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5 **Attorneys for Plaintiffs**
6 **Milton and Danae Reynolds**

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9 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**
10 **FOR THE COUNTY OF ALAMEDA**

12 MILTON AND DANAE REYNOLDS,
13 Plaintiffs,

14 v.

15 EZRICARE, LLC; EZRIRX, LLC; GLOBAL
PHARMA HEALTHCARE PRIVATE
16 LIMITED; ARU PHARMA, INC.;
AMAZON.COM, INC.; AND "DOE" AMAZON
17 DELIVERY SERVICE PARTNER,
18 Defendants.

) Case No: 23CV028265

) **COMPLAINT FOR DAMAGES**

-) (1) Strict Liability – Manufacturing Defect
) (2) Strict Liability – Design Defect
) (3) Strict Liability – Failure to Warn
) (4) Negligence & Gross Negligence
) (5) Negligent Failure to Warn
) (6) Negligent Failure to Recall
) (7) Negligence Per Se
) (8) Breach of Express Warranty
) (9) Breach of Implied Warranty
) (10) Fraud
) (11) Loss of Consortium

) **DEMAND FOR JURY TRIAL**

21
22 Plaintiff Milton Reynolds files this Complaint having suffered blindness in his right eye
23 from using contaminated EzriCare Artificial Tears. Plaintiff Danae Reynolds files this complaint
24 having suffered loss of consortium because of Mr. Reynold’s injuries. On information and belief,
25 the Reynolds allege as follows:

26 **PARTIES**

27 Plaintiffs Milton Reynolds and Danae Reynolds are a married couple. They are residents of
28 San Leandro, California. At all times relevant to this lawsuit, Mr. and Mrs. Reynolds were residents

1 of San Leandro, California. The injury for which Mr. and Mrs. Reynolds are suing occurred in San
2 Leandro, California.

3 Defendant Amazon.com, Inc. (“Amazon”) is incorporated under the laws of Delaware and
4 maintains its principal place of business in Washington. Amazon markets, sells, and distributes
5 products worldwide, including in California. Amazon does business in California, both online and
6 through its offices and operations in California. Amazon purposely directed its activities to
7 California and sold, distributed, advertised, and/or marketed the product that caused injury giving
8 rise to this lawsuit. Amazon’s contacts with California are substantial and sufficient that the
9 company should reasonably expect to be brought into court in California. Amazon may be served
10 through its registered agent, Corporation Service Company, at 300 Deschutes Way SW, Ste. 208 M;
11 C-CSC1, Tumwater, WA 98501.

12 Defendant “Doe” is a currently unidentified Amazon Delivery Service Partner (“DSP”)
13 added pursuant to California Code of Civil Procedure 474. On information and belief, Defendant
14 Doe is an independent, California company responsible for distributing packages “the last mile”
15 from a California-based facility to California customers when those customers place orders from
16 Defendant Amazon.¹ A search for California-based DSP jobs on ZipRecruiter returns 465 available
17 positions at various DSP companies.² On information and belief, Defendant Doe was responsible
18 for distributing and delivering the product that caused the injury in this lawsuit. Thus, Defendant
19 Doe purposely directed its activities to California. Doe’s contacts with California are substantial and
20 sufficient that the company should reasonably expect to be brought into court in California.

21 Defendant Aru Pharma, Inc. (“Aru Pharma”) is incorporated under the laws of the State of
22 New York, and its principal place of business is located at 925 Protano Lane, Mamaroneck, NY

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24
25 ¹ See *Rimson v. Amazon Logistics, Inc.* (W.D. Mo., Jan. 25, 2023, No. 4:21-00553-CV-RK) 2023 WL 405336, at *1 (In
26 its motion for summary judgment, Defendant Venus’ statement of uncontroverted material facts explains that Amazon
27 hires third-party companies, known as Delivery Service Partners (‘DSP’), to deliver Amazon packages. Amazon has
28 delivery stations, called DMCs, where the packages go for the last mile before they arrive to the customer.”; see also
*Amazon, Own Your Success: Start Your Own Business and Become an Amazon Delivery Service Partner, Delivering
Smiles Across Your Community*, accessed Feb. 16, 2023,
https://m.media-amazon.com/images/G/01/DSP2022/assets/desktop/DSP_Brochure_English_V4.pdf.

² ZipRecruiter, Amazon Delivery Partner Jobs (in California), accessed Feb. 16, 2023,
<https://www.ziprecruiter.com/Jobs/Amazon-Delivery-Partner/--in-California>.

1 10543. Aru Pharma is in the business of manufacturing, designing, importing, supplying,
2 packaging, labeling, distributing, marketing, and selling the product that caused injury in this case
3 in California. Thus, Aru Pharma purposely directed its activities to California. Aru Pharma's
4 contacts with California are substantial and sufficient that the company should reasonably expect to
5 be brought into court in California. Aru Pharma may be served with process via Kuppusamy
6 Arumugam at its principal place of business 925 Protano Lane, Mamaroneck, NY 10543 (or
7 alternatively on Jayakumar Arumugam at 7 Wingate Pl., Yonkers, NY 10705).

8 Defendant EzriCare, LLC ("EzriCare") is a limited liability company organized under the
9 laws of the State of New Jersey. EzriCare's principal place of business is located at 1525 Prospect
10 St., Ste. 204, Lakewood, NJ 08701. EzriCare is a citizen of the State of New Jersey. EzriCare is in
11 the business of manufacturing, designing, importing, labeling, packaging, supplying, distributing,
12 marketing, and selling the product that caused the injury in this lawsuit throughout the United
13 States, including in California. Thus, EzriCare purposely directed its activities to California.
14 EzriCare's contacts with California are substantial and sufficient that the company should
15 reasonably expect to be brought into court in California. EzriCare may be served through its
16 registered agent, Ezriel Green, at 1525 Prospect St., Ste. 204, Lakewood, NJ 08701.

17 Defendant EzriRx, LLC ("EzriRx") is organized under the laws of the State of Delaware.
18 EzriRx's principal place of business is located at 1525 Prospect St., Ste. 203, Lakewood, NJ 08701
19 or 2360 Rt. 9, Suite 3, #171, Toms River, NJ 08755. EzriRx is in the business of manufacturing,
20 designing, importing, supplying, packaging, labeling, distributing, marketing, and selling the
21 product that caused injury in this lawsuit throughout the United States, including in California.
22 Thus, EzriRx purposely directed its activities to California. EzriRx's contacts with California are
23 substantial and sufficient that the company should reasonably expect to be brought into court in
24 California. EzriRx may be served through its registered agent Registered Agent Solutions, Inc., 838
25 Walker Road, Suite 21-2, Dover, Delaware 19904.

26 Defendant Global Pharma Healthcare Private Limited ("Global Pharma") is a corporation
27 organized and existing under the laws of the Country of India. Global Pharma's principal place of
28 business located at No. 2A, 3rd F, 4th Street, Ganga Nagar, Chennai - 600 024, Tamilnadu, India.

1 Global Pharma is in the business of manufacturing, designing, importing, marketing, advertising,
2 packing, labeling, distributing, and selling the product that caused the injury that is the subject of
3 this lawsuit. As can be seen on its website, Global Pharma purposely directed its activities to the
4 U.S. market, including California.³ EzriRx’s contacts with California are substantial and sufficient
5 that the company should reasonably expect to be brought into court in California. Global Pharma
6 can be served at its offices and through its officers via the Hague Service Convention.

7 Each Defendant received direct financial benefit from its activities and the sale of the
8 product at issue in this lawsuit. Each Defendant was integral to the business enterprise such that
9 Defendants’ conduct was a necessary factor in bringing the product to the customer market. Each
10 Defendant had control over or a substantial ability to influence the distribution and marketing
11 process.

12 **JURISDICTION AND VENUE**

13 This Court has jurisdiction over the subject matter of this action as a tort committed upon
14 Alameda County residents and pursuant to Article VI, Section 10 of the California Constitution
15 because this case is not given by statute to other trial courts. Additionally, the amount in
16 controversy exceeds the amount for unlimited civil jurisdiction in this Court.

17 This court has jurisdiction over each Defendant because, on information and belief, each
18 Defendant conducts business in this state, has purposely availed itself of the laws of this state, and
19 purposely directed its business to the state. Moreover, the injuries that are the subject of this lawsuit
20 were caused by a product that was sold, distributed, delivered, used, and caused injury to the
21 Plaintiffs in Alameda County. Thus, the controversy arises out of Defendants contacts with the state
22 and the forum.

23 Venue lies in Alameda County because the conduct and events giving rise to the claims at
24 issue occurred in Alameda County. The Plaintiffs reside in this county, the purchase and injuries
25 occurred in the county, and relevant evidence and witnesses are believed to be located in the county.

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³ Global Pharma Healthcare, Our Presence, accessed Feb. 16, 2023, <https://global-pharma.com/ourpresence.html>.

1 Plaintiffs expressly disclaim that any of their causes of action rely upon federal law and/or
2 present a federal question.

3 **FACTS OF THE CASE**

4 Through the Christmas of 2022, Plaintiff Milton Reynolds was battling an eye infection so
5 severe that he feared doctors would have to remove his right eye. The infection melted his cornea,
6 causing him to endure, among other things, emergency room visits, two surgeries, and regular
7 intravitreal injections (shots in his eye). Ultimately, Mr. Reynolds went blind in his right eye.

8 In January 2023, Mr. Reynolds received a call from the Alameda County Office of Public
9 Health, inquiring about Mr. Reynolds’ injuries and whether he had purchased EzriCare Artificial
10 Tears. That was when he learned that his suffering and blindness was caused because of simple,
11 lubricating eye drops that he bought on Amazon.

12 **The Outbreak – Pseudomonas Aeruginosa**

13 On January 20, 2023, the US Center for Disease Control and Prevention (“CDC”) spotted an
14 outbreak of a rare bacterial infection in 11 (now 12) different states, including California.⁴ At the
15 time, the infections were known to have affected 55 people between May and December of 2022.⁵
16 Some of the people infected suffered permanent vision loss, and one person even died when the
17 infection entered his bloodstream.⁶

18 The CDC searched for a cause of the outbreak and found one: “Recent epidemiology and
19 laboratory evidence link these infections to use of EzriCare Artificial Tears.”⁷ The CDC obtained
20 bacterial samples from the people infected and reported that it found a strain of bacteria that has
21 never been reported in the United States, called Verona Integron-mediated Metallo-β-lactamase and
22 Guiana-Extended Spectrum-β-Lactamase producing carbapenem-resistant *Pseudomonas aeruginosa*

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25 ⁴ Center for Disease Control and Prevention (“CDC”), Update: Multistate Cluster of VIM- and GES-producing
26 Carbapenem-resistant *Pseudomonas aeruginosa* associated with Artificial Tears, Jan. 20, 2023,
27 [https://www.aao.org/Assets/3a187c94-7889-42e8-84a1-6b2e88e7d374/638098403609770000/epix-multistate-
pseudomonas-investigation-20jan2023-pdf?inline=1](https://www.aao.org/Assets/3a187c94-7889-42e8-84a1-6b2e88e7d374/638098403609770000/epix-multistate-pseudomonas-investigation-20jan2023-pdf?inline=1). The states affected were CA, CO, CT, FL, NJ, NM, NY, NV, TX,
UT, WA, and WI.

28 ⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

1 (“VIM-GES-CRPA”).⁸ The CDC then compared that strain of bacteria to the bacteria collected
2 from opened bottles of EzriCare Artificial Tears – they were the same bacteria.⁹ Testing of
3 unopened bottles of EzriCare Artificial Tears is ongoing.¹⁰

4 Both the CDC and the Food and Drug Administration (“FDA”) have advised citizens to stop
5 using Artificial Tears, because the strain of *Pseudomonas aeruginosa* bacteria that they found in the
6 outbreak is a danger to humans. For example, scientists have known for decades that, when
7 *Pseudomonas aeruginosa* is introduced into the eye, “as . . . in contaminated medicines, it acts with
8 **extreme virulence**, in many cases causing blindness and even necessitating enucleation.”¹¹
9 “Enucleation” means surgical removal of the entire eyeball.

10 The strain of *Pseudomonas aeruginosa* found in the outbreak is reported to be “extensively
11 drug-resistant,” making it especially difficult for doctors to treat.¹² The strain appears to resist
12 cefepime, ceftazidime, piperacillin-tazobactam, aztreonam, carbapenems, ceftazidime-avibactam,
13 ceftolozane-tazobactam, fluoroquinolones, polymyxins, amikacin, gentamicin, and tobramycin.¹³

14 **The Aftermath of the Outbreak**

15 Four days after the CDC issued its public statement specifically linking the potentially-
16 deadly *Pseudomonas aeruginosa* to EzriCare, EzriCare reported on its website that the CDC was
17 merely investigating “adverse events” related to “various” over the counter eye drops. Moreover,
18 although infections had been under investigation by the CDC for approximately nine months,
19 EzriCare disclaimed that it had received *any* consumer complaints or adverse event reports, and the
20 company reported that it had not been asked to recall Artificial Tears.¹⁴

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24 ⁸CDC, Outbreak of Extensively Drug-resistant *Pseudomonas aeruginosa* Associated with Artificial Tears, Feb. 1, 2023,
<https://emergency.cdc.gov/han/2023/han00485.asp>.

25 ⁹ *Id.*

26 ¹⁰ *Id.*

27 ¹¹ William H. Spencer, *Pseudomonas Aeruginosa Infections of the Eye*, Calif Med. 1953 Dec; Vol. 79(6) at 438–443.,
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1521875/> (emphasis added).

28 ¹² CDC, Outbreak of Extensively Drug-resistant *Pseudomonas aeruginosa* Associated with Artificial Tears, Feb. 7,
2023, <https://www.cdc.gov/hai/outbreaks/crpa-artificial-tears.html>.

¹³ *Id.*

¹⁴ EzriCare, EzriCare Artificial Tears - Discontinue Use, Jan. 24 – Feb. 2, 2023, <https://ezricare-info.com/>

1 Several days after that, on February 1, 2023, EzriCare issued a statement all but blaming the
2 bacterial contamination of Artificial Tears on its manufacturer, Global Pharma Healthcare, and/or
3 its distributor, Aru Pharma:

4 The EzriCare Artificial Tears product is manufactured in India by Global Pharma
5 Healthcare PVT Limited and imported into the United States by Aru Pharma Inc. . . .
6 EzriCare, LLC had no role in the formulation, packaging delivery system design or
7 actual manufacturing of this product.¹⁵

8 Though, in that same statement, EzriCare did specifically own that it is responsible for the labeling
9 and marketing of Artificial Tears: “EzriCare, LLC’s only role in introducing the product to the
10 market was to design an exterior label and to market it to our customers.”¹⁶

11 On February 2, 2023, Global Pharma Healthcare issued a nationwide recall of Artificial
12 Tears distributed by EzriCare “due to possible contamination.”¹⁷ The recall’s risk statement
13 specifically acknowledges that “[u]se of contaminated artificial tears can result in the risk of eye
14 infections that could result in blindness.”¹⁸

15 On February 3, 2023, the FDA placed Global Pharma Healthcare on import alert, preventing
16 Artificial Tears from entering the country, finding evidence that Artificial Tears appeared to be in
17 violation of U.S. laws and regulations.¹⁹ The FDA cited Global Pharma Healthcare for “not
18 complying with [Current Good Manufacturing Practice] requirements,” as well for providing an
19 inadequate response to FDA records requests.²⁰

20 **Artificial Tears & Violations of California Law**

21 California law forbids violations of Current Good Manufacturing Practice (“CGMP”)
22 requirements. Through the state’s Sherman Food Drug and Cosmetics Laws (“Sherman Laws”),
23 California has adopted as its own law all nonprescription drug regulations and good manufacturing

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25 ¹⁵ *Id.*

26 ¹⁶ *Id.*

27 ¹⁷ Global Pharma Healthcare, Global Pharma Healthcare Issues Voluntary Nationwide Recall of Artificial Tears
28 Lubricant Eye Drops Due to Possible Contamination, Feb. 2, 2023, <http://www.global-pharma.com/otc.pdf>.

¹⁸ *Id.*

¹⁹ Food and Drug Administration, FDA Warns Consumers Not to Purchase or Use EzriCare Artificial Tears Due to
Potential Contamination, Feb. 2, 2023, <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-ezricare-artificial-tears-due-potential-contamination>.

²⁰ *Id.*

1 practices found in the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 *et seq*, 21 C.F.R.
2 820 *et seq.*). E.g. Cal. Health & Safety Code §§ 110111, 110105. Thus, California law requires
3 sanitary conditions at the manufacturing facility (including packaging or similar facilities) and
4 testing to ensure that eye drops will be sterile and safe when used by the consumer.

5 Among CGMP violations that the FDA cited were (1) lack of appropriate microbial testing
6 and (2) a formulation issue (the fact that the company packages the eye drops in multi-use bottles
7 without a preservative). Although investigation currently remains ongoing, these are the ways that
8 the bacteria *Pseudomonas aeruginosa* came to contaminate Artificial Tears.

9 First, on information and belief, because of unsanitary conditions, the lack of appropriate
10 microbial testing, and the lack of adequate documentation and pharmacovigilance, *Pseudomonas*
11 *aeruginosa* contaminated Artificial Tears at the time of manufacturing or packaging. The CDC’s
12 investigation remains ongoing.

13 Global Pharma knows the danger presented by unsanitary conditions and the lack of
14 microbial testing. Its website touts that its “manufacturing process is studied and perfected by a
15 quality control department in order to ensure that Global Pharma formulations are of the highest
16 quality.”²¹ “Our team of dedicated professionals, with the help of computer controlled test
17 equipment, scrutinize each product as it goes through a series of checkpoints.”²² “A separate quality
18 assurance team monitors the entire process of production. Our laboratory is equipped with the latest
19 equipment It is well equipped to perform all necessary chemical and microbiological assays.”²³
20 “We at Global Pharma are committed to ensure our products are of the highest quality and
21 pharmacovigilance is an essential part of this. Our ongoing processes allow for feedback to be
22 received and acted upon in a timely and efficient manner.”²⁴ More specifically, Global Pharma touts
23 that its manufacturing facility “has been meticulously designed for the manufacturing of . . . sterile
24 eye drops It has been audited by the Ministries of Health of over 12 countries”²⁵

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26 ²¹ Global Pharma Healthcare, Quality and Pharmacovigilance, visited Feb. 21, 2023, [http://www.global-](http://www.global-pharma.com/quality.html)
27 [pharma.com/quality.html](http://www.global-pharma.com/quality.html).

28 ²² *Id.*

²³ *Id.*

²⁴ ²⁴ *Id.*

²⁵ Global Pharma Healthcare, Manufacturing, visited Feb. 21, 2023, <https://global-pharma.com/manufacturing.html>.

1 Similarly, EzriCare’s website touts itself as a “forward-thinking 21st century, Generic OTC
2 Drug Company” whose “products have the same high quality active ingredients as most leading
3 brands.”²⁶ “We pride ourselves on providing our customers the biggest bang for their buck while
4 also ensuring they remain highly satisfied in . . . our product quality”²⁷

5 The dangers of unsanitary conditions and the need for testing, pharmacovigilance, and
6 company oversight of drug manufacturing facilities in India has long been known to industry
7 members like Defendants. For example, a 2015 article in the Financial Times, titled *Indian Drugs:
8 Not What the Doctor Ordered* reported that, in 2015 alone, six Indian manufacturers were
9 blacklisted by the FDA and that 39 drug-manufacturing facilities – owned by 27 different
10 companies – lost their clearance to make drugs for U.S. markets because of regulatory problems.²⁸
11 Such “regulatory problems” have very real and very steep consequences: for example, in October
12 of last year, contaminated, Indian-made cough syrup killed 70 children in West Africa.²⁹ This is not
13 a one-time problem; activists say there is a “longstanding laxness in regulating India’s booming
14 pharmaceutical industry.”³⁰

15 Thankfully, companies that deal in pharmaceuticals sold in America are held to a higher
16 standard. California law recognizes, for example, that “[i]nformed medical opinion is in agreement
17 that all preparations offered or intended for ophthalmic use . . . should be sterile.” *Id.* (incorporating
18 21 C.F.R Parts 200.50, 211). “It is further evident that such preparations purport to be of such purity
19 and quality as to be suitable for safe use in the eye.” *Id.* “[A]ll such preparations, if they are not
20 sterile, fall below their professed standard of purity or quality and may be unsafe.” *Id.* Testing is
21 likewise required to ensure safety. *Id.*

22 Alternatively, on information and belief, because of a formulation issue – namely, that
23 Artificial Tears was placed in *multi-use* bottles and without a preservative to kill bacteria –
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25 ²⁶ EzriCare, About Us, visited Feb. 21, 2023, <https://ezricare.com/pages/about-us>.

26 ²⁷ *Id.*

27 ²⁸ Financial Times, *Indian Drugs: Not What the Doctor Ordered*, Sep. 2015, <https://www.ft.com/content/dc0ca3f4-5581-11e5-97e9-7f0bf5e7177b>

28 ²⁹ NPR, *Contaminated Cough Syrup from India Linked to 70 Child Deaths. It's Happened Before.*, Oct. 2022, <https://www.npr.org/sections/goatsandsoda/2022/10/18/1128530220/contaminated-cough-syrup-from-india-linked-to-70-child-deaths-its-happened-before>.

29 ³⁰ *Id.*

1 *Pseudomonas aeruginosa* foreseeably contaminated the bottles of Artificial Tears after they were
2 opened, even though they were used as directed. Medical professionals have long warned that
3 placing a preservative-free eyedrop inside a multi-use eyedrop bottle is dangerous, precisely
4 because there is no preservative to kill bacteria; even seemingly benign and foreseeable acts – like
5 brushing an eyelash while applying the drops – can cause harmful contamination of the multi-use
6 bottle when it lacks a preservative. When no preservative is added to eye drops, the drops must be
7 packaged more safely, for example, in single-use vials or specially-designed multi-use bottles (that
8 prevent drops and air from reentering and contaminating the bottle).

9 California’s Sherman Laws require that EzriCare’s eye drops be packaged more safely. If
10 eye drops are sold in a multi-dose container, like EzriCare’s, they must either contain a substance to
11 inhibit the growth of microorganisms *or* “be so packaged as to volume and type of container and so
12 labeled as to duration of use and with such necessary warnings to afford adequate protection and
13 minimize the hazard of injury resulting from contamination during use.” Cal. Health & Safety Code
14 §§ 110111, 110105 (incorporating 21 C.F.R. 200.50(b)). To this end, notably, the brand-name eye
15 drops, Refresh Plus (for which EzriCare is the generic), are sold in *single-use* vials, pictured below
16 – *not* a multidose bottle, like Artificial Tears.



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26 Especially given the manufacturing and formulation issues inherent in Artificial Tears,
27 EzriCare’s warning label was particularly weak. It warned not to use the product if the solution
28 changed color or became cloudy; to see a doctor if the user experienced eye pain, changes in

1 vision, or redness/irritation; and it stated that contamination *could be avoided* by not touching the
2 tip of the container to any surface, replacing the cap, and removing contact lenses before using.
3 The label did not warn, for example, because the product is preservative-free and irresponsibly
4 packaged it is more susceptible to contamination and more likely to cause serious, life-altering
5 infections.

6 Plaintiffs Milton Reynolds & Danae Reynolds

7 Like many Americans, Plaintiff Milton Reynolds gets dry eyes when he works on a
8 computer. He decided to purchase some lubricating eye drops. Sadly, that seemingly-innocuous
9 decision would change his life.

10 On June 24, 2022, Mr. Reynolds purchased two bottles of EzriCare Artificial Tears from
11 Amazon. He used the Artificial Tears dozens of times. Then, his right eye inexplicably began to
12 tear up, and he began experiencing eye pain.

13 In October 2022, Mr. Reynolds visited his ophthalmologist for treatment of his symptoms.
14 His ophthalmologist sent him to the emergency room. Mr. Reynolds was experiencing “cornea
15 melt” – an infection was eating his cornea.

16 Through Thanksgiving 2022, Mr. Reynolds continued receiving critical medical treatment
17 for his eye, including (but not limited to) shots in his right eye and emergency room visits. On two
18 occasions, doctors glued his right eyeball together to keep the eye from imploding from the
19 infection. Mr. Reynolds compared the physical pain caused by the infection to knives sticking into
20 his head. The doctors advised Mr. Reynolds that they may need to remove his infected eyeball.

21 On the day after Thanksgiving, Mr. Reynolds underwent surgery for a full cornea
22 replacement. Around that time, Mr. Reynolds’ doctors confirmed that Mr. Reynolds was suffering
23 from a rare strain of *Pseudomonas aeruginosa*.

24 However, Mr. Reynolds’ suffering was not over: He endured a second surgery to clear the
25 back of his eye. His injuries continued to force him into the emergency room. And Mr. Reynolds
26 continued to visit his doctors frequently for critical treatment, including more shots in his eye.

27 Mr. Reynolds has lost sight in his right eye. He continues to see doctors. Mrs. Reynolds, his
28 wife, must both see her husband suffer and participate in his care and treatment, which is

1 emotionally and physically taxing and puts a strain on the relationship. Ms. Reynolds can no longer
2 sleep in the same bed with Mr. Reynolds for fear of exacerbating his injury. The Reynolds have
3 been negatively impacted by loss of companionship, comfort, care, assistance, protection, affection
4 (both physical and emotional), society, and moral support. Mr. Reynolds has experienced severe
5 pain and suffering, both physical and emotional, and he will continue to require treatment in the
6 future.

7 **CAUSES OF ACTION**

8 **Count I**

9 **Strict Liability – Manufacturing Defect**

10 Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth
11 here in their entirety.

12 Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers,
13 marketers, advertisers, and/or sellers of the product Artificial Tears. Each Defendant received direct
14 financial benefit from its activities and the sale of the product at issue. Each Defendant was integral
15 to the business enterprise such that Defendants' conduct was a necessary factor in bringing the
16 product to the customer market. Each Defendant had control over or a substantial ability to
17 influence the distribution and marketing process.

18 The product was defective in that it was contaminated with *Pseudomonas aeruginosa*.
19 Because it was contaminated, it differed from the manufacturer's design or specifications or from
20 other typical units of the same product line. The product was defective when it left Defendants'
21 possession. Mr. Reynolds used Artificial Tears in a reasonably foreseeable manner. He suffered
22 harm, and the defect in the product was a substantial factor in causing that harm.

23 On information and belief, Defendants acted with malice, oppression, or fraud – including, but
24 not limited to, acting with willful and knowing disregard for the rights or safety of others, for
25 example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the
26 probable dangerous consequences of their conduct and deliberately failed to avoid those
27 consequences.

28

1 **Count II**

2 **Strict Liability – Design Defect**

3 Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth
4 here in their entirety.

5 Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers,
6 marketers, advertisers, and/or sellers of the product Artificial Tears. Each Defendant received direct
7 financial benefit from its activities and the sale of the product at issue. Each Defendant was integral
8 to the business enterprise such that Defendants’ conduct was a necessary factor in bringing the
9 product to the customer market. Each Defendant had control over or a substantial ability to
10 influence the distribution and marketing process.

11 The product’s design was defective because it enabled the product to be contaminated with
12 *Pseudomonas aeruginosa* and, thus, did not perform as safely as an ordinary consumer would have
13 expected it to perform when used or misused in an intended or reasonably foreseeable way.
14 Alternatively, the design was defective because it enabled the product to be contaminated with
15 *Pseudomonas aeruginosa* and the risks associated with the product’s design outweighed its benefits.
16 Mr. Reynolds was harmed. The product’s design or failure to perform safely was a substantial factor
17 in causing the harm suffered by Mr. Reynolds.

18 On information and belief, Defendants acted with malice, oppression, or fraud – including, but
19 not limited to, acting with willful and knowing disregard for the rights or safety of others, for
20 example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the
21 probable dangerous consequences of their conduct and deliberately failed to avoid those
22 consequences.

23 **Count III**

24 **Strict Liability – Failure to Warn**

25 Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth
26 here in their entirety.

27 Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers,
28 marketers, advertisers, and/or sellers of the product Artificial Tears. Each Defendant received direct

1 financial benefit from its activities and the sale of the product at issue. Each Defendant was integral
2 to the business enterprise such that Defendants' conduct was a necessary factor in bringing the
3 product to the customer market. Each Defendant had control over or a substantial ability to
4 influence the distribution and marketing process.

5 The product had potential risks, side effects, or adverse reactions that were known or
6 knowable in light of the scientific and/or medical knowledge at the time of the product's manufacture,
7 distribution, packaging, labeling, supplying, marketing, advertising, and/or selling – for example, that
8 it may be contaminated with a potentially-deadly bacteria. The potential risks, side effects, and/or
9 adverse reactions presented a substantial danger when the product was used or misused in an intended
10 or reasonably foreseeable way. Ordinary consumers would not have recognized the potential risks,
11 side effects, or adverse reactions. Defendants had a duty to warn and to continually update
12 warnings. Defendants failed to adequately warn or instruct or update the potential risks, side effects,
13 or adverse reactions. Mr. Reynolds was harmed. The lack of sufficient instructions or warnings was
14 a substantial factor in causing the harm that Mr. Reynolds suffered.

15 On information and belief, Defendants acted with malice, oppression, or fraud – including, but
16 not limited to, acting with willful and knowing disregard for the rights or safety of others, for
17 example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the
18 probable dangerous consequences of their conduct and deliberately failed to avoid those
19 consequences.

20 **Count IV**

21 **Negligence & Gross Negligence**

22 Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth
23 here in their entirety.

24 Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers,
25 marketers, advertisers, and/or sellers of the product Artificial Tears. As such, Defendants owed
26 Plaintiff a duty of care and a duty to assist and protect, including but not limited to a duty of
27 reasonable care to manufacture, test, design, distribute, package, label, supply, market, advertise,
28 and/or sell a product that was not unreasonably safe for human use. The product was either inherently

1 dangerous or reasonably certain, if negligently manufactured, designed, distributed, packaged,
2 labeled, supplied, marketed, advertised, and/or sold to place life and limb in peril. It was or became
3 contaminated with *Pseudomonas aeruginosa*. Defendants were negligent in manufacturing,
4 designing, distributing, packaging, labeling, supplying, marketing, advertising, and/or selling the
5 product. Defendants failed to use the amount of care in manufacturing, distributing, packaging,
6 labeling, supplying, marketing, advertising, and/or selling the product that a reasonably careful
7 manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or
8 sellers would use in similar circumstances to avoid exposing others to a foreseeable risk of harm.
9 Alternatively, Defendants failed to use any care or made an extreme departure from what a reasonably
10 careful person would do in the same situation to prevent harm to oneself or to others. Mr. Reynolds
11 was harmed, and Defendants' negligence was a substantial factor in causing that harm.

12 On information and belief, Defendants acted with malice, oppression, or fraud – including, but
13 not limited to, acting with willful and knowing disregard for the rights or safety of others, for
14 example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the
15 probable dangerous consequences of their conduct and deliberately failed to avoid those
16 consequences.

17 **Count V**

18 **Negligent Failure to Warn**

19 Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth
20 here in their entirety.

21 Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers,
22 marketers, advertisers, and/or sellers of the product Artificial Tears. As such, Defendants owed
23 Plaintiff a duty of care and a duty to assist and protect, including but not limited to a duty of
24 reasonable care to manufacture, test, design, distribute, package, label, supply, market, advertise,
25 and/or sell a product that was not unreasonably safe for human use.

26 Defendants had a duty to properly supervise, train, and monitor its agents, subcontractors, and
27 employees who prepared the product to ensure compliance with Defendants' operating standards and
28

1 to ensure compliance with all applicable regulations. Defendants failed to properly supervise, train,
2 and monitor these agents, subcontractors, and employees and thus breached that duty.

3 Defendants owed a duty to Plaintiff to comply with all statutory and regulatory provisions that
4 pertained or applied to the manufacture, testing, distribution, storage, labeling, and sale of its products,
5 including all applicable local, state, and federal health and safety regulations – as incorporated into
6 California law. Defendants failed to conform to this duty.

7 Defendants knew or reasonably should have known that the product was dangerous or was
8 likely to be dangerous when used or misused in a reasonably foreseeable manner. The product was or
9 became contaminated with *Pseudomonas aeruginosa*. Defendants knew or reasonably should have
10 known that users would not realize the danger. Defendants failed to adequately warn of the danger or
11 instruct on the safe use of the product. A reasonable manufacturer, designer, distributor, packager,
12 labeler, supplier, marketer, advertiser, and/or seller under the same or similar circumstances would
13 have warned of the danger or instructed on the safe use of the product.

14 Alternatively, Defendants failed to use any care or made an extreme departure from what a
15 reasonably careful person would do in the same situation to prevent harm to oneself or to others.

16 Mr. Reynolds was harmed. Defendants’ negligent failure to warn or instruct was a substantial
17 factor in causing the harm suffered by Mr. Reynolds.

18 On information and belief, Defendants acted with malice, oppression, or fraud – including, but
19 not limited to, acting with willful and knowing disregard for the rights or safety of others, for
20 example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the
21 probable dangerous consequences of their conduct and deliberately failed to avoid those
22 consequences.

23 **Count VI**

24 **Negligent Failure to Recall**

25 Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth
26 here in their entirety.

27 Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers,
28 marketers, advertisers, and/or sellers of the product Artificial Tears. As such, Defendants owed

1 Plaintiff a duty of care and a duty to assist and protect, including but not limited to a duty of
2 reasonable care to manufacture, test, design, distribute, package, label, supply, market, advertise,
3 and/or sell a product that was not unreasonably safe for human use.

4 Defendants knew or reasonably should have known that the product was dangerous or was
5 likely to be dangerous when used in a reasonably foreseeable manner. It was or became contaminated
6 with *Pseudomonas aeruginosa*. Defendants became aware of this defect after the product was sold.
7 Defendants failed to recall or warn of the danger of the product. A reasonable manufacturer, designer,
8 distributor, packager, labeler, supplier, marketer, advertiser, and/or seller under the same or similar
9 circumstances would have recalled the product. Alternatively, Defendants failed to use any care or
10 made an extreme departure from what a reasonably careful person would do in the same situation to
11 prevent harm to oneself or to others. Mr. Reynolds was harmed. Defendants' failure to recall the
12 product was a substantial factor in causing the harm suffered by Mr. Reynolds.

13 On information and belief, Defendants acted with malice, oppression, or fraud – including, but
14 not limited to, acting with willful and knowing disregard for the rights or safety of others, for
15 example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the
16 probable dangerous consequences of their conduct and deliberately failed to avoid those
17 consequences.

18 **Count VII**

19 **Negligence Per Se**

20 Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth
21 here in their entirety.

22 Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers,
23 marketers, advertisers, and/or sellers of the product Artificial Tears. Defendants were required to
24 follow the laws set forth in California's Sherman Food Drug and Cosmetics Laws. Such laws require,
25 for example, sanitary conditions at the manufacturing facility so that eye drops will be sterile and safe.
26 Cal. Health & Safety Code §§ 110111, 110105 (incorporating 21 U.S.C. Sec. 301 *et seq.* and
27 regulations, including but not limited to 21 C.F.R. Parts 200.50, 211 and 21 C.F.R. 820 *et seq.*).
28 Defendants violated the laws. Mr. Reynolds suffered harm. Mr. Reynolds was in the class of

1 persons intended to be protected by the laws that Defendants failed to follow. Defendants'
2 violations of the law were a substantial factor in bringing about the harm that Mr. Reynolds
3 suffered.

4 Plaintiff expressly disclaims that this – or any – of its causes of action are brought pursuant
5 to federal law. Plaintiff's claims are based on California law.

6 On information and belief, Defendants acted with malice, oppression, or fraud – including, but
7 not limited to, acting with willful and knowing disregard for the rights or safety of others, for
8 example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the
9 probable dangerous consequences of their conduct and deliberately failed to avoid those
10 consequences.

11 **Count VIII**

12 **Breach of Express Warranty**

13 Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth
14 here in their entirety.

15 Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers,
16 marketers, advertisers, and/or sellers of the product Artificial Tears. Defendants warranted to Mr.
17 Reynolds that the product was safe, effective, comparable to Refresh Plus Eye Drops, not adulterated
18 with harmful bacteria, could be used so that it would not become adulterated with harmful bacteria,
19 was prepared under sanitary conditions, and sterile. The product did not perform as promised; it was
20 or became contaminated with bacteria, and it was not comparable to Refresh Plus Eye Drops.
21 Defendants failed to make the product safe and effective. Mr. Reynolds was harmed. The failure of
22 the product to be as represented was a substantial factor in causing the harm that Mr. Reynolds
23 suffered.

24 On information and belief, Defendants acted with malice, oppression, or fraud – including, but
25 not limited to, acting with willful and knowing disregard for the rights or safety of others, for
26 example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the
27 probable dangerous consequences of their conduct and deliberately failed to avoid those
28 consequences.

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Count IX
Breach of Implied Warranty
[Common Law & CUCC § 1794(a)]

Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth here in their entirety.

Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers, marketers, advertisers, and/or sellers of the product Artificial Tears. Mr. Reynolds bought the product from Defendants. At the time of the purchase, Defendants were in the business of manufacturing, designing, distributing, packaging, labeling, supplying, marketing, advertising, and/or selling the product or held themselves out as having special knowledge or skill regarding these goods. Defendants warranted that the product was safe, effective, comparable to Refresh Plus Eye Drops, not adulterated with harmful bacteria, could be used so that it would not become adulterated with harmful bacteria, was prepared under sanitary conditions, and sterile. Instead, the product was or became contaminated with harmful bacteria. Thus, the product was not of the same quality as those generally acceptable in the trade; was not fit for the ordinary purposes for which such goods are used; was not adequately contained, packaged, or labeled; and did not measure up to the promises or facts stated on the container or label. Mr. Reynolds was harmed. The failure of the product to have the expected quality was a substantial factor in causing Mr. Reynold’s harm.

Alternatively, at the time of purchase, Defendants knew or had reason to know that Mr. Reynolds intended to use the product for a particular purpose and knew or had reason to know that Mr. Reynolds was relying on their skill and judgment to select or furnish a product that was suitable for the particular purpose. Mr. Reynolds justifiably relied on Defendants’ skill and judgment. The product was not suitable for the particular purpose because it was or became contaminated with bacteria. Mr. Reynolds was harmed. The failure of the product to be suitable was a substantial factor in causing the harm suffered by Mr. Reynolds.

On information and belief, Defendants acted with malice, oppression, or fraud – including, but not limited to, acting with willful and knowing disregard for the rights or safety of others, for example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the

1 probable dangerous consequences of their conduct and deliberately failed to avoid those
2 consequences.

3 **Count X**

4 **Fraud**

5 Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth
6 here in their entirety.

7 Defendants are the manufacturers, designers, distributors, packagers, labelers, suppliers,
8 marketers, advertisers, and/or sellers of the product Artificial Tears. Defendants represented that the
9 product was safe, effective, comparable to Refresh Plus Eye Drops, not adulterated with harmful
10 bacteria, could be used so that it would not become adulterated with harmful bacteria, was prepared
11 under sanitary conditions, and sterile. Instead, the product was or became contaminated with harmful
12 bacteria – or concealed information regarding the same. As such, Defendants’ representation was
13 false. Defendants knew that the representation was false when they made it, or they made the
14 representation recklessly and without regard for its truth. Alternatively, though Defendants may have
15 honestly believed that the representation was true, Defendants had no reasonable grounds for
16 believing the representation was true when they made it. Defendants intended for Mr. Reynolds to
17 rely on the representation, and he did reasonably rely on the representation. Mr. Reynolds was
18 harmed. His reliance on Defendants’ representation was a substantial factor in causing his harm.

19 On information and belief, Defendants acted with malice, oppression, or fraud – including, but
20 not limited to, acting with willful and knowing disregard for the rights or safety of others, for
21 example, including but not limited to, in failing to test for bacteria. Defendants had awareness of the
22 probable dangerous consequences of their conduct and deliberately failed to avoid those
23 consequences.

24 **Count XI**

25 **Loss of Consortium**

26 Mr. & Mrs. Reynolds incorporate the preceding paragraphs by reference as though set forth
27 here in their entirety.

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1 Mr. and Mrs. Reynolds are married and were married at all times relevant to this lawsuit.
2 Ms. Reynolds was harmed by the injury that Mr. Reynolds suffered because he used Artificial
3 Tears, as alleged herein. Ms. Reynolds suffered loss of love, companionship, comfort, care,
4 assistance, protection, affection (both physical and emotional), society, and moral support. For
5 example, the injuries have caused Mrs. Reynolds spend more time caretaking, thus putting undue
6 strain on the marital relationship. Seeing her husband suffer is emotionally taxing. Further, because
7 of Mr. Reynolds' injuries, they can no longer even sleep in the same bed for fear of exacerbating the
8 injuries. This loss of consortium was proximately caused by the injury that Mr. Reynolds suffered
9 when he used Artificial Tears.

10 DAMAGES

11 Mr. and Mrs. Reynolds incorporate the preceding paragraphs by reference as though set
12 forth here in their entirety. Defendants' conduct was a direct, proximate, and producing cause of
13 Plaintiff's injuries and damages, including but not limited to damages in the past and future, including
14 but not limited to: pain and suffering, mental anguish, emotional distress, physical impairment,
15 physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, travel and
16 travel-related expenses, emotional distress, lost wages, lost earning capacity, punitive and/or
17 exemplary damages and attorneys' fees (to the extent recoverable) and other general, special,
18 ordinary, incidental and consequential damages as would be anticipated to arise under the
19 circumstances. On information and belief, Defendants acted with malice, oppression, or fraud –
20 including, but not limited to, acting with willful and knowing disregard for the rights or safety of
21 others, for example, including but not limited to, in failing to test for bacteria. Defendants had
22 awareness of the probable dangerous consequences of their conduct and deliberately failed to avoid
23 those consequences.

1 **PRAYER FOR RELIEF**

2 WHEREFORE Plaintiffs pray for the following:

- 3 1. Past and future economic and non-economic damages, general and specific damages, in an
4 amount to be determined at trial;
- 5 2. Punitive damages;
- 6 3. Such other sums as shall be determined to fully and fairly compensate Plaintiffs for all
7 general, special, incidental, and consequential damages incurred or to be incurred as the direct
8 and proximate result of the acts and omissions of Defendants;
- 9 4. Costs, disbursements, and reasonable attorneys' fees to the extent allowed by law;
- 10 5. Pre- and post-judgment interest at the highest rate allowed by law;
- 11 6. That the Court award such other and further relief as it deems necessary and proper in the
12 circumstances; and
- 13 7. That the Court award Plaintiffs the opportunity to amend or modify the provisions of this
14 Complaint as necessary or appropriate after additional or further discovery is completed
15 in this matter, and after all appropriate parties have been served.

14 **JURY TRIAL DEMAND**

15 Plaintiffs demand a jury trial on all of the issues raised in this Complaint.

16
17 Dated: February 22, 2023

18
19 Respectfully submitted,

20 **THE LANIER LAW FIRM**

21 

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