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IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF ARIZONA

Stephen Dexter and Yurany Dexter, on behalf of E.D, minor, Plaintiffs, v. ByHeart, Inc., a Delaware corporation, Defendant.	NO. 3:25-cv-08241-MTL **PLAINTIFFS' FIRST AMENDED COMPLAINT** (Assigned to the Honorable Michael T. Liburdi) **DEMAND FOR JURY TRIAL**

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

PARTIES

1. Plaintiffs Stephen Dexter and Yurany Dexter reside in Coconino County, Arizona. Plaintiffs are the parents and legal guardians of E.D.

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 Arizona. 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.

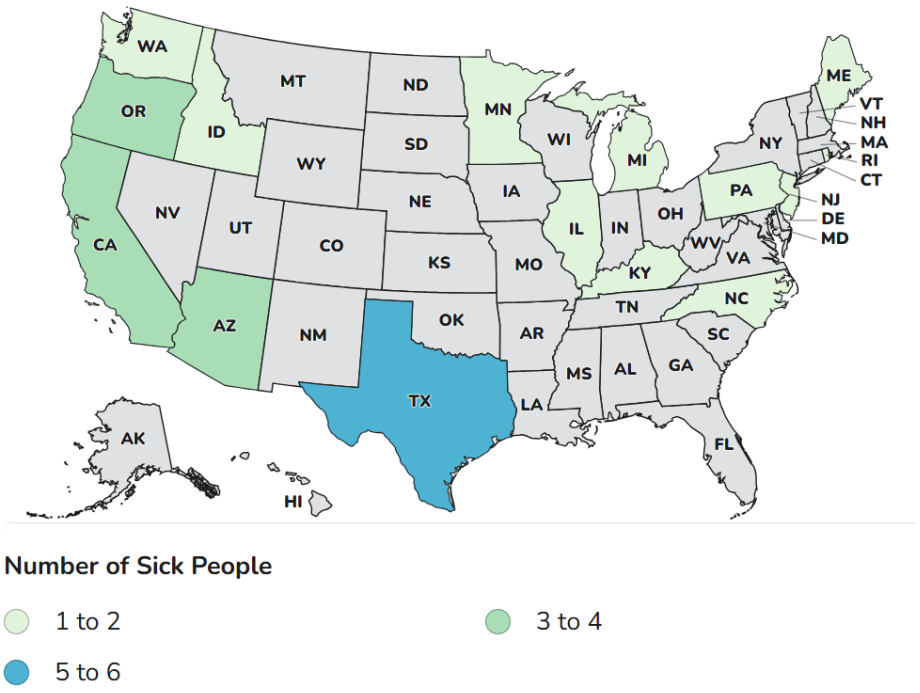
4. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district and because the Defendant was subject to personal jurisdiction in this judicial district at the time of the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

FACTUAL ALLEGATIONS

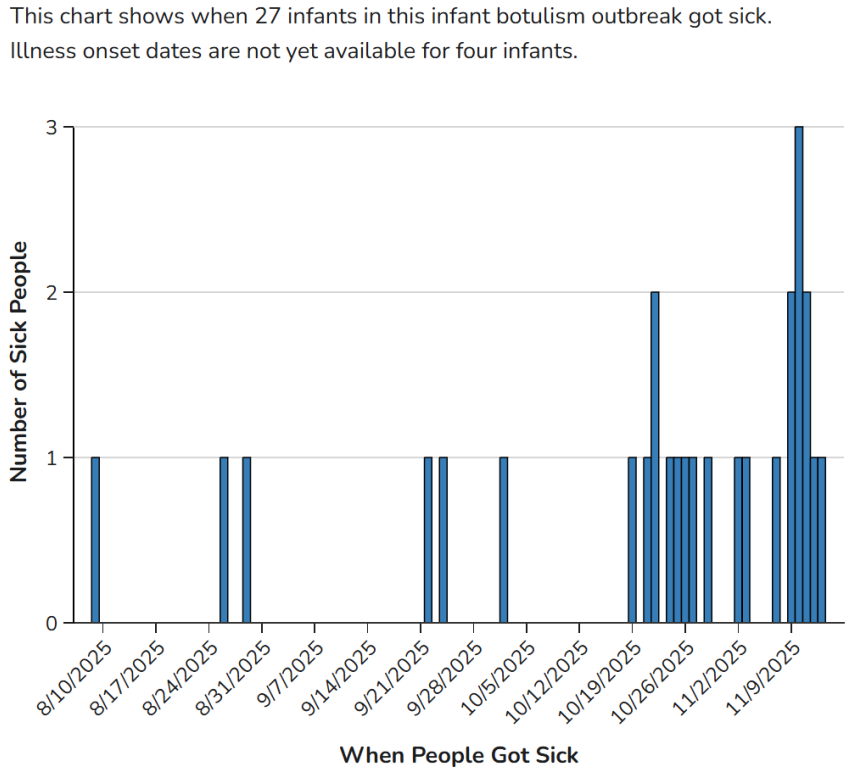
The ByHeart Botulism Outbreak

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:

- 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.

21. 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

22. 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.

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

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

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

E.D.'s *Botulism* Illness

25. Plaintiff's purchased Defendant's product directly online from defendant and from retailers in Coconino County. Plaintiffs fed E.D. the infant formula from July 2025 until E.D. developed signs of Infant *Botulism*.

26. E.D, was born healthy, alert, and happy on July 5th, 2025. On July 8, 2025, Plaintiffs decided to introduce formula as a supplement to breast milk. Plaintiffs went to Whole Foods thinking they might find a more natural option there. Looking at the available choices, they chose the ByHeart brand because of the healthy-looking labeling, top shelf placement, and higher price.

27. On August 21, 2025, however, E.D. began having stomach discomfort and gas. Over the next week, E.D.'s feeding steadily decreased. She appeared hungry but would refuse to eat as soon as the bottle touched her lips. Eventually, she stopped eating altogether.

28. Plaintiffs brought her to the doctor, but no cause of the symptoms was identified. When white patches appeared in her mouth, Plaintiffs returned and E.D. was diagnosed with thrush. She began treatment, but her weakness continued. Over the next few days, she struggled to swallow, and Plaintiffs began feeding her by syringe, hoping to get some nutrition into her.

29. Early in the morning on August 31, 2025, E.D. made a sound suggesting aspiration during feeding, and later that day, Plaintiffs could not wake her. At that point, Plaintiffs went to the emergency room.

30. E.D. was admitted to Flagstaff Medical Center on August 31, 2025 and was transported by air ambulance to Phoenix Children's Hospital on the night of September 2, 2025. Just before the medical flight, the doctor told Plaintiffs that, while *Botulism* was a possibility, it was so rare that he believed a form of muscular dystrophy was more likely.

31. At Phoenix Children's Pediatric Intensive Care Unit, E.D. received IV fluids, a feeding tube, the BabyBIG antitoxin, and occupational, physical, and speech therapy. During this time, she could not suck, swallow, smile, hold her head up, move her limbs normally, or cry with normal strength. Her cry was faint and weak. Plaintiffs feared E.D. might die or might never recover fully.

32. E.D. was discharged on September 13, 2025 with a feeding tube. Plaintiffs are still working for E.D. to regain strength and digestive function. E.D. continues to experience constipation and gas. Plaintiffs do not yet know whether there will be long-term effects, and that uncertainty remains with Plaintiffs every day.

33. During the hospital stay, E.D. would grasp her mother's finger constantly. It seemed to be her only source of security. Now that Plaintiffs are home, E.D. cannot be left alone while awake. If E.D. cannot see Plaintiffs, she cries immediately. The need for constant reassurance has changed the rhythm of daily life. Even routine tasks, such as preparing a meal or walking into another room, must now be planned around keeping E.D. close. Plaintiffs incurred hundreds of thousands in medical expenses. Local, State and Federal Health Authorities have confirmed to link between E.D.'s illness and the consumption of ByHeart's product.

CAUSES OF ACTION

COUNT ONE
STRICT PRODUCTS LIABILITY

34. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–33.

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

36. 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.

37. 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.

38. 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.

39. 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.

40. 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

41. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–40.

42. 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.

43. 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.

44. 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.

45. 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

46. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–45.

47. 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.

48. 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.

49. 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.

50. 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.

51. 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*

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

53. 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 the Arizona adulterated food statutes (A.R.S. § 36-901 *et seq*.).

54. 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.

55. 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

56. 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; travel and travel-related expenses, 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:

A. 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.

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

C. 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

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

JURY DEMAND

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.

O'STEEN MACLEOD COMBS PLC

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Attorneys for Plaintiffs

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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/ Jonathan V. O'Steen