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Attorneys for Plaintiffs

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.

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.

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

4 **JURISDICTION AND VENUE**

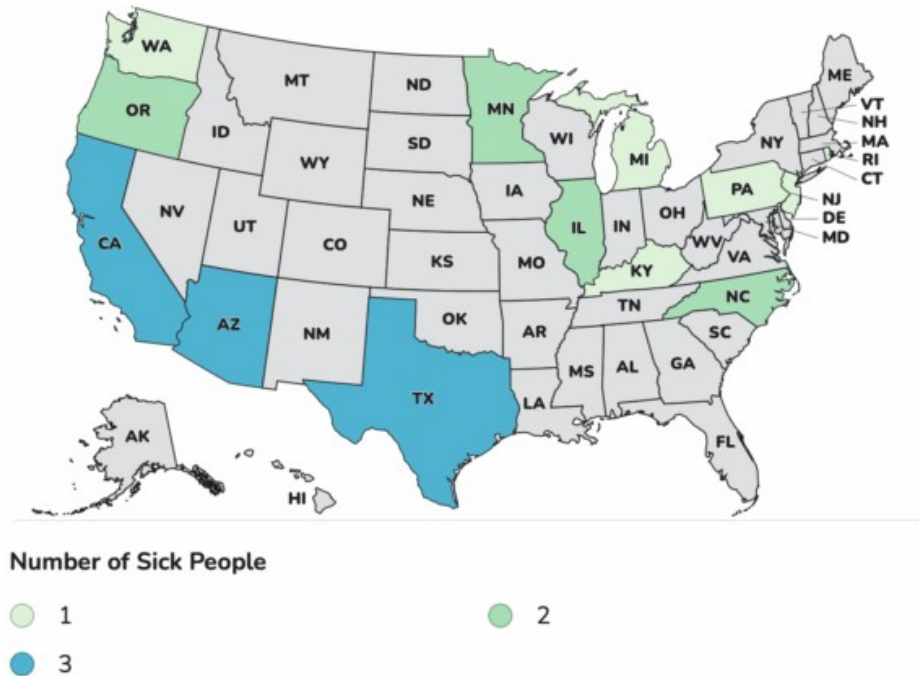
- 5 3. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332. The amount in
6 controversy far exceeds \$75,000 exclusive of interests and costs, and this is an action by
7 individual Plaintiffs against a Defendant with its principal place of business in another state.
8
9 4. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a)(2) because a
10 substantial part of the events or omissions giving rise to the claim occurred in this judicial
11 district and because the Defendant was subject to personal jurisdiction in this judicial district
12 at the time of the commencement of the action.

13 **FACTUAL ALLEGATIONS**

14 **The ByHeart Botulism Outbreak**

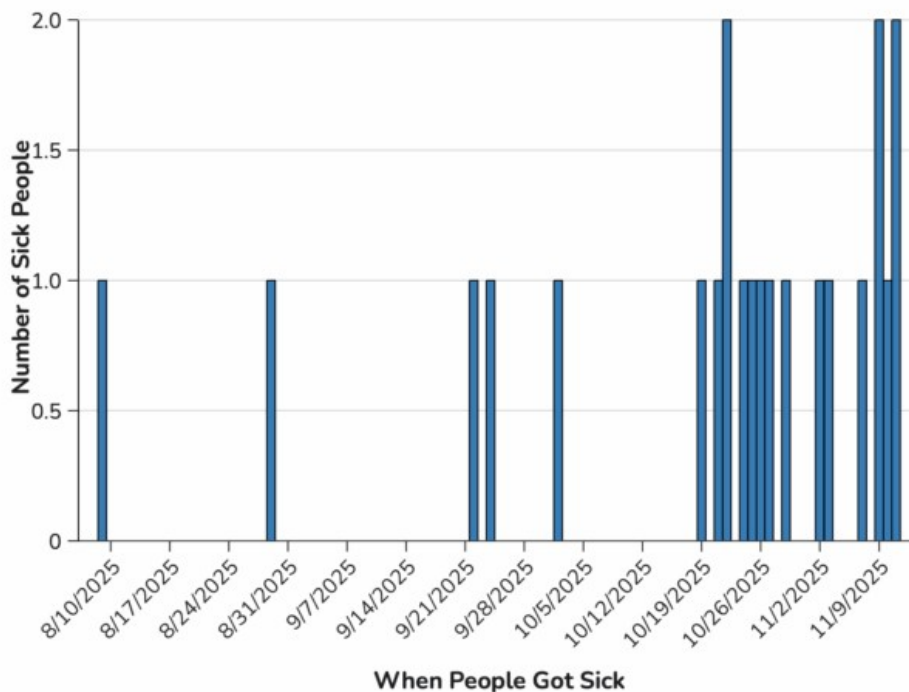
- 15
16 5. The FDA and CDC, in collaboration with the California Department of Public Health
17 (CDPH), Infant Botulism Treatment and Prevention Program (IBTPP), and other state and
18 local partners, continue to investigate a multistate outbreak of infant botulism.
19 Epidemiologic and laboratory data show that ByHeart Whole Nutrition infant formula
20 might be contaminated with *Clostridium botulinum*, which is causing infant illness in
21 multiple regions of the country.
22
23 6. Since the last update on November 11, 2025, eight new cases and one new state (Michigan)
24 have been added to this investigation. All 8 cases were hospitalized and treated with
25 BabyBIG®.
26
27
28

7. As of November 14, 2025, this outbreak includes 23 infants with suspected or confirmed infant botulism from 13 states – Arizona 3, California 3, Illinois 2, Kentucky 1, Michigan 1, Minnesota 2, North Carolina 2, New Jersey 1, Oregon 2, Pennsylvania 1, Rhode Island 1, Texas 3, Washington 1.



8. Laboratory confirmation for some cases is ongoing. For 22 cases with illness onset information available, illnesses started on dates ranging from August 9 to November 11, 2025. All 23 infants were hospitalized and treated with BabyBIG®. No deaths have been reported. For 22 infants with age and sex information available, they range in age from 16 to 200 days and 10 (45%) are female.

This chart shows when 22 infants in this infant botulism outbreak got sick. An illness onset date is not yet available for one infant.





ByHeart's History

10. 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.

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

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

5 13. When child illnesses were linked to *Cronobacter sakazakii* and infant formula in 2022, the
6 FDA chose to take an in-depth look at all the powdered infant formula manufacturing sites,
7 including ByHeart's Reading facility. What they found was disturbing, resulting in both
8 inspections being classified as "Official Action Indicated."
9

10 **Inspection End Date February 17, 2023**

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

- 13
- 14 • Lack of process control system, as evidenced by a finding of *Cronobacter sakazakii* in a
15 batch of ByHeart Whole Nutrition Infant Formula finished product. The infant formula
16 base which was incorporated into that batch had been manufactured in continuous process
17 from July 13, 2022 through August 23, 2022.
 - 18 • Discrepancy between company's root cause analysis of the *Cronobacter* contamination
19 problem and the conclusion of the third-party lab, in which the company blamed lab error
20 and the lab denied that they had erred.
 - 21 • Multiple notifications from third party lab of positive *Cronobacter sakazakii* findings
22 from July 25, 2022 through August 27, 2022 within the processing environment.
 - 23 • Two water events, during which water leaked into the manufacturing areas from outside.
24
25
26
27
28

Inspection End Date January 19, 2024

15. 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*?

16. 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

17. 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

18. 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.

- 1 • *Botulism* Immune Globulin (BIG): In the United States, a specific treatment called
2 BabyBIG (Botulism Immune Globulin) is administered to infants diagnosed with
3 botulism. This treatment helps to neutralize the *Botulinum* toxin and can reduce the
4 duration and severity of symptoms.
- 5 • Antibiotics: Antibiotics are not typically used for treating infant botulism as they do not
6 affect the toxin once produced and can also promote toxin production by encouraging the
7 growth of bacteria.
8

9 Long-Term Prognosis

- 10 19. The prognosis for infants with botulism is generally good, especially with early diagnosis and
11 appropriate treatment. Most infants recover fully within a few weeks or months, but the
12 recovery time can vary.
- 13 20. Recovery Time: Symptoms usually resolve over several weeks, but in some cases, full
14 recovery can take months, especially regarding muscle strength and tone.
- 15 21. No Long-Term Disabilities: Most children do not experience long-term complications or
16 disabilities if treated promptly and effectively.
- 17 22. Follow-Up: Regular follow-ups may be necessary to ensure continued recovery and to
18 monitor for any residual muscle weakness.
- 19
20

21 A.B.'s *Botulism* Illness

- 22 23. A.B. was born on September 29, 2025, at St. Joseph's Medical Center located in Stockton,
23 California as the first child of parents Anthony Barbera (father) and Thalia Flores (mother).
- 24 24. Throughout August 2025, A.B.'s parents purchased five 24 ounce ByHeart cans and one
25 ByHeart anywhere pack.
26
27
28

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

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

25. 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.

26. 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.

27. 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

28. 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.

29. 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

30. 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.

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

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

3 32. As the evening progressed A.B.'s condition deteriorated significantly. He became
4 increasingly lethargic and less responsive. Multiple nurses attempted to feed him, but he
5 was only able to consume between 5ml to 13ml of mixed formula each feeding.
6

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

8 33. During the early morning hours of October 26th, a comprehensive examination was
9 performed by a pediatric critical care physician. Key findings from the physician's exam
10 are as follows:
11

- 12 • A.B.'s mother stated that A.B.'s present cry, facial expression, alertness, body habitus,
13 strength are significantly depressed, even compared to when she brought A.B. to the
14 emergency room on the morning of October 25th.
- 15 • Exam showed tachycardia at rest (160's, occasionally over 170)
- 16 • Neurological: With much stimulation (including toe pinching), the physician woke A.B.
17 enough to get him to make repetitive weak moaning cry. A.B. waved his arms at bed level
18 (very little strength against gravity) and withdrew feet from painful stimuli, demonstrated
19 weak recoil strength, demonstrated completely floppy head, trunk, and lower extremities
20 when raised by his arms or when supported in sitting or standing positions. Facial muscles
21 are symmetric but also lax, especially around the mouth, which hangs open when A.B. is
22 held upright. A.B. is struggling to open his eyes and A.B.'s mother states he is unable to
23 open his eyes fully. A.B.'s suck is very weak and poorly effective. A.B.'s muscle strength
24 rating for his upper extremities and lower extremities is a ~3/5 and a 2/5, respectively.
25
26
27
28

- 1 • Bilateral eye crusting. Dry eyes with crusting could be indicative of being unable to shut
2 eyes completely due to muscle weakness.
- 3 34. Later that morning the medical team met with A.B.'s parents to discuss their collective
4 assessments. The medical team indicated the most probable diagnosis was botulism,
5 however they could not rule out various other differential diagnoses including, but not
6 limited to, spinal muscular atrophy (SMA Type 1) or a metabolic disorder. A.B.'s medical
7 team consulted with a specialist at the California Department of Public Health's Infant
8 Botulism Treatment and Prevention Program, who advised A.B. be treated immediately
9 with the BabyBig antitoxin.
- 10
11 35. At this point, A.B.'s parents were frightened and very concerned for A.B.'s health given
12 the severity of the prognosis for botulism and the various other differential diagnoses
13 indicated by the medical team. A.B.'s parents were especially concerned A.B. might have
14 spinal muscular atrophy given the similarities of spinal muscular atrophy's clinical
15 presentation to amyotrophic lateral sclerosis which A.B.'s maternal grandmother was
16 diagnosed with earlier in the year. Upon the advice and recommendation of A.B.'s medical
17 team, A.B.'s parents made the decision to initiate the order for the BabyBig antitoxin and
18 proceed with further testing to rule out all other differential diagnoses.
- 19
20 36. Given the severity of these diagnoses coupled with A.B.'s declining condition, the decision
21 was made to transfer him to the neonatal intensive care unit (NICU). A myriad of
22 diagnostic tests and supportive therapies were executed during A.B.'s first day in the
23 NICU, including, but not limited to:
- 24
25 • Encephalogram of A.B.'s brain
26
27 • Echocardiogram of A.B.'s heart
28

- 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

37. 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.

38. 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.

39. 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

40. 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.

41. 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

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

43. 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

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

45. 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 weighted one week prior.

NICU Day 5 - October 30, 2025

46. 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 80% of formula remaining	Use By 01 Dec 2026 BYHEART 206VABP 12:50:58 251131P2	Received by CDPH on November 4, 2025

24oz Can	Unopened – foil seal intact	Use By 01 Dec 2026 BYHEART 206VABP 20:52:43 251131P2	Currently in A.B.'s parents' possession
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NICU Day 6 - October 31, 2025 to NICU Day 12 – November 6, 2025

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

Post Discharge - November 7, 2025 to Present Date

48. 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.

49. 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

50. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–49.

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

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

4 53. The adulterated food product that the defendant manufactured, distributed, and/or sold was
5 delivered to the plaintiffs without any change in its defective condition. The adulterated food
6 product that the defendant manufactured, distributed, and/or sold was used in the manner
7 expected and intended, and was consumed by the plaintiffs.
8

9 54. The defendant owed a duty of care to the plaintiffs to design, manufacture, and/or sell food
10 that was not adulterated, which was fit for human consumption, that was reasonably safe in
11 construction, and that was free of pathogenic bacteria or other substances injurious to human
12 health. The defendant breached this duty.
13

14 55. The defendant owned a duty of care to the plaintiffs to design, prepare, serve, and sell food
15 that was fit for human consumption, and that was safe to the extent contemplated by a
16 reasonable consumer. The defendant breached this duty.
17

18 56. The plaintiffs suffered injury and damages as a direct and proximate result of the defective
19 and unreasonably dangerous condition of the adulterated food product that the defendant
20 manufactured, distributed, and/or sold.
21

22 **COUNT TWO**

23 **BREACH OF WARRANTY**

24 57. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–56.

25 58. The defendant is liable to the plaintiffs for breaching express and implied warranties that it
26 made regarding the adulterated food product that the plaintiffs purchased. These express and
27 implied warranties included the implied warranties of merchantability and/or fitness for a
28

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

4 59. The plaintiffs allege that the botulism-contaminated food that the defendant sold to them
5 would not pass without exception in the trade and was therefore in breach of the implied
6 warranty of merchantability.
7

8 60. The plaintiffs allege that the botulism-contaminated food that the defendant sold to them was
9 not fit for the uses and purposes intended, *i.e.* human consumption, and that this product was
10 therefore in breach of the implied warranty of fitness for its intended use.
11

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

14 COUNT THREE

15 NEGLIGENCE

16 62. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–61.
17

18 63. The defendant owed to the plaintiffs a duty to use reasonable care in the manufacture,
19 distribution, and sale of its food product, the breach of which duty would have prevented or
20 eliminated the risk that the defendant's food products would become contaminated with
21 botulism or any other dangerous pathogen. The defendant breached this duty.
22

23 64. The defendant had a duty to comply with all statutes, laws, regulations, or safety codes
24 pertaining to the manufacture, distribution, storage, and sale of its food product, but failed to
25 do so, and was therefore negligent. The plaintiffs are among the class of persons designed to
26 be protected by these statutes, laws, regulations, safety codes or provision pertaining to the
27 manufacture, distribution, storage, and sale of similar food products.
28

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

5 66. The defendant had a duty to use ingredients, supplies, and other constituent materials that
6 were reasonably safe, wholesome, free of defects, and that otherwise complied with applicable
7 federal, state, and local laws, ordinances and regulations, and that were clean, free from
8 adulteration, and safe for human consumption, but it failed to do so and was therefore
9 negligent.
10

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

13 14 **COUNT FOUR**

15 **NEGLIGENCE *PER SE***

16 68. Plaintiffs incorporate herein by reference the allegations in paragraphs 1-67.

17 69. The defendant had a duty to comply with all applicable state and federal regulations intended
18 to ensure the purity and safety of its food product, including the requirements of the Federal
19 Food, Drug and Cosmetics Act (21 U.S.C. § 301 *et seq.*), and its California equivalents,
20 including but not limited to the Sherman Food, Drug, and Cosmetic Laws (Cal. Health &
21 Safety Code §§ 109875 *et seq.*).
22

23 70. The defendant failed to comply with the provisions of the health and safety acts identified
24 above, and, as a result, was negligent *per se* in its manufacture, distribution, and sale of food
25 adulterated with botulism, a deadly pathogen.
26
27
28

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

3 **DAMAGES**

4 72. The plaintiffs have suffered general, special, incidental, and consequential damages as the
5 direct and proximate result of the acts and omissions of the defendant, in an amount that shall
6 be fully proven at the time of trial. These damages include but are not limited to damages
7 for general pain and suffering; damages for loss of enjoyment of life, both past and future;
8 medical and medical related expenses, both past and future; emotional distress, past and
9 future; pharmaceutical expenses, past and future; and all other ordinary, incidental, or
10 consequential damages that would or could be reasonably anticipated to arise under the
11 circumstances.
12

13 **PRAYER FOR RELIEF**

14 **WHEREFORE**, Plaintiffs pray for the following relief:
15

16 73. That the Court award Plaintiffs judgment against Defendant, in such sums as shall be
17 determined to fully and fairly compensate the Plaintiffs for all general, special, incidental and
18 consequential damages incurred, or to be incurred, as the direct and proximate result of the
19 acts and omissions of Defendant, in an amount to be proven at trial.
20

21 74. That the Court award Plaintiffs their costs, disbursements and reasonable attorneys' fees
22 incurred.
23

24 75. That the Court award Plaintiffs the opportunity to amend or modify the provisions of this
25 complaint as necessary or appropriate after additional or further discovery is completed in this
26 matter, and after all appropriate parties have been served; and
27
28

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

3 **JURY DEMAND**

4 77. Plaintiffs demand a trial by jury on all issues so triable with the maximum number of jurors
5 permitted by law.
6

7
8 RESPECTFULLY SUBMITTED this 17th day of November 2025.
9

10 **QUIRK LAW FIRM, LLP**

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24 *Attorneys for Plaintiffs*
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26
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CERTIFICATE OF SERVICE

I hereby certify that on the 17th 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

