UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

WILLIAM FRANZ and ANNALISA RIVERA FRANZ, Plaintiffs, v. TARGET CORP., Defendant.	Case No. **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs William Franz and his wife Annalisa Rivera Franz, by their attorneys, allege the following upon information and belief, except for those allegations pertaining to Plaintiffs, which are based on their personal knowledge:

NATURE OF THE ACTION

1. This action seeks to remedy physical injuries caused by recalled UP & UP High-Performance Lubricant Eye Drops (the "Eye Drops") manufactured, marketed, distributed, and sold by Defendant Target Corp. ("Target" or "Defendant"). The Eye Drops were contaminated with a rare and dangerous bacterium that caused Plaintiff William Franz to lose vision.

2. During the relevant time period, Defendant sold Eye Drops that were contaminated with *Pseudomonas aeruginosa*, an antibiotic resistant bacterium that can cause serious and life-threatening health issues, including vision loss.

3. In 2022 and the first half of 2023, long before Mr. Franz was injured by the contaminated Eye Drops, many eye drop manufacturers were on notice of a *pseudomonas* outbreak in their eye drops, particularly those that were manufactured at a few factories in India and imported into the United States. Some of those manufacturers recalled their eye drops and

pulled them off the store shelves in order to protect consumers. Target did not recall its Eye Drops until months after William Franz was injured.

4. By January 2023, the United States Centers for Disease Control and Prevention had identified more than 50 individuals in 12 states who had been diagnosed with the rare strain of *pseudomonas* bacteria that could cause vision loss, illness, and death after using contaminated eye drops that were made in India, like Defendant's Eye Drops.

5. By early February 2023, other eye drop manufacturers recalled their eye drops manufactured in India and had warned customers to stop using them because of the risk of *pseudomonas* contamination and injuries such as vision loss. Target continued to sell its Eye Drops and did not warn consumers about the dangers of the product, the risks of *pseudomonas* contamination, or the risks of vision loss. It continued to sell the Eye Drops that had been manufactured in India and that were at risk of contamination.

6. As 2023 progressed, more manufactures recalled their eye drops that had been made in India because of the grave risks of *pseudomonas* contamination.

7. Those recalled, contaminated eye drops manufactured in India were sold at Target and other stores, such as CVS, Rite Aid, and Walmart.

8. Eventually, the United States FDA halted the importation of eye drops from certain factories in India, a development of which Defendant would have been acutely aware. Yet, Target continued to sell its Eye Drops manufactured in India, including the eye drops that would later cause Mr. Franz to lose vision.

9. Instead of warning consumers that the Eye Drops were contaminated or were at risk of contamination, Defendant represented on every product label that the Eye Drops would provide "fast symptom relief" and would "reliev[e] dry and irritated eyes". Defendant made those representations even though, as demonstrated by its late 2023 recall (alleged below), the

Eye Drops could not be used for any purpose and posed life-threatening and vision-threatening risks.

10. During a nearly one-year span, Defendant negligently or recklessly placed the contaminated and potentially contaminated Eye Drops into the stream of commerce, exposing thousands of people to substantial risk of bacterial infection, vision loss, and death. Defendant's misconduct offended public policy, presented a substantial and unjustifiable risk of injury to consumers, and provided no countervailing benefit to consumers, considering the severe risk of personal injury and death.

11. In November 2023, Defendant finally disclosed the bacterial contamination for the first time after the United States Consumer Product Safety Commission ("CSPC") and/or the FDA intervened. By that time, months had passed since Defendant's competitors in the eye drop market (including CVS, Walmart, Rite Aid, EzriCare, Rugby, Leader, and Velocity) had disclosed and recalled eye drops based on the risk of *Pseudomonas aeruginosa* and other bacterial contamination, including eye drops that were manufacturers at the same factory where Defendant's Eye Drops were made.

12. But by that time, it was too late for Mr. Franz because he had already used Target's contaminated Eye Drops and he developed an infection and lost vision, as alleged below.

13. In April 2023, Plaintiffs purchased Defendant's contaminated Eye Drops that Defendant later and untimely identified as being at risk of bacterial contamination, including contamination by *Pseudomonas aeruginosa*.

14. The Eye Drops did not, however, disclose that they were contaminated by *Pseudomonas aeruginosa* (in the ingredient section or otherwise), and provided no warnings or instructions regarding the risk of bacterial contamination, the presence of *Pseudomonas aeruginosa*, or the signs of, and what do if a user suspected, an infection.

15. When Plaintiffs purchased, and Plaintiff William Franz used, the Eye Drops, Plaintiffs reviewed the inadequate product labeling and instructions and relied on Defendant's representations and omissions about the Eye Drops, including representations that the Products provide "fast symptom relief" and would "reliev[e] dry and irritated eyes", and Plaintiffs relied upon Defendant's omissions regarding bacterial contamination.

16. Plaintiff William Franz suffered physical injuries after purchasing and using the contaminated and defective Eye Drops, including losing vision in his right eye. Plaintiff Annalisa Rivera Franz, as Mr. Franz's wife, has been injured and seeks loss of consortium damages as alleged below.

17. Plaintiffs reasonably relied on Defendant to sell products that are safe and free from harmful known substances, including *Pseudomonas aeruginosa*, and to promptly and clearly inform and warn about the dangers of the Eye Drops.

18. Plaintiffs would not have purchased and used the Eye Drops and Plaintiff William Franz would not have suffered physical injuries had Defendant disclosed the risk that the Eye Drops were contaminated with dangerous bacteria. Consequently, Plaintiffs suffered injuries due to Defendant's dangerous conduct.

19. Based on Defendant's misconduct, Plaintiff William Franz brings claims against Defendant for Strict Liability-Design Defect (First Claim); Strict Liability-Manufacturing Defect (Second Claim); Strict Liability-Failure to Warn (Third Claim); and Negligence (Fourth Claim); and Plaintiff Annalisa Rivera Franz brings a Loss of Consortium claim against Defendant (Fifth Claim).

PARTIES

A. Plaintiffs

20. At all relevant times, Plaintiff William Franz has been and is a resident and a citizen of New York, living in Manhattan.

21. At all relevant times, Plaintiff Annalisa Rivera Franz has been and is a resident and a citizen of New York, living in Manhattan.

22. Plaintiffs have known each other since 2006, have been in a loving relationship since 2009, and were married on April 22, 2022.

B. Defendant

23. Defendant Target is a publicly traded retailer that operates a chain of retail stores throughout the United States. Target has its headquarters at 1000 Nicollet Mall, Minneapolis, Minnesota. Its stock trades in this District on the New York Stock Exchange under the ticker symbol "TGT".

24. Defendant Target operates the Target store at 500 East 14th Street, New York, New York in this District where Plaintiffs bought the UP & UP Eye Drops that injured Plaintiffs.

25. Defendant Target manufactured and sold the UP & UP Eye Drops that injured Plaintiffs, including selling those Eye Drops in this District.

26. At all relevant times, Defendant Target oversaw the manufacturer, production, promotion, distribution, and sale of the Eye Drops in this District and throughout the United States, including the Eye Drops that injured Plaintiffs.

27. The back of the bottle of the UP & Up Eye Drops used by Plaintiff William Franz that injured him said "Distributed by Target Corporation. Made in India."

JURISDICTION AND VENUE

28. This Court has original jurisdiction over this case pursuant to 28 U.S.C. § 1332(a) because the matter in controversy exceeds the sum or value of $75,000 exclusive of interest and costs and is between citizens of different states. Plaintiffs are citizens of New York and Defendant is a citizen of Minnesota.

29. This Court has personal jurisdiction over this case. Defendant is engaged in systematic and continuous business activity in New York, has sufficient minimum contacts in New York, or otherwise intentionally avails itself of the New York consumer market.

30. Venue is proper in this District pursuant to 28 U.S.C. § 1391. A substantial portion of the events or omissions giving rise to Plaintiffs' claims occurred in this District, and Defendant regularly conducts business and is subject to personal jurisdiction in this District.

FACTUAL BACKGROUND

A. Background on Plaintiffs

31. At all relevant times, Plaintiffs have been married. They live in Manhattan. Mr. Franz loves to read and write. He is a published author and silver age comic book writer. Mr. Franz is best-known for his Charlton Comics war stories, including "The Lonely War of Captain Willy Schultz" and "the Iron Corporal".

32. When Mr. Franz was 16 years old, he joined already-seasoned comic book illustrator Sam Glanzman to write what has been called, "one of the most dramatic, moving, and controversial comic book stories ever told!" The comic book series, entitled "The Lonely War of Captain Willy Schultz", tells the story of an American soldier of German heritage who finds himself on the wrong side of World War II.

33. During the Vietnam War, the United States military put significant pressure on the publisher, Charlton Comics, to stop publishing the series because of fear that it would encourage conscientious objectors to the War. At the time, Charlton Comics depended heavily on military bases for a significant part of its business and, in response to the pressure, Charlton Comics stopped publishing the series, leaving the series without a conclusion and frustrating devoted fans.

34. In the 2000s, Mr. Franz wrote the Roman centurion series "The Eagle". He

subsequently taught writing and hosted event nights for nonprofit organizations for Medicare patients with disabilities and other health issues.

35. In recent years, Mr. Franz began writing a conclusion to the "Lonely War" series and in January 2023, the story was published as a compilation, with a new final chapter that Mr. Franz wrote, providing a compelling conclusion to the original story.

Mr. Franz Was Diagnosed with Diabetes in 1964 and Had His Left Eye Removed in 1990

36. Since 1964, Mr. Franz has had Type 1 diabetes, which he has controlled with medication.

37. In or about 1986, Mr. Franz was diagnosed with diabetic retinopathy, damage to the retina (which is at the back of the eye). The cells in the retina absorb and convert light to electrochemical impulses which are transferred along the optic nerve and then to the brain, which interprets the impulses as images.

38. The following year, 1987, Mr. Franz had a vitrectomy of his left eye. (A vitrectomy is a type of eye surgery to treat various problems with the retina (the back of the eye) and the vitreous (the gel-like substance that fills the space between the lens and the retina).

39. Around that time, Mr. Franz also had cryogenics in his right eye related to retinopathy.

40. In 1990, Mr. Franz had his left eye removed (called "enucleation"). Following this, he was able to read and write and use his computer. He led a productive life and was independent.

41. Since being diagnosed with retinopathy, Mr. Franz has consistently used artificial tears and eye drops.

42. Plaintiffs typically bought eye drops for Mr. Franz approximately four times each year and Mr. Franz would use them as needed.

In 2022 There Were Numerous Reports of *Pseudomonas* Infections in Patients Who Had Used Eye Drops Manufactured in India

43. From May 2022 and through February 2023, at least 58 Americans had been infected by an extremely worrisome bacteria called *Pseudomonas*. All of the infections were linked to contaminated eyedrops from India.

44. In May 2022, a patient in Los Angeles was treated for a bad eye infection after using eye drops from India.[1]

45. The next month, June 2022, local health officials received another similar report of an eye infection after the patient used eye drops from India.[2]

46. Two more similar eye infection cases were reported during the summer of 2022.[3] The patient's eyes were inflamed with puss that obscured most of the pupil and two of the four patients had complete vision loss in the affected eye.

47. The hospital in Los Angeles that reported the first infection determined that it was caused by *pseudomonas*. Significantly, the California infections were in the patients' eyes, not in more common spots for infections like in the blood and in the lungs.

48. During the summer of 2022, there more reports of *pseudomonas* infections in patients who had used eye drops from India, including 25 patients in Connecticut and six cases in Utah that were reported to the CDC in August 2022.[4]

49. By October, 2022 genetic testing had established that the clusters of infections in California, Connecticut and Utah were all caused by the same *pseudomonas* bacteria strain.

50. As 2022 progressed there were more reports of *pseudomonas* infections and eye

[1] https://www.independent.co.uk/news/eye-drops-us-disease-los-angeles-blindness-b2291483.html

[2] *Id*.
[3] *Id.*
[4] *Id.*

injuries in patients throughout the United States who had used eye drops manufactured in India, including a man from Washington who died from the infection.

51. By November 2022, investigators had determined that most of the Connecticut patients had used artificial tears. That same month, on November 9, 2022, a Florida hospital contacted CDC to report bad eye infections connected with eye drops manufactured in India and sold in the United States.

52. In January 2023, genetic sequencing confirmed that the Florida infections were caused by the same *pseudomonas* bacteria as the clusters in California, Connecticut and Utah. The eye drops at issue were made in India and sold in the United States.

53. However, there was no recall or widespread public notice about the infections or the dangers of the eye drops manufactured in India, including Defendant's Eye Drops that Plaintiffs would later buy and that would cause Mr. Franz's infection and vision loss.

Plaintiffs Purchased Delsam Pharma Artificial Tears Which Were Subsequently Recalled

54. On January 1, 2023, Plaintiffs purchased a two-pack of Delsam Pharma Artificial Tears – Dry Eye Relief Drops – Lubricate, Refresh & Moisturize from Amazon (the "Delsam Amazon Eye Drops").

55. The Delsam Amazon Eye Drops were manufactured in India by a company called Global Pharma Healthcare (including some of its affiliates such as DELSAM Pharma LLC and Aru Pharma/Ezricare, LLC) (collectively, "Global/Ezricare").

56. Global/Ezricare also manufactured and sold eye drops called "EzriCare".

57. On January 20, 2023, Global/EzriCare received notice that the United States Center for Disease Control (the "CDC") was investigating a multistate cluster of *Pseudomonas aerugonisa* infections in the United States.

58. Around that time, other manufacturers and sellers of eye drops, including

Defendant, were notified, or learned, about the outbreak of *pseudomonas* infections associated with eye drops manufactured in India.

59. On January 24, 2023, Global/EzriCare issued a statement on the contamination of its artificial tears products, 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." The announcement also said: "The EzriCare Artificial Tears were formulated, designed, and imported by Aru Pharma Inc in the US and were manufactured by Global Pharma Healthcare PVT LTD in India. . . .We understand that the same product is also marketed under other brand names."

60. Defendant, as the manufacturer of competing eye drops made in India, would have been aware of this statement and the CDC investigation of eye drops manufactured in India (including Defendant's eye drops that were manufactured in India).

61. In January 2023, the FDA blocked imports of certain eye drops from India, including eye drops manufactured by Global Pharma in India.

62. Between January 20, 2023 and February 1, 2023 Global/Ezricare took action to stop any further distribution or sale of EzriCare Artificial Tears eye drops in the United States.

63. As a competitor that also imported eye drops made in India into the United States, Defendant would have been aware of Global/Ezricare's actions by February 2023, but it continued to sell its eye drops that were manufactured in India.

64. On February 1, 2023, Global/EzriCare initiated a voluntary recall of all unexpired lots of EzriCare Artificial Tears and Delsam Pharma's Artificial Tears[5] and it began contacting customers to advise them to stop using EzriCare eye drops because of the risk of *Pseudomonas aeruginosa* contamination.

[5] 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.

65. Defendant, as the manufacturer and seller of eye drops containing the same or similar ingredients as the Global/EzriCare drops, would have been acutely aware in at least February 2023 of the recall and the clusters of infections in people who had used eye drops from India.

66. On February 2, 2023, the CDC issued a health alert entitled "Outbreak of Extensively Drug-resistant *Pseudomonas aeruginosa* Associated with Artificial Tears." That health alert explained that CDC had received 55 reports associated with artificial tears in twelve states, including New York (where Plaintiffs live) from May 2022 through January 2023. 11 of those 55 reports involved cultures from the cornea:

> The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory about infections with an extensively drug-resistant strain of Verona Integron-mediated Metallo-β-lactamase (VIM) and Guiana-Extended Spectrum-β-Lactamase (GES)-producing carbapenem-resistant Pseudomonas aeruginosa (VIM-GES-CRPA) in 12 states. Most patients reported using artificial tears. Patients reported more than 10 different brands of artificial tears, and some patients used multiple brands. The majority of patients who used artificial tears reported using EzriCare Artificial Tears, a preservative-free, over-the-counter product packaged in multidose bottles. CDC laboratory testing identified the presence of the outbreak strain in opened EzriCare bottles with different lot numbers collected from two states. Patients and healthcare providers should immediately discontinue using EzriCare artificial tears pending additional guidance from CDC and the Food and Drug Administration (FDA).
> (emphasis supplied).
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> * * *
>
> As of January 31, 2023, CDC in partnership with state and local health departments identified 55 case-patients in 12 states (CA, CO, CT, FL, NJ, NM, NY, NV, TX, UT, WA, WI) with VIM-GES-CRPA, a rare strain of extensively drug-resistant P. aeruginosa. Thirty-five patients are linked to four healthcare facility clusters. Dates of specimen collection were from May 2022 to January 2023. Isolates have been identified from clinical cultures of sputum or bronchial wash (13), cornea (11), urine (7), other nonsterile sources (4), blood (2), and from rectal swabs (25) collected for surveillance; some patients had specimens collected from more than one anatomic site. These specimens

> were collected in both outpatient and inpatient healthcare settings. Patients had a variety of presentations including keratitis, endophthalmitis, respiratory infection, urinary tract infection, and sepsis. Patient outcomes include permanent vision loss resulting from cornea infection, hospitalization, and one death due to systemic infection.
>
> Isolates in this outbreak are sequence type (ST) 1203, harbor blaVIM-80 and blaGES-9 (a combination not previously observed in the United States) and are closely related based on analysis of whole genome sequencing (WGS) data. These isolates are not susceptible to cefepime, ceftazidime, piperacillin-tazobactam, aztreonam, carbapenems, ceftazidime-avibactam, ceftolozane-tazobactam, fluoroquinolones, polymyxins, amikacin, gentamicin, and tobramycin; the subset of isolates that underwent antimicrobial susceptibility testing for cefiderocol were susceptible to this agent.
>
> Review of common exposures revealed that most patients, including most patients with eye infections, used artificial tears prior to identification of VIM-GES-CRPA infection or colonization. Patients reported more than 10 brands of artificial tears, and some patients used multiple brands. The majority of patients who used artificial tears reported using EzriCare Artificial Tears, a preservative-free product dispensed in multidose bottles. This was the only common artificial tears product identified across the four healthcare facility clusters. CDC laboratory testing identified the presence of VIM-GES-CRPA in opened EzriCare Artificial Tears bottles from multiple lots; these bottles were collected from patients with and without eye infections in two states. These product-related VIM-GES-CRPA match the outbreak strain. VIM-GES-CRPA recovered from opened bottles could represent either bacterial contamination during use or during the manufacturing process.
>
> Testing of unopened bottles of EzriCare Artificial Tears is ongoing to assist in evaluating for whether contamination may have occurred during manufacturing.

67. That same day, February 2, 2023, the FDA published a warning that consumers should stop purchasing and using EzriCare eye drops and Delsam Pharma's eye drops "due to potential bacterial contamination. Using contaminated artificial tears increases risk of eye infections that could result in blindness or death. Patients who have signs or symptoms of an eye

infection should talk to their health care provider or seek medical care immediately."

68. The FDA noted that it had recommended the recall of the eye drops due to violations of "current good manufacturing practices (CGMP), including lack of appropriate microbial testing, formulation issues (the company manufactures and distributes ophthalmic drugs in multi-use bottles, without an adequate preservative), and lack of proper controls concerning tamper-evident packaging."

69. The FDA said it was investigating the outbreak of infections and that the infections "had been linked by epidemiologic and laboratory evidence to use of EzriCare Artificial Tears. Associated adverse events include hospitalization, one death with bloodstream infection, and permanent vision loss from eye infections." The FDA also restricted Global Pharma Healthcare Private Limited's ability to import products into the United States because the company had provided "an inadequate response to a records request and for not complying with CGMP requirements."

70. On February 3, 2023, Reuters published an article entitled "U.S. FDA says India-made Eye Drop Linked to Some Infections, Blindness and One Death".[6]

71. Plaintiffs had bought, and Mr. Franz had used, Delsam eye drops made in India.

72. On February 3, 2023, Mr. Franz received an email from Amazon with a recall notice for the Delsam Amazon Eye Drops urging him to stop using the drops immediately: "We write to notify you of a potential safety concern with a product that you purchased on Amazon.com."

73. The Amazon recall notice identified the product as "Delsam Pharma Artificial Tears- Dry Eye Relief Drops – Lubricate, Refresh & Moisturize (2-Pack), Order No. 113-2199947-7447425." It also said that "The U.S. Food and Drug Administration (FDA) has

[6] https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-says-india-made-eye-drop-linked-some-infections-blindness-one-death-2023-02-03/

informed us that the product listed may not current meet mandatory or voluntary safety standards. If you still have this product, we urge you to stop using it immediately. More details, including what you should do and where you can seek assistance, can be found in the following notification: [provides a link to an FDA web page about a safety alert concerning Global Pharma Healthcare issuing a voluntary nationwide recall of artificial tears products]."

74. Mr. Franz immediately stopped using the Delsam eye drops in response to the recall notice.

75. In March 2023, the FDA issued a 14-page report[7] with a lengthy list of violations observed by the FDA at Global Pharma's plant in southern India between February and March 2023. Among other things, the FDA highlighted multiple violations of procedures to protect against bacterial contaminations, including that, "Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process." It also noted that the surfaces that came into contact with the drug packaging "were not cleaned, sanitized, decontaminated, or sterilized", each of which increases the risk of contamination. The FDA report noted violations and deficient manufacturing practices starting in December 2020 for products that were shipped to customers in the United States.

76. During this time, Defendant continued to sell its eye drops that were made in India and that were at risk of *Pseudomonas* contamination.

Plaintiffs Purchased Defendant's Contaminated UP & UP High-Performance Lubricant Eye Drops That Defendant Later Recalled

77. On April 24, 2023, Plaintiffs purchased UP & UP High Performance Lubricant Eye Drops (Lot Code: KRPE3023, expires 01/2025) from Target.

78. The following is a picture of the product Plaintiffs purchased, and William Franz used:

[7] https://www.fda.gov/media/166739/download


high performance
lubricant eye
drops
lubricant
up&up
lief
lieves dry and
ritated eyes
STERILE 0.5 FL OZ (15 mL)

79. Plaintiffs reviewed the labeling which contained no warnings or instructions regarding *Pseudomonas aeruginosa* contamination and Plaintiff William Franz used the Eye Drops as directed in the instructions without any knowledge that the Eye Drops contained *Pseudomonas aeruginosa* and created a significant risk of infection, vision loss, and other injuries.

80. After using Defendant's contaminated Eye Drops, Plaintiff William Franz began to have significant difficulty seeing.

81. Since using the contaminated Eye Drops, Plaintiff William Franz has lost vision in his eye, severely limiting his ability to see and to perform the functions of daily life. Plaintiff William Franz continues to suffer debilitating and painful injuries as a result.

82. Moreover, due to the persistent and antibiotic-resistant nature of *Pseudomonas aeruginosa*, Plaintiff William Franz remains subject to life-threatening and vision-threatening risks.

83. Plaintiffs would not have purchased, and William Franz would not have used, the Eye Drops and would not have suffered physical injury had Defendant disclosed that the Eye Drops were contaminated with *Pseudomonas aeruginosa* and had Defendant properly warned that the Eye Drops contained *Pseudomonas aeruginosa* or could cause vision loss.

84. Accordingly, the Eye Drops and *Pseudomonas aeruginosa* caused and will continue to cause Plaintiffs to suffer injuries, and Plaintiffs were injured in fact because of Defendant's improper conduct.

85. Contrary to Defendant's representations, the Eye Drops were not safe, had no utility and, could not be used for any purpose (including as a lubricating eye drop) due to undisclosed bacterial contamination with *Pseudomonas aeruginosa.*

86. Defendant failed to disclose on the Eye Drops packaging and labeling (including

in the ingredients section) or otherwise that the Eye Drops contained *Pseudomonas aeruginosa*. Relatedly, Defendant never provided any warning or instructions on the Eye Drops packaging or labeling or otherwise about *Pseudomonas aeruginosa* contamination, the risks of *Pseudomonas aeruginosa*, the risks of vision loss, or the signs and what do if a user suspected an infection.

B. Life-Threatening, and Vision-Threatening Dangers of *Pseudomonas Aeruginosa*

87. *Pseudomonas aeruginosa* is a bacterium that can cause disease in plants and animals, including humans.

88. *Pseudomonas aeruginosa* causes life threatening infections in the eyes, blood, lungs, urinary and digestive systems, as well as skin and soft tissue infections. *Pseudomonas aeruginosa* causes, among other infections, pneumonia, sepsis, urinary, eye, and gastrointestinal infections, and hemorrhage and necrosis.

89. The risks of *Pseudomonas aeruginosa* cannot be understated and exposure to the bacterium, including through inhalation and direct contact (such as through placing contaminated eye drops directly into the eye) can cause blindness, severe illness, and death.[8] [9]

90. In 2019, the United States Centers for Disease Control and Prevention identified *Pseudomonas aeruginosa* as a serious antibiotic resistant threat. In 2017, for example, antibiotic resistant *Pseudomonas aeruginosa* was responsible for 32,600 estimated cases in hospitalized patients and 2,700 estimated deaths.

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[8] Yohei Migiyami, et al., *Pseudomonas aeruginosa Bacteremia among Immunocompetent and Immunocompromised Patients: Relation to Initial Antibiotic Therapy and Survival*, Jpn J Infect. Dis., 2016; 69(2):91-6, accessible at: https://pubmed.ncbi.nlm.nih.gov/26073727/.

[9] S. Sudharsanam, *Airborne Pseudomonas species in Healthcare Facilities in a Tropical Setting*, Curr Health Sci J.,2015 Apr-Jun; 41(2): 95-103, accessible at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6201198/; *see also* https://www.endosan.com/pseudomonas-aeruginosa-causes-symptoms-transmission-and-infection-prevention

91. *Pseudomonas aeruginosa* poses particular dangers for immunodeficient individuals, that is, individuals whose immune system's ability to fight infectious diseases and cancer is compromised or entirely absent. Serious infection occurs during existing diseases or conditions due to pernicious traits of the bacterium including the ability to form microcolonies and aggregations commonly known as biofilms, with research indicating that *Pseudomonas aeruginosa* can persist on inanimate surfaces for months.[10] The severe risks posed to immunocompromised individuals by *Pseudomonas aeruginosa* varies widely, including *Pseudomonas aeruginosa* being one of the leading causes of morbidity and death in cystic fibrosis patients.

92. Antibiotic resistance is one of *Pseudomonas aeruginosa*'s most sinister aspects. In 2017, the World Health Organization ("WHO") listed *Pseudomonas aeruginosa* as a priority pathogen, that is, one of twelve antibiotic resistant bacteria that "pose the greatest threat to humanity." WHO's priority pathogen list promotes research and development (R&D) of new antibiotics as part of WHO's efforts to address growing global resistance to antimicrobial medicines. WHO identified *Pseudomonas aeruginosa* as a "Priority 1: Critical pathogen" considering, among other things, the severity of infections and resistance frequency to existing antibiotics. In short, *Pseudomonas aeruginosa* presents a dire public health risk, and the proliferation of *Pseudomonas aeruginosa* in the environment increases the risk that that the bacterium will develop further antibiotic resistance by strengthening the mechanisms that lead to antibiotics resistance in the first instance.

93. The nature and intended uses of the Eye Drops creates unique infection risks for users, including Mr. Franz. To make matters worse, *Pseudomonas aeruginosa* thrives in moist environments and the Eye Drops do not warn about the risk of vision loss from using the drops.

[10] Axel Kramer, *How long do nosocomial pathogens persist on inanimate surfaces? A systematic review*, BMC Infect Dis., 2006; 6:130, accessible at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1564025/

C. Plaintiffs' Eye Drops Were Contaminated Due to Systemic Design or Manufacturing Issues Long Before Defendant's Recall and Plaintiffs' Purchase of The Eye Drops, and Defendant Knew or Should Have Known of that Risk

94. Defendant is in the unique and superior position of knowing the ingredients and raw materials (as well as the sources and integrity of its ingredients and raw materials) used in manufacturing its Eye Drops and possesses unique and superior knowledge regarding the manufacturing process for the Eye Drops, the manufacturing process for the ingredients and raw materials in the Eye Drops, and the risks associated with those processes, such as the risk of bacterial contamination, including *Pseudomonas aeruginosa* contamination.

95. Defendant, a top manufacturer of consumer products, including the UP & UP line of products, is a sophisticated manufacturer with access to cutting-edge research and technology. As a sophisticated manufacturer, Defendant is aware, or should be aware, of potential risks to its manufacturing processes and to the ultimate users of its products. Moreover, Defendant is subject to regulatory and internal quality assurance programs that—when properly implemented—should identify existing and emerging risks to its products and end-users, including bacterial contamination.

96. The risk that the Eye Drops and Defendant's manufacturing process were susceptible to bacterial contamination, including *Pseudomonas aeruginosa* contamination, were readily foreseeable long before the relevant time period here and long before Plaintiffs purchased the contaminated Eye Drops, particularly by a prominent manufacturer like Defendant. The risks of bacterial contamination are no secret and have been known and extensively studied in the manufacturing industry long before the contamination at issue in this case.

97. Bacterial contamination has resulted in product recalls for decades. For instance, an analysis of FDA enforcement reports from 2012 to 2019 found that 87% of recalls for sterile drugs were associated with microbial contamination. In the cosmetic and food manufacturing industries, between 1993 and September 1998, microbial contamination accounted for a total of

1,370 recalls (36% of all products recalled). Likewise, the European Commission's RAPEX database (which is the EU rapid alert system for unsafe consumer products and consumer protection), identified sixty-two (62) recalls of cosmetic products between 2008 and 2014, with *Pseudomonas aeruginosa* being the most frequent contaminant. In short, bacterial contamination, *Pseudomonas* bacteria, and particularly *Pseudomonas aeruginosa*, have been a notable bane to the manufacturing industry for decades and long before the Eye Drops were contaminated here.

98. Prior to April 2023, the risks of bacterial contamination, particularly *Pseudomonas aeruginosa* contamination, were readily apparent and easily foreseeable or should have been readily apparent and easily foreseeable to Defendant generally and specifically because of the composition and uses of the Eye Drops long before the bacterial contamination that injured Plaintiffs.

99. Defendant was required to design the Eye Drops to prevent the foreseeable risk of bacterial contamination, including the risk of *Pseudomonas aeruginosa*.

100. Defendant was also required to manufacture the Eye Drops to prevent the foreseeable risk of bacterial contamination (including *Pseudomonas aeruginosa* contamination), including by implementing rigorous quality control measures that have long been understood to prevent microbial contamination during manufacturing processes, including:

a. Microbial risk assessment of raw materials and finished ingredients;

b. Development of effective audit checklists for suppliers and Defendant focused on microbial control;

c. In-person audits of production;

d. Supplier quality agreements established with a focus on microbial control;

e. Control of storage conditions in warehouses, during transit, and post-production;

f. Effective maintenance and hygiene of facilities and equipment;

g. Effective cleaning of equipment and facilities;

h. Minimization of contact with humans and control of vermin and insects;

i. Control of containers used to store and ship materials;

j. Control of supply chain, water systems, and wastewater and waste;

k. Development of pasteurization or sterilization processes for natural ingredients and raw materials;

l. Development of microbial test methods and specifications based on risk assessments; and/or

m. Effective investigation of microbial contamination.

101. The contamination in this case did not occur overnight or in limited batches or in limited lots of Products.

102. The duration and scope of the *Pseudomonas aeruginosa* contamination at issue in this case means there was a catastrophic or systemic failure in the Eye Drops' design and specifications and/or Defendant's manufacturing processes (including quality controls) during production.

103. From at least February 2023 (when problems with other eye drops were revealed), the Eye Drops were unreasonably dangerous and unfit for sale based on a design defect: the lack of preservatives or antimicrobial or biocidal agent that would prevent bacterial contamination and extend shelf-life. The design defect made the Eye Drops unreasonably susceptible to bacterial contamination, including contamination by *Pseudomonas aeruginosa*.

104. The Eye Drops' defective design and the *Pseudomonas aeruginosa* contamination could have been reduced or avoided entirely by adopting a reasonable alternative design, including adding a preservative or antimicrobial or biocidal agent such as isothiazolones, bronopol, aldehydes, and carboxylic acids such as glyoxylic or glycolic acid. Those preservatives and agents are commonly included in consumer products to extend the shelf-life of the products.

105. To the extent the Eye Drops already included preservatives or antimicrobial or biocidal agents, the unreasonable risk of bacterial contamination stemming from the Eye Drops' defective design could have been reduced or avoided entirely by increasing the amount of preservative or antimicrobial or biocidal agents or by including a biocidal treatment for raw or finished materials.

106. In addition (or in the alternative), from at least February 2023, the Eye Drops were unreasonably dangerous and unfit for sale due to a manufacturing defect that made the Eye Drops unreasonably susceptible to the readily foreseeable risk of bacterial contamination, including *Pseudomonas aeruginosa* contamination. The Eye Drops deviated from Defendant's design specifications by, *inter alia*, including contaminated raw materials, water, or other ingredients; inadequate amounts of preservative; improper hygiene; inadequate testing and audit procedures, and/or poor shipping or storage conditions.

107. Starting in at least February 2023, Defendant knew or should have known of the Eye Drops' bacterial contamination and/or the systemic design and/or manufacturing issues that made the Eye Drops unreasonably susceptible to bacterial contamination, particularly because of the duration and scope of the bacterial contamination. Reasonable and necessary quality control measures, including the testing of manufacturing processes and facilities; the testing of raw or finished materials; and audit procedures targeting Defendant's manufacturing processes and facilities and/or raw or finished materials, revealed or would have revealed the *Pseudomonas aeruginosa* contamination or the unreasonable risk of contamination in February 2023, a time well before Plaintiffs purchased the Eye Drops.

108. Moreover, the FDA, the CDC, and other regulatory agencies were actively investigating an outbreak of *pseudomonas* infections in United States consumers who had used eye drops that, like the Eye Drops here, were manufactured in India and imported into the United States.

109. From at least February 2023, Defendant acted with gross negligence or recklessness (to the point of disregarding substantial risk to human safety and life) in failing to recognize and to prevent the bacterial contamination of the Eye Drops and to properly warn consumers of the risk of bacterial contamination. The general and specific manufacturing risks of bacterial contamination of the Eye Drops, including *Pseudomonas aeruginosa* contamination, as well as the methods to prevent bacterial contamination, have been well understood in the manufacturing industry for decades.

D. Defendant Had a Duty to Warn Plaintiffs and Consumers About the Risk of Bacterial Contamination and Systemic Issues That Made the Eye Drops Unreasonably Susceptible to Bacterial Contamination

110. Well before Plaintiffs purchased the Eye Drops, Defendant had a duty to warn consumers, including Plaintiffs, of the risk that the Eye Drops were contaminated with bacteria, including *Pseudomonas aeruginosa*, and/or warn of the systemic risks in the Eye Drops' design or manufacturing which made the Eye Drops unreasonably susceptible to bacterial contamination.

111. Well before Plaintiffs purchased the Eye Drops, Defendant knew or should have known of the substantial risk that the Eye Drops were contaminated with bacteria and/or regarding the systemic and catastrophic flaws in designing or manufacturing the Eye Drops that made the Eye Drops unreasonably susceptible to bacterial contamination.

112. During that time, Defendant knew that Plaintiffs and other consumers were purchasing and using the Eye Drops based on the belief that the Eye Drops were viable eye lubricating products, did not contain bacteria, and/or were not at an unreasonable risk of bacterial contamination, based on Defendant's representations and the Eye Drops' labeling and packaging and other promotional materials.

113. Moreover, Defendant knew or should have known that the Eye Drops were contaminated with *Pseudomonas aeruginosa* or were unreasonably susceptible to *Pseudomonas*

aeruginosa contamination based on reasonable and necessary quality control measures that would have revealed the contamination or unreasonable risk of contamination before Plaintiffs purchased the Eye Drops in April 2023.

E. In October 2023, The FDA Warned Consumers of the Bacterial Contamination in Target's UP & UP Eye Drops

114. On October 27, 2023, the FDA issued a health advisory warning consumers not to purchase and to immediately stop using Target UP & UP eye drops "due to the potential risk of eye infections that could result in partial vision loss or blindness. Patients who have signs or symptoms of an eye infection after using these products should talk to their health care provider or seek medical care immediately."

115. The FDA identified the products, including the Eye Drops purchased and used by Plaintiffs, and said that, "These products are intended to be sterile. Ophthalmic drug products pose a potential heightened risk of harm to users because drugs applied to the eyes bypass some of the body's natural defenses. FDA recommended the manufacturer of these products recall all lots on October 25, 2023, after agency investigators found unsanitary conditions in the manufacturing facility and positive bacterial test results from environmental sampling of critical drug production areas in the facility. FDA also recommends consumers properly discard these products."[11]

116. The FDA warning noted that Target was removing the products from its store shelves and websites.

117. On November 8, 2023 at 11:09 a.m., Target placed an automated call to Plaintiffs about its recall of the Eye Drops due to the "potential risk of eye infection". The Target automated call said, "Our records indicate that someone with this number purchased UP & UP Eye Drops. Consumers should immediately stop using the product and check the recall posted

[11] https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-certain-eye-drops-several-major-brands-due-risk-eye#eyedrops

on Target.com. . . . Consumers with an impacted product should not use it and contact Target at 800-440-0680 for a refund…."

118. On November 21, 2023, Ms. Franz spoke with a Target "Guest Relations" representative, who subsequently sent a $15 Target Gift Card along with a note saying, "Thanks again for contacting Target regarding your recent experience. We've sent this Target Gift Card because we want you to come back for a better experience. We look forward to serving you again soon at Target."

119. Target said it wanted Mr. and Mrs. Franz to "come back for a better experience". Mr. Franz does not want a $15 gift card. He wants his eyesight back.

120. Plaintiffs did not use the Target Gift Card.

121. On November 24, 2023 Plaintiffs were contacted by a claims management company calling on behalf of Defendant. In a follow-up message from the claims management company on November 29, 2023, the representative told Plaintiffs that they can send questions to the following email address: regulatory@kilitchhealthcare.com.

122. Defendant's Eye Drops recall and untimely warning was too little, too late for Plaintiffs because Mr. Franz had already used and been physically injured by the Eye Drops. Mr. Franz used the contaminated drops and lost vision, which has not returned.

123. Moreover, the Target recall did not offer any remedy to consumers, like Mr. Franz, who were physically injured by the Eye Drops and who continue to need medical monitoring given the persistence of *Pseudomonas aeruginosa* and the continuing risk of bacterial contamination and infection.

124. Before Defendant's Eye Drops recall, Plaintiff William Franz used the contaminated Eye Drops and was injured, including having significant vision loss and blurred vision in his right eye that did not improve after he stopped using the Eye Drops.

FIRST CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY: DESIGN DEFECT

125. Plaintiffs reallege and incorporate by reference the allegations elsewhere in the Complaint as if set forth fully herein.

126. Plaintiff William Franz asserts this claim on behalf of himself.

127. Defendant is the manufacturer, distributor, and/or seller of the Eye Drops.

128. A manufacturer, distributor, or seller may be held strictly liable for placing a defective product on the market if the plaintiff's injury results from a reasonably foreseeable use of the product, including injuries caused by a design defect.

129. A design defect exists when the product is built in accordance with its intended specifications, but the design itself is inherently defective under the consumer expectation and/or risk-utility test.

Consumer Expectation Test

130. The Eye Drops' design fails the consumer expectation test, which requires a product to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

131. Here, the facts permit an inference that Plaintiff William Franz could form minimum safety assumptions about the Eye Drops, including that the Eye Drops were safe and not contaminated with bacteria and would not cause bacterial infections and other related injuries when used for their intended purposes.

132. The Eye Drops did not meet Plaintiff William Franz's safety expectations. Although the Eye Drops are designed for repeated use in the eye, the Eye Drops contained bacteria, including *Pseudomonas aeruginosa*, the Eye Drops did not contain a preservative or biocidal or antimicrobial agent; contained inadequate amounts of preservatives or biocidal or antimicrobial agents; contained an inadequate preservative profile; and/or lacked biocidal

treatment of raw materials, ingredients or finished Eye Drops.

133. The use of preservatives and biocidal or microbial agents and treatments protect consumers, promote product integrity, and prevent bacterial contamination. The use of preservatives and biocidal or microbial agents or treatments do not alter the composition of the Eye Drops and are economically feasible and necessary considering the risks posed by product contamination and degradation.

Risk-Benefit Test

134. The Eye Drops' design fails the risk-benefit test. A product is defective under the risk-benefit test if the plaintiff demonstrates that the product's design proximately caused his injury and the defendant fails to establish, considering the relevant factors, that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design. The relevant factors include: the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design.

135. Plaintiff William Franz used the Eye Drops as intended and as Defendant directed, and suffered bacterial infections, loss of vision, and related injuries due to the Eye Drops' bacterial contamination.

136. In light of the relevant factors, on balance, the benefits of the challenged design (one without preservatives/biocidal/antimicrobial agents) far outweigh the risk of danger inherent in such design, including the gravity of the danger posed by the risk of bacterial contamination; the inevitability that bacterial contamination would occur given that the Eye Drops included bacteria and were manufactured in environments that promoted bacterial growth; the mechanical and economic feasibility of including preservatives/antimicrobial/biocidal agents

and treatments; the low financial cost of an improved design; and the total lack of adverse consequences to the Eye Drops and consumers that would result from an alternative design.

Reasonable Alternative Design

137. The unreasonable risk of bacterial contamination stemming from the Eye Drops' defective design could have been reduced or avoided entirely by adopting a reasonable alternative design, including adding a preservative or antimicrobial or biocidal agent such as isothiazolones, bronopol, aldehydes, and carboxylic acids such glyoxylic or glycolic acid. Those preservatives and agents are commonly included in household cleaning products to extend the shelf-life of cleaning products, particularly consumer products like the Eye Drops at issue in this case.

138. The Eye Drops' design defect (the lack of preservatives/biocidal/microbial agents or treatments and unreasonable susceptibility to bacterial contamination) existed when the Eye Drops left Defendant's hands, and Plaintiffs did not alter or modify the Eye Drops, and Mr. Franz used the Eye Drops as directed and in a reasonably foreseeable manner and suffered injuries, including bacterial infections, vision loss, and related injuries due to the Eye Drops' bacterial contamination.

139. The Eye Drops' design defect proximately caused and were a substantial factor in causing Plaintiff William Franz's injuries. Further, Defendant's actions and omissions as identified in this Complaint constitute a flagrant disregard for human life.

140. Plaintiff William Franz suffered physical injuries due to Defendant's misconduct in an amount to be determined at trial.

SECOND CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY: MANUFACTURING DEFECT

141. Plaintiffs reallege and incorporate by reference the allegations elsewhere in the Complaint as if set forth fully herein.

142. Plaintiff William Franz asserts this claim on behalf of himself.

143. Defendant is the manufacturer, distributor, and/or seller of the Eye Drops.

144. A manufacturer, distributor, or seller may be held strictly liable for placing a defective product on the market if the plaintiff's injury results from a reasonably foreseeable use of the product, including an injury caused by a manufacturing defect.

145. A manufacturing or production defect occurs when a product is manufactured in a substandard fashion or when a product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line. The "manufacturing defect" theory posits that a suitable design is in place, but that the manufacturing process has in some way deviated from that design.

146. Here, when the Eye Drops left Defendant's hands, the Eye Drops deviated from Defendant's intended result/design/specifications or deviated from other seemingly identical models, in one or more of the following ways:

a. The Eye Drops contained contaminated raw materials, water or other ingredients leading to bacterial contamination, including *Pseudomonas aeruginosa* contamination;

b. The Eye Drops and/or their constituent ingredients were cross contaminated by human or animal contact or raw materials, water or other ingredients leading to bacterial contamination, including *Pseudomonas aeruginosa* contamination;

c. The Eye Drops' manufacturing and storage facilities were not kept sufficiently clean or were subjected to improper or inadequate hygiene techniques, leading to bacterial contamination, including *Pseudomonas aeruginosa* contamination;

d. The Eye Drops were subject to inadequate or improper quality control, testing, and/or audit procedures, leading to bacterial contamination, including *Pseudomonas aeruginosa* contamination;

e. The Eye Drops were subject to inadequate or improper shipping or storage conditions, leading to bacterial contamination, including *Pseudomonas* contamination; and/or

f. The Eye Drops did not contain or receive the adequate or intended amount of preservatives/antimicrobial/or biocidal agents or treatment or contained or received an improper or inadequate preservative/biocidal/antimicrobial profile.

147. At this early stage, Plaintiffs cannot be sure of the precise design or manufacturing defect that led to the Eye Drops' bacterial contamination because the Eye Drops' design and manufacturing processes are uniquely within Defendant's knowledge and control as the manufacturer, distributor, or seller. However, the Eye Drops should not have been contaminated with bacteria (including *Pseudomonas aeruginosa*), and it is certain that the Eye Drops suffered from a manufacturing and or design defect because they were contaminated with bacteria (including *Pseudomonas aeruginosa*) and ultimately infected and injured Plaintiff William Franz. There was no other cause of Plaintiff's injuries because the Eye Drops were the only potential source of exposure to *Pseudomonas aeruginosa* and Plaintiff's infection and injuries, and the Eye Drops were recalled by Defendant due to safety concerns concerning bacterial contamination. Discovery will ultimately reveal the precise nature of the Eye Drops' design or manufacturing defect, but Defendant cannot avoid liability because it alone has knowledge and evidence of the source of the Eye Drops' contamination and defect.

148. The Eye Drops' manufacturing defect existed when the Eye Drops left Defendant's hands, and Plaintiff William Franz did not alter or modify the Eye Drops.

149. Plaintiff William Franz used the Eye Drops as directed and in a reasonably foreseeable manner and suffered injuries, including bacterial infections, vision loss, and related injuries due to the Eye Drops' manufacturing.

150. The Eye Drops' manufacturing defect proximately caused and was a substantial factor in causing Plaintiff William Franz's injuries, including bacterial infections, vision loss, and related injuries due to the Eye Drops' bacterial contamination. Further, Defendant's actions and omissions as identified in this Complaint constitute a flagrant disregard for human life.

151. Plaintiff William Franz suffered injuries and harm as a result of Defendant's misconduct in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY:
FAILURE TO PROVIDE ADEQUATE WARNING

152. Plaintiffs reallege and incorporate by reference the allegations elsewhere in the Complaint as if set forth fully herein.

153. Plaintiff William Franz asserts this claim on behalf of himself.

154. Defendant is the manufacturer, distributor, and/or seller of the Eye Drops.

155. A manufacturer, distributor, or seller may be held strictly liable for placing a defective product on the market if the plaintiff's injury results from a reasonably foreseeable use of the product, including an injury caused by failure to warn or provide adequate instructions.

156. A product may be defective because of the absence of an adequate warning of the dangers inherent in its use. A product may be found defective within the general strict liability rule and its manufacturer or supplier held strictly liable because of the failure to provide an adequate warning or instruction where the manufacturer knew or should have known of the risk at the time of manufacture, or the manufacturer learns of the risk after manufacture.

157. Whether a warning is adequate depends on several factors, among them the normal expectations of the consumer as to how a product will perform, degrees of simplicity or complication in its operation or use, the nature and magnitude of the danger to which the user is exposed, the likelihood of injury, and the feasibility and beneficial effect of including a warning.

158. Here, Defendant knew of or should have known of the risk that the Eye Drops were contaminated with bacteria or were at risk of bacterial contamination based on reasonable and necessary quality control measures that would have revealed the bacterial contamination or systemic flaws in the Eye Drops' design or manufacturing creating an unreasonable risk of

bacterial contamination. Manufacturers have well-understood the risks of bacterial contamination, including *Pseudomonas aeruginosa* contamination, for decades and long before the Eye Drops were contaminated by bacteria and Plaintiffs' Eye Drops purchases in this case.

159. Similarly, manufacturers have well-understood the product design features and manufacturing methods including reasonably and necessary quality control measures that prevent bacterial contamination for decades and long before the Eye Drops were contaminated by bacteria in this case, as well as the increased risk of bacterial contamination when proper design features and manufacturing methods are not implemented (as occurred here).

160. Defendant is one of the foremost manufacturers of eye drops in the United States and when the Eye Drops were manufactured, knew of the contamination risks that ultimately and inevitably manifested in the Products in (at least) early 2023.

161. The risk that the Eye Drops were contaminated or at risk of bacterial contamination due to inadequate product design and manufacturing methods presented a substantial danger to Plaintiff William Franz and other consumers when the Eye Drops were used in an intended or reasonably foreseeable way, and reasonable consumers, including Plaintiff William Franz, would not have recognized those potential risks and had no reason to know of those potential risks.

162. The Eye Drops manufactured, distributed, and/or sold by Defendant were defective due to inadequate warnings or instructions because Defendant knew or should have known, at the time of manufacture, distribution, or sale that the Eye Drops created significant risks of serious bodily harm to consumers, but Defendant failed to adequately warn consumers of such risks, including warnings that:

a. The Eye Drops were contaminated with bacteria, including *Pseudomonas aeruginosa*;

b. The Eye Drops were at unreasonable risk of being contaminated with

bacteria, including *Pseudomonas aeruginosa* contamination, due to deficiencies in product design and manufacturing methods; and

c. Potential signs of bacterial infection, the particularized risk of infection and what to do if a bacterial infection or contamination was suspected, including to stop using the Eye Drops immediately and to consult a doctor.

163. Defendant's inadequate or absence of the foregoing warnings and directions were a substantial factor in causing injuries to Plaintiff William Franz. Plaintiff reviewed the labeling and instructions for the Eye Drops and used the Eye Drops as directed without any knowledge the Eye Drops were at risk of bacterial contamination and could cause Mr. Franz's injuries because Defendant did not include any warnings or instructions regarding those risks. Plaintiff William Franz would not have purchased or used the Eye Drops had Defendant included proper warnings and instructions on the risks of bacterial contamination.

164. The Eye Drops' failure to warn or properly instruct on the risks of bacterial contamination proximately caused and were a substantial factor in causing Plaintiff William Franz's injuries, including vision loss and related injuries, due to the Eye Drops' bacterial contamination. Further, Defendant's actions and omissions as identified in this Complaint constitute a flagrant disregard for human life.

165. Plaintiff William Franz suffered physical injuries as a result of Defendant's misconduct in an amount to be determined at trial.

FOURTH CLAIM FOR RELIEF
NEGLIGENCE

166. Plaintiffs reallege and incorporate by reference the allegations elsewhere in the Complaint as if set forth fully herein.

167. Plaintiff William Franz asserts this claim on his own behalf.

168. Defendant is the manufacturer, distributor, and/or seller of the Eye Drops.

169. Defendant had a duty to exercise reasonable care in designing, manufacturing,

testing, marketing, and distributing the Eye Drops into the stream of commerce, including a duty to ensure that the Eye Drops did not pose a significantly increased risk of injury to Plaintiffs and other consumers based on design and manufacturing defects and to warn consumers of known and knowable risks regarding the Eye Drops.

170. Defendant breached those duties and failed to exercise reasonable care in designing, manufacturing, testing, marketing and distributing the Eye Drops. As described above in the First Claim for Relief, the Second Claim for Relief, and the Third Claim for Relief, the Eye Drops were defective, unreasonably dangerous, and not fit for their intended and ordinary purposes, causing Plaintiff William Franz to suffer physical injuries. The Eye Drops were unreasonably dangerous based on design, manufacturing, and/or warning defects that caused bacterial contamination by *Pseudomonas aeruginosa*.

171. Defendant's negligence and/or recklessness and duty of care breaches caused and were a substantial factor in causing Plaintiff William Franz's injuries, including vision loss and related injuries, due to the Eye Drops' bacterial contamination. Further, Defendant's actions and omissions as identified in this Complaint constitute a flagrant disregard for human life.

172. Defendant's negligence or recklessness caused Plaintiff William Franz's injuries and damages in an amount to be determined at trial. Further, Defendant's actions and omissions as identified in this Complaint constitute a flagrant disregard for human life.

FIFTH CLAIM FOR RELIEF
LOSS OF CONSORTIUM

173. This Count is asserted for Ms. Franz.

174. Plaintiffs reallege and incorporate by reference the allegations elsewhere in the Complaint as if set forth fully herein.

175. Plaintiffs are married and were married at all times relevant to this claim.

176. Ms. Franz was harmed by the injuries to Mr. Franz because he used the Eye

Drops, as alleged herein.

177. Ms. Franz has suffered loss of love, companionship, comfort, care, assistance, protection, affection (both physical and emotional), society, and moral support. The injuries to Mr. Franz have caused Ms. Franz to spend more time caretaking, thus putting undue strain on the marital relationship. Seeing her husband suffer is emotionally taxing.

178. This loss of consortium was proximately caused by the injuries that Mr. Franz suffered as a result of the contaminated Eye Drops.

179. Plaintiff Ms. Franz suffered, and continues to suffer, injuries and damages as a result of Defendant's misconduct in an amount to be determined at trial.

JURY DEMAND

180. Plaintiffs demand a trial by jury on all issues.

WHEREFORE, Plaintiffs, on behalf of themselves, pray for judgment as follows:

(a) Awarding actual, compensatory, and punitive damages;

(b) An Order requiring Defendant to establish a medical monitoring protocol for Plaintiff William Franz to monitor his health and diagnose at an early stage any additional ailments and injuries associated with exposure to *Pseudomonas aeruginosa.*

(c) Awarding Plaintiffs their costs and expenses incurred in this action, including reasonable allowance of fees for Plaintiffs' attorneys, experts, and reimbursement of Plaintiffs' expenses; and

(d) Granting such other and further relief as the Court may deem just and proper.

Dated: December 18, 2023

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