

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

DONNA FIKE

(b) County of Residence of First Listed Plaintiff Berks (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Barry Magen, Kline & Specter, PC, 1525 Locust Street, Philadelphia, PA 19102

DEFENDANTS

GLOBAL PHARMA HEALTHCARE PRIVATE, LTD.

County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, 1 1, 2 2, 3 3, 4 4, 5 5, 6 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

Table with columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Personal Injury, Property Damage, Labor, etc.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District, 6 Multidistrict Litigation - Transfer, 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. § 1332. Brief description of cause: Product Liability

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: [X] Yes [ ] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE 8/3/2023 SIGNATURE OF ATTORNEY OF RECORD /s/ Barry Magen

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

**INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44**

## Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.  
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.  
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.  
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.  
 Original Proceedings. (1) Cases which originate in the United States district courts.  
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.  
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.  
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.  
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.  
 Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.  
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.  
**PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.  
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.  
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA**

**DONNA FIKE**  
211 Tower Court  
Topton, PA 19562

*Plaintiff,*

v.

**GLOBAL PHARMA HEALTHCARE  
PRIVATE, LTD.,**

and

**EZRICARE, LLC,**

and

**EZRIRX, LLC,**

and

**ARU PHARMA, INC.**

and

**AMAZON.COM, INC.**

*Defendants.*

**CIVIL ACTION NO: 23-2981**

**JURY TRIAL DEMANDED**

**CIVIL ACTION - COMPLAINT**

Plaintiff, Donna Fike, by and through her undersigned counsel, Kline & Specter, PC, hereby bring this action against Defendants, Global Pharma Private Ltd., Ezricare, LLC, EzriRx, LLC, Aru Pharma, Inc. and Amazon.com, Inc. in support thereof aver as follows:

**PARTIES, JURISDICTION, AND VENUE**

1. Plaintiff, Donna Fike, is an adult person, resident, and citizen of the Commonwealth of Pennsylvania residing at 211 Tower Court, Topton, Pennsylvania 19562.

2. Defendant Global Pharma Private Ltd. (“Global Pharma”) is, and at all times relevant to this action was, a foreign corporation organized and existing under the laws of the Country of India, with its principal place of business at No. 2A, 3rd F, 4th Street, Ganga Nagar, Chennai – 600 024, Tamilnadu, India. Global Pharma Healthcare Private Ltd. manufactures, designs, tests, markets, advertises, labels, distributes, and sells the EzriCare Artificial Tears product (NDC# 79503-101-15) at issue in this litigation. This includes marketing and selling the product in the Commonwealth of Pennsylvania, where Plaintiff purchased the product.

3. 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. EzriCare LLC markets, advertises, labels, distributes, and sells the EzriCare Artificial Tears product at issue in this litigation. This includes marketing and selling the product in the Commonwealth of Pennsylvania, where Plaintiff purchased the product.

4. Defendant EzriRx LLC (“ExriRx”) is, and at all times relevant to this action was, a company incorporated under the laws of Delaware with its principal place of business located at 1525 Prospect Street, Suite 204, Lakewood, New Jersey 08701. Process may be served upon its registered agent: Registered Agent Solutions, Inc., 838 Walker Road, Suite 21-2, Dover, Delaware 19904. EzriRx LLC markets, advertises, labels, distributes, and sells the EzriCare Artificial Tears product at issue in this litigation. This includes marketing and selling the product in the Commonwealth of Pennsylvania, where Plaintiff purchased the product.

5. Defendant Aru Pharma, Inc. (“Aru”) is, at all times relevant to this action was, a company incorporated in the State of New York with its principal place of business located at 925 Protano Lane, Mamaroneck, NY 10543, and/or 696 Locust Street, Mount Vernon, NY 10552, both in Westchester County. Aru Pharma 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 the Commonwealth of Pennsylvania, where Plaintiff purchased the product. Aru Pharma may be served with process at its principal place of business 925 Protano Lane, Mamaroneck, NY 10543.

6. 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, including to the Commonwealth of Pennsylvania.

7. Subject matter jurisdiction is proper under 28 U.S.C. § 1332 as Plaintiff and Defendants are residents of separate states and because the amount in controversy is in excess of local arbitration limits exclusive of interest and costs.

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

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

**OPERATIVE FACTS**

**EzriCare Artificial Tears**

10. Global Pharma, Ezricare, EzriRx, Aru, and Amazon (“Defendants”) designed, manufactured, marketed, warranted, distributed, and/or sold the EzriCare Artificial Tears at issue.

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

12. 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.

13. These artificial tears are designed to be “preservative free.” This product design removes any chemical used to prevent the growth of bacteria in the product.

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

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, Sodium Chlorite, Sodium Hydroxide, and Water for Injection.



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



Source: <https://dailymed.nlm.nih.gov/dailymed/fda/drugXsl.cfm?setid=ac1ea23c-f1c6-418f-921e-58553ce919cb&type=display>.

**Pseudomonas Aeruginosa and EzriCare Artificial Tears**

17. The current outbreak of the Pseudomonas Aeruginosa bacteria resulting from the use of the EzriCare Artificial Tears was first detected by the U.S. Centers for Disease Control (“CDC”) in May 2022 and has now been linked to sixteen states.

18. The CDC has isolated the specific strain of Pseudomonas Aeruginosa and identified it as Verona Integron-mediated Metallo-β-lactamase (VIM) and Guiana-Extended Spectrum-

$\beta$ Lactamase (GES)-producing carbapenem-resistant *Pseudomonas aeruginosa* (“VIM-GESCRPA”). This particular strain is incredibly drug-resistant and dangerous.

19. The CDC reported that this particular strain of *Pseudomonas Aeruginosa* “had never been reported in the United States.”

20. 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.”

21. Out of the 81 individuals who have been identified as having been infected with the *Pseudomonas Aeruginosa* bacteria from use of the Product thus far, at least fourteen (14) people have suffered permanent vision loss, four (4) people have had their eyeballs removed, and four (4) people have died due to a systemic infection.

### **Product Recall**

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

23. After development of this story, on February 1, 2023, Defendant EzriCare LLC issued another statement: “EzriCare, LLC first received notice of the CDC’s ongoing investigation into a multistate cluster of *Pseudomonas aeruginosa* infections on January 20, 2023. As of today, we are not aware of any testing that definitively links the *Pseudomonas aeruginosa* outbreak to EzriCare Artificial Tears. Nonetheless, we immediately took action to stop any further distribution or sale of EzriCare Artificial Tears. To the greatest extent possible, we have been contacting customers to advise them against continued use of the product. We also immediately reached out



to both CDC and FDA and indicated our willingness to cooperate with any requests they may have of us.”

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

25. 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.” 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.”

26. 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.” According to the FDA, the import alert “prevents these products from entering the United States.”

### **Donna Fike’s Usage of the Product and Injuries**

27. Plaintiff purchased EzriCare Artificial Tears from Defendant Amazon.com on at least three (3) occasions in 2022, May 16<sup>th</sup>, July 23<sup>rd</sup>, and December 10<sup>th</sup>.

28. In late January 2023, Plaintiff began experiencing an eye discharge, burning eyes, eye redness, and tearing in her left eye. During the same period, Plaintiff began experiencing associated symptoms of ear pain and nasal congestion.

29. On January 31, 2023, Plaintiff presented to Joseph Blasiol, DO at Topton Family Practice Associates for evaluation of the symptoms she was experiencing in her left eye. Dr. Blasiol assessed Plaintiff with squamous blepharitis in her left eye and eye lid and prescribed Bactrim DS 800-160 tablets and gentamicin eye drops to treat her symptoms.

30. On February 2, 2023, Plaintiff again presented to Dr. Blasiol with “goopy stuff” coming out of her left eye. At this time, the eye has turned completely white. She also complained of being clammy and not feeling right. Dr. Blasiol prescribed another antibiotic to control Plaintiff’s pain and discomfort.

31. Later that evening, Plaintiff presented to Dr. Joseph Matz at Reading Hospital complaining of severe pain in her left eye. Dr. Matz noted the discharge from her left eye was purulent and bloody.

32. On February 5, 2023, after attempts to manage the pain and infection had failed, Dr. Christina Lippe surgically removed Plaintiff’s left eye at Reading Hospital and replaced the eye with a plastic implant.

33. As a direct and proximate result of the conduct of the Defendants in manufacturing, importing, compounding, packaging, distributing, supplying, and marketing of the contaminated EzriCare Artificial Tears, Mrs. Fike has been permanently injured both physically and emotionally. Plaintiff was catastrophically injured and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

**COUNT I**  
**STRICT PRODUCTS LIABILITY**  
**Plaintiff v. All Defendants**

34. Plaintiff incorporates by reference all of the above paragraphs as though set forth fully herein.

35. At all relevant times hereto, Defendants knew or should have known of the foreseeable risk of infection from the presence Pseudomonas Aeruginosa bacteria in the EzriCare Artificial Tears product.

36. At the time Defendants designed, manufactured, marketed, sold, and distributed the subject EzriCare Artificial Tears, it was defective in its design, unreasonably dangerous, and unsafe for its intended purpose because it did not provide adequate protection and/or warning against the foreseeable risk of infection related to the presence of Pseudomonas Aeruginosa bacteria in its product.

37. The EzriCare Artificial Tears at issue were in the same or substantially similar condition as when they left the possession of Defendants.

38. Plaintiff did not misuse or materially alter the EzriCare Artificial Tears.

39. The EzriCare Artificial Tears did not perform as safely as an ordinary consumer would have expected it to perform when used in a reasonably foreseeable way.

40. Further, a reasonable person would conclude that the possibility and seriousness of harm outweighs the burden or cost of manufacturing, labeling, and distributing EzriCare Artificial Tears in a safe manner.

41. The EzriCare Artificial Tears was defective, subjecting Defendants to strict liability, in one or more of the following respects:

- a) the EzriCare Artificial Tears was manufactured such that it contained the Pseudomonas Aeruginosa bacteria;
- b) the EzriCare Artificial Tears did not comport with the applicable product safety standards;
- c) the EzriCare Artificial Tears was not adequately tested before distribution and sale;

- d) the EzriCare Artificial Tears were designed in a manner that allowed for the growth of Pseudomonas Aeruginosa bacteria;
- e) the EzriCare Artificial Tears marketing, instructions, and/or packaging, misrepresented its safety characteristics and its potential to contain the Pseudomonas Aeruginosa bacteria;
- f) Defendants failed to design and/or utilize proper designs for the manufacture of its product;
- g) Defendants failed to adequately and properly inform and warn purchasers and ultimate users of the EzriCare Artificial Tears that it might contain Pseudomonas Aeruginosa bacteria;
- h) Defendants failed to adequately and properly inform purchasers as to the risks and benefits of the product;
- i) Defendants designed, manufactured, sold, supplied and/or distributed a product in a defective condition;
- j) Defendants designed, manufactured, sold, supplied and/or distributed a product that was unreasonably dangerous to the user;
- k) Defendants designed, manufactured, sold, supplied and/or distributed a product which was not reasonably fit, suitable or safe for its intended and represented purpose;
- l) Defendants designed, manufactured, sold, supplied and/or distributed a product which lacked all necessary safety features to protect users of said product;
- m) Defendants designed, manufactured, sold, supplied and/or distributed a product which could be designed more safely;
- n) Defendants marketed the EzriCare Artificial Tears as safe;
- o) Defendants delayed in issuing post-sale warnings in an effort to eliminate the unreasonably dangerous nature of the EzriCare Artificial Tears;
- p) other misrepresentations regarding the EzriCare Artificial Tears that may be identified in the course of discovery;
- q) unsafe manufacturing defects which cause the improper exposure of the product Pseudomonas Aeruginosa bacteria;
- r) delay in recalling the product upon learning that it was unsafe for its intended and/or foreseeable use; and

s) being otherwise defective as may be learned through discovery.

42. The defectiveness and unreasonably dangerous condition of the EzriCare Artificial Tears were direct and proximate causes of Plaintiff, Donna Fike's severe and permanent injuries and damages, as previously set forth herein.

43. Defendants are strictly liable to Plaintiff for designing, manufacturing, and failing to warn of the dangers of a defective and unreasonably dangerous product. The inherent risks associated with the EzriCare Artificial Tears outweighed the benefits of its use, as a safer better manufacturing practices were economically and technologically feasible at the time the product left the control of Defendants.

**WHEREFORE**, Plaintiff demands judgment in her favor and against Defendants, jointly and severally, with all Defendants named herein, for compensatory and punitive damages, in a sum in excess of local arbitration limits, exclusive of pre-judgment interest, post-judgment interest and costs.

**COUNT II**  
**STRICT PRODUCTS LIABILITY – FAILURE TO WARN**  
**Plaintiff v. Global Pharma Healthcare Private, Ltd., Ezricare, LLC, Ezrirx, LLC, and Aru**  
**Pharma, Inc.**

44. Plaintiff incorporates by reference all of the above paragraphs as though set forth fully herein.

45. At all relevant times hereto, Defendants knew or should have known of the substantial dangers and inherent risks of Pseudomonas Aeruginosa bacteria-related injuries involved in the reasonably foreseeable use of the EzriCare Artificial Tears.

46. Defendants knew or should have known that the substantial dangers and inherent risks of Pseudomonas Aeruginosa bacteria-related injuries and death involved in the reasonably

foreseeable use of the EzriCare Artificial Tears were not readily recognizable to an ordinary consumer or user and that such person would be able to know of defects.

47. Defendants knew or should have known of the foreseeable risk of *Pseudomonas Aeruginosa* bacteria related injuries and death inherent in the design and manufacture of the EzriCare Artificial Tears.

48. Defendants acted negligently and recklessly by failing to provide necessary safety materials and failing to adequately warn of the substantial dangers and known and foreseeable risk of *Pseudomonas Aeruginosa* bacteria-related injuries, by failing to provide adequate warnings regarding one or more of the following:

- a) the EzriCare Artificial Tears was manufactured such that it contained the *Pseudomonas Aeruginosa* bacteria;
- b) the EzriCare Artificial Tears did not comport with the applicable product safety standards;
- c) the EzriCare Artificial Tears was not adequately tested before distribution and sale;
- d) the EzriCare Artificial Tears were designed in a manner that allowed for the growth of *Pseudomonas Aeruginosa* bacteria;
- e) Defendants failed to design and/or utilize proper designs for the manufacture of its product;
- f) Defendants failed to adequately and properly inform and warn purchasers and ultimate users of the EzriCare Artificial Tears that it might contain *Pseudomonas Aeruginosa* bacteria;
- g) Defendants failed to adequately and properly inform purchasers as to the risks and benefits of the product;
- h) Defendants designed, manufactured, sold, supplied and/or distributed a product in a defective condition;
- i) Defendants designed, manufactured, sold, supplied and/or distributed a product that was unreasonably dangerous to the user;

- j) Defendants designed, manufactured, sold, supplied and/or distributed a product which was not reasonably fit, suitable or safe for its intended and represented purpose;
- k) Defendants designed, manufactured, sold, supplied and/or distributed a product which lacked all necessary safety features to protect users of said product;
- l) Defendants designed, manufactured, sold, supplied and/or distributed a product which could be designed more safely;
- m) Defendants marketed the EzriCare Artificial Tears as safe;
- n) Defendants delayed in issue of post-sale warnings in an effort to eliminate the unreasonably dangerous nature of the EzriCare Artificial Tears;
- o) other misrepresentations regarding the EzriCare Artificial Tears that may be identified in the course of discovery;
- p) unsafe manufacturing defects which cause the improper exposure of the product *Pseudomonas Aeruginosa* bacteria;
- q) delay in recalling the product upon learning that it was unsafe for its intended and/or foreseeable use;
- r) the EzriCare Artificial Tears marketing, instructions, and/or packaging, misrepresented its safety characteristics and its potential to contain the *Pseudomonas Aeruginosa* bacteria; and
- s) being otherwise defective as may be learned through discovery.

49. Any such safety material and/or warning that may have been provided and/or attached to the EzriCare Artificial Tears was inadequate, nullified, or rendered ineffective by contrary representations made by Defendants regarding the safety of the eye drops.

50. As a result of Defendants' recklessness and failure to adequately warn, Plaintiff neither knew nor had reason to know about the existence of defects in the EzriCare Artificial Tears.

51. At all relevant times hereto, Plaintiff used the EzriCare Artificial Tears in a reasonably foreseeable manner.

52. Defendants' failure to warn of the substantial dangers and inherent risks of *Pseudomonas Aeruginosa* bacteria-related injuries associated with the reasonably foreseeable use



of the EzriCare Artificial Tears was the direct and proximate cause of Plaintiff's injuries and damages, as previously set forth.

53. Defendants are strictly liable for failing to warn consumers and users of the substantial dangers and inherent risks of Pseudomonas Aeruginosa bacteria-related injuries associated with the reasonably foreseeable use of the EzriCare Artificial Tears.

**WHEREFORE**, Plaintiff demands judgment in her favor and against Defendants, jointly and severally, with all Defendants named herein, for compensatory and punitive damages, in a sum in excess of local arbitration limits, exclusive of pre-judgment interest, post-judgment interest and costs.

**COUNT III**  
**NEGLIGENCE**  
**Plaintiff v. All Defendants**

54. Plaintiff incorporates by reference all of the above paragraphs as though set forth fully herein.

55. At all relevant times hereto, Defendants owed a duty to consumers to use reasonable care in the way they designed, manufactured, marketed, sold, and distributed the EzriCare Artificial Tears.

56. At all relevant times hereto, Defendants knew or should have known of the foreseeable risk of Pseudomonas Aeruginosa bacteria related injuries inherent in the EzriCare Artificial Tears.

57. Defendants breached the duty of care they assumed to consumers and were negligent, careless, and reckless in designing, manufacturing, marketing, selling, and distributing the EzriCare Artificial Tears in one or more of the following respects:

- a) the EzriCare Artificial Tears was manufactured such that it contained the Pseudomonas Aeruginosa bacteria;

- b) the EzriCare Artificial Tears did not comport with the applicable product safety standards;
- c) the EzriCare Artificial Tears was not adequately tested before distribution and sale;
- d) the EzriCare Artificial Tears were designed in a manner that allowed for the growth of Pseudomonas Aeruginosa bacteria;
- e) Defendants failed to design and/or utilize proper designs for the manufacture of its product;
- f) Defendants failed to adequately and properly inform and warn purchasers and ultimate users of the EzriCare Artificial Tears that it might contain Pseudomonas Aeruginosa bacteria;
- g) Defendants failed to adequately and properly inform purchasers as to the risks and benefits of the product;
- h) Defendants designed, manufactured, sold, supplied and/or distributed a product in a defective condition;
- i) Defendants designed, manufactured, sold, supplied and/or distributed a product that was unreasonably dangerous to the user;
- j) Defendants designed, manufactured, sold, supplied and/or distributed a product which was not reasonably fit, suitable or safe for its intended and represented purpose;
- k) Defendants designed, manufactured, sold, supplied and/or distributed a product which lacked all necessary safety features to protect users of said product;
- l) Defendants designed, manufactured, sold, supplied and/or distributed a product which could be designed more safely;
- m) Defendants marketed the EzriCare Artificial Tears as safe;
- n) Defendants delayed in issuing post-sale warnings in an effort to eliminate the unreasonably dangerous nature of the EzriCare Artificial Tears;
- o) other misrepresentations regarding the EzriCare Artificial Tears that may be identified in the course of discovery;
- p) unsafe manufacturing defects which cause the improper exposure of the product Pseudomonas Aeruginosa bacteria;

- q) delay in recalling the product upon learning that it was unsafe for its intended and/or foreseeable use;
- r) the EzriCare Artificial Tears marketing, instructions, and/or packaging, misrepresented its safety characteristics and its potential to contain the Pseudomonas Aeruginosa bacteria; and
- s) being otherwise defective as may be learned through discovery.

58. Defendants' negligence, carelessness, and recklessness in designing, manufacturing, marketing, selling, and distributing the EzriCare Artificial Tears were the direct and proximate cause of Plaintiff's severe injuries and damages, as previously set forth herein.

**WHEREFORE**, Plaintiff demands judgment in her favor and against Defendants, jointly and severally, with all Defendants named herein, for compensatory and punitive damages, in a sum in excess of local arbitration limits, exclusive of pre-judgment interest, post-judgment interest and costs.

**COUNT IV**  
**NEGLIGENT/RECKLESS MISREPRESENTATION**  
**Plaintiff v. Global Pharma Healthcare Private, Ltd., Ezricare, LLC, Ezrinx, LLC, and Aru Pharma, Inc.**

59. Plaintiff incorporates by reference all of the above paragraphs as though set forth fully herein.

60. At all relevant times hereto, Defendants knew or should have known of the foreseeable risk of Pseudomonas Aeruginosa bacteria-related injuries inherent in the EzriCare Artificial Tears.

61. Defendants negligently and recklessly misrepresented material facts regarding the safety of the EzriCare Artificial Tears in one or more of the following respects:

- a) marketing the EzriCare Artificial Tears as safe;

- b) failing to warn that the EzriCare Artificial Tears could contain *Pseudomonas Aeruginosa* bacteria which could cause infections and/or the need for removal of the eye;
- c) delaying in issue of post-sale modifications or additional warnings in effort to eliminate the unreasonably dangerous nature of the EzriCare Artificial Tears, which was reasonably foreseeable; and
- d) other misrepresentations regarding the EzriCare Artificial Tears that may be identified in the course of discovery.

62. Defendants knew or should have known that consumers and users, including Plaintiff, would accept the material misrepresentations made regarding the EzriCare Artificial Tears' safety as true and accurate.

63. Defendants knew or should have known that consumers, including Plaintiff, would rely on the material misrepresentations made regarding the EzriCare Artificial Tears' safety when deciding whether to purchase and use it.

64. Defendants made material misrepresentations regarding the safety of the EzriCare Artificial Tears with the intent to induce consumers, including Plaintiff, to purchase and use it.

65. Plaintiff justifiably relied on Defendants' material misrepresentations regarding the safety of the EzriCare Artificial Tears when deciding whether to purchase it on May 16<sup>th</sup>, July 23<sup>rd</sup>, and December 10<sup>th</sup> of 2022 and any other dates Plaintiff may have purchased the product.

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

67. As a direct and proximate result of Defendants' material misrepresentations, Plaintiff suffered severe injuries and damages while the EzriCare Artificial Tears was being used in a reasonably foreseeable manner, as previously set forth herein. As such, Plaintiff is entitled to recover damages.

**WHEREFORE**, Plaintiff demands judgment in her favor and against Defendants, jointly and severally, with all Defendants named herein, for compensatory and punitive damages, in a sum in excess of local arbitration limits, exclusive of pre-judgment interest, post-judgment interest and costs.

**COUNT V**  
**BREACH OF EXPRESS WARRANTY**  
**Plaintiff v. Global Pharma Healthcare Private, Ltd., Ezricare, LLC, Ezrirx, LLC, and Aru Pharma, Inc.**

68. Plaintiff incorporates by reference all of the above paragraphs as though set forth fully herein.

69. All Defendants expressly warranted that its EzriCare Artificial Tears were safe and effective to members of the consuming public, including Plaintiff.

70. More specifically, the labeling for the EzriCare Artificial Tears expressly warranted 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.

71. The EzriCare Artificial Tears does not conform to these express representations because it was not safe to use to refresh, lubricate or moisturize the eyes. Instead, it posed a serious and dangerous health risk because the drops are contaminated with the *Pseudomonas Aeruginosa* bacteria—a dangerous and deadly bacterium.

72. Therefore, the Defendants breached their express warranties to the consuming public, including, but not limited to, Plaintiff.

73. As a direct and proximate result of the Defendant's breach of express warranties, Plaintiff suffered the injuries and damages set forth herein, entitling them to damages.

**WHEREFORE**, Plaintiff demands judgment in her favor and against Defendants, jointly and severally, with all Defendants named herein, for compensatory and punitive damages, in a sum in excess of local arbitration limits, exclusive of pre-judgment interest, post-judgment interest and costs.

**COUNT VI**  
**BREACH OF IMPLIED WARRANTY OF FITNESS**  
**FOR A PARTICULAR PURPOSE**  
**Plaintiff v. All Defendants**

74. Plaintiff incorporates by reference all of the above paragraphs as though set forth fully herein.

75. Defendants designed, manufactured, marketed, distributed, supplied, and sold its EzriCare Artificial Tears with an implied warranty that they were fit for the particular purpose of charging safely, knowing that consumers would rely on their skill and/or judgment to furnish suitable goods.

76. Members of the consuming public, including consumers such as Plaintiff, were the intended third-party beneficiaries of the warranty.

77. Defendants' EzriCare Artificial Tears was not fit for the particular purpose as a safe means of charging, due to the unreasonable risks of bodily injury and death associated with its use.

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

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

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

81. Plaintiff in this case reasonably and justifiably relied on Defendants' representations that the EzriCare Artificial Tears was safe to charge.

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

83. 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.

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

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

86. 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.

87. Defendants breached the implied warranty of fitness for a particular purpose, which was the direct and proximate cause of Plaintiff's injuries and damages.

**WHEREFORE**, Plaintiff demands judgment in her favor and against Defendants, jointly and severally, with all Defendants named herein, for compensatory and punitive damages, in a sum in excess of local arbitration limits, exclusive of pre-judgment interest, post-judgment interest and costs.

**COUNT VII**  
**VIOLATION OF PENNSYLVANIA UNFAIR TRADE**  
**PRACTICES AND CONSUMER PROTECTION LAW**  
**73 PA. CONS. STAT. § 201-1, et seq.**  
**Plaintiff v. Defendants**

88. Plaintiff incorporates by reference all of the above paragraphs as though set forth fully herein.



89. At the time Defendants designed, manufactured, marketed, distributed, supplied, and sold the EzriCare Artificial Tears Defendants represented that the products had certain benefits that they, in fact, did not have.

90. At the time Defendants designed, manufactured, marketed, distributed, supplied, and sold its EzriCare Artificial Tears, represented that these products are of a quality that they, in fact, are not.

91. Defendants violated the Unfair Trade Practices and Consumer Protection Law, giving rise to a cause of action to Plaintiff Donna Fike, as a purchaser of EzriCare Artificial Tears, in one or more of the following respects:

- a) Defendants warranted and represented that its EzriCare Artificial Tears was safe and free of defects in materials and manufacture and that they possessed safety features, which influenced reasonable consumers including Donna Fike's decision whether to purchase the EzriCare Artificial Tears; and
- b) Defendants warranted and represented that its EzriCare Artificial Tears was safe for use, which was not true.

92. Defendants' failure to warn of its EzriCare Artificial Tears' defects was a material omission that would influence a reasonable consumer's decision whether to purchase its products. Plaintiff, Donna Fike, was aware of Defendants' representation regarding the characteristics, qualities, and standard of the EzriCare Artificial Tears due to the representations contained in the user manual, websites, packaging, and other promotional materials of Defendants relating to the EzriCare Artificial Tears.

93. Plaintiff, Donna Fike, was aware of Defendants' representations regarding the characteristics, qualities, and standards of the EzriCare Artificial Tears due to the representations contained in the user manual, website, packaging, and other promotional materials of Defendants relating to the EzriCare Artificial Tears.

94. Plaintiff, Donna Fike, relied on the claimed truth of Defendant's representations and warranties concerning the EzriCare Artificial Tears, and she suffered personal injury damages as result of this reliance, as set forth herein.

95. Had Plaintiff, Donna Fike, been adequately warned concerning the likelihood that the EzriCare Artificial Tears could cause Pseudomonas Aeruginosa bacteria-related infections and injuries, she would have taken steps to avoid damages by, among other things, not purchasing this product.

96. As a result of these violations of consumer protection laws, Plaintiff, Donna Fike, has incurred and will continue to incur severe physical and emotional distress and pecuniary expenses related to her own treatment, for which Defendants are liable.

**WHEREFORE**, Plaintiff demands judgment in her favor and against Defendants, jointly and severally, with all Defendants named herein, for compensatory and punitive damages, in a sum in excess of local arbitration limits, exclusive of pre-judgment interest, post-judgment interest and costs.

**COUNT VIII**  
**NEGLIGENT INFLECTION OF EMOTIONAL DISTRESS**  
**Plaintiff v. All Defendants**

97. Plaintiff incorporates by reference all of the above paragraphs as though set forth fully herein.

98. Plaintiff Donna Fike has lived with pain and suffering related to her Pseudomonas Aeruginosa bacteria-related infection and subsequent surgery to remove her left eye, and during all times giving rise to this Complaint, and its aftermath.

99. More specifically, Plaintiff, Donna Fike, has lost enjoyment of her life, loss of pride in her appearance, she has suffered impairment and severe pain, and a loss of comfort, which

occurred as a result of the negligence, carelessness, and recklessness of Defendants as previously set forth herein, and she has lived through the consequences of that negligence, carelessness, and recklessness, including the pain and suffering, as previously set forth herein.

100. The trauma and shock of Plaintiff, Donna Fike's continuing experience of the loss of her eye and of the events previously set forth herein caused her to suffer in the past and will continue to cause her to suffer in the future, severe emotional and psychological distress and injuries, all of which have manifested physically, including but not limited to depression, stress, anxiety, and physical and psychological ailments.

**WHEREFORE**, Plaintiff demands judgment in her favor and against Defendants, jointly and severally, with all Defendants named herein, for compensatory and punitive damages, in a sum in excess of local arbitration limits, exclusive of pre-judgment interest, post-judgment interest and costs.

**COUNT IX**  
**PUNITIVE DAMAGES**  
**Plaintiff v. All Defendants**

101. Plaintiff incorporates by reference all of the above paragraphs as though set forth fully herein.

102. The conduct of Defendants was outrageous and/or done willfully and/or with reckless indifference to the users of EzriCare artificial tears, including Plaintiff Donna Fike, by and through the acts and/or omissions of the Defendants.

103. Defendants knew or should have known that designing a 'preservative free' product would result in conditions where harmful bacteria could grow. Despite this, Defendants designed, marketed, and sold a 'preservative free' product which, ultimately, did produce the bacteria which led to Plaintiff losing her eye.

104. Defendants failed to adequately warn about the risks of the bacteria once its existence in their product became known to them. Further, Defendants failed to swiftly recall their product, one they knew it was dangerous to the public. Both of these acts/omissions evidence a reckless indifference to the users of EzriCare Artificial Tears.

105. All of these acts constitute a reckless indifference to the risk of injury to Plaintiff Donna Fike. As a result, Plaintiff is seeking an award of punitive damages against all Defendants for designing, manufacturing, marketing, selling, and distributing the EzriCare Artificial Tears.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants, jointly and severally, with all Defendants named herein, for compensatory and punitive damages, in a sum in excess of local arbitration limits, exclusive of pre-judgment interest, post-judgment interest and costs.

Respectfully Submitted,

**KLINE & SPECTER, PC**

By: /s/ Barry Magen  
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*Attorneys for Plaintiff*

Date: August 3, 2023

**VERIFICATION**

I, Donna Fike, hereby verify that I am the Plaintiff in the foregoing action and that the attached Complaint is based upon information which I have furnished to my counsel and information which has been gathered by my counsel in the preparation of this lawsuit. The language of the Complaint is that of counsel and not of affiant. I have read the Complaint and to the extent that the allegations therein are based upon information I have given counsel, they are true and correct to the best of my knowledge, information, and belief. To the extent that the contents of the Complaint are that of counsel, I have relied upon counsel in making this Verification. I understand that false statements made herein are made subject to the penalties of 18 Pa. C.S.A. § 904 relating to unsworn falsifications to authorities.

  
Donna Fike

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**DESIGNATION FORM**

*(to be used by counsel to indicate the category of the case for the purpose of assignment to the appropriate calendar)*

Address of Plaintiff: 211 Tower Court, Topton, PA 19562

Address of Defendant: No. 2 3rd F, 4th Street, Ganga Nagar, Chennai- 600 024 Tamilnadu, India

Place of Accident, Incident or Transaction: Topton, PA

**RELATED CASE IF ANY:**

Case Number: \_\_\_\_\_ Judge: \_\_\_\_\_ Date Terminated \_\_\_\_\_

Civil cases are deemed related when **Yes** is answered to any of the following questions:

- |  |                              |                             |
|--|------------------------------|-----------------------------|
| 1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?  | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit Pending or within one year previously terminated action in this court?            | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. Does this case involve the validity or infringement of a patent already in suit or any earlier Numbered case pending or within one year previously terminated action of this court? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4. Is this case a second or successive habeas corpus, social security appeal, or pro se case filed by the same individual?   | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

I certify that, to my knowledge, the within case  is /  is not related to any now pending or within one year previously terminated action in this court except as note above.

DATE: \_\_\_\_\_

*Attorney-at-Law (Must sign above)*

*Attorney I.D. # (if applicable)*

**Civil (Place a  $\checkmark$  in one category only)**

**A. Federal Question Cases:**

- 1. Indemnity Contract, Marine Contract, and All Other Contracts
- 2. FELA
- 3. Jones Act-Personal Injury
- 4. Antitrust
- 5. Wage and Hour Class Action/Collective Action
- 6. Patent
- 7. Copyright/Trademark
- 8. Employment
- 9. Labor-Management Relations
- 10. Civil Rights
- 11. Habeas Corpus
- 12. Securities Cases
- 13. Social Security Review Cases
- 14. Qui Tam Cases
- 15. All Other Federal Question Cases. *(Please specify):* \_\_\_\_\_

**B. Diversity Jurisdiction Cases:**

- 1. Insurance Contract and Other Contracts
- 2. Airplane Personal Injury
- 3. Assault, Defamation
- 4. Marine Personal Injury
- 5. Motor Vehicle Personal Injury
- 6. Other Personal Injury *(Please specify):* \_\_\_\_\_
- 7. Products Liability
- 8. All Other Diversity Cases: *(Please specify)* \_\_\_\_\_

**ARBITRATION CERTIFICATION**

*(The effect of this certification is to remove the case from eligibility for arbitration)*

I, Barry G. Magen, Esq., counsel of record *or* pro se plaintiff, do hereby certify:

Pursuant to Local Civil Rule 53.2 § 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs:

Relief other than monetary damages is sought.

DATE: 8/3/23

/s/ Barry Magen  
*Attorney-at-Law (Sign here if applicable)*

84398  
*Attorney ID # (if applicable)*

NOTE: A trial de novo will be a jury only if there has been compliance with F.R.C.P. 38.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**  
**CASE MANAGEMENT TRACK DESIGNATION FORM**

Donna Fike	:	CIVIL ACTION
	:	
v.	:	
	:	
Global Pharma Healthcare Private, LTD.	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

**SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:**

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ( x )
- (f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

8/3/23	Barry G. Magen, MD, JD	Plaintiff
<b>Date</b>	<b>Attorney-at-law</b>	<b>Attorney for</b>
215-772-1339	215-792-5506	Barry.Magen@klinespecter.com
<b>Telephone</b>	<b>FAX Number</b>	<b>E-Mail Address</b>

(Civ. 660) 10/02