BEFORE THE UNITED STATES

JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE BYHEART INFANT BOTULISM LITIGATION	**MDL DOCKET NO. _____**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO TRANSFER AND CENTRALIZE RELATED ACTIONS IN THE SOUTHERN DISTRICT OF NEW YORK PURSUANT TO 28 U.S.C. § 1407

Pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, Plaintiffs in the Related Actions[1] respectfully request that the Panel centralize these actions in the United States District Court for the Southern District of New York before the Honorable Denise L. Cote.

All Related Actions arise from the same nationwide outbreak of infant botulism caused by contaminated infant formula manufactured and distributed by Defendant ByHeart, Inc. ("ByHeart"). The outbreak has sickened at least 51 infants across 19 states[2], resulting in overlapping lawsuits asserting common factual allegations and substantially identical legal

[1] Plaintiffs' counsel, William D. Marler, has filed five related actions to date and is currently investigating 25 additional claims arising from the outbreak (of at least 51 total known cases). The filed actions are: *Wescott et al v. ByHeart, Inc. et al*, No. 3:2025-cv-06039 (W.D. Wash.); *Dexter et al v. ByHeart, Inc. et al*, No. 3:2025-cv-08241 (D. Ariz.); *Mazziotti et al v. ByHeart, Inc. et al*, No. 2:2025-cv-12116 (C.D. Cal.); *Barbera et al v. ByHeart, Inc. et al*, No. 2:2025-cv-03339 (E.D. Cal.); *Joseph et al v. ByHeart, Inc. et al*, No. 3:2025-cv-00391 (S.D. Tex.). Plaintiffs' counsel is awaiting admission Pro Hac Vice in four of the five cases which are *Dexter et al v. ByHeart, Inc. et al*, No. 3:2025-cv-08241 (D. Ariz.); *Mazziotti et al v. ByHeart, Inc. et al*, No. 2:2025-cv-12116 (C.D. Cal.); *Barbera et al v. ByHeart, Inc. et al*, No. 2:2025-cv-03339 (E.D. Cal.); and *Joseph et al v. ByHeart, Inc. et al*, No. 3:2025-cv-00391 (S.D. Tex.).has intentionally refrained from filing additional actions at this time to avoid unnecessarily depleting limited insurance proceeds.

[2] *See* CDC report - https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/investigation.html and FDA report - https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025

theories, including claims for strict products liability, negligence, breach of warranty, and violations of consumer protection statutes.

Absent centralization, these actions will proceed in courts across the country, requiring multiple judges to oversee duplicative discovery and expert testimony, and adjudicate identical pretrial issues. Such fragmentation creates a significant risk of inconsistent rulings and needless expenditure of judicial and party resources.

Centralization is particularly important here because the funds available to satisfy claims are limited. ByHeart reportedly maintains only $10 million in liability insurance, subject to "burning limits"[3] that are being rapidly depleted by defense costs. Allowing parallel litigation to proceed independently across numerous jurisdictions threatens to exhaust all available coverage, to the detriment of injured infants and their families.

Though some Plaintiffs may prefer other fora, the Southern District of New York is the most appropriate transferee forum because it is the location of ByHeart's principal place of business, the district with the largest concentration of pending actions, and the locus of key witnesses, documents, and decision-making relevant to this litigation.

I. INTRODUCTION AND BACKGROUND

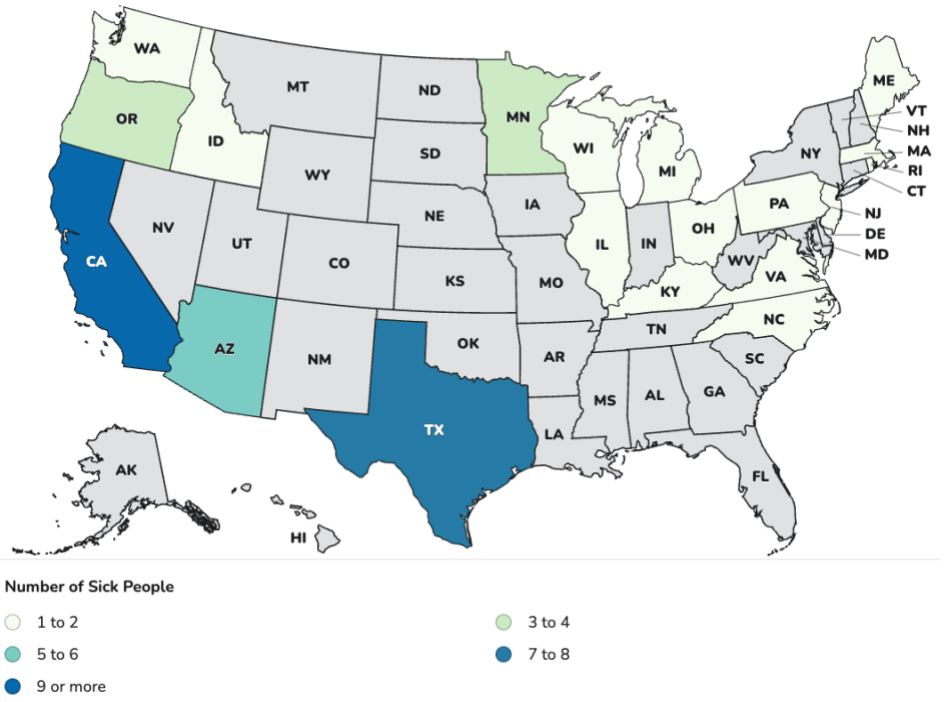
A. The 2025 ByHeart Botulism Outbreak

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

[3] "Burning limits" refers to a type of liability insurance policy under which the costs of legal defense (*e.g.,* attorney fees, court costs, and expert witness expenses) are deducted from the total policy limits. Such policies are also commonly referred to as eroding limits, wasting policies, or defense-within-limits ("DWL") coverage. Given the scope of this litigation and ByHeart's retention of multiple national law firms (including Munger, Tolles & Olson and DLA Piper), the available insurance coverage is expected to be rapidly depleted in the coming months.

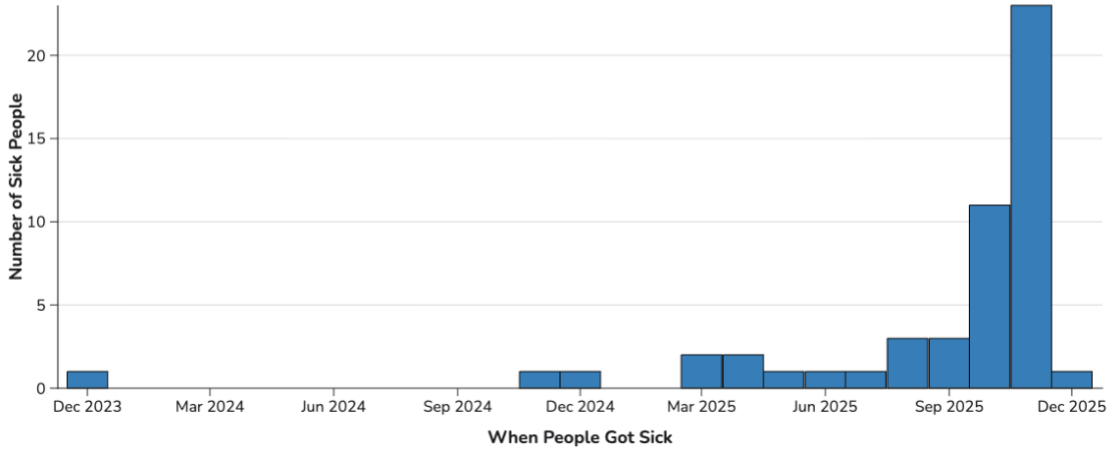
partners, continue to investigate a multistate outbreak of infant botulism. Epidemiologic and laboratory data show that ByHeart Whole Nutrition infant formula is the source of this multistate outbreak of infant botulism.

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.



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.

This chart shows when 51 infants in this infant botulism outbreak got sick.



As part of this investigation, product sampling and testing is being conducted by FDA, CDC, state partners, and ByHeart. As of December 3, 2025, six samples of ByHeart infant formula have tested positive for *Clostridium botulinum*. 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.

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

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."

Recalled products were sold through online marketplaces, including Amazon.com, and were shipped to customers outside of the United States. 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.

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

B. ByHeart's Prior Inspections

In 2022, after infant illnesses were linked to *Cronobacter sakazakii* contamination in infant formula, the FDA issued a "Call to Action" letter to "infant formula manufacturers, packers, distributors, exporters, importers, and retailers" that stated, in relevant part:

> Historical associations between powdered infant formula and pathogens such as *Cronobacter* spp., *Salmonella*, and *Clostridium botulinum* should be considered when designing and implementing controls for the safe manufacture of all foods for infants and young children.

The FDA also undertook comprehensive inspections of powdered infant formula manufacturing facilities, including ByHeart's facility in Reading, Pennsylvania. What they found was disturbing, resulting in both inspections being classified as "Official Action Indicated."

i. Inspection End Date February 17, 2023

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.

ii. Inspection End Date January 19, 2024

The FDA conducted its next inspection eleven months later. According to information posted on the FDA's inspection data dashboard, investigators uncovered several serious problems:

- did not implement a system of production and in-process controls for an infant formula
- did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition
- did not minimize the potential for contamination of raw materials using appropriate measures

- did not ensure that all surfaces that contacted ingredients, in-process materials and infant formula were cleaned and sanitized and maintained to protect infant formula from being contaminated by any source
- did not monitor the temperature in a thermal processing equipment at a point where temperature control is necessary to prevent adulteration
- did not exclude pests from your food plant to protect against contamination of food

C. What is Infant Botulism?

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.

i. <u>Symptoms of Infant Botulism</u>

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.

ii. Treatment

Infants diagnosed with botulism often require hospitalization to monitor respiratory function and general health.

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.

iii. Long-Term Prognosis

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. Symptoms usually resolve over several weeks, but in some cases, full recovery can take months, especially regarding muscle strength and tone. Most children do not

experience long-term complications or disabilities if treated promptly and effectively. Regular follow-ups may be necessary to ensure continued recovery and to monitor for any residual muscle weakness.

II. ARGUMENT

a. Transfer and centralization of the various Related Actions is warranted under 28 U.S.C § 1407 because they present common questions of law and fact.

Section 1407(a) authorizes the Judicial Panel on Multidistrict Litigation (the "Panel") to transfer and centralize civil actions for "coordinated or consolidated pretrial proceedings" when the actions involve "common questions of fact" and transfer will be convenient for the parties and witnesses and "will promote the just and efficient conduct" of the litigation. 28 U.S.C. § 1407(a). The MDL process is designed to "eliminate duplicative discovery, prevent inconsistent pretrial rulings on class certification and other issues, and conserve the resources of the parties, their counsel, and the judiciary." *In re Folgers Coffee Mktg. & Sales Practices Litig.*, 532 F. Supp. 3d 1416, 1417 (J.P.M.L. 2021) (consolidating five putative class actions alleging defendant engaged in deceptive advertising and marketing practices with respect to labeling of coffee products).

The Panel should transfer and consolidate the instant cases in a single district. Each of the Related Actions arises from the same nationwide outbreak of infant botulism and alleges that ByHeart's infant formula was contaminated with *Clostridium botulinum*, causing infant to develop botulism as a result of failures in manufacturing controls, sanitation, quality assurance, and regulatory compliance. Although the cases were filed in different districts on behalf of different families, they are factually and legally indistinguishable in all material respects.

Every action will require the resolution of common factual and legal questions, including, among others:

- Whether ByHeart's infant formula was contaminated with *Clostridium botulinum*;

- Whether ByHeart's manufacturing processes complied with applicable FDA regulations and industry standards;
- Whether prior FDA inspections, inspection findings, and warning letters placed ByHeart on notice of contamination risks;
- Whether defects in manufacturing, sanitation, or quality control caused or contributed to contamination;
- Issues of general and specific causation;
- The adequacy, timing, and scope of ByHeart's recall and its post-recall conduct;
- The nature and extent of damages suffered by affected infants and their families.

Discovery across the Related Actions will necessarily focus on the same corporate witnesses, the same internal documents, the same regulatory history, and the same expert testimony. Absent centralization, multiple courts will be required to oversee substantially identical discovery, adjudicate identical motions, and rule on the same Daubert and pretrial issues—creating a significant risk of inconsistent rulings and imposing enormous and unnecessary costs on the parties and the judiciary.

Centralization is particularly critical here given the limited insurance proceeds available to satisfy claims. ByHeart reportedly maintains only $10 million in liability insurance subject to "defense-within-limits" provisions, under which defense costs erode the available coverage. Allowing dozens of actions to proceed independently across the country will require ByHeart to retain and coordinate separate defense teams, including local counsel across numerous jurisdictions. Those additional, unnecessary costs—incurred solely as a result of fragmented proceedings—will rapidly deplete finite insurance proceeds, further diminishing the funds available to compensate injured infants and their families.

Finally, Plaintiffs in the filed actions are represented by multiple law firms across jurisdictions, reflecting the nationwide scope of the litigation. No single firm represents more than

a small fraction of the actions currently pending in federal court, and informal coordination among counsel cannot reasonably substitute for formal centralization under 28 U.S.C. § 1407.

Centralization is routine in mass tort actions involving defective or contaminated consumer products, and the Panel has repeatedly exercised its authority to centralize similar litigation to promote efficiency and fairness. *See, e.g., In re Allura Fiber Cement Siding Prods. Liab. Litig.*, 366 F. Supp. 3d 1365, 1365-66 (J.P.M.L. 2019) (granting consolidation of seven putative class actions pending in seven districts that involved defects in cement siding after noting two potential tag-along actions existed and informal coordination of discovery would not be practicable given the number of plaintiffs' counsel and districts involved (eight)). This case presents an even stronger basis for centralization given the identical factual nucleus, the vulnerability of the injured population, and the risk of insurance exhaustion.

b. The Southern District of New York is the most appropriate transferee forum under a balancing of the factors.

The Southern District of New York is the most appropriate forum in which to centralize the Related Actions. In determining the appropriate transferee forum, the Panel should conduct a "balancing test based on the nuance of a particular litigation" that considers several factors, including the number of the underlying cases pending before the district, the experience of the judiciary with the issues, the location of documents and witnesses, the centrality of the location, and common parties. *See* Robert A. Cahn, A Look at the Judicial Panel on Multidistrict Litigation, 72 F.R.D. 211, 214 (1977); *see also In re Regents of Univ. of Cal.*, 964 F.2d 1128, 1136 (Fed. Cir. 1992); MANUAL OF COMPLEX LITIGATION (Fourth) (2010). Transfer is appropriate when it enhances the convenience of the litigation. But because transfer and centralization is done for pre-trial purposes, there will be no need for any witnesses not located near the transferee forum to travel there for trial. *In re Asbestos Prod. Liab. Litig. (No. VI)*, 771 F. Supp. 415, 422 (J.P.M.L. 1991).

Here, all factors weigh in favor of centralization in the Southern District of New York. First, the Southern District of New York is the clear center of gravity of this litigation. Eight of the eighteen Related Actions—nearly half—are already pending in this District. The remaining cases are dispersed across ten different districts nationwide, with no other district hosting more than a single action: District of Arizona (1); Central District of California (1); Eastern District of California (1); Eastern District of Kentucky (1); District of Minnesota (1); Eastern District of New York (1); Middle District of Pennsylvania (1); Northern District of Texas (1); Southern District of Texas (1); Western District of Washington (1).

Second, the Southern District of New York is the locus of ByHeart's corporate operations. ByHeart—the sole defendant common to all actions—maintains its principal place of business in New York, New York. As a result, the District is where key corporate witnesses, decision-makers, and relevant documents are expected to be located. The Panel has repeatedly ruled that one of the most important factors in deciding where to send the MDL is the presence of key documents and witnesses. *See, e.g., In re Avandia Mktg.*, 528 F. Supp. 2d 1339, 1341 (J.P.M.L. 2007); *In re Air Crash Disaster Near Coolidge, Arizona*, 362 F. Supp. 572, 573 (J.P.M.L. 1973); *In re Samsung Customer Data Security Breach Litig.*, 655 F. Supp. 3d 1368, 1369 (J.P.M.L. 2023); *In re Blackbaud, Inc., Customer Data Sec. Breach Litig.*, 509 F.Supp.3d 1362, 1364 (J.P.M.L. 2020).

Third, the Southern District of New York is exceptionally well equipped to manage this litigation. Its judges have extensive experience overseeing complex civil and multidistrict proceedings and currently preside over thirteen active MDLs.[4]

Finally, overall convenience and efficiency strongly favor transfer to the Southern District of New York. Because MDL transfer is for pretrial purposes only, concerns about trial location or

[4] *See* https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-January-5-2026.pdf

inconvenience to individual parties carry limited weight. The Panel evaluates convenience in terms of the litigation as a whole, not the preferences of individual plaintiffs or defendants. *See In re Aqueous Film-Forming Foams Prod. Liab. Litig.*, 669 F. Supp. 3d 1375, 1380 (J.P.M.L. 2023) ("[T]ransfer is appropriate if it furthers the expeditious resolution of the litigation taken as a whole, even if some parties to the action might experience inconvenience or delay"); *In re Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d 1350, 1351–52 (J.P.M.L. 2012) ("[W]e look to the overall convenience of the parties and witnesses, not just those of a single plaintiff or defendant in isolation.").

III. CONCLUSION

Centralizing the Related Actions in the Southern District of New York before the Honorable Denise L. Cote will eliminate duplicative discovery, prevent inconsistent pretrial rulings, conserve judicial resources, preserve limited insurance proceeds, and ensure the efficient and fair resolution of claims for injured infants and their families. Judge Cote's experience, expertise, and ability to manage complex multidistrict litigation make her exceptionally well-suited to oversee these cases. For these reasons, Plaintiffs respectfully request that the Panel transfer and centralize the Related Actions listed in the attached Schedule of Actions to the United States District Court for the Southern District of New York before the Honorable Denise L. Cote.

DATED: January 15, 2026

Respectfully submitted,

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