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*Attorneys for Plaintiffs*

**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF TEXAS**

| | |
|---|---|
| Anit Joseph and Luke Pooley, as next friend of K.P, a minor,<br><br>Plaintiffs,<br><br>v.<br><br>ByHeart, Inc., a Delaware corporation,<br><br>Defendant. | NO.<br><br>**COMPLAINT**<br><br>**DEMAND FOR JURY TRIAL** |

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

## PARTIES

1. Plaintiffs Anit Joseph and Luke Pooley reside in League City, Galveston County, Texas. Plaintiffs are the parents and legal guardians of K.P.

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 Texas. 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.

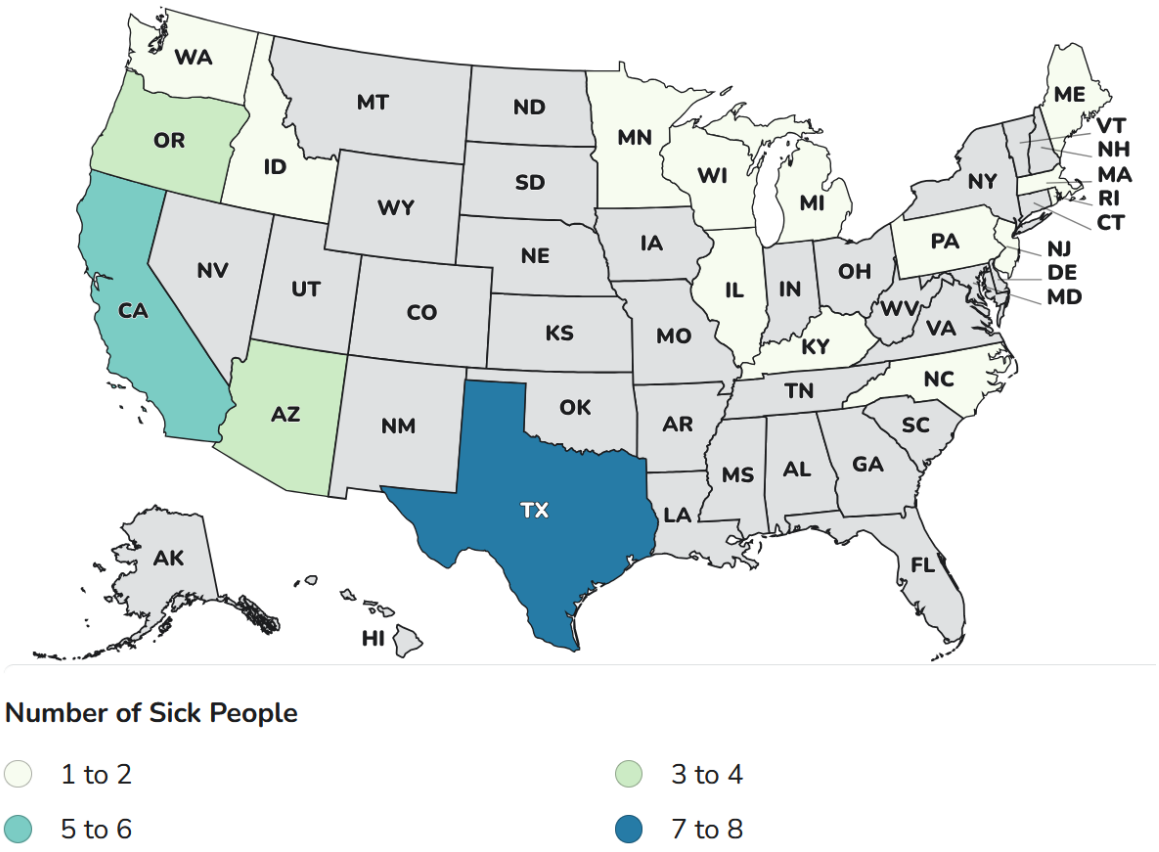
4. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district and because the Defendant was subject to personal jurisdiction in this judicial district at the time of the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

## FACTUAL ALLEGATIONS

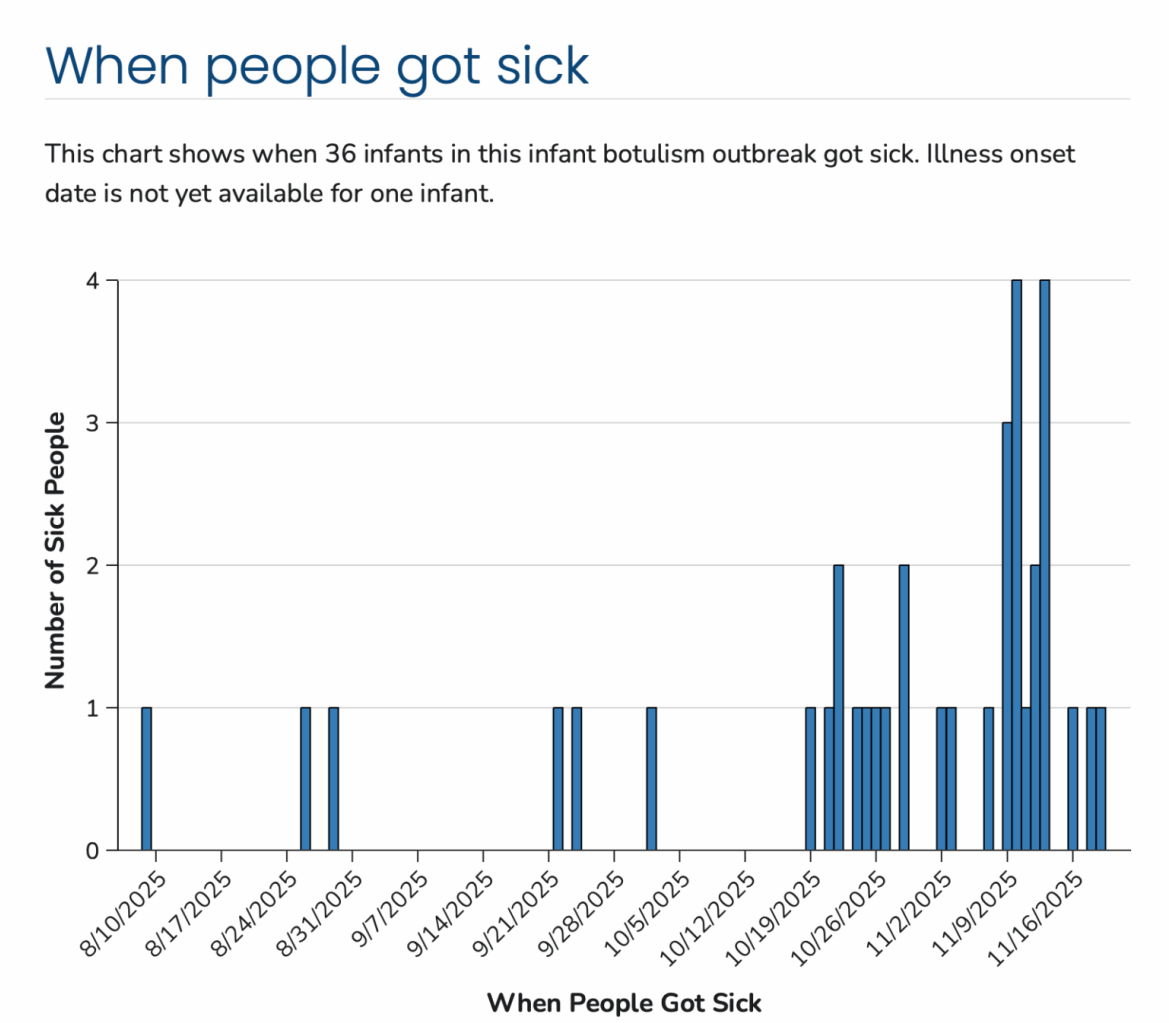
### The ByHeart Botulism Outbreak

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 26, 2025, a total of 37 infants with suspected or confirmed infant botulism and confirmed exposure to ByHeart Whole Nutrition infant formula (various lots) have been reported from 17 states – Arizona 3, California 5, Idaho 1, Illinois 2, Kentucky 1, Massachusetts 2, Maine 1, Michigan 1, Minnesota 2, North Carolina 2, New Jersey 1, Oregon 3, Pennsylvania 1, Rhode Island 1, Texas 8, Washington 2, and Wisconsin 1. Laboratory confirmation for some cases is ongoing. All 37 infants were hospitalized and treated with BabyBIG®, a specific botulism immune globulin treatment. No deaths have been reported to date. For 35 infants with age and sex information available, they range in age from 16 to 264 days and 15 (43%) are female.




7. For 36 cases with illness onset information available, illnesses started on dates ranging from August 9 to November 19, 2025.




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. 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, Acme, Jewel-Osco, Shaw's, Star Market, Smith's, King Sooper's, Albertson's, Whole Foods, Wegman's, and Publix locations. FDA is working with state partners and retailers to ensure an effective recall and immediate removal of these products from store shelves across the country. 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.

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. Closed in 2024.
- Blendhouse Allerton, LLC (Allerton, IA), a manufacturing site.
- Blendhouse Portland LLC (Portland, OR), a packaging site.

13. The FDA inspected the Blendhouse Allerton facility in 2025. Its Inspection Report stated:

> At the close-out of the inspection, a Form FDA 483, Inspectional Observations, was issued for 3 items, along with 2 "Additional Observations", and 7 "General Discussion with Management". The three 483 items included, receiving, and releasing _____ ingredient used in infant formula base powder that was not held under conditions to prevent adulteration, not taking actions to eliminate all potential harborage areas when issues with rodent arose during the year 2024-2025; and not monitoring the floor conditions adequately at the dryer ____ (level __ and level __) when there were findings of confirmed *Cronobacter Sakazakii*. The two additional observations consists of the firm not having clear barriers separating hygiene zones; and not monitoring bathhouse differential pressures.
>
> Also shared with the firm on February 14, 2025, was that the FDA observed "consecutive ___ pest control service tickets between October 2024 and December

2024 that reported up to 200 large black flies caught in insect light traps in the IF ____ ."

Further, Form **483 2025** stated: "Observation 1: You approved and released for use an ingredient that was not manufactured, packaged, labeled, or held under conditions to prevent adulteration." "Observation 2: You did not exclude pests from your food plant to protect against contamination of food." "Observation 3: You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition."

14. The FDA also inspected the Blendhouse Portland facility in 2025. Its Inspection Report found consumer complaints of infant illnesses: *Salmonella* – 8 Complaints, *Campylobacter* – 1 Complaint 1, *E. coli* – 1 Complaint.

**What is Infant *Botulism*?**

15. 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**

16. 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**

17. 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**

18. 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.

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

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

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

**K.P.'s *Botulism* Illness**

22. K.P. was born on July 11, 2025. Plaintiffs began feeding K.P. ByHeart formula on September 30, 2025.

23. In hindsight, K.P. started to exhibit symptoms on November 6th, ten days before hospitalization and three days before he stopped consuming ByHeart infant formula. K.P. was becoming increasingly fussy as well as sleeping during the day. Over the next days K.P.'s appetite decreased and he appeared constipated.

24. By November 15th, K.P.'s cry was weak and he was having difficulty keeping his head up when on his stomach. K.P. refused both breast milk and a bottle.

25. On November 16th, K.P. seemed "floppy." He was taken to Methodist Hospital ER. The physicians were concerned about his "head lag and droopiness."

26. The family informed them that K.P. had been consuming ByHeart formula. Given the recall and the symptoms consistent to botulism, K.P. was transferred to Texas Children's Hospital for emergency care via ambulance.

27. As seen from a mother's perspective:

> "I just remember a lot of hours (4pm-10pm) being spent in the ER where he was poked and prodded and monitored. We tried feeding him a bottle and he only took about 3 ounces which took 30-40 minutes for him to finish. They had to take blood, insert a catheter to collect pee, and check his stats to make sure his stats were okay. I remember the ER telling us they needed to insert a new IV before he was moved to the PICU. Because he was a baby, it's harder to see his veins and insert an IV . The nurses came and tried about three or four times to get an IV started. he bled so much and, in the end, they had to call a nurse to do an ultrasound to locate a vein and put in an IV. By the end of it all, his hands were so blue and seemed to be bruised. Around 10 pm, he was transferred to the PICU. The nurses had to put a bunch of wires on him to monitor him, and we were told he couldn't eat in case he needed to be intubated as he could aspirate. That night the only thing he was able to drink was small packets of sugar water - it was so horrible seeing him be so hungry and sick."

28. The following day K.P.'s symptoms worsened. He was so weak, that the decision was made to intubate him and her remained so for three days. For nutrition, he was placed on a feeding tube.

29. K.P. was given the botulism anti-toxin, BabyBig, which was flown in from California.

30. On November 25th, K.P. was able to be released; however, he is still weak and recovering.

31. In the end, it was a parent's worst nightmare:

> I'm not sure words can describe the impact this situation had on my son and our entire family. As a mother, this was the most stressful and painful thing I have ever endured. No one expects their 4-month-old to be sick to the point of intubation – especially from something like baby formula, one of the safest and trusted items out there. When he got sick, we didn't even think it was due to botulism because even after the recall, we had some sort of trust in ByHeart and assumed it was a minor mistake from the company. We did not realize how massive the issue would become. I initially exclusively breastfed our son, but I had to consider formula because I was not making enough. I already felt guilty as a mother for not being able to give him what he needed, but I knew I had to feed him to ensure that he was growing and getting the appropriate amount of milk to meet his nutritional needs. I researched and looked at many baby formulas, reading through reviews and parent experiences to get him the best on the

> market. I ended up landing on ByHeart, thinking it would be perfect for my child. We didn't even have much time to process the fact that he had to be intubated and there were also some complications with intubation, as it took three tries for him to be intubated. We watched his oxygen go down with every try- it was extremely scary and we were worried he might not make it. Watching my little baby go through so much at such a young age will never leave my mind. It was an awful situation that took a toll on my mental and physical health. I feel guilty that I chose to give my child something that could have potentially killed him – nothing will ever change that. My family and I now worry that something like this will happen again every time we give him a bottle of milk – that fear will never go away. I am constantly worried about the long-term impacts this incident will have on him. I know most children recover fully, but a 4-month-old should not have to worry about recovering from something like this – he should be able to eat, sleep, play like any other baby.

32. K.P. tested positive for botulism and has been linked to the ByHeart infant Formula Outbreak.

## CAUSES OF ACTION

### COUNT ONE
### STRICT PRODUCTS LIABILITY

33. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–32.

34. At all relevant times, the Defendant was the manufacturer, distributor, and/or seller of the adulterated food product that is the subject of the action.

35. 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 spores.

36. 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 K.P.

37. 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.

38. The Defendant owed 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.

39. 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**

40. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–39.

41. 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.

42. The Plaintiffs allege that the botulism spore-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.

43. The Plaintiffs allege that the botulism spore-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.

44. 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**

45. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–44.

46. 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 spores or any other dangerous pathogen. The Defendant breached this duty.

47. 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.

48. 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.

49. 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.

50. 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***

51. Plaintiffs incorporate herein by reference the allegations in paragraphs 1-50.

52. 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 but not limited to the requirements of the Federal Food, Drug and Cosmetics Act (21 U.S.C. § 301 *et seq*.) and its Texas equivalents.

53. 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 spores.

54. 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**

55. 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, both past and future; physical impairment, past and future; reasonable and necessary medical care and medical related expenses, both past and future; loss of wages-earning capacity, both past and future; mental anguish, past and future; disfigurement, 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:

56. 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.

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

58. 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

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

## JURY DEMAND

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

RESPECTFULLY SUBMITTED this 1st day of December 2025.

Respectfully submitted,

By: _____

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 1st day of December 2025, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing.

By: _____
Justin A. Hill