UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY

RICHARD MOSLEY, on behalf of himself and all others similarly situated, Plaintiff, vs. EZRICARE LLC; EZRIRX LLC; DELSAM PHARMA LLC; GLOBAL PHARMA HEALTHCARE PRIVATE LTD., and ARU PHARMA INC., Defendants.	**Civil Action No. _____** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiff Richard Mosley ("Plaintiff"), on behalf of himself and all others similarly situated, files this Class Action Complaint ("CAC") against Defendants EzriCare LLC, EzriRx LLC, Delsam Pharma LLC, Global Pharma Healthcare Private Ltd., and Aru Pharma Inc. ("Defendants"), and in support state the following:

NATURE OF THE ACTION

1. This is a class action lawsuit by Plaintiff, and others similarly situated, who purchased EzriCare Artificial Tears and Delsam Pharma Artificial Tears manufactured, imported, sold, marketed, labeled, and distributed by Defendants. Defendants manufacture, design, import, advertise, label, distribute, market, and sell several over-the-counter pharmaceutical products, including the above named artificial tears, which contain a solution of Carboxymethylcellulose Sodium 10 MG in 1 ml. Defendants' artificial tears are adulterated and contaminated with "a rare,

extensively drug-resistant strain of *Pseudomonas aeruginosa* bacteria."[1] The presence of the *Pseudomonas Aeruginosa* bacteria in Defendants' EzriCare and Delsam Pharma Artificial Tear products is due to Defendants' violation of Current Good Manufacturing Processes (as identified by the Food and Drug Administration), including "lack of appropriate microbial testing, formulation issues (the company manufactures and distributes ophthalmic drugs in multi-use bottles, without an adequate preservative), and lack of proper controls concerning tamper-evident packaging."[2] 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 and the putative class, who purchased and used Defendants' artificial tear products. Plaintiff and the putative class suffered economic damages due to Defendants' misconduct (as set forth below) and seek injunctive relief and restitution for the full purchase price of the artificial tear products they purchased. Plaintiff alleges the following based upon personal 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.

JURISDICTION AND VENUE

2. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of $5,000,000 and is a class action in which there are in excess of 100 class members, and Plaintiff is a citizen of a state different from Defendants.

3. This Court has jurisdiction over each Defendant because Defendants are authorized

[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.*

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

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

THE PARTIES

A. Plaintiff

5. Plaintiff Richard Mosley is a citizen and resident of Kentucky, and at all times relevant hereto has been a resident of Perry County. Mr. Mosely purchased EzriCare Artificial Tears from Walmart stores in Perry County. During that time, based on the false and misleading claims by Defendants, Plaintiff was unaware that Defendants' artificial tear product(s) may be adulterated and contaminated with the dangerous *Pseudomonas Aeruginosa* bacteria. Mr. Mosley purchased Defendants' artificial tear product(s) on the assumption that the labeling of Defendants' artificial tears was accurate and that the products were unadulterated, safe, and effective and, most importantly, were not contaminated with this deadly bacterium. Mr. Mosley would not have purchased Defendants' artificial tear product(s) had he known there was a risk the product may contain the *Pseudomonas Aeruginosa* bacteria and cause severe infection. As a result, Plaintiff suffered injury in fact when he spent money to purchase products he would not otherwise have purchased absent Defendants' misconduct and failure to adhere to current good manufacturing

practices, as alleged herein. Plaintiff also suffered personal injury as a result of use of EzriCare Artificial Tears. However, Plaintiff would be interested in purchasing similar artificial tear products in the future provided they are not adulterated and/or contaminated.

B. Defendants

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

7. Defendant EzriRx LLC is, and at all times relevant to this action was, a company incorporated under the laws of Delaware with its principal place of business located at 1525 Prospect Street, Suite 204, Lakewood, New Jersey 08701, and process may be served upon its registered agent: Registered Agent Solutions, Inc., 838 Walker Road, Suite 21-2, Dover, Delaware 19904. EzriRx LLC markets, advertises, labels, distributes, and sells the artificial tear product(s) at issue in this litigation.

8. Defendant Delsam Pharma LLC is, and at all times relevant to this action was, a New York Limited Liability Company with its principal place of business located in Bronx, New York 10567, and process may be served upon its registered agent, Kuppusamy Arumugam at 925 Protano Lane, Mamaroneck, New York, 10543. Delsam Pharma LLC markets, advertises, labels, distributes, and sells the artificial tear product(s) at issue in this litigation.

9. Defendant Global Pharma Healthcare Private Limited is, and at all times relevant to this action was, a corporation organized and existing under the laws of the Country of India, with its principal place of business located at No. 2A, 3rd F, 4th Street, Ganga Nagar, Chennai -

600 024, Tamilnadu, India. Global Pharma Healthcare Private Ltd. manufactures, markets, advertises, labels, distributes, and sells the artificial tear product(s) at issue in this litigation.

10. Defendant Aru Pharma Inc. 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, and process may be served upon its registered agent, The Corporation at 925 Protano Lane, Mamaroneck, New York, 10543. Aru Pharma Inc. imports, markets, and distributes the artificial tear product(s) at issue in this litigation.

FACTUAL ALLEGATIONS

EzriCare Artificial Tears

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

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

13. EzriCare Artificial Tears are intended to be used in the following manner: (1) as a protectant against further irritation or to relieve dryness of the eye; and (2) for the temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun.[3]

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

15. The active ingredient in the EzriCare Artificial Tears is a solution of Carboxymethylcellulose Sodium 10 MG in 1 ml. The inactive ingredients include Boric Acid, Potassium Chloride, Sodium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride,

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

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

Sodium Chlorite, Sodium Hydroxide, and Water for Injection.[5]

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

Inner Package

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

[5] *Id.*

Delsam Pharma's Artificial Tears

17. The NDC number for Delsam Pharma's Artificial Tears is 72570-121-15.

18. Delsam Pharma LLC began marketing these artificial tears on or about July 23, 2020.

19. Delsam Pharma's Artificial Tears are a similar product to EzriCare Artificial Tears' they are just a different brand of the same chemical solution (in terms of active ingredient). Delsam Pharma's Artificial Tears are intended to be used in the following manner: (1) as a protectant against further irritation or to relieve dryness of the eye; and (2) for the temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun.

20. According to its website, Delsam Pharma's Artificial Tears use preservatives "to keep bacteria from growing in the bottle of the drops."[6]

21. The active ingredient in the Delsam Pharma's Artificial Tears 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.[7]

22. Delsam Pharma's Artificial Tears' packaging and labeling appears as follows:

[6] *See* https://delsampharma.com/store/delsam-pharma-artificial-tears.
[7] *Id.*

Outer package label

Inner package label

Source: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=fbbfda9c-588b-4e82-b66c-83cea663b967&type=display.

The *Pseudomonas Aeruginosa* Bacteria

23. 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.

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

25. 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]

Pseudomonas Aeruginosa and EzriCare / Delsam Pharma Artificial Tears

26. The current outbreak of the *Pseudomonas Aeruginosa* bacteria resulting from the use of the EzriCare and/or Delsam Pharma Artificial Tears began in May 2022 and has been linked to 12 states, so far: California, Colorado, Connecticut, Florida, New Jersey, New Mexico, New York, Nevada, Texas, Utah, Washington, and Wisconsin.[10]

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

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

[9] *Id.*

[10] *Id.*

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

28. 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."[12]

29. The CDC also reported that it was able to isolate the outbreak strain from 13 sputum or bronchial washes, 11 cornea swabs, seven urine samples, two blood samples, 25 rectal swabs, and four other nonsterile sources.[13,14]

30. As a result of using Defendants' EzriCare and/or Delsam Pharma Artificial Tear products, out of the 55 individuals who have been identified as having been infected with the *Pseudomonas Aeruginosa* bacteria from use of EzriCare artificial tears thus far, approximately three people have suffered permanent vision loss, and one person has died due to a systemic infection. Others have endured extensive treatment to treat their infections.

Product Recall

31. On January 24, 2023, Defendant EzriCare LLC first issued a statement on the contamination of its artificial tears 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."[15]

32. After development of this story, on February 1, 2023, 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

[12] *Id.*
[13] Beth Mole, *Extremely drug-resistant germ found in eye drops infects 55 in 12 states; 1 dead*, ARS TECHNICA (Feb. 2, 2023), located at https://arstechnica.com/science/2023/02/extremely-drug-resistant-germ-found-in-eye-drops-infects-55-in-12-states-1-dead/.
[14] *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.
[15] EzriCare Artificial Tears - Discontinue Use (Feb. 2, 2023), located at https://ezricare-info.com.

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."[16]

33. Additionally, on February 1, 2023, Defendant Global Pharma Healthcare initiated a voluntary recall of all unexpired lots of EzriCare Artificial Tears and Delsam Pharma's Artificial Tears.[17]

34. 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."[18] The FDA highlighted that it recommended Defendant Global Pharma initiate a product recall due to "the company's current good manufacturing practice (CGMP) . . . violations, including lack of appropriate microbial testing, formulation issues (the company manufactures and distributes ophthalmic drugs in multi-use bottles, without an adequate preservative), and lack of proper controls concerning tamper-evidence packaging."[19]

35. Further, the FDA also "placed [Defendant] Global Pharma Healthcare Private Limited on import alert . . . for providing an inadequate response to a records request and for not complying with CGMP requirements."[20] According to the FDA, the import alert "prevents these products from entering the United States."[21]

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[16] *Id.*
[17] *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.
[18] *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.
[19] *Id.*
[20] *Id.*
[21] *Id.*

CLASS ALLEGATIONS

36. Plaintiff brings this action on behalf of himself and all other similarly situated class members (the "Class") pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Class and/or Sub-Class against Defendants for violations of Kentucky state laws and/or similar laws in other states:

Multi-State Class Action

All consumers who purchased the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears Products in the United States of America and its territories (excluding California) from May 1, 2022 to the present for personal use.

Excluded from the Class are any Defendant, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

37. In the alternative, Plaintiff brings this action on behalf of himself and all other similarly situated Kentucky consumers pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Sub-Classes:

Kentucky Sub-Class

All consumers who purchased EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears Product in the Commonwealth of Kentucky from May 1, 2022 to the present for personal use.

Excluded from the Class are any Defendants, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

38. The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiff is informed and believes that the proposed Class/Sub-Classes contains hundreds of purchasers of EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears who

have been damaged by Defendants' conduct as alleged herein. The precise number of Class members is unknown to Plaintiff at this time.

39. Plaintiff's claims are typical to those of all Class members because members of the Class are similarly injured through Defendant's uniform misconduct described above and were subject to Defendant's deceptive claims that its artificial tear products were not contaminated. Plaintiff is advancing the same claims and legal theories on behalf of himself and all members of the Class/Sub-Class.

40. Plaintiff's claims raise questions of law and fact common to all members of the Class, and they predominate over any questions affecting only individual Class members. The claims of Plaintiff and all prospective Class members involve the same alleged defect/contamination. These common legal and factual questions include the following:

(a) whether Defendants' EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears Products contained the *Pseudomonas Aeruginosa* bacteria;

(b) whether Defendants' omissions are true, or are misleading, or objectively reasonably likely to deceive.

(c) whether the alleged conduct constitutes violations of the laws asserted;

(d) whether Defendants' alleged conduct violates public policy;

(e) whether Defendants' engaged in false or misleading advertising;

(f) whether Defendants were unjustly enriched as a result of its labeling, marketing, advertising, and/or selling of the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears Products;

(g) whether Plaintiff and the Class members are entitled to damages and/or restitution and the proper measure of that loss; and

(h) whether an injunction is necessary to prevent Defendants from continuing to market and sell defective and adulterated/contaminated Artificial Tears.

41. Plaintiff and his counsel will fairly and adequately protect and represent the interests of each member of the class. Plaintiff has retained counsel experienced in complex litigation and class actions. Plaintiff's counsel has successfully litigated other class action cases similar to that here and has the resources and abilities to fully litigate and protect the interests of the class. Plaintiff intends to prosecute this claim vigorously. Plaintiff has no adverse or antagonistic interests to those of the Class, nor is Plaintiff subject to any unique defenses.

42. A class action is superior to the other available methods for a fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by Plaintiff and the individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendants. It would thus be virtually impossible for Plaintiff and Class members, on an individual basis, to obtain meaningful and effective redress for the wrongs done to them. Further, it is desirable to concentrate the litigation of the Class members' claims in one forum, as it will conserve party and judicial resources and facilitate the consistency of adjudications. Plaintiff knows of no difficulty that would be encountered in the management of this case that would preclude its maintenance as a class action.

43. The Class also may be certified because Defendants have acted or refused to act on grounds applicable to the Class, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

44. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent

Defendants from engaging in the acts described above, such as continuing to market and sell EzriCare Artificial Tears and Delsam Pharma's Artificial Tears that may be adulterated or contaminated with the Pseudomonas aeruginosa bacteria, and requiring Defendants to provide a full refund of the purchase price of the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears to Plaintiff and the Class members.

45. Unless a Class is certified, Defendants will retain monies received as a result of their conduct that was taken from Plaintiff and the Class members. Notwithstanding Defendant Global Pharma Healthcare Private Ltd.'s voluntary recall, unless a Class-wide injunction is issued, Defendants may continue to commit the violations alleged and the members of the Class and the general public will continue to be misled and placed in harms' way.

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

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

47. 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.

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

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

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

FIRST CAUSE OF ACTION

Violation of the Kentucky Consumer Protection Act

KRS §§ 367.170, 367.220

(On Behalf of Plaintiff and the Kentucky Sub-Class and Against All Defendants)

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

52. Plaintiff brings this Count individually and on behalf of the Kentucky Sub-Class who purchased the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears.

53. The Kentucky Consumer Protection Act ("KCPA") declares unlawful any "unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." KRS § 376.170. The statute continues by stating that:

> Any person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property, real or personal, as a result of the use or employment by another person of a method, act or practice declared unlawful by KRS 367.170, may bring an action under the Rules of Civil Procedure in the Circuit Court in which the seller or lessor resides or has his principal place of business or is doing business, or in the Circuit Court in which the purchaser or lessee of goods or services resides, or where the transaction in question occurred, to recover actual damages. The court may, in its discretion, award actual damages and may provide such equitable relief as it deems necessary or proper. Nothing in this subsection shall be construed to limit a person's right to seek punitive damages where appropriate.

KRS § 367.220.

54. Plaintiff and the Kentucky Sub-Class members used the EzriCare Artificial Tears

and/or Delsam Pharma's Artificial Tears for personal purposes.

55. Plaintiff and the Kentucky Sub-Class acted as a reasonable consumer would in light of all circumstances.

56. Defendants have violated and continue to violate the KCPA by, among other things, (1) misrepresenting that the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears were safe and not contaminated when in fact these products are unsafe because they are contaminated with a dangerous and deadly bacteria, (2) failing to disclose to consumers in their labeling or otherwise that the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears were contaminated with a dangerous and deadly bacteria, and (3) continuing to manufacture, market, advertise, and sell the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears contaminated with a dangerous and deadly bacteria.

57. Defendants knew, or through the exercise of reasonable care should have known, that the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears were adulterated or contaminated with the *Pseudomonas Aeruginosa* bacteria. Defendants' unfair and violative conduct, as described herein, is intentional, and Defendants intended and intend for consumers to rely on its unfair and misleading practices—*i.e.*, knowingly violating CGMPs.

58. Defendants' unfair conduct, as described herein, occurred in the course of trade or commerce.

59. Defendants' conduct offends the public policy of Kentucky in that it violates a standard of conduct contained in an existing statute or common law doctrine that typically applies to such a situation. Specifically, among other things, it is unfair and misleading to represent to consumers that a product is safe and contains the ingredients identified on the label when in fact the product is unsafe because it contains a dangerous and deadly bacterium not identified or warned

of on the label.

60. Defendants' conduct, as described herein, has caused and continues to cause substantial injury to consumers, including Plaintiff the members of the Kentucky Sub-Class.

61. Defendants' deceptive statements and omissions are material because they concern contaminants and safety, which are among the types of information that consumers, including Plaintiff and the members of the Kentucky Sub-Class, would be expected to rely upon in making purchasing decisions.

62. Defendants' deceptive statements and omissions have the capacity to deceive consumers, including Plaintiff and the Kentucky Sub-Class, by inducing them to purchase the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears.

63. Defendants' deceptive statements and omissions succeeded in deceiving consumers, including Plaintiff and the Kentucky Sub-Class, who relied upon the statements and omissions and were induced to buy and use Defendants' artificial tear products.

64. Defendants' intended for consumers, including Plaintiff and the members of the Kentucky Sub-Class, to rely on the deceptive statements and omissions by purchasing the artificial tear products at issue.

65. Defendants made the deceptive statements and omissions in the course of conduct involving trade or commerce.

66. Plaintiff and the members of the Kentucky Sub-Class have been injured as a direct and proximate result of Defendants' deceptive conduct in violation of KCPA. Plaintiff and the members of the Kentucky Sub-Class paid for the artificial tears at issue as a result of Defendants' deceptive statements and omissions.

67. Through its deceptive practices, Defendants have improperly obtained and continue

to improperly obtain and retain money from Plaintiff and the members of the Kentucky Sub-Class.

68. The injury caused by Defendants' conduct is not outweighed by any countervailing benefits to consumers or to competition.

69. The injury caused by Defendants' conduct could not reasonably have been avoided by consumers because they did not know and could not have known that the EzriCare Artificial tears and/or Delsam Pharma's Artificial Tears were adulterated/contaminated with *Pseudomonas Aeruginosa* bacteria.

70. Plaintiff therefore requests that this Court grant the relief enumerated below. Otherwise, Plaintiff and the members of the Kentucky Sub-Class may be irreparably harmed and/or denied an effective and complete remedy.

SECOND CAUSE OF ACTION

Unjust Enrichment

(On Behalf of the Multi-State Class and the Kentucky Sub-Class and Against All Defendants)

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

72. As a result of Defendants' wrongful and deceptive conduct alleged herein, Defendants knowingly and voluntarily accepted and retained wrongful benefits in the form of money paid by the Plaintiff and members of the Class when they purchased the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears.

73. In so doing, Defendants acted with conscious disregard for the rights of Plaintiff and members of the Class.

74. As a result of Defendants' wrongful conduct as alleged herein, Defendants have been unjustly enriched at the expense of, and to the detriment of, Plaintiff and members of the

Class.

75. Defendants' unjust enrichment is traceable to, and resulted directly and proximately from, the conduct alleged herein.

76. Under the common law doctrine of unjust enrichment, it is inequitable for Defendants to be permitted to retain the benefits it received, and is still receiving, without justification, from the false and deceptive manufacturing, labeling, and marketing of the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears to Plaintiff and members of the Class.

77. Defendants' retention of such funds under circumstances making it inequitable to do so constitutes unjust enrichment.

78. The financial benefits derived by Defendants rightfully belong to Plaintiff and members of the Class.

79. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and members of the Class all wrongful or inequitable proceeds received by them.

80. Finally, Plaintiff and members of the Class may assert an unjust enrichment claim even though a remedy at law may otherwise exist.

THIRD CAUSE OF ACTION

Negligent Misrepresentation/Omission

(On Behalf of the Multi-State Class and the Kentucky Sub-Class and Against All Defendants)

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

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

and/or Delsam Pharma's Artificial Tears.

83. Defendants intended that the Plaintiff and the Class members rely on their representations.

84. Defendants' representations were material to Plaintiff and the Class members' decision to purchase the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears.

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

86. Defendants failed to fulfill its duty to accurately disclose in its labeling and advertising that the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears were contaminated with a dangerous and deadly bacterium.

87. Additionally, Defendants have a duty to not make false representations with respect to the EzriCare Artificial Tears and/or Delsam Pharma's Artificial Tears.

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

89. 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.

90. Plaintiff and the other members of the Class reasonably relied upon such representations and omissions to their detriment.

91. By reason thereof, Plaintiff and the other Class members have suffered damages in an amount to be proven at trial.

FOURTH CAUSE OF ACTION

Breach of Express Warranty

(On Behalf of the Multi-State Class and the Kentucky Sub-Class and Against All Defendants)

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

93. As detailed above, Defendants, through its advertising, marketing, packaging, and labeling, expressly warranted that the EzriCare Artificial Tears and/or Delsam Pharma's 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.

94. Moreover, the labeling for the EzriCare Artificial Tears and/or Delsam Pharma's 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.

95. Defendants breached this express warranty because the EzriCare Artificial Tears and/or Delsam Pharma's 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.

96. Plaintiff and the other Class members read and relied on these express warranties provided by Defendants in the labeling, packaging, and advertisements.

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

98. Defendants knew or should have known that the EzriCare Artificial tears and/or

Delsam Pharma's Artificial Tears did not conform to their express warranties and representations and that, in fact, the they are not safe and pose serious health risks because they are contaminated with a dangerous and deadly bacterium.

99. Plaintiff and the other Class members read and relied on these express warranties provided by Defendants in the labeling, packaging, and advertisements.

100. Defendants' representations were made to induce Plaintiff and other Class members to purchase the artificial tears at issue and were material factors in Plaintiff and other Class members' decisions to purchase these products.

101. Plaintiff and the other Class members have suffered harm on account of Defendants' breach of its express warranty regarding the fitness for use and safety of the EzriCare and Delsam Pharma Artificial Tears and are entitled to damages to be determined at trial.

FIFTH CAUSE OF ACTION

Breach of Implied Warranty

(On Behalf of the Multi-State Class and the Kentucky Sub-Class and Against All Defendants)

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

103. Because the EzriCare and Delsam Pharma 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.

104. Plaintiff and members of the Class purchased the EzriCare and Delsam Pharma Artificial Tears in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

105. The EzriCare and Delsam Pharma Artificial Tears were not altered by Plaintiff or members of the Class.

106. Plaintiff and members of the Classes were foreseeable users of the EzriCare and Delsam Pharma Artificial Tears.

107. Plaintiff and members of the Class used the EzriCare and Delsam Pharma Artificial Tears in the manner intended.

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

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

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

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

112. 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.

113. By reason thereof, Plaintiff and the other Class members have suffered damages in an amount to be proven at trial.

SIXTH CAUSE OF ACTION

Strict Product Liability – Failure to Warn

(On Behalf of the Multi-State Class and the Kentucky Sub-Class and Against All Defendants)

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

115. Defendants sold the EzriCare and Delsam Pharma Artificial Tears in the course of Defendants' business.

116. Defendants knew or should have known that their artificial tears were contaminated with a dangerous and deadly bacterium.

117. Defendants had a duty to warn Plaintiff and the other Class members about the presence of *Pseudomonas Aeruginosa* bacteria their artificial tear products.

118. In addition, Defendants had a duty to warn Plaintiff and the other Class members about the dangers of the presence of *Pseudomonas Aeruginosa* bacteria in the EzriCare and Delsam Pharma Artificial Tear products.

119. 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.

120. Defendants did not warn/did not give adequate warnings to Plaintiff and the other Class members that the EzriCare and Delsam Pharma Artificial Tears were contaminated with the *Pseudomonas Aaeruginosa* bacteria or about the dangers of the presence of *Pseudomonas Aeruginosa* bacteria in their artificial tear products.

121. Plaintiff and the other Class members used the EzriCare and Delsam Pharma Artificial Tears in a manner that as reasonably anticipated by Defendants.

122. Plaintiff and the other Class members suffered damages by purchasing EzriCare and Delsam Pharma Artificial Tears and using them in a manner promoted by Defendants and in a manner that was reasonably foreseeable by Defendants. Plaintiff and the members of the Class

would not have purchased Defendants' EzriCare and Delsam Pharma Artificial Tears had they known they contained Pseudomonas aeruginosa bacteria.

123. Plaintiff and the other Class members were justified in their reliance on Defendants' manufacturing, labeling, packaging, marketing, and advertising of the product for use as artificial tears.

124. Plaintiff and the other Class members have suffered damages in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION

Strict Product Liability – Manufacturing Defect

(On Behalf of the Multi-State Class and the Kentucky Sub-Class and Against All Defendants)

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

126. Defendants manufactured and sold the EzriCare and Delsam Pharma Artificial Tears in the course of Defendants' business.

127. The EzriCare and Delsam Pharma Artificial Tears contained a manufacturing defect when they left the possession of Defendants. Specifically, the EzriCare and Delsam Pharma Artificial Tears differ from Defendants' intended result or from other lots of the same product line because they were contaminated with the *Pseudomonas Aeruginosa* bacteria.

128. Plaintiff and the other Class members used the EzriCare and Delsam Pharma Artificial Tears in a way that was reasonably foreseeable to and anticipated by Defendants.

129. As a result of the defects in the manufacture of the EzriCare and Delsam Pharma Artificial Tears, Plaintiff and the other Class members suffered damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and all others similarly situated, prays for judgment against the Defendants as to each and every count, including:

A. An order declaring this action to be a proper class action, appointing Plaintiff and his counsel to represent the Class/Sub-Class, and requiring Defendants to bear the costs of class notice;

B. An order enjoining Defendants from selling the EzriCare Artificial Tears and Delsam Pharma's Artificial Tears;

C. An order enjoining Defendants from suggesting or implying that the EzriCare and Delsam Pharma Artificial Tears are safe and effective for human application;

D. An order requiring Defendants to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief, such as continuing to recall existing EzriCare Artificial Tears and Delsam Pharma's Artificial Tears, as well as prevent them from importing these products while still violating CGMPs;

E. An order awarding declaratory relief and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Defendants from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendants' past conduct;

F. An order requiring Defendants to pay restitution/damages to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, plus pre- and post-judgment interest thereon;

G. An order requiring Defendants to disgorge any ill-gotten benefits received from

Plaintiff and members of the Class/Sub-Class as a result of any wrongful or unlawful act or practice, such as violating the CGMPs when manufacturing and selling these products;

H. An order requiring Defendants to pay all actual and statutory damages permitted under the counts alleged herein;

I. An order awarding attorneys' fees and costs to Plaintiff and the Class/Sub-Class; and

J. An order providing for all other such equitable relief as may be just and proper.

DEMAND FOR JURY TRIAL

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

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DATED: February 4, 2023

/s/ David G. Bryant
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