POGUST GOODHEAD, LLC
Michael G. Daly, Esq., ID No. 025812010
Joshua M. Neuman, Esq., ID No. 209832016
161 Washington Street, Suite 250
Conshohocken, PA 19428
mdaly@pogustgoodhead.com
jneuman@pogustgoodhead.com
Phone: (610) 941-4204
Fax: (610) 941-4245
Attorneys for Plaintiff, Beverly Jennings

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BEVERLY JENNINGS, **Plaintiff,** **v.** **EZRICARE LLC; EZRIRX LLC; GLOBAL PHARMA HEALTHCARE PRIVATE LTD; ARU PHARMA, INC.; and AMAZON.COM, INC.** **Defendants.**	**Civil Action No. _____** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Beverly Jennings ("Plaintiff"), by and through her undersigned counsel, files this Complaint against Defendants EzriCare LLC, EzriRx LLC, Global Pharma Healthcare Private Ltd., Aru Pharma, Inc., and Amazon.com, Inc. ("Defendants"), and in support thereof 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" 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 *Pseudomonas aeruginosa* bacteria in Defendants' Product is due to, *inter alia*, Defendants' violations of the Food and Drug Administration's ("FDA") Current Good Manufacturing Processes ("CGMP"), 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' Product.

4. 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.

5. Plaintiff has suffered, and continues to suffer, economic damages due to Defendants' misconduct and seeks injunctive relief and restitution for the full purchase price of the artificial tear products she purchased. Plaintiff alleges the following based upon personal

[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-warns-consumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination.
[2] *Id*.

knowledge as well as investigation by counsel, and as to all other matters, upon information and belief. Plaintiff further believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

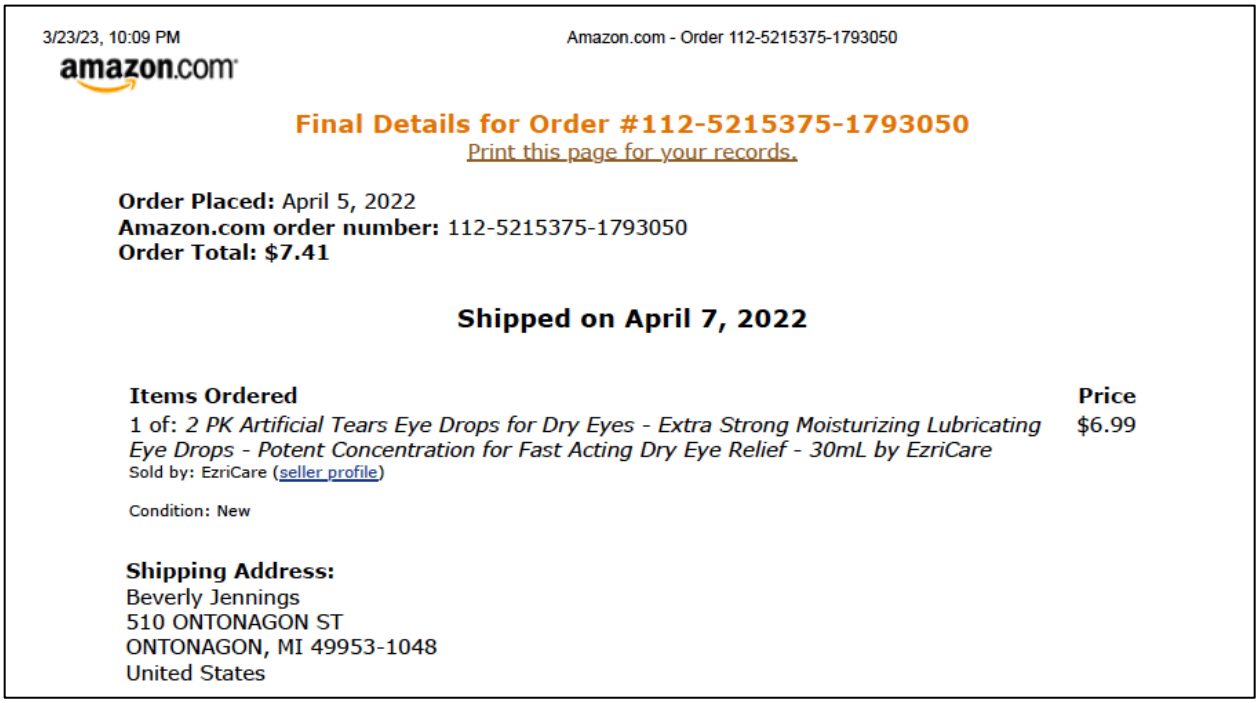
THE PARTIES

Plaintiff

6. Plaintiff, Beverly Jennings is, and at all times relevant hereto has been, a citizen and resident of Ontonagon, Michigan.

7. On April 5, 2022, Plaintiff purchased EzriCare Artificial Tears online via Amazon.com, which she began to use after it was delivered by Amazon on April 7, 2022.

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



3/23/23, 10:09 PM Amazon.com - Order 112-5215375-1793050

amazon.com

Final Details for Order #112-5215375-1793050

Print this page for your records.

Order Placed: April 5, 2022
Amazon.com order number: 112-5215375-1793050
Order Total: $7.41

Shipped on April 7, 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:
Beverly Jennings
510 ONTONAGON ST
ONTONAGON, MI 49953-1048
United States

9. Prior to purchasing the EzriCare Artificial Tears from Amazon.com, Plaintiff reviewed the Product information on Amazon's website. After receiving the EzriCare Artificial Tears from Amazon.com, Plaintiff reviewed the Product packaging and labeling, including the instructions for use.

10. Approximately two months after using the Product, Plaintiff began experiencing pain and redness in her right eye.

11. On June 2, 2022, Plaintiff was diagnosed with a Neurotrophic Ulcer in her right eye.

12. On June 14, 2022, Plaintiff visited the ophthalmologist again and was diagnosed with a Corneal Ulcer. During this visit, cultures were obtained, which returned positive for pseudomonas aeruginosa.

13. On June 17, 2022, Plaintiff returned to the ophthalmologist complaining of general pain and intermittent sharp stabbing pains in her right eye. Plaintiff was also experiencing an increase in mucus and discharge, as well as poor vision in her right eye. During this visit, Plaintiff was diagnosed with a pan-resistant pseudomonal corneal ulcer in her right eye and was prescribed Vigamox, Tobramycin, and Atropine to treat her injury.

14. On June 20, 2022, Plaintiff returned to the ophthalmologist due to recurring right eye pain, difficulty seeing, flashes of light, and discharge.

15. Thereafter, Plaintiff continued her medication regiment, with treatment and weekly visits to the ophthalmologist.

16. On August 12, 2022, Plaintiff reported irritation and burning in her right eye, along with floaters in her vision.

17. Thereafter, Plaintiff's vision in her right eye continued to worsen, and her medication regiment now included Fortified Tobramycin, Xiidra, Atropine, Erythromycin ointment, and Doxycycline.

18. On September 9, 2022, Plaintiff was experiencing a tight sensation on her right eye with pressure. As for her vision, while she was able to see peripheral shadows, she was unable to

make out figures. At this time, her diagnosis remained the same, pan-resistant pseudomonal corneal ulcer in her right eye with severe hypopyon and hyphema.

19. By September 21, 2022, Plaintiff lost all vision in her right eye, and she was experiencing consistent pain in her right eye described as a sharp pain to a dull ache.

20. Thereafter, Plaintiff was diagnosed with a dense corneal scar with vascularization in her right eye and complete vision loss.

21. As a result of Plaintiff's use of EzriCare Artificial Tears, she contracted a serious Pseudomonas aeruginosa bacterial infection, which caused her to develop a corneal ulcer, scarring, and complete vision loss in her right eye.

22. Plaintiff injuries to her right eye are debilitating and permanent.

Defendants

23. Defendant EzriCare LLC ("EzriCare") 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 markets, advertises, labels, distributes, packages, imports, supplies, and sells the Product at issue in this litigation.

24. Defendant EzriRx LLC ("EzriRx") 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 0870. EzriRx markets, advertises, labels, distributes, packages, imports, supplies, and sells the Product at issue in this litigation.

25. Defendant Global Pharma Healthcare Private Limited ("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 located at Third Floor, 2A Ganga

Nagar, Fourth Street, Kodambakkam, Chennai, Tamil Nadu, 600024, India. Global Pharma's Corporate Identification Number (CIN) with India's Ministry of Corporate Affairs is U51102TN1986PTC013099. Global Pharma manufactures, designs, tests, labels, distributes, and sells the Product at issue in this litigation.

26. Defendant Aru Pharma Inc. ("Aru Pharma") is, and at all times relevant to this action was, a New York Limited Liability Company with its principal place of business located at 696 Locust Street, Mount Vernon, New York 10552. Aru Pharma Inc. designs, tests, manufactures, imports, and distributes the Product at issue in this litigation.

27. Defendant Amazon.com, Inc. ("Amazon") is, and at all relevant times was, a Delaware Corporation with its principal place of business located at 410 Terry Avenue North, Seattle, WA 98109. Amazon.com, Inc. markets, advertises, distributes, and sells the Product at issue in this litigation.

28. 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 Product was contaminated with a dangerous and deadly bacterium and, thus, was hazardous to the life, health, and safety of persons, such as Plaintiff, who were exposed to the Product.

29. At all pertinent times, Defendants were engaged in the research, development, manufacture, design, testing, packaging, labeling, sale, and marketing of the Product throughout the United States and within the State of New Jersey.

JURISDICTION AND VENUE

30. 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.

31. At all relevant times, Defendants, individually and/or collectively, manufactured, designed, marketed, labeled, distributed, promoted and/or sold, to consumers like Plaintiff, the Product at issue in this litigation, which was contaminated with a rare and drug-resistant strain of *Pseudomonas aeruginosa* bacteria within New Jersey and the United States.

32. This Court has personal jurisdiction over Defendants because Defendants have purposefully availed themselves in New Jersey and have engaged in significant, continuous, and systemic business activities and targeted contacts with the State of New Jersey. Further, Defendants regularly conduct business in the State of New Jersey relating to the design, development, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of the Product. As such, jurisdiction over Defendants would not offend due process or traditional notions of fair play and substantial justice.

General Personal Jurisdiction

33. This Court has general personal jurisdiction over Defendants EzriCare and Defendant EzriRx, because Defendants have their principal places of business located in New Jersey.

34. 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 Michigan.

35. This Court also has general personal jurisdiction over the manufacturer of the Product, Defendant Global Pharma. Defendant Global Pharma either directly, or through its agents, apparent agents, servants and/or employees engaged in a distribution deal that would see

the continuous and systematic sale of the Product in the State of New Jersey. Defendant Global Pharma accepts money from purchasers located in New Jersey, has engaged in systematic and continuous business activities in New Jersey, transacts substantial business with New Jersey entities and residents, and generally has sufficient minimum contacts in New Jersey.

36. This Court has personal jurisdiction over Defendant Aru Pharma because Aru Pharma conducts business in New Jersey, including business with Defendants EzriCare and/or EzriRx, who are headquartered in Ocean County, New Jersey. Defendant Aru Pharma designed, manufactured, supplied, distributed, and/or shipped the Product in the State of New Jersey, accepts money from purchasers located in New Jersey, has engaged in systematic and continuous business activities in New Jersey, transacts substantial business with New Jersey entities and residents, and generally has sufficient minimum contacts in New Jersey.

37. Further, this Court has general personal jurisdiction over Defendant Amazon because Amazon conducts substantial business in New Jersey, with, *inter alia*, 19 fulfillment and sortation centers and 20 delivery stations physically located in the State of New Jersey.[3]

38. Additionally, Amazon conducts business with Defendants EzriCare and/or EzriRx, who are headquartered in Ocean County, New Jersey. Defendant Amazon sells, supplies, distributes, ships, advertises, and/or markets the sale of Defendants' consumer products, including the EzriCare Artificial Tears Product, out of New Jersey, has engaged in systematic and continuous business activities in New Jersey, transacts substantial business with New Jersey entities and residents, and generally has sufficient minimum contacts in New Jersey.

Specific Personal Jurisdiction

39. This Court also has specific personal jurisdiction over the Defendants due to the

[3] https://www.nj.com/business/2022/05/amazon-to-shrink-warehouse-space-in-nj-after-decade-of-rapid-expansion.html (last accessed May 3, 2023).

Product-specific business activities, including but not limited to the development, testing, packaging, safety monitoring, promotion, marketing, distribution, labeling and/or sale of the adulterated and contaminated Product that took place in the State of New Jersey.

40. Defendants are engaged in substantial and not isolated business activities within the State of New Jersey.

41. Upon information and belief, Defendant EzriCare operates its business practices out of its New Jersey office(s). Within the State of New Jersey, Defendant EzriCare is engaged in, *inter alia*, the development, testing, packaging, safety monitoring, promotion, marketing, distribution, labeling and/or sale, of the Product.

42. Upon information and belief, Defendant EzriRx operates its business practices out of its New Jersey office(s). Within the State of New Jersey, Defendant EzriRx is engaged in, *inter alia*, the development, testing, packaging, safety monitoring, promotion, marketing, distribution, labeling and/or sale, of the Product. As described above, EzriRx operates an online platform from its principal place of business in New Jersey that allows pharmacies to purchase over tens of thousands of medications and over-the-counter products from wholesalers throughout the United States, including the Product at issue in this litigation.[4]

43. This Court has specific personal jurisdiction over Defendant Global Pharma because Global Pharma engaged in substantial and not isolated activity within the State of New Jersey related to the design, development, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of the EzriCare Artificial Tears Product. Defendant Global Pharma purposefully established minimum contacts within the forum by contracting with the New Jersey based Defendants, EzriCare and EzriRx, to assist in the design, development, testing, packaging,

[4] https://www.ezrirx.com/ (last accessed May 15, 2023).

promotion, marketing, distribution, labeling, and/or sale of the Product. Global Pharma purposefully availed itself of this forum by conducting substantial, continuous, and planned activities in the State of New Jersey through its communications and interactions with the New Jersey based Defendants, which ultimately led to the wide-scale distribution of the product throughout New Jersey and the United States. Such activity was substantial, continuous, and planned so that Defendant Global Pharma, within the Product's supply chain, from its direct conduct in the State of New Jersey.

44. This Court has specific personal jurisdiction over Defendant Aru Pharma because Aru Pharma engaged in substantial and not isolated activity within the State of New Jersey related to the design, development, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of the EzriCare Artificial Tears Product. Defendant Aru Pharma purposefully established minimum contacts within the forum by contracting with the New Jersey based Defendants, EzriCare and EzriRx, to assist in the design, development, testing, packaging, promotion, marketing, distribution, labeling, and/or sale of the Product. Aru Pharma purposefully availed itself of this forum by conducting substantial, continuous, and planned activities in the State of New Jersey through its communications and interactions with the New Jersey based Defendants, which ultimately led to the wide-scale distribution of the product throughout New Jersey and the United States. Such activity was substantial, continuous, and planned so that Defendant Aru Pharma, within the Product's supply chain, from its direct conduct in the State of New Jersey.

45. Additionally, this Court has specific personal jurisdiction over Defendant Amazon because Amazon engaged in substantial and not isolated activity within the State of New Jersey related to the marketing, advertising, sale, supply, distribution, and/or shipment of the EzriCare

Artificial Tears Product. Defendant Amazon purposefully established minimum contacts within the forum by contracting with the New Jersey based Defendants, EzriCare and EzriRx, to conduct the marketing, advertising, sale, supply, distribution, and/or shipment of Product. Amazon purposefully availed itself of this forum by conducting substantial, continuous, and planned activities in the State of New Jersey through its communications and interactions with the New Jersey based Defendants, which ultimately led to the wide-scale distribution of the product throughout New Jersey and the United States. Such activity was substantial, continuous, and planned so that Defendant Amazon, within the Product's supply chain, would profit from its direct conduct in the State of New Jersey.

46. All Defendants derive substantial revenue from the Product, which was initially designed, developed, and tested by the New Jersey Based Defendants out of their New Jersey offices. Thereafter, the Product was promoted, marketed, distributed, shipped, and sold within the State of New Jersey. As such, Defendants expected or should have expected that their business activities, which originated and were centralized out of the State of New Jersey, could or would subject them to legal action in New Jersey.

47. Upon information and belief, Defendants are subject to jurisdiction within the State of New Jersey and this Court because at all relevant times, Defendants committed tortuous acts within the State of New Jersey out of which these causes of action arise.

48. Further, all Defendants were involved in the business of monitoring and reporting adverse events concerning the Product, and had a role in the decision process and response of Defendants, if any, related to these adverse events.

49. Additionally, Defendant Amazon was involved in the business of retail distribution of the Product, and further had a role in the decision process of how consumers, like Plaintiff, were

able to purchase and obtain the Product.

50. Plaintiff has reviewed potential legal claims and causes of action against Defendants and has chosen to only pursue state-law claims. Any reference to any federal agency, regulation or rule is stated solely as background information and does not raise a federal question.

51. 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.

52. 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.

53. 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.

FACTUAL ALLEGATIONS

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

55. Defendant EzriCare began packaging, labeling, advertising, marketing, and selling the Product on or about November 22, 2020.

56. The Product is 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.[5]

[5] *See* EzriCare Artificial Tears Product Monograph, located at https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=ac1ea23c-f1c6-418f-921e58553ee919cb&type=display (last accessed April 27, 2023).

57. The Product is "preservative free," which removed any chemical used to prevent the growth of bacteria in the product.[6]

58. The Product is 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.[7]

59. The active ingredient in the Product is a solution of Carboxymethylcellulose Sodium 10 MG in 1 ml. The inactive ingredients include Boric Acid, Potassium Chloride, Sodium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride, Sodium Chlorite, Sodium Hydroxide, and Water for Injection.

60. The Product's packaging and labeling appears as follows:

[6] *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 (last accessed April 27, 2023).

[7] 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) (last accessed April 27, 2023).

The *Pseudomonas Aeruginosa* Bacteria

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

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

63. 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.[9]

64. But, new therapies—known as "phage" therapies—may be utilized to treat

[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-dropsinfects-55-in-12-states-1-dead/.
[9] *Id*.

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."[10]

***Pseudomonas Aeruginosa* and EzriCare Artificial Tears**

65. The current outbreak of the *Pseudomonas Aeruginosa* bacteria resulting from the use of the Product was first detected by the U.S. Centers for Disease Control ("CDC") in May 2022 and has now been linked to 16 states.[11]

66. The CDC has isolated the specific strain of *Pseudomonas Aeruginosa* as Verona Integron-mediated Metallo-β-lactamase (VIM) and Guiana-Extended Spectrum-β- Lactamase (GES)-producing carbapenem-resistant Pseudomonas aeruginosa ("VIM-GESCRPA").[12] This particular strand is incredibly drug-resistant and dangerous.

67. Prior to this outbreak, the CDC reported that this particular strain of *Pseudomonas Aeruginosa* "had never been reported in the United States."[13]

68. 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.[14]

69. The CDC also reported that it was able to isolate the outbreak strain from 15 sputum

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[10] 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 (last accessed April 27, 2023).

[11] 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 (last accessed April 27, 2023).

[12] *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 (last accessed April 27, 2023).

[13] *Id*.

[14] *Id*.

or bronchial washes, 17 cornea swabs, 10 urine samples, two blood samples, 26 rectal swabs, and four other nonsterile sources.[15]

70. As of March 2023, out of the 68 individuals who had been identified as having been infected with the *Pseudomonas Aeruginosa* bacteria from use of the Product, approximately eight (8) people had suffered permanent vision loss, four (4) people had to have their eyeballs removed, and three (3) people died due to systemic infection.[16]

71. On January 24, 2023, Defendant EzriCare 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."[17]

72. After development of this story, on February 1, 2023, Defendant EzriCare issued another statement: "EzriCare, LLC first received notice of the CDC's ongoing investigation into a multistate cluster of Pseudomonas aeruginosa infections on January 20, 2023. As of today, we are not aware of any testing that definitively links the Pseudomonas aeruginosa outbreak to EzriCare Artificial Tears. Nonetheless, we immediately took action to stop any further distribution or sale of EzriCare Artificial Tears. To the greatest extent possible, we have been contacting customers to advise them against continued use of the product. We also immediately reached out to both CDC and FDA and indicated our willingness to cooperate with any requests they may have of us."[18]

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[15] *Id.*; *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 (last accessed April 27, 2023).

[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/ (last accessed April 27, 2023).

[17] EzriCare Artificial Tears - Discontinue Use (Feb. 2, 2023), located at https://ezricare-info.com (last accessed April 27, 2023).

[18] *Id.*

73. Additionally, on February 1, 2023, Defendant Global Pharma initiated a voluntary recall of all unexpired lots of the Product.[19]

74. 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."[20] The FDA highlighted that it recommended Defendant Global Pharma Healthcare Private Ltd. 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."[21]

75. Further, the FDA also "placed [Defendant] Global Pharma Healthcare Private Ltd. on import alert . . . for providing an inadequate response to a records request and for not complying with CGMP requirements."[22] According to the FDA, the import alert "prevents these products from entering the United States."[23]

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

76. Despite diligent investigation by Plaintiff into the cause of her injuries, including

[19] *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.

[20] *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-andavailability/fdawarnsconsumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination.

[21] *Id.*

[22] *Id.*

[23] *Id.*

consultations with her medical providers, the nature of her injuries and damages and their relationship to the Product was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

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

78. Because of the self-concealing nature of Defendants' actions and their affirmative acts of violating the requisite CGMPs, Plaintiff asserts the tolling of any applicable statutes of limitations affecting the claims raised herein.

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

80. 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 fraudulent concealment.

81. As pled below, Plaintiff seeks the application of the law of the forum state, New Jersey, which is also home to Defendants EzriCare and EzriRx. However, should this court determine in a "choice of law" analysis that another state's law should apply to this matter, Plaintiff reserves the right to recover under the laws of that state.

COUNT ONE: STRICT PRODUCTS LIABILITY – FAILURE TO WARN
(Against All Defendants)

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

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

84. Prior to purchasing the EzriCare Artificial Tears from Amazon.com, Plaintiff reviewed the Product information on Amazon's website. After receiving the EzriCare Artificial Tears from Amazon.com, Plaintiff reviewed the Product packaging and labeling, including the instructions for use.

85. At all pertinent times, Plaintiff used the Product in her eyes, which is a reasonably foreseeable use.

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

87. 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* 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, thus breaching the duty owed by Defendants to Plaintiff.

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

89. Defendants did not adequately test and/or give adequate warnings to Plaintiff that the EzriCare Artificial Tears were contaminated with the *Pseudomonas Aeruginosa* bacteria or about the dangers of the presence of *Pseudomonas Aeruginosa* bacteria in their Products.

90. Plaintiff was justified in her reliance on Defendants' manufacturing, labeling,

packaging, marketing, and advertising of the product for use as artificial tears. Had Plaintiff received notice or a warning that the EzriCare Artificial Tears were contaminated with the *Pseudomonas Aeruginosa* bacteria, she would not have used it and would not have suffered eye and vision damage that is permanent.

91. 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 Aeruginosa* 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.

92. Defendants' EzriCare Artificial Tears product failed to contain adequate warnings and/or instructions regarding the presence of—and dangers of—the *Pseudomonas Aeruginosa* bacteria with the use of the EzriCare Artificial Tears.

93. 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.

94. Defendants are strictly liable to Plaintiff for their wrongful and reckless conduct pursuant to New Jersey common and statutory law.

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 PRODUCTS LIABILITY – DEFECTIVE DESIGN AND MANUFACTURE
(Against All Defendants)

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

96. 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.

97. 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.

98. 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.

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

100. 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.

101. EzriCare Artificial Tears failed to perform safely when used by Plaintiff in a reasonably foreseeable manner; that is, the presence of the *Pseudomonas Aeruginosa* 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 permanent.

102. 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* bacteria, and Defendants failed to properly and adequately test the Product for the presence of bacteria before distributing it.

103. 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.

104. 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.

105. Defendants are strictly liable to Plaintiff for their wrongful and reckless conduct pursuant to New Jersey common and statutory law.

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: NEGLIGENCE / GROSS NEGLIGENCE
(Against All Defendants)

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

107. Defendants owed a duty of reasonable care to Plaintiff and other reasonably

foreseeable consumers to not only ensure that the EzriCare Artificial Tears Product was safe for intended use, but also that its labeling adequately warned of any and all risks associated with its use.

108. Defendants also owed a duty of reasonable care to Plaintiff and other reasonably foreseeable consumers to not market, design, manufacture, produce, supply, 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 the Pseudomonas Aeruginosa bacteria.

109. 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.

110. 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.

111. 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 warn of the inherent dangers associated with the presence of the Pseudomonas Aeruginosa 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 her left eye and to her vision.

112. 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 the Product was defective and/or contaminated;

h. In failing to instruct the Product user, such as Plaintiff, as to the methods for reducing the type of exposure to the *Pseudomonas aeruginosa* bacteria which caused increased risk of vison loss;

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 a dangerous and deadly bacterium.

113. 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.

114. 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 their

reasonably anticipated use.

115. 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.

116. 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.

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

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

119. Defendants are liable in tort to Plaintiff for their wrongful and reckless conduct pursuant to New Jersey common and statutory law.

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 – NEGLIGENT FAILURE TO WARN
(Against All Defendants)

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

121. 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.

122. 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.

123. 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.

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

125. 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.

126. Defendants' failure to adequately warn about their defective Product, 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.

127. 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.

128. 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.

129. Prior to purchasing the EzriCare Artificial Tears from Amazon.com, Plaintiff reviewed the Product information on Amazon's website. After receiving the EzriCare Artificial Tears from Amazon.com, Plaintiff reviewed the Product packaging and labeling, including the instructions for use.

130. 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.

131. 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.

132. 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.

133. Defendants are liable in tort to Plaintiff for their wrongful and reckless conduct pursuant to New Jersey common and statutory law.

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: PRODUCTS LIABILITY – NEGLIGENT DESIGN AND MANUFACTURE DEFECT
(Against All Defendants)

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

135. 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.

136. 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.

137. 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.

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

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

140. The propensity to the exposure of Pseudomonas Aeruginosa 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.

141. Safer alternatives, including products that contain a preservative to prevent

contamination with bacteria, such as the Pseudomonas Aeruginosa bacteria, have been readily available for decades.

142. Additionally, Defendants defectively designed the bottle that contained the EzriCare Artificial Tears, such that it contributed to the contamination and growth of Pseudomonas Aeruginosa bacteria.

143. The multi-use bottle design also made the Product more susceptible to the contamination and growth of Pseudomonas Aeruginosa bacteria.

144. 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.

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

146. 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.

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

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

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

150. 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.

151. Defendants are liable in tort to Plaintiff for their wrongful and reckless conduct pursuant to New Jersey common and statutory law.

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 AND OMISSION
(Against All Defendants)

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

153. 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.

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

155. Defendants' representations were material to Plaintiff's decision to purchase and use the Product.

156. 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.

157. Defendants failed to fulfill their duty to provide accurate information and disclose in the Product labeling and advertising the Product was contaminated with a dangerous and deadly bacterium.

158. Additionally, Defendants have a duty to not make false representations with respect to the Product.

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

160. 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.

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

162. 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.

163. Defendants are liable in tort to Plaintiff for their wrongful and reckless conduct pursuant to New Jersey common and statutory law.

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)

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

165. 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.

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

167. 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.

168. 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.

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

170. 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.

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

172. 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.

173. Defendants are liable in tort to Plaintiff for their fraudulent conduct pursuant to New Jersey common and statutory law.

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)

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

175. 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.

176. 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 Plaintiff's 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, such as Plaintiff, to Pseudomonas Aeruginosa bacteria.

177. Defendants knew or should have known that use of EzriCare Artificial Tears may expose a consumer to Pseudomonas Aeruginosa bacteria.

178. 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.

179. 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.

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

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

182. 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.

183. Defendants are liable in tort to Plaintiff for their fraudulent conduct pursuant to New Jersey common and statutory law.

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 NINE: BREACH OF EXPRESS WARRANTY
(Against All Defendants)

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

185. 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.

186. 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.

187. 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 the Pseudomonas Aeruginosa bacteria—a dangerous and deadly bacterium.

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

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

190. 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 a dangerous and deadly bacterium.

191. 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.

192. 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.

193. Defendants are liable in tort to Plaintiff for their wrongful and reckless conduct pursuant to New Jersey common and statutory law.

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)

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

195. Because the EzriCare Artificial Tears are contaminated with the Pseudomonas Aeruginosa 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.

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

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

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

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

200. As alleged, Defendants' artificial tears were not adequately labeled and did not disclose that they were contaminated with Pseudomonas Aeruginosa bacteria.

201. 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.

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

203. Defendants further impliedly warranted that the EzriCare Artificial Tears were fit

for the particular purposes for which they were intended and sold.

204. 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.

205. 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.

206. Defendants are liable in tort to Plaintiff for their wrongful and reckless conduct pursuant to New Jersey common and statutory law.

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)

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

208. 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.

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

210. 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.

211. 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.

212. Defendants also owed a continuing duty to Plaintiff to remove, recall, or retrofit unsafe and defective products, such as EzriCare Artificial Tears, across New Jersey and the United States.

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

214. 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.

215. 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.

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

217. 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, distributer, and/or retailer would under the same or similar circumstances and failed to exercise reasonable care.

218. 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.

219. Defendants are liable in tort to Plaintiff for their wrongful and reckless conduct pursuant to New Jersey common and statutory law.

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 CONSUMER FRAUD ACT
(Against All Defendants)

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

221. 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.

222. 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 a dangerous and drug-resistant bacterium, and are not safe.

223. 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 a dangerous and drug-resistant bacterium that can lead to / cause permanent damage to the eye and vision.

224. 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, the violation of CGMPs by Defendants, and Plaintiff had no reason to otherwise suspect that EzriCare Artificial Tears were contaminated.

225. 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.

226. 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.

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

228. Defendants owed Plaintiff a duty to disclose the true and unsafe nature of EzriCare Artificial Tears.

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

230. 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.

231. Plaintiff would not have purchased EzriCare Artificial Tears had she known that the Product was contaminated with a dangerous and deadly bacterium.

232. 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.

233. 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.

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

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

236. 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 the *Pseudomonas Aeruginosa* bacteria.

237. 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.

238. Defendants are liable in tort to Plaintiff for their wrongful and reckless conduct pursuant to New Jersey common and statutory law.

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 NJ PLA, N.J. STAT. § 2A:58C-1, *et seq.*
(Against All Defendants)

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

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

241. Defendant EzriCare 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.

242. Defendant EzriRx 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.

243. Defendant Global Pharma 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.

244. Defendant Aru Pharma 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.

245. Defendant Aru Pharma is also 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.

246. Defendant Amazon 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.

247. Defendants, as product manufacturers and/or 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.

248. Defendants, as product manufacturers and/or 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 *Pseudomonas Aeruginosa* bacteria contamination) which caused the injury. N.J.S. § 2A:58C-9(d).

249. 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).

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

251. Defendants are liable in tort to Plaintiff for their wrongful and reckless conduct pursuant to New Jersey common and statutory law.

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 FOURTEEN: PUNITIVE DAMAGES UNDER NEW JERSEY COMMON LAW, NEW JERSEY PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9, et seq.) and NEW JERSEY PRODUCTS LIABILITY ACT (NJ PLA) (N.J.S.A. 2A:58C-1, et seq.) (Against All Defendants)

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

253. Plaintiff is entitled to punitive damages because Defendants' wrongful acts and/or omissions were wanton or in conscious disregard of the rights of others. Defendants misled the public at large, including Plaintiff, by making false representations about the safety and efficacy

of the Product and by contaminating the Product with *Pseudomonas Aeruginosa* bacteria. Defendants affirmatively disregarded the FDA's CGMP, including, as detailed in the factual allegations section, the lack of appropriate microbial testing and/or failure to include proper formulation to prevent bacterial growth.

254. 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, or should have known, 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 and/or conscious disregard of the risk of exposure to the Pseudomonas Aeruginosa 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 and/or inactions outlined above, Defendants exhibited a reckless indifference to the safety of users of EzriCare Artificial Tears, including Plaintiff as described herein, knowing and/or consciously disregarding 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.

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

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

257. Plaintiff is entitled to punitive damages as a result of Defendants' reckless conduct

in wanton disregard of Plaintiff's safety pursuant to N.J.S.A. 2A:15-5.9, *et seq.*, and N.J.S.A. 2A:58C-1, *et seq.*

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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment and an award of damages against Defendants, as follows:

a) special damages, to include past and future medical and incidental expenses, according to proof;
b) past and future loss of earnings and/or earning capacity, according to proof;
c) past and future general damages, to include pain and suffering, emotional distress and mental anguish, according to proof;
d) pre-judgment and post-judgment interest;
e) the costs of this action; and
f) treble and/or punitive damages to Plaintiff; and
g) granting any and all such other and further legal and equitable relief as the Court deems necessary, just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury to the full extent permitted by law.

Dated: May 19, 2023

/s/ Michael G. Daly

POGUST GOODHEAD, LLC
Michael G. Daly, Esq., ID No. 025812010
Joshua M. Neuman, Esq., ID No. 209832016
161 Washington Street, Suite 250
Conshohocken, Pennsylvania 19428
mdaly@pogustgoodhead.com
jneuman@pogustgoodhead.com
T: 610-941-4204
F: 610-941-4245
Attorneys for Plaintiff, Beverly Jennings