	Case 3:23-cv-00153-MMH-MCR Doo	cument 1	Filed 02/09/23	Page 1 of 15 PageID 1
1 2 3 4 5 6 7 8 9 10	Jory D. Lange, Jr. ( <i>Pro Hac Vice</i> Forthcor THE LANGE LAW FIRM PLLC 6300 West Loop South, Suite 350 Houston, TX 77401 Telephone: (833) 330-3663 Email: jory@jorylange.com www.MakeFoodSafe.com Rebecca S. Vinocur Rebecca S. Vinocur, P.A. 5915 Ponce De Leon Blvd., Suite 14 Coral Gables, FL 33146 Telephone: (786) 691-1282 Email: rvinocur@rsv-law.com	ning)		
	Attorneys for Plaintiff			
11	UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA			
12	MIDDLE DISTRICT OF FLORIDA			
13	TERESA PHILLIPS, Plaintiff,	)	CASE NO.	
14	V.	)		
15	EZRICARE, LLC, a New Jersey Limited	) l )		
16	Liability Company; EZRIRX, LLC, a Delaware Limited Liability Company; A	) PU ) (	COMPLAINT	
17	PHARMA INC., a New York Corporatio	on; )		
18	WAL-MART STORES EAST, LP, a Delay Company; and WALMART, INC., a Delay	,		
19	Company, Defendants.	) )		
20	Detendants.	J		
21				
22	Plaintiff, Teresa Phillips, by and through her attorneys of record, The Lange Law Firm,			
23	PLLC (pro hac vice forthcoming) and Rebecca S. Vinocur, P.A., and for their causes of action			
24	against EZRICARE, LLC, EZRIRX, LLC, ARU PHARMA INC., WAL-MART STORES EAST,			
25	LP, and WALMART, INC. ("Defendants"), state and allege as follows:			
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#### **PARTIES**

At all times relevant to this action, Plaintiff resides in the city of Starke, Bradford County,
 Florida. Plaintiff is a citizen of the State of Florida.

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

3. Defendant EzriRx, LLC ("EzriRx") is a corporation organized, incorporated, and existing under the laws of the State of New Jersey with its principal place of business in New Jersey. EzriRx is thus a citizen of the state of New Jersey. EzriRx's principal place of business is located in New Jersey at 1525 Prospect St., Ste. 203, Lakewood, NJ 08701 in Ocean County or 2360 Rt. 9, Suite 3, #171, Toms River, NJ 08755 in Ocean County. EzriRx is engaged in the business of importing, selling, supplying, packaging, distributing, and marketing artificial tears products throughout the United States, including to Florida. EzriRx may be served with process at its registered agent The Corporation Trust Company located at 820 Bear Tavern Road, Ewing, NJ 08628.

4. Defendant Aru Pharma, Inc. ("Aru") is a corporation organized, incorporated, and existing under the laws of the State of New York with its principal place of business in New York. Aru is thus a citizen of the state of New York. Aru's principal place of business is located in New York at 925 Protano Lane, Mamaroneck, NY 10543 and/or 696 Locust Street, Mount Vernon 10552, both in Westchester County. Aru is engaged in the business of importing, selling, supplying, distributing, packaging, and marketing artificial tears products throughout the United States, including to Florida. Aru may be served with process at its principal place of business at 925 Protano Lane, Mamaroneck, NY 10543.

5. Defendant Walmart, Inc. ("Walmart, Inc.") is a worldwide seller and distributor of products. Walmart, Inc. is a Delaware corporation with its principal place of business in the State of Arkansas. Walmart, Inc. regularly does business in Florida either through its stores, online, or the many wholly owned subsidiaries and affiliated corporations and entities it controls. Walmart, Inc. has sufficient contacts with the State of Florida by regularly selling and distributing products in Florida, including artificial tears, and by serving a market for artificial tears in Florida. Walmart, Inc. sold, distributed, advertised, and/or marketed the artificial tears which are the subject of this Complaint to Teresa. Walmart, Inc.'s contacts with Florida are sufficient that Walmart, Inc. should reasonably expect to be brought into court in Florida. Walmart, Inc. may be served with process through its registered agent CT Corporation System located at 1200 S. Pine Island Rd., Plantation, FL 33324 or its principal place of business at 702 SW 8th St., Bentonville, AR 72716. 6. Defendant Wal-Mart Stores East, LP ("WSE") is a worldwide seller and distributor of products. WSE is a Delaware corporation with its principal place of business in the State of Arkansas. WSE regularly does business in Florida either through its stores, online, or the many wholly owned subsidiaries and affiliated corporations and entities it controls. WSE has sufficient contacts with the State of Florida by regularly selling and distributing products in Florida, including artificial tears, and by serving a market for artificial tears in Florida. WSE sold, distributed, advertised and/or marketed the artificial tears which are the subject of this Complaint

to Teresa. WSE's contacts with Florida are sufficient that WSE should reasonably expect to be brought into court in Florida. WSE may be served with process through its registered agent CT Corporation System located at 1200 S. Pine Island Rd., Plantation, FL 33324 or its principal place of business at 702 SW 8th St., Bentonville, AR 72716.

7. Defendant Walmart, Inc. and Wal-mart Stores East, LP collectively shall be referred to as "Walmart Defendants."

## JURISDICTION AND VENUE

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

9. This Court has specific personal jurisdiction over EzriCare because EzriCare committed a tort in whole or in part in Florida. Specifically, EzriCare sold, supplied, distributed, shipped, advertised, and/or marketing artificial tears to Florida residents and/or Florida businesses, including the artificial tears that harmed Teresa.

10. This Court has specific personal jurisdiction over EzriRx because EzriRx committed a tort in whole or in part in Florida. Specifically, EzriRx sold, supplied, distributed, shipped, advertised, and/or marketing artificial tears to Florida residents and/or Florida businesses, including the artificial tears that harmed Teresa.

11. This Court has general personal jurisdiction over Aru because Aru committed a tort in whole or in part in Florida. Specifically, Aru sold, supplied, distributed, shipped, advertised, and/or marketing artificial tears to Florida residents and/or Florida businesses, including the artificial tears that harmed Teresa.

12. This court has specific personal jurisdiction over Walmart, Inc. because Walmart, Inc.

committed a tort in whole or in part in Florida. Specifically, Walmart, Inc. sold, supplied, distributed, shipped, advertised, and/or marketing artificial tears to Florida residents and/or Florida businesses, including the artificial tears that harmed Teresa.

13. This court has specific personal jurisdiction over WSE because WSE committed a tort in whole or in part in Florida. Specifically, WSE sold, supplied, distributed, shipped, advertised, and/or marketing artificial tears to Florida residents and/or Florida businesses, including the artificial tears that harmed Teresa.

14. Further, this Court has jurisdiction over each Defendant because Defendants are authorized to conduct and do business in Florida.

15. Further, this Court has jurisdiction over each Defendant because each Defendant engages in substantial, continuous, and systematic contacts with the State of Florida, purposefully directing their activities towards Florida, including the placement of their goods into the stream of commerce with the intent and expectation that they will likely be purchased and used by consumers in Florida. This litigation arises out of those activities.

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

## **FACTS**

# A. <u>The 2023 Outbreak of VIM-GES-CRPA (Pseudomonas Aeruginosa) Linked to</u> <u>Artificial Tears</u>

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

artificial tears products, EzriCare Artificial Tears.

Defendants EzriCare, EzriRx, and Aru imported, packaged, labeled, sold, supplied, distributed, and/or marketed the contaminated artificial tears products. Defendants EzriCare, EzriRx, and Aru then sold these products through retailers, such as Walmart, Amazon, and eBay.
 According to the CDC, as of February 3, 2023, a total of 55 people infected with the outbreak strain were reported from 12 states, including: California, Colorado, Connecticut, Florida, New Jersey, New Mexico, New York, Nevada, Texas, Utah, Washington, and Wisconsin.
 One person has died, and there have been 5 reports of vision loss.

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

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

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

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

As such, multiple retailers and distributors have recalled or removed Defendants'

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artificial tears products.

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

# B. <u>VIM-GES-CRPA (Pseudomonas Aeruginosa)</u>

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

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

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

C. <u>Pseudomonas aeruginosa and Eve Infections</u>

30. Studies showing the severity of *Pseudomonas aeruginosa* eye infections go as far back as the 1950s.

31. *Pseudomonas aeruginosa* eye infections can lead to a severe infection.

32. What that can be said for certain is that infections with *Pseudomonas aeruginosa* can

cause long-term complications, can lead to sepsis or bacteremia (blood stream infections), and permanent injury, including vision loss.

# D. <u>Teresa Phillips's Pseudomonas Aeruginosa Infection</u>

33. Teresa Phillips purchased EzriCare Artificial tears in the weeks before her *Pseudomonas aeruginosa* infection.

34. By May of 2022, Teresa felt itchy and unrelenting pain in her eyes. She called her optometrist, who prescribed her antibiotics. However, after a week, it became apparent that the antibiotics weren't working to stop the infection.

35. Teresa then met with her primary care physician, who ordered culture testing. In May of 2022, Teresa tested positive for *Pseudomonas aeruginosa*.

36. Teresa's primary care doctor sent her to meet with an infectious disease specialist, who placed Teresa on IV antibiotics.

37. Teresa spent months on IV antibiotics. She recalls requiring (at least) three different antibiotics, as most were not working to fight the infection.

38. Since this time, Teresa's eyes continue to have various medical concerns. She also needed surgery to remedy some of these issues.

39. Teresa continues to recover from her surgery and faces uncertain future medical complications.

# CAUSES OF ACTION

## COUNT I STRICT PRODUCT LIABILITY

40. Plaintiff incorporates the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

41. Defendants are the manufacturers, distributors, packagers, labelers, suppliers, marketers,

advertisers, and/or sellers of the artificial tears products that were the source of the *Pseudomonas aeruginosa* outbreak as described, and the cause of Plaintiff's infection and injuries.

42. Because Defendants' eye drops were contaminated with *Pseudomonas aeruginosa*, the eye drops that Defendants manufactured, distributed, packaged, labeled, supplied, marketed, advertised, and/or sold, and that Plaintiff purchased and used, as described previously, were in a condition that Plaintiff had not contemplated, and were in a condition that rendered the products unreasonably dangerous for their ordinary and expected use.

43. The products that Defendants, manufactured, distributed packaged, labeled, supplied, marketed, advertised, and/or sold, and that Plaintiff purchased and used, as described previously, was expected to reach Plaintiff, and be used by them, without substantial change. Plaintiff used the products in the manner expected and intended, including when they used it.

44. Plaintiff suffered the aforementioned injuries as a direct and proximate result of their use of the contaminated, defective products manufactured, distributed, and sold by the Defendants.
45. Defendants are strictly liable to Plaintiff for the harm proximately caused by the manufacture and sale of an unsafe and defective product.

#### COUNT II BREACH OF WARRANTY

46. Plaintiff incorporates the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

47. Plaintiff is a consumer.

48. Defendants are manufacturers, packagers, labelers, retailers, producers, distributors, suppliers, and/or merchants who sell products.

49. By offering products for sale to the public, Defendants impliedly and expressly warranted that such products were safe to use, that it was not adulterated with a deadly pathogen, and that

the products had been safely prepared under sanitary conditions.

50. Defendants breached the implied warranties about the products they manufactured, distributed packaged, labeled, supplied, marketed, advertised, and/or sold, which were used by Plaintiff, causing Plaintiff's injuries and losses.

51. Plaintiff's injuries proximately and directly resulted from Defendants' breach of implied and express warranties, and Plaintiff is thus entitled to recover for all actual, consequential, and incidental damages that flow directly and in a foreseeable fashion from these breaches.

## COUNT III NEGLIGENCE

52. Plaintiff incorporates the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

53. Defendants, as the manufacturer and/or seller of artificial tears products, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, distribute, and sell products free of unreasonable risk of harm to users and patients, when said product is used in its intended manner.

54. Defendants manufactured, prepared, distributed, and sold products that were adulterated with *Pseudomonas aeruginosa*, contaminated with *Pseudomonas aeruginosa*, and that were not reasonably safe as designed, manufactured, or sold.

55. Defendants manufactured, distributed packaged, labeled, supplied, marketed, advertised, and/or sold products that were adulterated with *Pseudomonas aeruginosa*, contaminated with *Pseudomonas aeruginosa*, and that were not reasonably safe as designed, manufactured, or sold. 56. Defendants were negligent in how they manufactured, distributed packaged, labeled, supplied, marketed, advertised, and/or sold products that were adulterated with *Pseudomonas aeruginosa*, contaminated with *Pseudomonas aeruginosa*, and not reasonably safe because they were contaminated with *Pseudomonas aeruginosa* and because adequate warnings or instructions were not provided, including but not limited to the warning that its products may contain *Pseudomonas aeruginosa*, and thus should not be given to, or used by humans.

57. Defendants had a duty to properly supervise, train, and monitor its employees, or the employees of its agents or subcontractors, engaged in the preparation of its products, to ensure compliance with Defendants' operating standards and to ensure compliance with all applicable health regulations. Defendants failed to properly supervise, train, and monitor these employees, or the employees of its agents or subcontractors engaged in the import, manufacture, preparation and delivery of the products, and thus breached that duty.

58. Defendants owed a duty to Plaintiff to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling, and sale of its products, including all applicable local, state, and federal health and safety regulations. Defendants, by their manufacture, distribution, storage, labeling, and sale of adulterated and unsafe products, failed to conform to this duty.

59. Defendants owed Plaintiff the duty to exercise reasonable care in the preparation and sale of its products, as it was reasonably foreseeable that the defendant's manufacture, distribution and sale of products contaminated with *Pseudomonas aeruginosa* would cause injury and harm to all persons potentially exposed to *Pseudomonas aeruginosa* as a result. Defendants breached that duty, thereby causing injury to Plaintiff.

60. Defendant was negligent in manufacturing, preparing, distributing and selling products adulterated and/or contaminated with *Pseudomonas aeruginosa*, a dangerous pathogen. Defendants' negligent acts and omissions included, but were not limited to the following: Defendants' current good manufacturing practice (CGMP) violations, including lack of

appropriate microbial testing, formulation issues (the company manufactures and distributes ophthalmic drugs in multi-use bottles, without an adequate preservative), and lack of proper controls concerning tamper-evident packaging.

61. Defendants owed Plaintiff a duty to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling and sale of its products, including the applicable provisions of the federal U.S. Food, Drug and Cosmetic Act.
62. The products that Defendants manufactured, distributed and sold, and that the consumers purchased and consumed, was "adulterated" within the meaning of the federal Food, Drug and Cosmetic Act.

63. Defendants violated federal, state, and local safety regulations by its manufacture, distribution, and sale of adulterated products.

64. The federal, state, and local product safety regulations applicable here, and as set forth above, establish a positive and definite standard of care in the manufacture, distribution and sale of products, and the violation of these regulations constitutes negligence per se.

65. Plaintiff was in the class of persons intended to be protected by these statutes and regulations and was injured as the direct and proximate result of Defendants' violation of applicable federal, state, and local safety regulations.

66. Plaintiff's injuries proximately and directly resulted from the negligence of Defendants, and from Defendants' violations of statutes, laws, regulations, and safety codes pertaining to the manufacture, production, supply, distribution, storage, and sale of products.

67. Defendants breached the aforementioned duties as alleged herein, which breach constituted the proximate cause of Plaintiff's injuries.

## COUNT IV NEGLIGENCE *PER SE*

68. Plaintiff incorporates the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

69. Defendants had a duty to comply with all applicable state and federal regulations intended to ensure the purity and safety of their products, including, but not limited to, the requirements of the Federal Food, Drug and Cosmetics Act.

70. Defendants failed to comply with the provisions of the health and safety acts identified above and, as a result, were negligent per se in their manufacture, distribution, and/or sale of products adulterated with *Pseudomonas aeruginosa*, a dangerous and deadly pathogen.

71. Defendants violated federal, state, and local safety regulations by its manufacture, distribution, and sale of adulterated products.

72. The federal, state, and local product safety regulations applicable here, and as set forth above, establish a positive and definite standard of care in the manufacture, distribution and sale of products, and the violation of these regulations constitutes negligence per se.

73. Plaintiff was in the class of persons intended to be protected by these statutes and regulations and was injured as the direct and proximate result of Defendants' violation of applicable federal, state, and local safety regulations.

74. Plaintiff's injuries proximately and directly resulted from the negligence of Defendants, and from Defendants' violations of statutes, laws, regulations, and safety codes pertaining to the manufacture, production, supply, distribution, storage, and sale of products.

75. As a direct and proximate result of conduct by Defendants that was negligent *per se*, Plaintiff weas harmed.

#### DAMAGES

76. Plaintiff incorporates the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

77. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future for the following: pain and suffering, mental anguish, emotional distress, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, travel and travel-related expenses, emotional distress, lost wages, lost earning capacity, punitive and/or exemplary damages and attorneys' fees (to the extent recoverable) and other general, special, ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

- 1. That the Court award Plaintiff judgment against Defendants for past and future economic and non-economic damages;
- 2. That the Court award all such other sums as shall be determined to fully and fairly compensate Plaintiff for all general, special, incidental and consequential damages incurred, or to be incurred, by Plaintiff as the direct and proximate result of the acts and omissions of Defendants;
- 3. That the Court award Plaintiff costs, disbursements and reasonable attorneys' fees incurred;
- 4. Pre- and post-judgment interest at the highest rate allowed by law;

5. That the Court award Plaintiff the opportunity to amend or modify the provisions of this Complaint as necessary or appropriate after additional or further discovery is completed in this matter, and after all appropriate parties have been served; and

6. That the Court award such other and further relief as it deems necessary and proper in the circumstances.

#### JURY TRIAL DEMAND

Plaintiff demands trial by jury on all issues raised herein.

Dated: February 9, 2023.

Respectfully submitted,

# By: *Rebecca S. Vinocur*

Rebecca S. Vinocur Rebecca S. Vinocur, P.A. 5915 Ponce De Leon Blvd., Suite 14 Coral Gables, FL 33146 Telephone: (786) 691-1282 Email: <u>rvinocur@rsv-law.com</u>

—And—

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#### **ATTORNEYS FOR PLAINTIFFS**