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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

Madison Wescott and Tyler Wescott, individually and on behalf of K.W, a minor, Plaintiffs, v. ByHeart, Inc., a Delaware corporation; Target Corporation, a Minnesota corporation; Organic West, Inc., a California corporation; and Dairy Farmers of America, Inc., a Kansas corporation, Defendants.	NO. 3:25-cv-06039 **THIRD AMENDED COMPLAINT** **DEMAND FOR JURY TRIAL**

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

PARTIES

1. Plaintiffs Madison Wescott and Tyler Wescott reside in Eatonville, Pierce County, Washington. Plaintiffs are the parents and legal guardians of K.W.

2. Defendant ByHeart, Inc. ("ByHeart") is a for-profit corporation organized and existing under the laws of the State of Delaware. It conducts business throughout the United States, including in the State of Washington. Its principal place of business is located at 131 Varick Street, 11th Floor, New York, NY 10013.

3. Defendant Target Corporation ("Target") is a publicly traded, for-profit corporation organized and existing under the laws of the State of Minnesota. It conducts business throughout the United States, including in the State of Washington. One of its Washington state retail locations is 10302 156th St. E, Puyallup, WA 98374. Its principal place of business is located at 1000 Nicollet Mall, Minneapolis, MN 55403.

4. Defendant Organic West, Inc. ("Organic West") is a for-profit corporation organized and existing under the laws of the State of California. It conducts business throughout the United States, including in the State of Washington. Its principal place of business is located at 1252 Van Ryn Avenue, Manteca, CA 95336.

5. Defendant Dairy Farmers of America, Inc., ("Dairy Farmers of America") is a for-profit corporation and global dairy cooperative organized and existing under the laws of the State of Kansas. It conducts business throughout the United States, including in the State of Washington. Its principal place of business is located at 1405 N. 98th Street, Kansas City, KS 66111.

6. At all relevant times, Defendants ByHeart, Target, Organic West, and Dairy Farmers of America were engaged in the business of manufacturing, producing, processing, distributing,

marketing, supplying, and/or selling the subject infant formula and/or its component ingredients that were contaminated with *Clostridium botulinum*.

JURISDICTION AND VENUE

7. 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 Defendants with their principal places of business in other states.

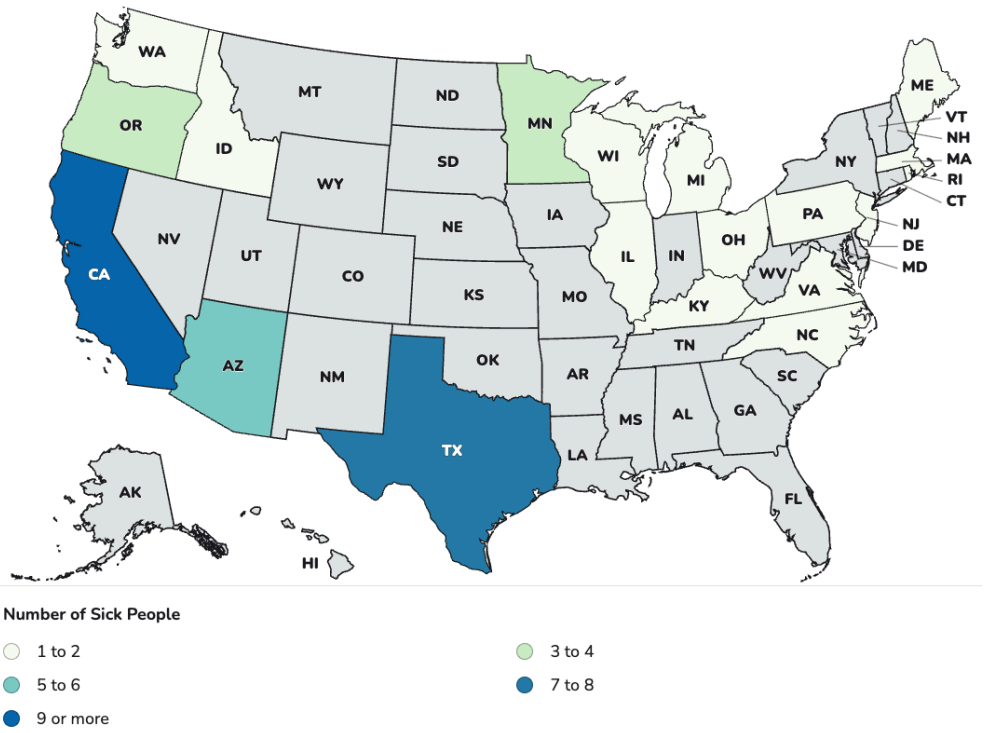
8. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district and because Defendants were subject to personal jurisdiction in this judicial district at the time of the commencement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

FACTUAL ALLEGATIONS

The ByHeart Botulism Outbreak

9. 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 is the source of this multistate outbreak of infant botulism.

10. As of December 17, 2025, this outbreak includes fifty-one infants with suspected or confirmed infant botulism from nineteen states – Arizona 5, California 12, Idaho 2, Illinois 2, Kentucky 1, Massachusetts 2, Maine 1, Michigan 1, Minnesota 3, North Carolina 2, New Jersey 1, Ohio 1, Oregon 4, Pennsylvania 1, Rhode Island 1, Texas 8, Virginia 1, Washington 2, and Wisconsin 1.



11. Per the FDA's December 17, 2025 Update: "All ByHeart infant formula products have been recalled, and these products should not be available for sale in stores or online. This includes all formula cans and single-serve 'anywhere pack' sticks."

12. On December 12, 2025, FDA sent warning letters to four major retailers, including Target Corporation, for failing to remove recalled ByHeart infant formula from their store shelves despite being notified of the recall.

13. On December 15, 2025, FDA issued a press release and reminded industry about its legal duties regarding food recalls under the Federal Food Drug and Cosmetic Act. FDA asked companies to follow best practices when carrying out recalls.

14. Despite these repeated notifications, the FDA has received reports that recalled formula is still being found on store shelves in multiple states, including at multiple Walmart, Target,

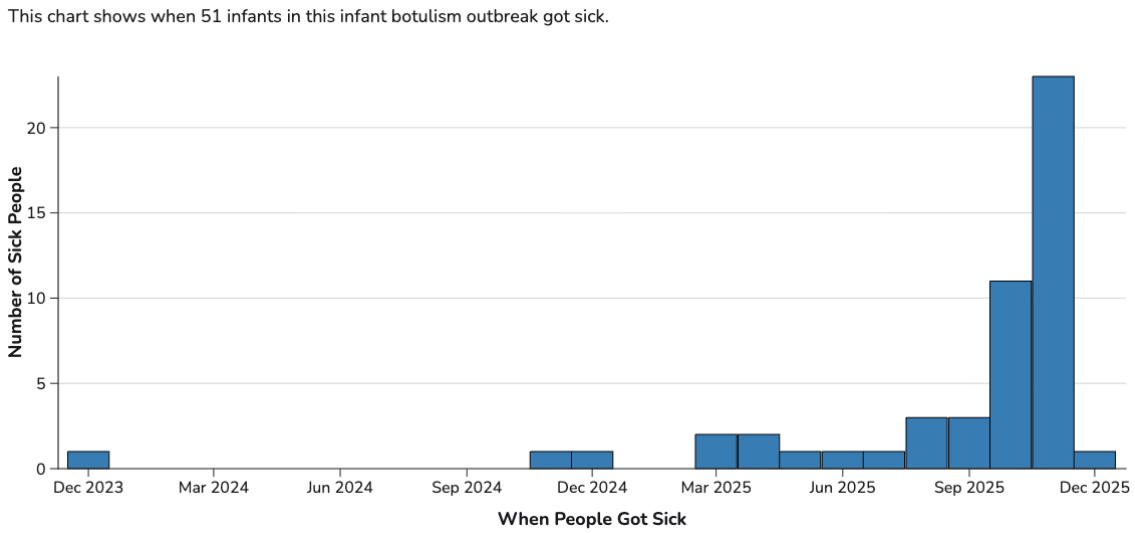
and Kroger locations, and at one or more Sprouts Organic Market, Safeway, Jewel-Osco, Shaw's, and Star Market locations.

15. Specifically, on November 19, 2025, the FDA held a call with Defendant Target Corporation to discuss the ineffectiveness of the recall within its stores. During this discussion, FDA requested actions Target Corporation was prepared to implement to ensure recalled product was no longer available for purchase at Target stores nationwide.

16. Despite follow-up emails from the FDA on November 20, 21, 24, and 26, 2025 and December 1, 3, and 8, 2025, Target Corporation did not provide FDA with any information demonstrating that corrective actions to effectuate the recall were implemented throughout Target Corporation to prevent adulterated food from being received in interstate commerce and subsequently offered for sale.

17. The inadequacy of Target Corporation's recall response was further demonstrated on November 20, 2025, when Arkansas state partners observed ByHeart Whole Nutrition Infant Formula single-serve "anywhere pack" sticks on a Target store shelf with promotional "Sale!" signage offering a $2.00 discount on the recalled formula from November 16 to November 22, 2025. This observation indicates not only Target's failure to remove recalled infant formula from store shelves, but the *active promotion and discounted sale* of recalled infant formula product implicated in an infant botulism outbreak.

18. Laboratory confirmation for some cases is ongoing. Illnesses started on dates ranging from December 24, 2023 to December 1, 2025. All 51 infants were hospitalized. No deaths have been reported to date. The infants range in age from sixteen to 264 days and 22 (43%) are female.



19. As part of this investigation, product sampling and testing is being conducted by FDA, CDC, state partners, and ByHeart. On December 3, 2025, six samples of ByHeart infant formula tested positive for *Clostridium botulinum*. These six samples were taken from two batches (Batch 251261P2 and Batch 251131P2), which were both included in the initial product recall.

Sample Collected/Analyzed by	Product	Test Result	Toxin Type
CDPH	Opened container of ByHeart Infant Formula (Batch No. 251131P2)	**Positive**	Type A
ByHeart	ByHeart Infant Formula (Batch/Batches Not Reported)	Positive	Type A
ByHeart	ByHeart Infant Formula (Batch/Batches Not Reported)	Positive	Type A
ByHeart	ByHeart Infant Formula (Batch/Batches Not Reported)	Positive	Type A
ByHeart	ByHeart Infant Formula (Batch/Batches Not Reported)	Positive	Type A
ByHeart	ByHeart Infant Formula (Batch/Batches Not Reported)	Positive	Type A

20. 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 the British Virgin Islands.

21. As of January 23, 2026, the FDA confirmed that two more samples collected during its investigation tested positive for *Clostridium botulinum* type A. One such sample was an unopened, finished product sample of ByHeart powdered infant formula. Whole genome sequencing (WGS) analysis demonstrated that the *Clostridium botulinum* detected in the finished product sample was a genetic match to a clinical isolate obtained from an infant sickened in the outbreak.

22. The *Clostridium botulinum* detected in the finished ByHeart infant formula sample also genetically matched two isolates obtained from samples of whole milk powder—an ingredient used by ByHeart in the manufacture of its powdered infant formula—which were collected and tested by ByHeart as part of its internal investigation.

23. A second whole milk powder sample was collected by the FDA from a supplier to ByHeart and analyzed by the New York Department of Health's Wadsworth Laboratory. WGS analysis showed that the *Clostridium botulinum* found in that sample of whole milk powder is a genetic match to the *Clostridium botulinum* detected in the finished product sample of ByHeart's infant formula.

24. The whole milk powder sample collected by the FDA that tested positive for *Clostridium botulinum* type A was made from whole milk supplied by Defendant Organic West.

25. Organic West transported whole milk to Defendant Dairy Farmers of America for processing into whole milk powder at a facility owned and operated by Dairy Farmers of America in Fallon, Nevada.

26. Following the processing of whole milk into whole milk powder, Dairy Farmers of America delivered, shipped, and/or sold the whole milk powder back to Organic West, which subsequently distributed and/or sold it to ByHeart for use as an ingredient in ByHeart's powdered infant formula.

27. Organic West has halted the sale of the whole milk powder used in any product intended for babies and children.

ByHeart's History

28. 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.

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

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

31. Two subsequent FDA inspections, however, found multiple problems. 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 two inspections—one in February 2023 and another in January 2024—being classified as "Official Action Indicated."

Inspection – End Date February 17, 2023

32. 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

33. 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*?

34. 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

35. 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

36. 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

37. 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.

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

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

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

K.W.'s *Botulism* Illness

41. K.W. was born on September 13, 2025. Beginning on October 22, 2025, Plaintiffs fed K.W. ByHeart infant formula in amounts of approximately four ounces per day.

42. K.W.'s parents purchased the ByHeart formula from the Target store located at 10302 156th St. E, Puyallup, Washington 98374.

43. Beginning in early November 2025, Plaintiffs observed significant changes in K.W.'s behavior and health. She experienced difficulty feeding, frequently choking and spilling milk from her mouth, suffered from chronic constipation that required suppositories, and exhibited extreme fatigue, often sleeping for ten-hour stretches without waking.

44. On November 7, 2025, K.W. was diagnosed with severe tongue and lip tie. She underwent laser treatment to correct both conditions on November 11, 2025.

45. Following the procedure, K.W. was unable to latch during breastfeeding, which was a marked change from her prior feeding behavior. Plaintiffs continued to bottle-feed her, but her symptoms did not subside.

46. On November 13, 2025, her two-month birthday, Plaintiffs brought her to the emergency room, where she was immediately admitted for evaluation.

47. Plaintiffs had become aware of the ByHeart infant formula recall through a notice from Target regarding the formula they had purchased. Upon arrival at the hospital, physicians researched the recall and contacted the CDC and local health department. The medical team determined that K.W. required treatment for botulism and admitted her to the pediatric unit.

48. Within four hours, K.W. underwent extensive medical interventions, including placement of an intravenous line, bloodwork, transfer to another floor, insertion of a feeding tube, and three X-rays. Plaintiffs anxiously awaited the arrival of the botulism antitoxin from California. Hospital staff warned that without timely administration, K.W. could experience paralysis and lose the ability to breathe independently. Plaintiffs remained at her bedside overnight, watching over her and experiencing significant emotional distress.

49. K.W. continued to cry throughout the night. At approximately 3:00 a.m. on November 14, 2025, Plaintiffs were informed that the antitoxin would arrive at 3:00 p.m.

50. After the antitoxin was administered, Plaintiffs monitored K.W. closely for any reaction, taking turns comforting her throughout the night. By the following morning, they observed minimal signs of improvement.

51. Throughout the day, K.W. was continually monitored by her medical team and evaluated by multiple specialists, including a lactation consultant who assisted K.W. and her mother in relearning how to latch during breastfeeding.

52. Later on, November 14, 2025, K.W. underwent an enema to obtain a sample for testing. On November 15, 2025, the test confirmed a positive result for botulism.

53. K.W.'s mother writes from the hospital: "Since she is still so weak, it will take time for her to breastfeed again. We will be able to go home once they determine she is getting enough food and gaining weight properly. When at home, I am producing between 15-20oz a day, just shy of the total needed to feed K.W. Knowing that I can't fully feed my child, and I can't trust formula companies has really taken a toll on our family."

54. K.W. and family were released from the hospital on November 19, 2025.

CAUSES OF ACTION

COUNT ONE

STRICT PRODUCTS LIABILITY

55. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–54.

56. At all relevant times, Defendants were the manufacturers, distributors, processors, and/or sellers of the adulterated food product that is the subject of the action.

57. The adulterated food product that the Defendants manufactured, processed, distributed, and/or sold was, at the time it left the Defendants' control, defective and unreasonably dangerous for its ordinary and expected use because it contained botulism spores.

58. The adulterated food product that the Defendants manufactured, processed, distributed, and/or sold was delivered to the Plaintiffs without any change in its defective condition. The adulterated food product that the Defendants manufactured, processed, distributed, and/or sold was used in the manner expected and intended, and was consumed by K.W.

59. The Defendants owed a duty of care to the Plaintiffs to design, manufacture, process, 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 Defendants breached this duty.

60. The Defendants owed a duty of care to the Plaintiffs to design, prepare, process, serve, and sell food that was fit for human consumption, and that was safe to the extent contemplated by a reasonable consumer. The Defendants breached this duty.

61. 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 Defendants manufactured, processed, distributed, and/or sold.

COUNT TWO

BREACH OF WARRANTY

62. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–61.

63. The Defendants are liable to the Plaintiffs for breaching express and implied warranties that they made regarding the adulterated food product that the Plaintiffs purchased and/or that was supplied into the stream of commerce. These express and implied warranties included the implied warranties of merchantability and/or fitness for a particular use. Specifically, the Defendants expressly warranted, through their sale and supply of food to the public and by the statements and conduct of their employees and agents, that the food they manufactured,

processed, distributed, and sold was fit for human consumption and not otherwise adulterated or injurious to health.

64. The Plaintiffs allege that the botulism spore-contaminated food that the Defendants sold and/or supplied to them would not pass without exception in the trade and was therefore in breach of the implied warranty of merchantability.

65. The Plaintiffs allege that the botulism spore-contaminated food that the Defendants sold and/or supplied 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.

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

COUNT THREE

NEGLIGENCE

67. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–66.

68. The Defendants owed to the Plaintiffs a duty to use reasonable care in the manufacture, processing, distribution, and sale of their food product, the breach of which duty would have prevented or eliminated the risk that the Defendants' food products would become contaminated with botulism spores or any other dangerous pathogen. The Defendants breached this duty.

69. The Defendants had a duty to comply with all statutes, laws, regulations, or safety codes pertaining to the manufacture, processing, distribution, storage, and sale of their food product, but failed to do so, and were 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, processing, distribution, storage, and sale of similar food products.

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

71. The Defendants 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 they failed to do so and were therefore negligent.

72. As a direct and proximate result of the Defendants' acts of negligence, the Plaintiffs sustained injuries and damages in an amount to be determined at trial.

COUNT FOUR

NEGLIGENCE *PER SE*

73. Plaintiffs incorporate herein by reference the allegations in paragraphs 1-72.

74. The Defendants had a duty to comply with all applicable state and federal regulations intended to ensure the purity and safety of their food product, including the requirements of the Federal Food, Drug and Cosmetics Act (21 U.S.C. § 301 *et seq*.), and its Washington State equivalents, including but not limited to the Uniform Washington Food, Drug, and Cosmetic Act, RCW 69.04.001 to 69.04.880, inclusive.

75. The Defendants failed to comply with the provisions of the health and safety acts identified above, and, as a result, were negligent *per se* in their manufacture, processing, distribution, and sale of food adulterated with botulism spores.

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

DAMAGES

77. The Plaintiffs have suffered general, special, incidental, and consequential damages as the direct and proximate result of the acts and omissions of the Defendants, 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, both past and future; damages for loss of enjoyment of life, both past and future; medical and medical related expenses, both past and future; loss of wages, both past and future; emotional distress, past and future; pharmaceutical expenses, both 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:

78. That the Court award Plaintiffs judgment against Defendants, 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 Defendants, in an amount to be proven at trial.

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

80. 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

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

JURY DEMAND

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

RESPECTFULLY SUBMITTED this 4th day of February 2026.

MARLER CLARK, INC., P.S.
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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on the 4th day of February 2026, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing.

/s/Patrick Leary