have been readily available for decades.

76. Defendants knew, or by the exercise of reasonably care should have known, that EzriCare Artificial Tears were unreasonably dangerous but have continued to design, manufacture, package, label, sell, distribute, market, promote, and supply EzriCare Artificial Tears so as to maximize sales and profits at the expense of public health and safety in conscious disregard of the foreseeable harm to the consuming public, including Plaintiff.

77. Defendants owed a duty to all reasonably foreseeable users to design a safe product.

78. Defendants breached their duty by failing to use reasonable care in the design and/or manufacturing of EzriCare Artificial Tears because it was unreasonably dangerous in that it increased the risks of vison loss and thus renders EzriCare Artificial Tears unreasonably dangerous when used in the manner it was intended and to an extent beyond what would be contemplated by the ordinary consumer.

79. Defendants also breached their duty by failing to use reasonable care by failing to use cost-effective, reasonably feasible alternative designs in the design and/or manufacturing of EzriCare Artificial Tears.

80. A reasonable actor under the same or similar circumstances would have designed a safer product.

81. A reasonable actor under the same or similar circumstances would have not allowed EzriCare Artificial Tears to become contaminated with *Pseudomonas Aeruginosa* or other bacteria.

82. As a proximate result of Defendants' design, manufacture, marketing, sale, and

distribution of EzriCare Artificial Tears, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT FIVE – Negligence / Gross Negligence
(Against All Defendants)

83. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

84. Defendants' owed a duty of reasonable care to Plaintiff and other reasonably foreseeable consumers to not only ensure that the EzriCare Artificial Tears was safe for intended use but that its labeling adequately warned of any and all risks associated with its use.

85. Defendants also owed a duty of reasonable care to Plaintiff and other reasonably foreseeable consumers to not market, design, manufacture, produce, supply, inspect, test, sell, and/or distribute unsafe and dangerous products that they knew or should have known through the exercise of reasonable diligence were unsafe and dangerous due to the presence of *Pseudomonas Aeruginosa* and other bacteria.

86. Defendants breached this duty of care owed to Plaintiff by failing to ensure that EzriCare Artificial Tears were safe for use, as intended, and were properly tested and stored, as well as placing into the stream of commerce an unsafe and dangerous/adulterated product.

87. Consequently, it was reasonably foreseeable that Plaintiff—as a reasonable, foreseeable consumer—would purchase and use Defendants' EzriCare Artificial Tears and suffer injury from such use due to the presence of the dangerous and deadly *Pseudomonas Aeruginosa*

bacteria (and other bacteria).

88. Plaintiff's injuries are also directly caused by Defendants' breach of the duty of reasonable care owed to Plaintiff, as but for Defendants' failure to appropriately test for and/or warn of the inherent dangers associated with the presence of the *Pseudomonas Aeruginosa* bacteria (and other bacteria) within the bottles and/or packaging of the EzriCare Artificial Tears, Plaintiff would not have purchased and/or used it and would not have suffered serious injury to his left eye and to her vision.

89. Defendants' negligence and extreme carelessness includes, but is not limited to: their marketing, designing, manufacturing, producing, supplying, inspecting, testing, selling, and/or distributing the EzriCare Artificial Tears in one or more of the following respects:

a. In failing to comply with Current Good Manufacturing Practices, as described by the FDA and as discussed above;

b. In failing to manufacture the Product with a preservative to decrease the risk of bacterial growth in the Product;

c. In failing to manufacture and package the Product in single use containers, thus reducing the risk of bacterial growth in the Product from multiple uses;

d. In failing to warn Plaintiff of the hazards associated with the use of the product;

e. In failing to properly test their products for microbials, as well as to determine adequacy and effectiveness or safety measures, if any, prior to releasing EzriCare Artificial Tears on the market for consumer use;

f. In failing to inform product users, such as Plaintiff, as to the safe and proper methods of handling and using the EzriCare Artificial Tears;

g. In failing to remove EzriCare Artificial Tears from the market when Defendants knew or should have known this product was defective and/or contaminated;

h. In failing to adopt written procedures for handling written and oral complaints for their drug products and failing to document and investigate complaints that were/are received;[30]

[30] *See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ezricare-llc-658390-02132024.

i. In failing to inform the public in general and Plaintiff, in particular, of the known dangers of using EzriCare Artificial Tears—a preservative-free and multi-use bottle product;

j. In marketing and labeling EzriCare Artificial Tears as safe for all uses despite knowledge to the contrary;

k. In failing to act like a reasonably prudent actor under similar circumstances;

l. In failing to accurately disclose in its labeling and advertising that the EzriCare Artificial Tears were contaminated with dangerous and deadly bacteria.

90. Each and all of these acts and omissions, taken singularly or in combination, were a proximate cause of the injuries and damages sustained by Plaintiff and constitute gross negligence.

91. At all pertinent times, Defendants knew or should have known that the EzriCare Artificial Tears were unreasonably dangerous and defective (*i.e.*, contaminated) when put to its reasonably anticipated use.

92. Defendants' acts and/or omissions constitute gross negligence because they constitute a total lack of care and an extreme departure from what a reasonably careful actor would do in the same situation to prevent foreseeable harm to Plaintiff.

93. Defendants acted and/or failed to act willfully, and with a conscious and reckless disregard for the rights and interests of Plaintiff; their acts and omissions had a great probability of causing significant harm and in fact resulted in such harm to Plaintiff.

94. Plaintiff was injured as a direct and proximate result of negligence and/or gross negligence as described herein.

95. Defendants' negligence and/or gross negligence was a substantial factor in causing and/or contributing to Plaintiff's harms.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's

favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT SIX – Negligence (Negligent Misrepresentation/Omission)
(Against All Defendants)

96. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

97. Through their labeling and advertising and the course of their regular business, Defendants made representations to Plaintiff concerning the active and inactive ingredients (as well as the alleged uncontaminated nature) in the EzriCare Artificial Tears.

98. Defendants intended that the Plaintiff rely on their representations.

99. Defendants' representations were material to Plaintiff's decision to purchase and use the EzriCare Artificial Tears.

100. Defendants have a duty to provide accurate information to consumers with respect to the ingredients and/or contaminants identified in the EzriCare Artificial Tears, as detailed above.

101. Defendants failed to fulfill their duty to accurately disclose in the Product's labeling and advertising that the EzriCare Artificial Tears were contaminated with a dangerous and deadly bacterium.

102. Additionally, Defendants have a duty to not make false representations with respect to the EzriCare Artificial Tears.

103. Defendants failed to fulfill their duty or use ordinary care when they made false representations regarding the quality and safety of the EzriCare Artificial Tears, as detailed above.

104. Such failures to disclose on the part of Defendants amount to negligent omission, and the representations regarding the quality and safety of the product amount to negligent misrepresentation.

105. Plaintiff reasonably relied upon such representations and omissions to her detriment.

106. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of EzriCare Artificial Tears, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT SEVEN – Fraud
(Against All Defendants)

107. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

108. Defendants engaged in the development, manufacture, design, packaging, labeling, marketing, sale, and distribution of certain products, including EzriCare Artificial Tears, owed a duty to provide accurate and complete information regarding said products.

109. Defendants fraudulently misrepresented the use of EzriCare Artificial Tears as "safe" and "sterile."

110. Defendants knew that these misrepresentations and omissions were material, false, incomplete, misleading, deceptive, and deceitful when they were made. Alternatively, Defendants concealed information and made the representations with such reckless disregard for the truth that knowledge of the falsity can be imputed to them.

111. Defendants made the misrepresentations and omissions for the purpose of deceiving and defrauding consumers, including Plaintiff, with the intention of having them act and

rely on such misrepresentations and/or omissions.

112. Plaintiff relied, with reasonable justification, on the misrepresentations by Defendants, which induced her to purchase and use EzriCare Artificial Tears to her detriment.

113. Defendants profited significantly from their unethical and illegal conduct that fraudulently induced Plaintiff and other consumers to purchase and use a dangerous and defective product.

114. Defendants' actions, and Plaintiff's justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.

115. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of EzriCare Artificial Tears, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT EIGHT – Fraudulent Concealment
(Against All Defendants)

116. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

117. Defendants owed consumers, including Plaintiff, a duty to fully and accurately disclose all material facts regarding EzriCare Artificial Tears, not to conceal material defects related thereto, not to place this defective product into the stream of commerce, and to fully and accurately label product packaging. To the contrary, Defendants explicitly and/or implicitly represented that EzriCare Artificial Tears were safe and sterile.

118. Defendants actively and intentionally concealed and/or suppressed material facts, in whole or in part, to induce Plaintiff to purchase and use EzriCare Artificial Tears. Defendants did so at her expense. Specifically, Defendants knew or should have known through the exercise of reasonable diligence, that the use of EzriCare Artificial Tears may expose a consumer to *Pseudomonas Aeruginosa* or other bacteria.

119. Defendants know or should have known that use of EzriCare Artificial Tears may expose a consumer to *Pseudomonas Aeruginosa* or other bacteria.

120. Defendants made the misrepresentations and omissions for the purpose of deceiving and defrauding Plaintiff and with the intention of having her act and rely on such misrepresentations and/or omissions.

121. Defendants knew that their concealments, misrepresentations, and omissions were material, false, incomplete, misleading, deceptive, and deceitful when they were made. Alternatively, Defendants concealed information and made the representations with such reckless disregard for the truth that knowledge of the falsity can be imputed to them.

122. Defendants profited significantly from their unethical and illegal conduct that caused Plaintiff to purchase and use a dangerous and defective (*i.e.*, contaminated) product.

123. Defendants' actions and representations, and Plaintiff's justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.

124. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of EzriCare Artificial Tears, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's

favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUT NINE – Breach of Express Warranty
(Against All Defendants)

125. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

126. As detailed above, Defendants, through its advertising, marketing, packaging, and labeling, expressly warranted that the EzriCare Artificial Tears were safe and fit for the purposes intended, that they were of merchantable quality, and that they did not pose dangerous health risks.

127. Moreover, the labeling for the EzriCare Artificial Tears represents that the use of these artificial tears serves to protect the eye from dryness and/or irritation, and that these artificial tears are safe for use in the eye. Such statements constitute an affirmation of fact or promise or a description of the product as being safe and not posing a dangerous health risk.

128. Defendants breached this express warranty because the EzriCare Artificial Tears are not safe. To the contrary, these artificial tears pose a serious and dangerous health risk because they are contaminated with *Pseudomonas Aeruginosa* or other bacteria.

129. Plaintiff read and relied on these express warranties provided by Defendants in the labeling, packaging, and advertisements.

130. Defendants breached their express warranties because the artificial tears at issue are adulterated/contaminated and not reasonably safe for their intended use.

131. Defendants knew or should have known that the EzriCare Artificial tears did not conform to their express warranties and representations and that, in fact, they are not safe and pose serious health risks because they are contaminated with dangerous and deadly bacteria.

132. Defendants' representations were made to induce Plaintiff to purchase the artificial

tears at issue and were material factors in Plaintiff's decision to purchase this product.

133. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of EzriCare Artificial Tears, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT TEN – Breach of Implied Warranty
(Against All Defendants)

134. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

135. Because the EzriCare Artificial Tears are contaminated with *Pseudomonas Aeruginosa* and other bacteria, they were not of the same quality as those generally acceptable in the trade and were not fit for the ordinary purposes for which such artificial tears are used.

136. Plaintiff purchased the EzriCare Artificial Tears in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

137. The EzriCare Artificial Tears were not altered by Plaintiff.

138. Plaintiff was a foreseeable user of the EzriCare Artificial Tears.

139. Plaintiff used the EzriCare Artificial Tears in the manner intended.

140. As alleged, Defendants' artificial tears were not adequately labeled and did not disclose that they were contaminated with *Pseudomonas Aeruginosa* and/or other bacteria.

141. The EzriCare Artificial Tears did not measure up to the promises or facts stated in the marketing, packaging, labeling, advertisement, and communications by and from Defendants.

142. Defendants impliedly warranted that the EzriCare Artificial Tears were merchantable, fit, and safe for ordinary use.

143. Defendants further impliedly warranted that the EzriCare Artificial Tears were fit for the particular purposes for which they were intended and sold.

144. Contrary to these implied warranties, Defendants' artificial tears were defective, unmerchantable, and unfit for their ordinary use when sold and unfit for the particular purpose for which they were sold.

145. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of EzriCare Artificial Tears, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT ELEVEN – Negligent Failure to Timely Recall
(Against All Defendants)

146. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

147. At all relevant times, Defendants designed, developed, managed, operated, inspected, marketed, advertised, promoted, disseminated, made publicly available, and/or benefited from the EzriCare Artificial Tears and, therefore, owed a duty of reasonable care to avoid causing harm to those who used EzriCare Artificial Tears, such as Plaintiff.

148. Defendants knew or should have known through the exercise of reasonable care, the risks to consumers posed by EzriCare Artificial Tears.

149. Defendants knew or, by the exercise of reasonable care, should have known use of EzriCare Artificial Tears was harmful and had the potential to increase the risks vision loss and/or significant damage to the eye, which renders it unreasonably dangerous when used in the manner it was intended and to an extent beyond what would be contemplated by the ordinary consumer.

150. Defendants owed a duty to Plaintiff to exercise reasonable care in conducting their business to properly and reasonably design, research, develop, manufacture, produce, process, assemble, inspect, supply, distribute, deliver, broker, market, warn, maintain, repair, modify, recall, retrofit, engineer, test, recommend, advertise, and/or make available EzriCare Artificial Tears.

151. Defendants also owed a continuing duty to Plaintiff to remove, recall, or retrofit unsafe and defective products, such as EzriCare Artificial Tears, across the United States (including in Plaintiff's state of California).

152. Defendants knew or reasonably should have known that EzriCare Artificial Tears were dangerous and not safe for use.

153. Defendants knew or, in the exercise of reasonable and ordinary care, should have known that EzriCare Artificial Tears were defective and unsafe for Plaintiff, who is a person likely to use EzriCare Artificial Tears for the purpose and in the manner for which it was intended to be used and for purposes reasonably foreseeable to Defendants.

154. At all times, Defendants negligently breached said duties and unreasonably and negligently allowed EzriCare Artificial Tears to be used by Plaintiff without proper recall, retrofit, or warning.

155. As cited by the FDA, Defendants failed to have adequate procedures in place for processing and analyzing product complaints, including complaints for the EzriCare Artificial

Tears.

156. Defendants failed to properly and timely remove, retrofit, or warn of the serious safety risk posed by EzriCare Artificial Tears to consumers.

157. In failing to properly and timely recall, retrofit, or warn of the serious safety risks the Products pose to consumers and the public, Defendants have failed to act as a reasonable manufacturer, designer, or distributer would under the same or similar circumstances and failed to exercise reasonable care.

158. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of EzriCare Artificial Tears, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT TWELVE – Violation of New Jersey's Consumer Fraud Act (N.J. Stat. § 56:8-2 et seq.)
(Against Defendants EzriCare LLC and EzriRx LLC)

159. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

160. New Jersey's Consumer Fraud Act ("NJCFA") section 56:8-2 states:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

N.J. Stat. § 56:8-2.

161. Defendants violated the NJCFA by misrepresenting the sterile, uncontaminated, and safe nature of EzriCare Artificial Tears; that is, EzriCare Artificial Tears are not sterile, are contaminated with dangerous bacteria and are not safe.

162. In the course of business, Defendants made affirmative misrepresentations that conveyed to Plaintiff and the general public that EzriCare Artificial Tears were safe and suitable as a treatment for the symptoms related to dry eyes. Defendants, however, concealed and suppressed material facts concerning EzriCare Artificial Tears, including that the Product is unsafe and contaminated with dangerous and drug-resistant bacteria that can lead to / cause permanent damage to the eye and vision.

163. Plaintiff had no way of discerning that Defendants' representations were false and misleading because the labeling did not disclose the presence of the *Pseudomonas Aeruginosa* bacteria (or other bacteria), the violation of CGMPs by Defendants, and Plaintiff had no reason to otherwise suspect that EzriCare Artificial Tears were contaminated.

164. Defendants thus violated New Jersey law by making statements, when considered as a whole from the perspective of the reasonable consumer, that conveyed that EzriCare Artificial Tears were safe and suitable as a treatment for the symptoms related to dry eyes.

165. Defendants made affirmative misrepresentations about the safety and quality of the EzriCare Artificial Tears that were not true, and they failed to disclose material facts regarding the design, manufacture, testing, packaging, and labeling of the EzriCare Artificial Tears, which mislead Plaintiff.

166. Defendants knew or should have known that their conduct violated New Jersey law.

167. Defendant owed Plaintiff a duty to disclose the true and unsafe nature of EzriCare

Artificial Tears.

168. Defendants' misrepresentation of the true characteristics of EzriCare Artificial Tears (*i.e.*, that the Product is contaminated) was material to Plaintiff.

169. Defendants' unfair or deceptive acts or practices were likely to and did in fact deceive reasonable consumers, including Plaintiff, about the true, unsafe nature of EzriCare Artificial Tears.

170. Plaintiff would not have purchased EzriCare Artificial Tears had she known that the Product was contaminated with dangerous and deadly bacteria, including but not limited to *Pseudomonas Aerginosa*.

171. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, including public health. Thus, Defendants' unlawful acts and practices complained of herein affect the public interest.

172. Plaintiff suffered ascertainable loss and actual damages as a direct and proximate result of Defendants' misrepresentations and failure to disclose material information. Defendants have an ongoing duty to all customers and the public to refrain from unfair and deceptive practices under New Jersey law. Plaintiff suffered ascertainable loss because of Defendants' deceptive and unfair acts and practices made in the course of Defendants' business.

173. Through its deceptive practices, Defendants have improperly obtained and retained money from Plaintiff.

174. The injury caused by Defendants' conduct is not outweighed by any countervailing benefits to consumers, including Plaintiff, or to competition.

175. The injury caused by Defendants' conduct could not reasonably have been avoided by Plaintiff because she did not know and could not have known that the Product was contaminated

with *Pseudomonas Aeruginosa* and other bacteria.

176. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of EzriCare Artificial Tears, Plaintiff was injured catastrophically and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

WHEREFORE, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT THIRTEEN – Violation of the New Jersey Products Liability Act, N.J. Stat. § 2A:58C-1 et seq.
(Against All Defendants)

177. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

178. Plaintiff brings a product liability action against Defendants, as that term is defined under N.J. Stat. § 2A:58C-1(3).

179. Defendant EzriCare LLC is a product seller, as that term is defined under N.J.S. § 2A:58C-8, because it, in the course of a business, "sells; distributes; leases; installs; prepares or assembles a manufacturer's product according to the manufacturer's plan, intention, design, specifications or formulations; blends; packages; labels; markets; repairs; maintains or otherwise is involved in placing a product in the line of commerce." N.J.S. § 2A:58C-8.

180. Defendant EzriRx LLC is a product seller, as that term is defined under N.J.S. § 2A:58C-8, because it, in the course of a business, "sells; distributes; leases; installs; prepares or assembles a manufacturer's product according to the manufacturer's plan, intention, design, specifications or formulations; blends; packages; labels; markets; repairs; maintains or otherwise

is involved in placing a product in the line of commerce." N.J.S. § 2A:58C-8.

181. Defendant Global Pharma Healthcare Private Limited is considered a manufacturer under N.J.S. § 2A:58C-8 because it (1) designs, formulates, produces, creates, makes, packages, labels or constructs any product or component of a product, (2) is a product seller with respect to a given product to the extent the product seller designs, formulates, produces, creates, makes, packages, labels or constructs the product before its sale, and (3) holds itself out as a manufacturer to the user of the product.

182. Defendants, as product sellers, are liable to Plaintiff under the New Jersey Product Liability Act because EzriCare Artificial Tears deviated from the design specifications, formulae, or performance standards of the manufacturer, failed to contain adequate warnings or instructions, and was designed in a defective manner. N.J.S. § 2A:58C-2.

183. Defendants EzriCare LLC and EzriRx LLC as product sellers, exercised some significant control over the design, manufacture, packaging, and/or labeling of the EzriCare Artificial Tears relative to the alleged defect in the product (*i.e.*, the contamination with *Pseudomonas Aeruginosa* and other bacteria) which caused the injury. N.J.S. § 2A:58C-9(d).

184. Further, EzriCare Artificial Tears were and are defective in both design and manufacture, as there were, and remain, "a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product." N.J.S. § 2A:58C-3(a)(1).

185. As a result of Defendants' violations of the New Jersey Products Liability Act, Plaintiff suffered damage, likely permanent, to her eyes and vision.

COUNT FOURTEEN – Punitive Damages
(Against All Defendants)

186. Plaintiff incorporates by reference and re-alleges each and every allegation

contained above, as though fully set forth herein.

187. The Defendants have acted willfully, wantonly, and/or recklessly in one or more of the following ways:

a. By designing and manufacturing a "preservative-free" product in a "multi-use" bottle, Defendants knew of the risk of exposure to bacteria—specifically, the *Pseudomonas Aeruginosa* bacteria—by the EzriCare Artificial Tears before designing, manufacturing, packaging, labeling, marketing, distributing, and/or selling it yet purposefully proceeded with such action;

b. Despite their knowledge of the risk of exposure to *Pseudomonas Aeruginosa* and other bacteria within the EzriCare Artificial Tears, Defendants affirmatively minimized this risk through the violation of CGMPs, like failing to perform proper microbial testing, among other things; and

c. Through the actions outlined above, Defendants exhibited a reckless indifference to the safety of users of EzriCare Artificial Tears, including Plaintiff as described herein, knowing the dangers and risks of the EzriCare Artificial Tears yet concealing and/or omitting this information. The concerted action was outrageous due to Defendants' reckless indifference to the safety of users of the EzriCare Artificial Tears, including Plaintiff.

188. As a direct and proximate result of the willful, wanton, and/or reckless conduct of the Defendants, Plaintiff has sustained damage as set forth above.

189. All of the Defendants have been or should have been aware that their products were contaminated with *Pseudomonas Aeruginosa* and other bacteria through proper testing. Despite this all the Defendants have failed to inform their consumers of this known hazard. As such, all Defendants should be liable for punitive damages to Plaintiff.

DEMAND FOR JURY TRIAL

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as to each and every count,

including:

A. Awarding compensatory damages including but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other noneconomic damages in an amount to be determined at trial of this action;

B. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings, and other economic damages in an amount to be determined at trial of this action;

C. Punitive and/or exemplary damages for the wanton, willful, fraudulent, and/or reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

D. Prejudgment interest;

E. Postjudgment interest;

F. Awarding Plaintiff's reasonable attorneys' fees;

G. Awarding Plaintiff the costs of these proceedings; and

H. Such other and further relief as this Court deems just and proper.

DATED: June 26, 2024

/s/ James D. Barger

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