

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

**MAX SCHNEIDER, individually and on
behalf of all others similarly situated,**

Plaintiff,

v.

BYHEART, INC.,

Defendant.

Case No:

**CLASS ACTION COMPLAINT
JURY TRIAL DEMANDED**

Plaintiff Max Schneider, individually and on behalf of all other similarly situated individuals, by and through his attorneys, alleges the following upon information and belief, except for those allegations pertaining to Plaintiff which are based on personal knowledge:

NATURE OF THE ACTION

1. This is a consumer class action brought on behalf of purchasers of ByHeart infant formula products which were subject to a nationwide recall announced after the U.S. Food and Drug Administration (“FDA”) reported a link between cases of infant botulism and the consumption of ByHeart formula.

2. In response to the FDA’s findings, Defendant ByHeart Inc. (hereinafter “Defendant” or “ByHeart”) instructed consumers to immediately discontinue use and discard all ByHeart infant formula products, rendering the purchased products useless.

3. Plaintiff and Class Members purchased ByHeart infant formula believing it to be safe, nutritionally adequate, and fit for consumption by infants. The recall and associated safety concerns destroyed the value of those products and deprived consumers of the benefit of their bargain.

4. Plaintiff bring this action to recover damages for economic losses suffered by consumers nationwide who purchased recalled ByHeart infant formula products.

PARTIES

5. Plaintiff Max Schneider is a resident of Montana and is a member of the proposed Class. Plaintiff purchased ByHeart Whole Nutrition Infant Formula, a ByHeart product, for his infant child on February 2, 2025.

6. Defendant ByHeart, Inc. is a Delaware corporation headquartered at 131 Varick Street, New York, New York, and is engaged in the manufacture, marketing, and sale of infant formula products throughout the United States.

JURISDICTION

7. This Court has original jurisdiction over this case under the provisions of the Class Action Fairness Act codified at 28 U.S.C. § 1332(d)(2). There is diversity of citizenship because, among other reasons: (i) Plaintiff is a citizen of Montana, and (ii) Defendant is a citizen, for diversity purposes, of New York. The amount in controversy in this action exceeds \$5,000,000, and there are more than 100 members in the Class.

8. This Court has personal jurisdiction over Defendant for reasons including but not limited to the following: Defendant purposefully avails itself of the privilege of conducting business activities within the territorial boundaries of the United States District Court for the Southern District of New York, thus invoking the benefits and protections of the laws of the State of New York, through Defendant's promotion, marketing, distribution, and sale of consumer goods in the consumer markets within the Southern District of New York. Defendant knows (or should reasonably anticipate) that its activities within the Southern District of New York render it foreseeable that it may be hauled into court here. Further, Defendant is engaged in systematic and

continuous business activity in the Southern District of New York, such that Defendant is essentially at home in Southern District of New York.

9. Venue is proper pursuant to 28 U.S.C. § 1391(b)(1) because Defendant resides in this District for venue purposes in that Defendant would be subject to personal jurisdiction in the Southern District of New York. 28 U.S.C. § 1391(c)(2), (d).

FACTUAL ALLEGATIONS

A. ByHeart Infant Formula

10. Parents of newborns and infants make purchasing decisions about formula with exceptional care and deliberation. Infant formula, for many, is not a discretionary product – it is often a sole or primary source of nutrition during a child’s most vulnerable developmental stages.

11. Parents devote substantial time to researching ingredients, safety records, manufacturing sources, and medical endorsements before selecting a brand, because they must entrust that product with their child’s health and survival.

12. ByHeart is an infant-nutrition company founded in 2016. ByHeart Whole Nutrition Infant Formula Powder costs \$42 for a 38 ounce can. ByHeart also offers a subscription program in which consumers are charged the formula at a discounted rate, at \$39 per 38 ounce can.

13. ByHeart was launched with the stated mission of creating a fully integrated infant formula brand that controlled every stage of production – from sourcing and testing raw ingredients to manufacturing finished product – in order to offer parents a cleaner and safer alternative to legacy formula brands.

14. Unlike many formula companies that rely on third-party manufacturers, ByHeart acquired and retrofitted its own manufacturing facility in Reading, Pennsylvania in 2019. ByHeart publicly represented that this “farm-to-formula” model ensured the highest safety and nutritional

standards and distinguished it from competitors that merely licensed or repackaged formula produced by contract manufacturers.

15. In 2021 and 2022, ByHeart obtained FDA registration and approval for its proprietary infant-formula recipe, becoming the first new U.S.-based manufacturer in more than 15 years to do so. The company's marketing emphasized that its formula was the first new-to-market FDA-registered infant formula in a generation, touting ingredients such as whole milk, organic lactose, and DHA and ARA fatty acids.

16. ByHeart's products were sold nationwide beginning in late 2022 through the company's website and retail partners such as Target, Walmart, and Amazon. ByHeart promoted its products as "safe, clean, and backed by science," claiming that every batch underwent over 30,000 quality tests and that its supply chain was "vertically integrated to eliminate contamination risk."

17. ByHeart's growth accelerated during the 2022 national infant-formula shortage, when the shutdown of Abbott Laboratories' Sturgis, Michigan facility left widespread gaps in supply. ByHeart capitalized on that disruption, marketing itself as a trustworthy domestic alternative and securing tens of thousands of new customers.

18. Despite its promises of safety and rigorous oversight, ByHeart has experienced repeated manufacturing and quality-control issues in its short time in the public market.

19. In December of 2022, ByHeart announced a voluntary recall of certain batches of its whole Nutrition Infant Formula due to potential cross-contamination with *Cronobacter sakazakii* bacteria, the same pathogen that led to the Abbott formula crisis. ByHeart acknowledged that its third-party blending facility had failed to maintain sanitary standards.

20. On August 30, 2023, the FDA issued a warning letter to ByHeart after an inspection of its facilities and found significant violations of Title 21, Code of Federal Regulations, Part 106 (21 C.F.R. Part 106), Infant Formula Requirements Pertaining to Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications (“the Infant Formula Rule”). The FDA specifically found that ByHeart did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment.¹

21. On November 7, 2025, ByHeart was notified by the FDA that it had connected 15 recent cases of infant botulism to consumption of ByHeart products.

B. Infant Botulism Recall

22. On November 8, 2025, ByHeart announced that it was voluntarily recalling two batches of ByHeart Whole Nutrition Infant Formula following notification from the FDA of an ongoing investigation into a recent outbreak of infant botulism.²

23. The FDA discovered that of the estimated 83 cases of infant botulism that were reported nationwide since August 2025, 13 of those infants had previously consumed ByHeart formula.

24. Botulism is a rare but potentially fatal illness that presents a serious threat to the health of infants which occurs when *Clostridium botulinum* spores are ingested and colonize the intestinal tract, producing botulinum neurotoxins in the immature gut of infants. Affected infants

¹ See U.S. Food and Drug Administration, *Warning Letter*, ByHeart, Inc., August 30, 2023, Warning Letter Ref. No. 653854, available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/byheart-inc-653854-08302023>.

² See <https://byheart.com/pages/nov-8-an-update-from-our-founders-on-our-voluntary-recall-november-2025>.

can present with constipation, poor feeding, drooping eyelids, sluggish pupils, low muscle tone, difficulty sucking and swallowing, weak or altered cries, generalized weakness, respiratory difficulty, and respiratory arrest.

25. ByHeart instructed consumers with ByHeart infant formula bearing batch codes 251261P2 or 251131P2 to immediately discontinue use and dispose of the products. In its November 8th announcement, ByHeart offered to replace the discarded cans, but did not offer consumers a direct refund.

26. Even more, ByHeart further recommended that consumers sanitize any items that may have come in contact with ByHeart formula, and urged consumers to wash bottles, preparation equipment, countertops, and utensils using hot soapy water or run them through the dishwasher to eliminate contamination risk.

27. On November 11, 2025, ByHeart issued another announcement, this time informing consumers that the company was voluntarily recalling all ByHeart formula nationwide, including both its cans and single-serve Anywhere Pack sticks. According to ByHeart, on November 10, 2025 the FDA informed ByHeart of an additional two cases of botulism in infants that consumed ByHeart.

28. Armed with this new information, ByHeart told consumers: “the most important thing for you to know is that all ByHeart product must be discarded” and once again encouraged consumers to immediately discontinue use.³

C. Plaintiff and Class Members Have Been Harmed

29. Plaintiff Schneider purchased two 38 ounce cans of ByHeart Whole Nutrition Infant

³ <https://byheart.com/pages/an-update-from-our-founders-on-our-voluntary-recall-november-2025?srsId=AfmBOopBI-LL1dZCvCGgECfKF45uabn1XM7HTq6uMphJhhcfzey6s15S>.

Formula for his infant on February 2, 2025.

30. Plaintiff paid a premium price of \$42 per can for the ByHeart formula, reasonably relying on ByHeart's representations that the product was safe, pure, and subject to rigorous testing.

31. After the announcement linking ByHeart formula to cases of infant botulism, and Defendant's instruction that consumers throw away all ByHeart infant formula immediately, Plaintiff was forced to discard the product without refund.

32. The formula Plaintiff purchased became worthless, depriving him of the benefit of his bargain and causing out-of-pocket losses.

33. In addition, Plaintiff expended time and effort identifying and replacing the recalled formula to ensure his child's safety.

34. These monetary and practical losses suffered by Plaintiff are typical of those sustained by the class as a whole. Thousands of parents and caregivers across the United States purchased ByHeart formula products that were later recalled and rendered unusable.

35. Upon Defendant's instruction to discard the products immediately, these consumers lose the full economic value of their purchases and received no reimbursement.

36. Plaintiff and Class Members would not have purchased ByHeart formula had they known the risk of contamination and the likelihood of recall.

CLASS ACTION ALLEGATIONS

37. Plaintiff brings this action on behalf of himself as well on behalf of:

All persons who purchased ByHeart products subject to the recall announced on November 11, 2025 (the "Nationwide Class").

38. Excluded from the Nationwide Class is the judge or magistrate assigned to this case and the members of their respective staffs, Defendant, any entity in which Defendant has a

controlling interest, and Defendant's officers, directors, legal representatives, successors, and assigns.

39. *Numerosity*: The Nationwide Class is so numerous that joinder of all members is impracticable. The Nationwide Class includes thousands of consumers who purchased Defendant's products.

40. *Typicality*: Plaintiff's claims are typical of the claims of the Class members because, like the other Class members, Plaintiff suffered economic harm as a result of Defendant's business practices and subsequent recall of products.

41. *Adequacy*: Plaintiff will fairly and adequately protect the interests of the Class and has retained counsel experienced in class action litigation. Plaintiff has no interests that are adverse to the members of the Class he seeks to represent.

42. *Commonality*: Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class, including, without limitation:

- a. whether ByHeart materially misrepresented or omitted material facts regarding product safety;
- b. whether ByHeart's products were defective;
- c. whether ByHeart breached express or implied warranties; and
- d. whether Plaintiff and Class Members are entitled to compensation.

43. These and other questions of law and fact are common to the Class and predominate over any questions affecting only individual members of the Class.

44. Discovery will inform the proper form and manner of notice to Class members. Plaintiff anticipates, however, that notice by direct mail will be given to Class members who can

specifically identified, including, without limitation, by the use of store records where ByHeart was purchased. In addition, notice may be published in appropriate publications, on the Internet, in press releases, and in similar communications in a way that is targeted to reach those who may have purchased ByHeart infant formula.

CAUSES OF ACTION
COUNT I
VIOLATION OF NEW YORK GENERAL BUSINESS LAW § 349

45. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

46. New York General Business Law Section 346 (“GBL § 349”) declares unlawful “[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state . . .”

47. The conduct of ByHeart alleged herein constitutes ByHeart engaged in deceptive acts and practices by representing that its infant formula was safe, thoroughly tested, and suitable for infants, when in fact it was subject to contamination posing risk of infant botulism.

48. Defendant’s conduct was consumer-oriented and materially misleading.

49. There is no adequate remedy at law.

50. Defendant misleadingly, inaccurately, and deceptively advertises and markets its products to consumers.

51. Defendant’s improper consumer-oriented conduct – including failing to disclose that the products are at risk of contamination – is misleading in a material way in that it induced Plaintiff and Class Members to purchase ByHeart products and to use these Products instead of other infant formula products.

52. Defendant made the untrue and misleading statements and omissions willfully, wantonly, and with reckless disregard for the truth.

53. Plaintiff and Class Members have been injured inasmuch as they purchased products that were not only mislabeled and unhealthy, but entirely worthless. Plaintiff and Class Members received less than what they bargained and paid for.

54. As a direct and proximate result of Defendant's misrepresentations and omissions, Plaintiff and Class Members have suffered economic injury and seek damages and statutory relief.

COUNT II
BREACH OF EXPRESS WARRANTY

55. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

56. ByHeart expressly warranted through product labeling, advertising, and marketing that its infant formula was safe, pure and of high quality.

57. ByHeart aggressively marketed its products as superior to other infant formulas, promising that its manufacturing approach was safer, cleaner, and more innovative than that of competitors.

58. These promises and affirmations formed part of the basis of the bargain between Defendant and consumers.

59. Plaintiff and Class Members were the intended beneficiaries of these express warranties.

60. The products did not conform to these representations, as evidenced by the recall and FDA findings regarding *Clostridium botulinum*, a dangerous bacteria.

61. ByHeart breached its express warranties in the following ways:

- a. Defendant's formula was not safer or cleaner than its competitor's products as evidenced by the recall and FDA findings related to *Clostridium botulinum*; and
- b. Defendant's manufacturing process was not more innovative than its competitors because it failed to prevent *Clostridium botulinum* from contaminating its products.

62. Plaintiff and Class Members used the infant formula with the reasonable expectation that it was properly designed and manufactured, safe and free of bacteria, and that it was safe for consumption by infants.

63. Defendant's breach of its express warranties was the direct and proximate cause of Plaintiff and Class Members' economic injuries.

COUNT III
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

64. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

65. When ByHeart designed, manufactured, marketed, and sold its infant formula to Plaintiff and Class Members, ByHeart impliedly warranted that its infant formula was of merchantable quality and fit for its ordinary purpose, which is, namely, consumption by infants.

66. Plaintiff and Class Members were the intended beneficiaries of the implied warrant of merchantability.

67. Plaintiff and Class Members reasonably relied on ByHeart's representations that its infant formula was safe for consumption.

68. The recalled products were indeed not safe for infant consumption due to the risk of *Clostridium botulinum* contamination and were therefore unmerchantable.

69. Plaintiff and Class Members purchased the infant formula with the reasonable expectation that it was properly designed and manufactured, free from defects of any kind, and that it was safe for its intended, foreseeable use of consumption by infants.

70. ByHeart's breach of the implied warranty of merchantability was the direct cause of Plaintiff and Class Member's injuries.

71. Plaintiff and Class Members are entitled to damages and restitution.

COUNT IV
UNJUST ENRICHMENT

72. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

73. Defendant was unjustly enriched at the expense of Plaintiff and Class Members by selling infant formula products that were unsafe, misrepresented, and ultimately recalled. ByHeart knowingly accepted and retained the money paid by consumers who purchased its formula in reasonable reliance on defendant's false assurances of purity and safety.

74. At the time of sale, Defendant had superior knowledge of material facts not known to consumers – namely, that its manufacturing processes were susceptible to bacterial and toxin contamination, and that its prior contamination issues had not been fully resolved. Defendant's failure to disclose these facts rendered its enrichment inequitable.

75. Further, as a result of the recall, Plaintiff and Class Members received no value for the products they purchased, were forced to discard all remaining formula, and were offered no refund. Meanwhile, Defendant retained the revenues from those sales, avoided full restitution, and benefitted from the goodwill generated by its false safety claims.

76. Defendant's unjust enrichment was not the result of a valid or enforceable contract

negotiated with consumers on equal footing; instead, it arose from Defendant's deceptive marketing and concealment of material information regarding product safety. Equity and good conscience therefore require restitution and disgorgement of the profits ByHeart wrongfully obtained.

77. Plaintiff and Class Members seek restitution of all amounts paid for ByHeart retaining the purchase price of unsafe, unusable products.

78. Equity and good conscience require restitution of such ill-gotten gains to Plaintiff and Class Members.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and all others similarly situated, respectfully request that the Court:

- A. Certify the proposed Nationwide Class and appoint Plaintiff and his counsel as representative thereof;
- B. Award compensatory, statutory, and/or punitive damages as permitted by law;
- C. Order restitution and disgorgement of Defendant's ill-gotten gains;
- D. Award pre- and post-judgment interest;
- E. Award reasonable attorneys' fees and costs; and
- F. Grant such further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: November 14, 2025

/s/ Madeline Sheffield

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**pro hac vice forthcoming*