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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CAROLYN WARD, Plaintiff, v. EZRICARE, LLC, a New Jersey Limited Liability Company; EZRIRX, LLC, a Delaware Limited Liability Company; ARU PHARMA INC., a New York Corporation; and WALMART, INC., a Delaware Company, Defendants.	)	CASE NO. **COMPLAINT**

Plaintiff, Carolyn Ward, by and through her attorneys of record, The Lange Law Firm, PLLC (*pro hac vice forthcoming*) and Cohen, Placitella & Roth, and for their causes of action against EZRICARE, LLC, EZRIRX, LLC, ARU PHARMA INC., and WALMART, INC. ("Defendants"), state and allege as follows:

PARTIES

1. At all times relevant to this action, Plaintiff resided in the city of Post Falls, Kootenai County, Idaho. Plaintiff is a citizen of the State of Idaho.

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

3. Defendant EzriRx, LLC ("EzriRx") is a corporation organized, incorporated, and existing under the laws of the State of New Jersey with its principal place of business in New Jersey. EzriRx is thus a citizen of the state of New Jersey. EzriRx's principal place of business is located in New Jersey at 1525 Prospect St., Ste. 203, Lakewood, NJ 08701 in Ocean County or 2360 Rt. 9, Suite 3, #171, Toms River, NJ 08755 in Ocean County. From its principal place of business in New Jersey, EzriRx is engaged in the business of manufacturing, packaging, labeling, importing, selling, supplying, distributing, advertising, and/or marketing artificial tears products throughout the United States, including to Idaho. EzriRx may be served with process at its registered agent, Ezriel Green located at 1970 Swarthmore Avenue, Unit 4, Lakewood, NJ 08701, or at its principal place of business located at 1525 Prospect St., Ste. 203, Lakewood, NJ 08701 in Ocean County or 2360 Rt. 9, Suite 3, #171, Toms River, NJ 08755 in Ocean County.

4. Defendant Aru Pharma, Inc. ("Aru") is a corporation organized, incorporated, and existing under the laws of the State of New York with its principal place of business in New York. Aru is

thus a citizen of the state of New York. Aru's principal place of business is located in New York at 925 Protano Lane, Mamaroneck, NY 10543, and/or 696 Locust Street, Mount Vernon 10552, both in Westchester County. Aru is engaged in the business of manufacturing, packaging, labeling, importing, selling, supplying, distributing, advertising, and/or marketing artificial tears products throughout the United States, including to Idaho. Aru may be served with process at its principal place of business at 925 Protano Lane, Mamaroneck, NY 10543.

5. Defendant Walmart, Inc. ("Walmart, Inc.") is a worldwide seller and distributor of products. Walmart, Inc. is a Delaware corporation with its principal place of business in the State of Arkansas at 702 SW 8th St., Bentonville, AR 72716. Walmart, Inc. may be served with process through its registered agent CT Corporation System located at 820 Bear Tavern Road, West Trenton, NJ 08628, or its principal place of business at 702 SW 8th St., Bentonville, AR 72716.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 USC § 1332(a) because the matter in controversy exceeds $75,000, exclusive of costs and it is between citizens of different states (Idaho, New York, New Jersey, and Delaware).

7. This Court has both general and specific personal jurisdiction over EzriCare. This Court has general jurisdiction over EzriCare because EzriCare's principal place of business is located in New Jersey at 1525 Prospect St., Ste. 204, Lakewood, NJ 08701 in Ocean County. This Court has specific jurisdiction over EzriCare because EzriCare committed a tort in whole or in part in New Jersey. Specifically, EzriCare manufactured, packaged, labeled, imported, sold, supplied, distributed, advertised, and/or marketed artificial tears from its principal place of business in New Jersey, including the artificial tears that harmed Carolyn.

8. This Court has both general and specific personal jurisdiction over EzriRx. This Court

has general jurisdiction over EzriRx because EzriRx's principal place of business is located in New Jersey at 1525 Prospect St., Ste. 203, Lakewood, NJ 08701 in Ocean County or 2360 Rt. 9, Suite 3, #171, Toms River, NJ 08755 in Ocean County. This Court has specific jurisdiction over EzriRx because EzriRx committed a tort in whole or in part in New Jersey. Specifically, EzriCare manufactured, packaged, labeled, imported, sold, supplied, distributed, advertised, and/or marketed artificial tears from its principal place of business in New Jersey, including the artificial tears that harmed Carolyn.

9. This Court has specific personal jurisdiction over Aru Pharma because Aru Pharma committed a tort in whole or in part in New Jersey. Specifically, Aru Pharma sold, supplied, distributed, shipped, advertised, and/or marketed artificial tears to New Jersey businesses, specifically EzriCare and/or EzriRx in New Jersey, including the artificial tears that harmed Carolyn. EzriCare and/or EzriRX then sold the artificial tears to Walmart. Walmart then sold the artificial tears to Carolyn.

10. This court has general and specific personal jurisdiction over Walmart, Inc. because Walmart engages in substantial, continuous, and systematic contacts with the State of New Jersey, purposefully directing its activities towards New Jersey, including the placement of their goods into the stream of commerce with the intent and expectation that they will likely be purchased and used by consumers in New Jersey. Walmart marketed, advertised, and sold the very same brand of EzriCare artificial tears in New Jersey as the ones it sold in Idaho to Carolyn.

11. Walmart, Inc. regularly does business in New Jersey either through its stores, online, or the many wholly owned subsidiaries and affiliated corporations and entities it controls. Walmart, Inc. has sufficient contacts with the State of New Jersey by regularly selling and distributing products in New Jersey, including artificial tears, and by serving a market for artificial tears in

New Jersey. Walmart, Inc. sold, distributed, advertised, and/or marketed the artificial tears which are the subject of this Complaint to Carolyn. Walmart, Inc.'s contacts with New Jersey are sufficient that Walmart, Inc. should reasonably expect to be brought into court in New Jersey.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (b) because a substantial part of the events or omissions giving rise to the claims herein occurred in this judicial district, and because Defendants were at all times relevant hereto subject to personal jurisdiction in this judicial district.

13. The District of New Jersey's "Vicinage Lines for Case Assignment" would assign this case to the District of New Jersey at Trenton. Both EzriCare and EzriRx have their principal places of business in Ocean County. EzriCare's principal place of business is located at 1525 Prospect St., Ste. 204, Lakewood, NJ 08701 in Ocean County. EzriRx's principal place of business is located at 1525 Prospect St., Ste. 203, Lakewood, NJ 08701 in Ocean County or 2360 Rt. 9, Suite 3, #171, Toms River, NJ 08755 in Ocean County.

FACTS

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

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

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

16. According to the CDC, as of February 3, 2023, a total of 55 people infected with the outbreak strain were reported from 12 states, including: California, Colorado, Connecticut, Florida, New Jersey, New Mexico, New York, Nevada, Texas, Utah, Washington, and Wisconsin. These numbers of people infected, and states affected, is expected to grow.

17. One person has died, and there have been 5 reports of vision loss.

18. The epidemiologic evidence available to investigators at this time indicates that artificial tears was the source of the outbreak. EzriCare Artificial Tears, a preservative-free, over-the-counter product packaged in multidose bottles, was the brand most commonly reported.

19. Laboratory testing by CDC and FDA identified the presence of VIM-GES-CRPA in opened EzriCare bottles from multiple lots. These bottles were collected from patients with and without eye infections and from two states. VIM-GES-CRPA recovered from opened products match the outbreak strain.

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

21. Further, since the initial announcement, the FDA recommended this recall due to Defendants' current good manufacturing practice (CGMP) violations, including lack of appropriate microbial testing, formulation issues (the company manufactures and distributes ophthalmic drugs in multi-use bottles, without an adequate preservative), and lack of proper controls concerning tamper-evident packaging.

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

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

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

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

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

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

C. Pseudomonas aeruginosa and Infection Spread

27. Exposure to *Pseudomonas aeruginosa* can lead to a severe infection.

28. People with weakened immune systems (i.e. those recovering from cancer) can develop serious complications from a *Pseudomonas aeruginosa* infection which unfortunately, may be fatal for some.

29. What that can be said for certain is that infections with *Pseudomonas aeruginosa* can cause long-term complications, can lead to sepsis or bacteremia (blood stream infections),

permanent injury, including vision loss, and death.

30. *Pseudomonas aeruginosa* can also spread to other parts of the body or organ systems. These bacteria tend to cause multi-site infections (as seen in Carolyn's case), of which bacteremia is fatal, with a mortality rate ranging from 18% to 61%.[1]

D. Carolyn Ward's *Pseudomonas Aeruginosa* Infection

31. Carolyn Ward is an eye cancer survivor, who completed radiation therapy in 2022. As a result of her cancer treatment, Carolyn is immunocompromised and at high risk for infections.

32. She purchased EzriCare Artificial tears on August 10, 2022, a few weeks before her *Pseudomonas aeruginosa* infection symptoms began.

33. By mid-August of 2022, Carolyn felt itchy and unrelenting pain in her eyes. She called her optometrist, who prescribed her antibiotics and a steroid.

34. By September of 2022, the infection spread to Carolyn's torso, abdomen, and back.

35. Carolyn then met with her primary care physician, who recognized the rash on her body as *Pseudomonas aeruginosa.*

36. Carolyn's primary care doctor placed Carolyn on antibiotics, however, antibiotics have not been effective in combatting the infection.

37. Carolyn continues to suffer from medical complications from *Pseudomonas aeruginosa*.

38. Carolyn faces uncertain future medical complications.

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[1] Zhang Y, Li Y, Zeng J, Chang Y, Han S, Zhao J, Fan Y, Xiong Z, Zou X, Wang C, Li B, Li H, Han J, Liu X, Xia Y, Lu B, Cao B. Risk Factors for Mortality of Inpatients with *Pseudomonas aeruginosa* Bacteremia in China: Impact of Resistance Profile in the Mortality. Infect Drug Resist. 2020 Nov 12;13:4115-4123. doi: 10.2147/IDR.S268744. PMID: 33209041; PMCID: PMC7669529.

CAUSES OF ACTION

COUNT 1: PRODUCTS LIABILITY

(N.J. Products Liability Act – N.J.S.A. 2A:-58C-1 *et seq.*)

39. Plaintiff realleges and incorporates the above allegations as though fully set forth herein.

40. Defendants are liable under a theory of strict products liability as set forth in N.J.S.A. 2A:58C-1, *et seq.*

41. Defendants are in the business of manufacturing, packaging, labeling, importing, selling, supplying, distributing, advertising, and/or marketing artificial tears products.

42. Defendants manufactured, packaged, labeled, imported, sold, supplied, distributed, advertised, and/or marketed the adulterated product, artificial tears, that caused Carolyn's injuries.

43. Carolyn was a reasonably foreseeable and intended user of Defendants' defective products, artificial tears.

44. The artificial tears manufactured, packaged, labeled, imported, sold, supplied, distributed, advertised, and/or marketed by Defendants, were defective and unreasonably dangerous for their reasonably foreseeable uses because they were contaminated with a harmful and deadly bacteria, *Pseudomonas aeruginosa*.

45. Artificial tears contaminated with *Pseudomonas aeruginosa* are an adulterated product that is unfit, unsuitable, and unreasonably dangerous for its intended and ordinary and expected use.

46. The artificial tears were contaminated with *Pseudomonas aeruginosa* when they left Defendants' control.

47. Defendants owed a duty to Plaintiff, and other consumers similarly situated, to use reasonable care in the manufacturing, packaging, labeling, importing, selling, supplying, distributing, advertising, and/or marketing of the artificial tears products that caused Plaintiff's injuries. Defendants owed a duty to consumers, including Plaintiff, to abide by all applicable state

and federal statutes, laws, and regulations regarding product safety. Defendants breached these duties.

48. Defendants had a duty to comply with the Federal Food, Drug, and Cosmetic Act, and all of the rules, regulations, and policies promulgated pursuant to it. Defendants did not comply with these duties in its manufacturing, packaging, labeling, importing, selling, supplying, distributing, advertising, and/or marketing into interstate commerce of the artificial tears contaminated with *Pseudomonas aeruginosa* to which Plaintiff was exposed.

49. In particular, the artificial tears that Defendants manufactured, packaged, labeled, imported, sold, supplied, distributed, advertised, and/or marketed were adulterated and contaminated under 21 U.S.C. § 301, *et seq*., the Federal Food, Drug, and Cosmetic Act.

50. Defendants' violations of the Federal Food, Drug, and Cosmetic Act include without limitation: Defendants failed to implement and/or utilize adequate, appropriate, and effective processes and quality controls; failed to implement adequate, appropriate, and effective preventative controls; failed to verify that preventative controls were consistently implemented and were effectively and significantly minimizing or preventing the hazards; and failed to implement a supply-chain program that assured that a hazard requiring a supply-chain applied control had been significantly minimized or prevented.

51. At all times relevant to this action, Defendants also had a duty to comply with N.J.S.A. 24:5-1 ("Sale, distribution or manufacture of adulterated or misbranded articles").

52. Plaintiff was in the class of people intended to be protected by these statutes, laws, and regulations regarding product safety. Failure by Defendants to comply with these statutes, laws, and regulations was a direct and proximate cause of Plaintiff's injuries.

53. Defendants' artificial tears products suffered from design and/or manufacturing defects

sufficient to cause each Defendant to be liable to Plaintiff under theories of product liability and strict liability. The subject product was defective, *inter alia*, the product suffered from a design defect, and/or a manufacturing defect.

54. The existing manufacturing defects and/or design defects in the subject product were the proximate cause of Plaintiffs' injuries, as well as all damages sought by Plaintiff in this action.

55. Alternative safer designs were available to and economically feasible to Defendants when they sold, supplied, labeled, packaged, distributed, marketed, and advertised their artificial tears products. The cost of any such alternative design was insignificant compared to the seriousness and severity of the harm that could result and did result to Carolyn. The cost of the alternative design was a cost that the market and consumers could bear, and any potential cost was far outweighed by the known benefits of such alternative design and marketing.

56. Defendants are liable to Plaintiff for the harm proximately caused by the sold, supplied, labeled, packaged, distributed, marketed, and advertised of an unreasonably dangerous and defective product, artificial tears contaminated with *Pseudomonas aeruginosa*.

57. Plaintiff suffered injury and damages as a direct and proximate result of the defective and unreasonably dangerous condition of the adulterated product, artificial tears contaminated with *Pseudomonas aeruginosa*, that Defendants sold, supplied, labeled, packaged, distributed, marketed, and advertised. Plaintiff was caused to endure severe physical pain and suffering, severe mental anguish and suffering, lost wages and earnings and severe pecuniary loss, all to Plaintiff's great loss.

58. WHEREFORE, Plaintiff demands judgment against Defendants jointly, severally, or in the alternative, for compensatory damages, punitive damages, and costs of suit as provided by law.

COUNT 2: BREACH OF WARRANTY

59. Plaintiff realleges and incorporates the above allegations as though fully set forth herein.

60. Defendants expressly or impliedly warranted that their artificial tears products, which they sold, supplied, labeled, packaged, distributed, marketed, advertised, or otherwise placed in the stream of commerce, were merchantable, reasonably fit for use and safe for their intended purposes.

61. Defendants breached said warranties in that their artificial tears products were defective, ultra-hazardous, dangerous, unfit for use, unfit for human consumption, not merchantable and not safe for their intended, ordinary and foreseeable use and purpose.

62. Defendants are liable to Plaintiff for breaching express and implied warranties that they made regarding their adulterated product, artificial tears, that Plaintiff purchased and used. These express and implied warranties include the implied warranties of merchantability and/or fitness for a particular use. Specifically, Defendants expressly warranted, through their sale of products to the public and by statement and conduct of their employees and agents, that the products they manufactured and sold was fit for human use and not otherwise adulterated or injurious to health.

63. Plaintiff alleges that the artificial tears contaminated with Pseudomonas aeruginosa that Defendants sold, supplied, labeled, packaged, distributed, marketed, and advertised, and which Plaintiff purchased and consumed, would not pass without exception in the trade and was, therefore, in breach of the implied warranty of merchantability.

64. Plaintiff alleges that the artificial tears contaminated with Pseudomonas aeruginosa that Defendants sold, supplied, labeled, packaged, distributed, marketed, and advertised, and which Plaintiff purchased and used, was not fit for the uses and purposes intended, and that this product was, therefore, in breach of the implied warranty of fitness for its intended use.

65. Defendants impliedly and expressly warranted that their artificial tears products were merchantable, fit for use, and safe for human use. Defendants further warranted that their products were properly packaged and labeled.

66. Defendants' artificial tears products violated N.J.S.A 24:5-1 et seq. ("Sale, distribution or manufacture of adulterated or misbranded articles"); and 21 U.S.C. § 841(a).

67. Defendants' breaches of warranty caused Carolyn's injuries.

68. At the time Defendants' artificial tears products were sold, supplied, labeled, packaged, distributed, marketed, and advertised, Defendants knew or reasonably should have known that they were not reasonably safe for their intended and foreseeable uses and/or misuses.

69. At the time Defendants' artificial tears products were sold, supplied, labeled, packaged, distributed, marketed, and advertised, Defendants knew or reasonably should have known that they posed an unreasonable risk of injury to their users. Defendants expressly and impliedly represented and/or warranted that their products were of merchantable quality and safe and fit for intended and foreseeable uses and/or misuses and did not, at any time, retract or amend such representations and warranties, nor did Defendants at any time disclose the truth known to them—that Defendants' products did in fact pose an unreasonable risk of injury to their users when used in the intended and foreseeable uses and/or misuses.

70. The defects in Defendants' products breached Defendants' implied and express warranties of merchantability and fitness for use.

71. As a direct and proximate result of Defendants' breach of warranties, Carolyn suffered injury and died resulting from the ordinary and foreseeable use of Defendants' artificial tears products. Plaintiff was caused to suffer the injuries, expenses and losses alleged in prior counts of this complaint. Plaintiff was caused to endure severe physical pain and suffering, severe mental

anguish and suffering, and severe pecuniary loss, all to Plaintiff's great loss.

72. WHEREFORE, Plaintiff demands judgment against Defendants jointly, severally, or in the alternative, for compensatory damages, punitive damages, and costs of suit as provided by law.

COUNT 3: NEGLIGENCE

73. Plaintiff realleges and incorporates the above allegations as though fully set forth herein.

74. Defendants, at all times material hereto, acted through their respective officers, employees and agents, who in turn were acting within the scope of their authority and employment in furtherance of the business of Defendants.

75. Defendants were engaged, directly or indirectly, in the selling, supplying, labeling, packaging, distributing, marketing, and advertising a product, artificial tears.

76. Defendants, directly or indirectly, caused their product, artificial tears products, to be sold to, supplied to, distributed to, marketed to, or used by Plaintiff Carolyn.

77. Plaintiff Carolyn was infected with *Pseudomonas aeruginosa* after using Defendants' artificial tears products.

78. As a direct and proximate result of Plaintiff Carolyn's exposure to *Pseudomonas aeruginosa* from consuming Defendants' artificial tears products, Plaintiff Carolyn suffered injury.

79. During the time that Defendants sold, supplied, labeled, packaged, distributed, marketed, advertised their artificial tears products, Defendants knew, or in the exercise of reasonable care should have known, that their artificial tears products were defective, ultra-hazardous, dangerous, and otherwise highly harmful to consumers, such as Plaintiff Carolyn.

80. Plaintiff did not know the nature and extent of the injury that would result from use of Defendants' artificial tears products.

81. Defendants knew, or in the exercise of reasonable care should have known, that consumers

such as Carolyn would use Defendants' artificial tears products and would be exposed to dangerous and/or fatal *Pseudomonas aeruginosa*, causing injury and/or death as a result of the ordinary and foreseeable uses and/or misuses of Defendants' artificial tears products.

82. Despite the facts as set forth above, Defendants negligently, recklessly and intentionally:

a. Designed the products such that there are latent and not obvious dangers for consumers and patients while the products are being used in a foreseeable and intended manner;

b. The products contained hidden and dangerous design defects and were not reasonably safe as intended to be used, subjecting consumers to risks of serious bodily injury and death in that the products' design and/or manufacture amounted to and/or resulted in a defect failure mode of the products;

c. Failing to collect data to determine if its products were safe for consumers;

d. Failing to collect data to determine when and how its products could be used safely;

e. Failing to utilize the significant peer reviewed research to develop instructions;

f. Failing to develop evidence-based guidelines or instructions to decrease the risk of its products causing eye infections and death;

g. Failing to provide evidence-based guidelines or instructions to decrease the risk of its products causing eye infections and death;

k. Failing to utilize economical and technically available safer artificial tears products;

l. Failing to adopt an adequate or sufficient quality control program; and/or

m. Failing to inspect or test its products with sufficient care.

83. Each Defendant had a duty to comply with all statutory and regulatory provisions that pertained or applied to the selling, supplying, labeling, packaging, distributing, advertising, and/or marketing of the products that injured Carolyn, including the applicable provisions of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq*. and the N.J.S.A. 24:5-1 ("Sale, distribution or manufacture of adulterated or misbranded articles").

84. Defendants' artificial tears products exposed Carolyn to *Pseudomonas aeruginosa*. As a direct and proximate result of the acts and omissions and negligence of each Defendant, Carolyn suffered injury.

85. At all times relevant hereto, each Defendant knew, or should have known that its products would be used without inspection for defects and that any such inspection would not have advised Plaintiff of the fact that the products were contaminated with *Pseudomonas aeruginosa* and could cause serious bodily injury and/or death.

86. Defendants' artificial tears products were, at all times relevant to this action, being used in the manner in which the Defendants intended the products to be used and/or in a manner that was reasonably foreseeable to Defendants.

87. Defendants' products failed to perform as safely as Plaintiff and others similarly situated expected they would, in that the products caused Plaintiff and others to develop serious bodily injury and potentially die.

88. Defendants owed the following duties to all persons who consumed and/or used their products, including Carolyn:

a. To sell, supply, distribute, and/or market products that were safe to use and/or use, including their reasonably foreseeable uses and/or misuses; that were not contaminated or adulterated with Pseudomonas aeruginosa; and that were not in violation of applicable local, state, and federal product safety or controlled substance laws, statutes, regulations, codes, or provisions.

b. To comply with all applicable local, state, and federal product safety or controlled substance laws, statutes, regulations, codes, or provisions that pertained or applied to the selling, supplying, labeling, packaging, distributing, advertising, and/or marketing of their products.

c. To use reasonable care in the selling, supplying, labeling, packaging, distributing, advertising, and/or marketing of their products to prevent contamination or adulteration with Pseudomonas aeruginosa.

d. To use ordinary care to inspect their product in order to protect users of the product from unreasonable risk of harm.

e. To not sell products that has been adulterated or contaminated rendering it injurious to the health of consumers.

89. Defendants breached each of these duties.

90. Had Defendants properly performed their duties, that would have prevented or eliminated the risk that Defendants' products would be contaminated or adulterated with *Pseudomonas aeruginosa* or any other dangerous substance at the time the products left Defendants' control, thus preventing injury to consumers and/or users of their products, including Carolyn.

91. If Defendants had fulfilled their duties, Carolyn would not have been injured as a result of her use of artificial tears products. The above breaches of care by Defendants were the proximate cause of Plaintiff's injuries. Upon information and belief, Plaintiff relied upon the marketing of the artificial tears products by Defendants. Such reliance contributed and caused her injuries from the artificial tears products. Upon information and belief, Defendants knew or should have known that the products contained dangerous *Pseudomonas aeruginosa*. Defendants breached this duty,

92. Defendants were negligent, grossly negligent, and/or reckless in the sale, supply, labeling, packaging, distribution, advertisement, and marketing of their artificial tears products.

93. Each of Defendants' acts or omissions was a substantial factor in and direct, proximate, and legal cause of Plaintiff's injuries. Plaintiff's injuries would not have occurred but for Defendants' negligence.

94. As a direct and proximate result of the acts and omissions of Defendants, Plaintiff was exposed to dangerous *Pseudomonas aeruginosa* from the ordinary and reasonably foreseeable use of Defendants' artificial tears products. Plaintiff, Carolyn, suffered infection and injury as a direct and proximate result of consuming and/or using Defendants' artificial tears products. Plaintiff,

Carolyn, was caused to endure severe physical pain and suffering, severe mental anguish and suffering, lost wages and earnings and severe pecuniary loss, all to Plaintiff's great loss.

95. Plaintiff was caused to endure severe physical pain and suffering, severe mental anguish and suffering, lost wages and earnings and severe pecuniary loss, all to Plaintiff's great loss.

96. WHEREFORE, Plaintiff demands judgment against Defendants jointly, severally, or in the alternative, for compensatory damages, punitive damages, and costs of suit as provided by law.

COUNT 4: NEGLIGENCE PER SE
(N.J.S.A. 24:5-1 *et seq.*)

97. Plaintiff realleges and incorporates the above allegations as though fully set forth herein.

98. Defendant owed a duty to the public, including Carolyn, to exercise reasonable care in selling, supplying, labeling, packaging, distributing, marketing, advertising, delivering, and/or receiving in commerce their artificial tears products. Defendants breached this duty (and others) by selling, supplying, distributing, marketing, delivering, and/or receiving in commerce artificial tears products in a negligent and unlawful manner, in violation of applicable state and federal statutes, regulations, ordinances, codes, standards, and customs.

99. Defendants had a duty to comply with all applicable local, state, and federal regulations intended to ensure the purity and safety of their products, including, but not limited to, the requirements of the Federal Food, Drug and Cosmetics Act and N.J.S.A. 24:5-1 et seq. ("Sale, distribution or manufacture of adulterated or misbranded articles"). Defendants' artificial tears products were adulterated under the U.S. Food, Drug and Cosmetics Act in violation of N.J.S.A. 24:5-1.

100. Carolyn was among the class of persons designed to be protected by these local, state, and federal product safety and controlled substance statutes, laws, regulations, codes, or provisions pertaining to the selling, supplying, labeling, packaging, distributing, marketing, advertising,

delivering, and/or receiving in commerce of similar products.

101. Defendants failed to comply with the provisions of the health and safety acts identified above, and, as a result, were negligent per se in their selling, supplying, labeling, packaging, distributing, marketing, delivering, and/or receiving in commerce of adulterated products.

102. Defendants' wrongful conduct included without limitation: selling, supplying, labeling, packaging, distributing, marketing, advertising, delivering, and/or receiving in commerce artificial tears products with unsafe bacteria, *Pseudomonas aeruginosa,* sufficient to cause injuries.

103. The fact that Defendants failed to comply with these statutes, laws, and regulations regarding product safety is evidence that Defendants breached their duty of reasonable care and is negligence per se.

104. Carolyn was in the class of people intended to be protected by these statutes, laws, and regulations regarding product safety. Failure by Defendants to comply with these statutes, laws, and regulations was a direct and proximate cause of Carolyn' injuries.

105. Plaintiff suffered injury and damages as a direct and proximate result of Defendants' acts and omissions constituting negligence *per se*. Plaintiff was caused to endure severe physical pain and suffering, severe mental anguish and suffering, lost wages and earnings and severe pecuniary loss, all to Plaintiff's great loss.

106. WHEREFORE, Plaintiff demands judgment against Defendants jointly, severally, or in the damages, punitive damages, and costs of suit as provided by law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

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

2. That the Court award all such other sums as shall be determined to fully and fairly compensate Plaintiff for all general, special, incidental and consequential damages incurred, or to be incurred, by Plaintiff as the direct and proximate result of the acts and omissions of Defendants;
3. That the Court award Plaintiff costs, disbursements and reasonable attorneys' fees incurred;
4. Pre- and post-judgment interest at the highest rate allowed by law;
5. That the Court award Plaintiff the opportunity to amend or modify the provisions of this Complaint as necessary or appropriate after additional or further discovery is completed in this matter, and after all appropriate parties have been served; and
6. That the Court award such other and further relief as it deems necessary and proper in the circumstances.

JURY TRIAL DEMAND

Plaintiff demands trial by jury on all issues raised herein.

Dated: February 11, 2023.

Respectfully submitted,

By: /s/ Rachel A. Placitella

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