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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

Anthony Barbera and Thalia Flores, on behalf of A.B, minor, Plaintiffs, v. ByHeart, Inc., a Delaware corporation, Defendant.	NO. 2:25-cv-03339-CKD **AMENDED COMPLAINT** **DEMAND FOR JURY TRIAL**

Plaintiffs, by and through undersigned counsel, and for their claims against the Defendant, allege as follows:

PARTIES

1. Plaintiffs Anthony Barbera and Thalia Flores reside in San Joaquin County, California. Plaintiffs are the parents and legal guardians of A.B.

2. Defendant ByHeart, Inc. is a corporation organized and existing under the laws of Delaware and conducts business throughout the United States, including the State of California. Its principal place of business is at 131 Varick Street, 11th Floor, New York, NY 10013.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332. The amount in controversy far exceeds $75,000 exclusive of interests and costs, and this is an action by individual Plaintiffs against a Defendant with its principal place of business in another state.

4. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district and because the Defendant was subject to personal jurisdiction in this judicial district at the time of the commencement of the action.

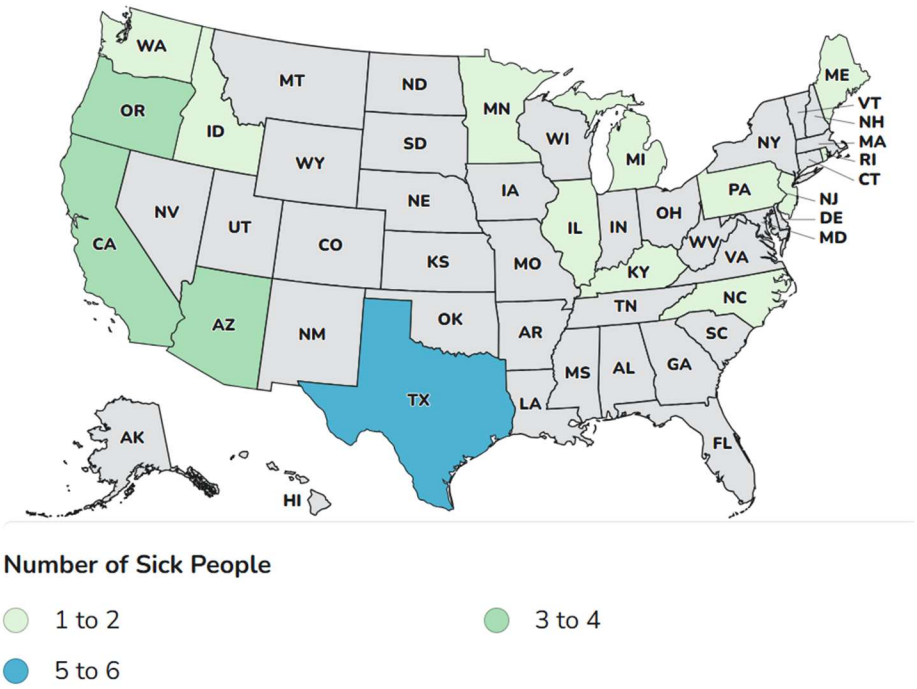
FACTUAL ALLEGATIONS

The ByHeart Botulism Outbreak

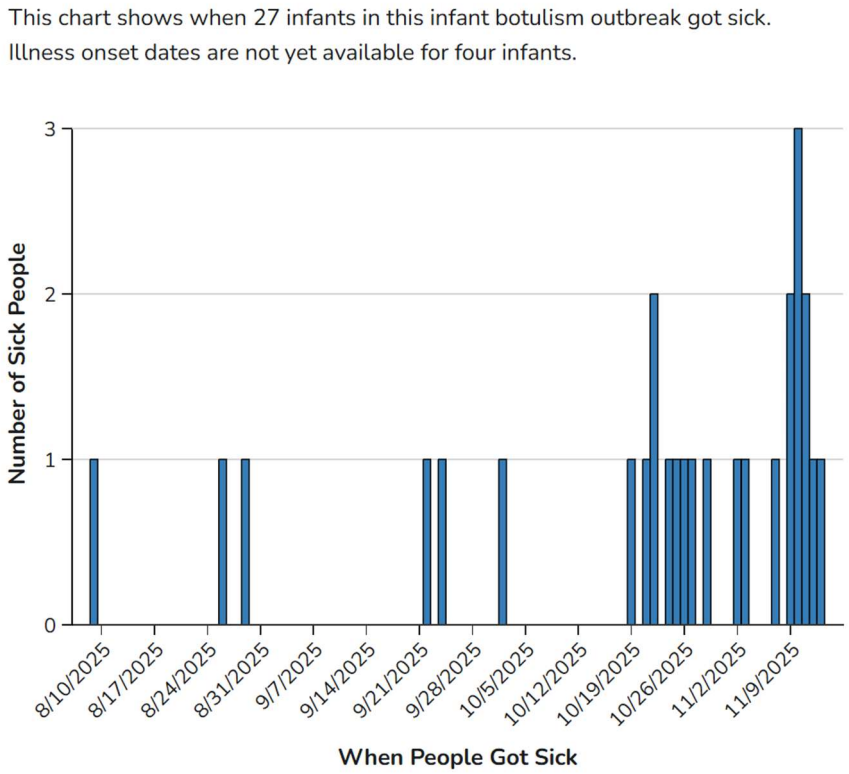
5. The United States Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), in collaboration with the California Department of Public Health (CDPH), Infant Botulism Treatment and Prevention Program (IBTPP), and other state and local partners, continue to investigate a multistate outbreak of infant botulism. Epidemiologic and laboratory data show that ByHeart Whole Nutrition infant formula might be contaminated with *Clostridium botulinum*, a bacterium which is causing infant illness in multiple regions of the country.

6. As of November 19, 2025, this outbreak includes thirty-one infants with suspected or confirmed infant botulism from fifteen states – Arizona 3, California 4, Idaho 1, Illinois 2, Kentucky 1, Maine 1, Michigan 1, Minnesota 2, North Carolina 2, New Jersey 1, Oregon

3, Pennsylvania 1, Rhode Island 1, Texas 6, Washington 2. Since the last update on November 14, 2025, eight new cases and two new states (Idaho and Maine) have been added to this investigation.



7. Laboratory confirmation for some cases is ongoing. For twenty-seven cases with illness onset information available, illnesses started on dates ranging from August 9 to November 13, 2025. All thirty-one infants were hospitalized and treated with BabyBIG®, a specific botulism immune globulin treatment. No deaths have been reported. For twenty-three infants with age and twenty-four infant with sex information available, they range in age from sixteen to 200 days and eleven (46%) are female.



8. As part of this investigation, officials in several states have collected leftover infant formula for testing. On November 8, 2025, preliminary laboratory results reported by the California Department of Public Health suggest the presence of the bacteria that produce botulinum toxin in an open can of ByHeart infant formula (lot 206VABP/251131P2) that was fed to an infant with infant botulism. Additional testing is underway, and results are expected in the coming weeks. Detection of *Clostridium botulinum* in infant formula is difficult, and a negative test result does not rule out the presence of the bacteria in the product.

9. As part of the investigation, ByHeart tested unopened infant formula products retained at its facility. According to ByHeart, third party laboratory analysis of some of these samples identified *Clostridium botulinum*, which produces the toxin that is making infants sick in this outbreak.

10. The FDA has received reports that recalled formula is still being found on store shelves in multiple states, including at multiple Walmart, Target, and Kroger locations, and at one or more Sprouts Organic Market, Safeway, Jewel-Osco, Shaw's, and Star Market locations.

11. Recalled products were sold through online marketplaces and were shipped to customers outside of the United States. Consumers worldwide should not use any ByHeart brand infant formula as all ByHeart products are included in the recall. Customer information provided by Amazon shows that a limited quantity of recalled ByHeart infant formula was distributed to Argentina, Brazil, Brunei, Canada, Chile, China, Colombia, Ecuador, Egypt, Hong Kong, Israel, Jamaica, Japan, Republic of Korea, Peru, Philippines, Romania, Singapore, South Africa, Thailand, and Virgin Islands.

ByHeart's History

12. ByHeart, Inc. is the parent company for three manufacturing / packaging facilities:

- Blendhouse LLC (Reading, PA), a manufacturing site.
- Blendhouse Allerton, LLC (Allerton, IA), a manufacturing site.
- Blendhouse Portland LLC (Portland, OR), a packaging site.

13. Of these, the Reading facility manufactures the infant formula base product, which is then blended and packaged at a different facility.

14. The Reading location achieved its FDA registration on April 28, 2022 and was subjected to an initial, and successful, FDA inspection in June 2022.

15. When child illnesses were linked to *Cronobacter sakazakii* and infant formula in 2022, the FDA chose to take an in-depth look at all the powdered infant formula manufacturing sites, including ByHeart's Reading facility. What they found was disturbing, resulting in both inspections being classified as "Official Action Indicated."

Inspection End Date February 17, 2023

16. The FDA investigation team uncovered numerous problems, which were summarized in a Warning Letter, dated August 30, 2023. These included:

- Lack of process control system, as evidenced by a finding of *Cronobacter sakazakii* in a batch of ByHeart Whole Nutrition Infant Formula finished product. The infant formula base which was incorporated into that batch had been manufactured in continuous process from July 13, 2022 through August 23, 2022.
- Discrepancy between company's root cause analysis of the *Cronobacter* contamination problem and the conclusion of the third-party lab, in which the company blamed lab error and the lab denied that they had erred.
- Multiple notifications from third party lab of positive *Cronobacter sakazakii* findings from July 25, 2022 through August 27, 2022 within the processing environment.

- Two water events, during which water leaked into the manufacturing areas from outside.

Inspection End Date January 19, 2024

17. The FDA conducted its next inspection eleven months later. According to information posted on the FDA's inspection data dashboard, investigators uncovered several serious problems. ByHeart:

- did not implement a system of production and in-process controls for an infant formula
- did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition
- did not minimize the potential for contamination of raw materials using appropriate measures
- did not ensure that all surfaces that contacted ingredients, in-process materials and infant formula were cleaned and sanitized and maintained to protect infant formula from being contaminated by any source
- did not monitor the temperature in a thermal processing equipment at a point where temperature control is necessary to prevent adulteration
- did not exclude pests from your food plant to protect against contamination of food

What is Infant *Botulism*?

18. Infant botulism is a rare but serious condition caused by the ingestion of *Clostridium botulinum* spores, which can grow in the intestines of infants (typically those under one year old) and produce a potent toxin. This condition usually occurs when infants consume contaminated foods, particularly honey, which is known to harbor spores. The spores can germinate in the immature gastrointestinal tract of infants, leading to toxin production and subsequent illness.

Symptoms

19. Symptoms of infant botulism typically appear between 12 to 36 hours after ingestion of the spores and may include:

- Constipation: Often the first sign, with stools that may become less frequent and harder.
- Weakness: A general lethargy or decreased muscle tone (hypotonia), often described as "floppy baby syndrome."
- Poor Feeding: Difficulty feeding or sucking.
- Cranial Nerve Dysfunction: This can lead to symptoms such as:
  - Weak cry or inadequate vocalization.
  - Difficulty swallowing.
  - Drooping eyelids or poor eye movement (ptosis).
- Respiratory Problems: In severe cases, difficulty breathing due to muscle weakness can occur.
- Weakness in Movement: Reduced ability to move arms and legs.
- Irritability or unusual crying.

Treatment

20. Hospitalization: Infants diagnosed with botulism often require hospitalization to monitor respiratory function and general health.

Supportive Care: Treatment primarily focuses on supportive measures such as:

- Nutritional support, often via intravenous fluids or feeding tubes if necessary.
- Monitoring and management of respiratory function; in some cases, mechanical ventilation may be required if breathing difficulties arise.

- *Botulism* Immune Globulin (BIG): In the United States, a specific treatment called BabyBIG (Botulism Immune Globulin) is administered to infants diagnosed with botulism. This treatment helps to neutralize the *Botulinum* toxin and can reduce the duration and severity of symptoms.
- Antibiotics: Antibiotics are not typically used for treating infant botulism as they do not affect the toxin once produced and can also promote toxin production by encouraging the growth of bacteria.

Long-Term Prognosis

21. The prognosis for infants with botulism is generally good, especially with early diagnosis and appropriate treatment. Most infants recover fully within a few weeks or months, but the recovery time can vary.

22. Recovery Time: Symptoms usually resolve over several weeks, but in some cases, full recovery can take months, especially regarding muscle strength and tone.

23. No Long-Term Disabilities: Most children do not experience long-term complications or disabilities if treated promptly and effectively.

24. Follow-Up: Regular follow-ups may be necessary to ensure continued recovery and to monitor for any residual muscle weakness.

A.B..'s *Botulism* Illness

25. A.B. was born on September 29, 2025, at St. Joseph's Medical Center located in Stockton, California as the first child of parents Anthony Barbera (father) and Thalia Flores (mother).

26. Throughout August 2025, A.B.'s parents purchased five 24 ounce ByHeart cans and one ByHeart anywhere pack.

Purchase Date	Product	Retailer
August 20, 2025	24oz Can 8.4oz Anywhere Pack	ByHeart, Inc *Ordered online at ByHeart.com*
August 23, 2025	24oz Can 24oz Can	Target – *Purchased in-store by A.B.'s parents:*
August 29, 2025	24oz Can 24oz Can	Target *Purchased in-store by A.B.'s parents:*

First Month Home - October 2, 2025 to October 22, 2025

27. Upon his arrival home, A.B. was fed ByHeart infant formula exclusively. The formula was prepared using distilled water. All of his bottles were washed and sterilized after each use.

28. As the month of October progressed, A.B. would consume 3 to 4 ounces of mixed formula (1.5 to 2 scoops of ByHeart powdered formula) consistently every 3 hours.

29. On October 22nd, A.B. was seen by one of his pediatricians for a routine check-up and procedure. A full physical examination was performed and no issues or concerns were identified. A.B.'s weight was measured at 9 pounds.

Symptom Onset - October 23, 2025 to October 24, 2025

30. On October 23rd, A.B.'s parents started noticing that A.B. was taking longer to finish his usual 3-ounce bottle. By the evening, he was barely consuming a 2 ounce bottle every 3 hours.

31. On October 24th, A.B.'s intake had dropped to less than 1 ounce every 3 hours; his cries were less frequent and weaker than normal, and his urine output was decreasing.

Emergency Room - October 25, 2025

32. On the morning of October 25th, A.B.'s parents called his pediatrician who advised them to seek emergency medical attention. Around 10:30 am, they arrived at the St. Joseph's Medical Center Emergency Room in Stockton, California.

33. The emergency room physicians performed a physical examination of A.B. and noted his

weak cry, his inability latch onto a bottle, and his dehydration. The decision was made to admit A.B. to the hospital overnight for further observation.

34. As the evening progressed A.B.'s condition deteriorated significantly. He became increasingly lethargic and less responsive. Multiple nurses attempted to feed him, but he was only able to consume between 5ml to 13ml of mixed formula each feeding.

Neonatal Intensive Care Unit (NICU) Day 1 - October 26, 2025

35. During the early morning hours of October 26th, a comprehensive examination was performed by a pediatric critical care physician. Key findings from the physician's exam are as follows:

- A.B.'s mother stated that A.B's present cry, facial expression, alertness, body habitus, strength are significantly depressed, even compared to when she brought A.B to the emergency room on the morning of October 25th.
- Exam showed tachycardia at rest (160's, occasionally over 170).
- Neurological: With much stimulation (including toe pinching), the physician woke A.B. enough to get him to make repetitive weak moaning cry. A.B. waved his arms at bed level (very little strength against gravity) and withdrew feet from painful stimuli, demonstrated weak recoil strength, demonstrated completely floppy head, trunk, and lower extremities when raised by his arms or when supported in sitting or standing positions. Facial muscles are symmetric but also lax, especially around the mouth, which hangs open when A.B. is held upright. A.B. is struggling to open his eyes and A.B.'s mother states he is unable to open his eyes fully. A.B.'s suck is very weak and poorly effective. A.B.'s muscle strength rating for his upper extremities and lower extremities is a ~3/5 and a 2/5, respectively.

- Bilateral eye crusting. Dry eyes with crusting could be indicative of being unable to shut eyes completely due to muscle weakness.

36. Later that morning the medical team met with A.B.'s parents to discuss their collective assessments. The medical team indicated the most probable diagnosis was botulism, however they could not rule out various other differential diagnoses including, but not limited to, spinal muscular atrophy (SMA Type 1) or a metabolic disorder. A.B's medical team consulted with a specialist at the California Department of Public Health's Infant Botulism Treatment and Prevention Program, who advised A.B. be treated immediately with the BabyBig antitoxin.

37. At this point, A.B.'s parents were frightened and very concerned for A.B's health given the severity of the prognosis for botulism and the various other differential diagnoses indicated by the medical team. A.B.'s parents were especially concerned A.B. might have spinal muscular atrophy given the similarities of spinal muscular atrophy's clinical presentation to amyotrophic lateral sclerosis which A.B.'s maternal grandmother was diagnosed with earlier in the year. Upon the advice and recommendation of A.B.'s medical team, A.B.'s parents made the decision to initiate the order for the BabyBig antitoxin and proceed with further testing to rule out all other differential diagnoses.

38. Given the severity of these diagnoses coupled with A.B.'s declining condition, the decision was made to transfer him to the neonatal intensive care unit (NICU). A myriad of diagnostic tests and supportive therapies were executed during A.B.'s first day in the NICU, including, but not limited to:

- Encephalogram of A.B.'s brain
- Echocardiogram of A.B's heart

- X-ray of A.B's chest and abdomen
- Multiple blood tests
- Urine and tissue cultures
- A high-flow nasal cannula was inserted in A.B's nose to deliver supplemental oxygen

39. The abdomen X-ray indicated that A.B. was severely constipated. Despite the constipation a stool sample needed to be obtained and sent for laboratory testing in order to confirm the botulism diagnosis.

40. For A.B.'s parents, it was heartbreaking to watch A.B.'s medical team administer multiple sterile, non-bacteriostatic water enemas throughout the day and A.B. barely having the strength to respond. By late Sunday, A.B's medical team was finally able to secure a small stool specimen, which was sent to the California Department of Public Health for testing.

41. Around 11:00 PM on October 26th, the BabyBIG antitoxin arrived and was administered to A.B. By this point, A.B. was in an extremely fragile state as he was no longer eating, connected to multiple IV lines and monitors, and so weak that he could no longer cry. Watching A.B. in this condition was agonizing for A.B.'s parents; they felt utterly helpless and could only cling to the hope that the BabyBig antitoxin would save him.

NICU Day 2 - October 27, 2025

42. A.B.'s condition began to marginally improve by the evening of October 27th. A feeding tube was inserted through his mouth as a precaution, and he remained constipated with no bowel movements.

43. A.B.'s parents were contacted by the California Department of Public Health, for a background interview to determine the source of A.B.'s exposure to botulism.

NICU Day 3 - October 28, 2025

44. A.B.'s condition continued to show small signs of improvement, and he started to fully open his eyes.

45. A.B. continued to be extremely constipated with no bowel movements. At the end of the day, A.B.'s parents were still awaiting laboratory test results to confirm A.B.'s diagnosis of either botulism, SMA Type 1, or a metabolic disorder.

NICU Day 4 - October 29, 2025

46. On the morning of October 29th, A.B.'s parents were notified that A.B's stool specimen tested positive for botulism type A.

47. As the day progressed, the doctor discontinued the supplemental oxygen delivered through A.B.'s high-flow nasal cannula. A.B.'s weight was measured at 8 pounds 10 ounces which was a concerning decrease from the 9 pounds he weighed one week prior.

NICU Day 5 - October 30, 2025

48. On October 30th, A.B.'s parents were contacted again by an epidemiologist with the California Department of Public Health. The epidemiologist indicated the California Department of Public Health would be interested in testing all of A.B.'s open cans of ByHeart formula for botulism. A.B.'s parents collected and provided the two opened cans of ByHeart formula to the California Department of Public Health (CDPH) as indicated in the table below.

Product	Usage	Batch Number / Expiration	Possession
24oz Can	Opened – approximately 20% of formula remaining	Use By 01 Dec 2026 BYHEART 206VABP 13:33:36 251261P2	Received by CDPH on November 4, 2025
24oz Can	Opened – approximately	Use By 01 Dec 2026 BYHEART 206VABP	Received by CDPH on November 4, 2025

	80% of formula remaining	12:50:58 251131P2	
24oz Can	Unopened – foil seal intact	Use By 01 Dec 2026 BYHEART 206VABP 20:52:43 251131P2	Currently in A.B.'s parents' possession

NICU Day 6 - October 31, 2025 to NICU Day 12 – November 6, 2025

49. Each day A.B. continued to show small, steady signs of improvement.

Post Discharge - November 7, 2025 to Present Date

50. It is still too early to say what the short-term and long-term impacts of A.B.'s recovery will be. He continues to be constipated and has irregular bowel movements. He is also slowly building back up to 3-ounce bottles.

51. Overall, this experience shattered the trust A.B.'s parents placed in the ByHeart brand which promised safety, quality, and transparency. They state, "We believed we were making a well-informed choice by feeding [A.B.] ByHeart, but instead, we feel like we have inadvertently participated in the poisoning of our baby. No family should ever have to endure this kind of pain, and no baby should suffer severe medical consequences from ingesting contaminated formula. We hope sharing [A.B.]'s story will ensure accountability and to protect other families from experiencing what we went through."

CAUSES OF ACTION

COUNT ONE

STRICT PRODUCTS LIABILITY

52. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–51.

53. The defendant was always relevant hereto the manufacturer and seller of the adulterated food product that is the subject of the action.

54. The adulterated food product that the defendant manufactured, distributed, and/or sold was, at the time it left the defendant's control, defective and unreasonably dangerous for its ordinary and expected use because it contained botulism, a deadly pathogen.

55. The adulterated food product that the defendant manufactured, distributed, and/or sold was delivered to the plaintiffs without any change in its defective condition. The adulterated food product that the defendant manufactured, distributed, and/or sold was used in the manner expected and intended, and was consumed by the plaintiffs.

56. The defendant owed a duty of care to the plaintiffs to design, manufacture, and/or sell food that was not adulterated, which was fit for human consumption, that was reasonably safe in construction, and that was free of pathogenic bacteria or other substances injurious to human health. The defendant breached this duty.

57. The defendant owned a duty of care to the plaintiffs to design, prepare, serve, and sell food that was fit for human consumption, and that was safe to the extent contemplated by a reasonable consumer. The defendant breached this duty.

58. The plaintiffs suffered injury and damages as a direct and proximate result of the defective and unreasonably dangerous condition of the adulterated food product that the defendant manufactured, distributed, and/or sold.

COUNT TWO

BREACH OF WARRANTY

59. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–58.

60. The defendant is liable to the plaintiffs for breaching express and implied warranties that it made regarding the adulterated food product that the plaintiffs purchased. These express and implied warranties included the implied warranties of merchantability and/or fitness for a

particular use. Specifically, the defendant expressly warranted, through its sale of food to the public and by the statements and conduct of its employees and agents, that the food it prepared and sold was fit for human consumption and not otherwise adulterated or injurious to health.

61. The plaintiffs allege that the botulism-contaminated food that the defendant sold to them would not pass without exception in the trade and was therefore in breach of the implied warranty of merchantability.

62. The plaintiffs allege that the botulism-contaminated food that the defendant sold to them was not fit for the uses and purposes intended, *i.e.* human consumption, and that this product was therefore in breach of the implied warranty of fitness for its intended use.

63. As a direct and proximate cause of the defendant's breach of warranties, as set forth above, the plaintiffs sustained injuries and damages in an amount to be determined at trial.

COUNT THREE

NEGLIGENCE

64. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–63.

65. The defendant owed to the plaintiffs a duty to use reasonable care in the manufacture, distribution, and sale of its food product, the breach of which duty would have prevented or eliminated the risk that the defendant's food products would become contaminated with botulism or any other dangerous pathogen. The defendant breached this duty.

66. The defendant had a duty to comply with all statutes, laws, regulations, or safety codes pertaining to the manufacture, distribution, storage, and sale of its food product, but failed to do so, and was therefore negligent. The plaintiffs are among the class of persons designed to be protected by these statutes, laws, regulations, safety codes or provision pertaining to the manufacture, distribution, storage, and sale of similar food products.

67. The defendant had a duty to properly supervise, train, and monitor its respective employees, and to ensure their compliance with all applicable statutes, laws, regulations, or safety codes pertaining to the manufacture, distribution, storage, and sale of similar food products, but it failed to do so, and was therefore negligent.

68. The defendant had a duty to use ingredients, supplies, and other constituent materials that were reasonably safe, wholesome, free of defects, and that otherwise complied with applicable federal, state, and local laws, ordinances and regulations, and that were clean, free from adulteration, and safe for human consumption, but it failed to do so and was therefore negligent.

69. As a direct and proximate result of the defendant's acts of negligence, the plaintiffs sustained injuries and damages in an amount to be determined at trial.

COUNT FOUR

NEGLIGENCE *PER SE*

70. Plaintiffs incorporate herein by reference the allegations in paragraphs 1-69.

71. The defendant had a duty to comply with all applicable state and federal regulations intended to ensure the purity and safety of its food product, including the requirements of the Federal Food, Drug and Cosmetics Act (21 U.S.C. § 301 *et seq*.), and its California equivalents, including but not limited to the Sherman Food, Drug, and Cosmetic Laws (Cal. Health & Safety Code §§ 109875 *et seq.*).

72. The defendant failed to comply with the provisions of the health and safety acts identified above, and, as a result, was negligent *per se* in its manufacture, distribution, and sale of food adulterated with botulism, a deadly pathogen.

73. As a direct and proximate result of conduct by the defendant that was negligent *per se*, the plaintiffs sustained injury and damages in an amount to be determined at trial.

DAMAGES

74. The plaintiffs have suffered general, special, incidental, and consequential damages as the direct and proximate result of the acts and omissions of the defendant, in an amount that shall be fully proven at the time of trial. These damages include but are not limited to damages for general pain and suffering; damages for loss of enjoyment of life, both past and future; medical and medical related expenses, both past and future; emotional distress, past and future; pharmaceutical expenses, past and future; and all other ordinary, incidental, or consequential damages that would or could be reasonably anticipated to arise under the circumstances.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

75. That the Court award Plaintiffs judgment against Defendant, in such sums as shall be determined to fully and fairly compensate the Plaintiffs for all general, special, incidental and consequential damages incurred, or to be incurred, as the direct and proximate result of the acts and omissions of Defendant, in an amount to be proven at trial.

76. That the Court award Plaintiffs their costs, disbursements and reasonable attorneys' fees incurred.

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

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

JURY DEMAND

79. Plaintiffs demand a trial by jury on all issues so triable with the maximum number of jurors permitted by law.

RESPECTFULLY SUBMITTED this 21st day of November 2025.

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CERTIFICATE OF SERVICE

I hereby certify that on the 21st day of November 2025, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing.

/s/ Trevor Quirk