



DELAWARE COUNTY HEALTH DEPARTMENT

Environmental Health Division

Infant Botulism Outbreak - Update

ByHeart infant formula recall grows as U.S. botulism cases climb to 37

Botulism found in unopened ByHeart cans; formula shipped to 21 countries



James R. Hood, Founder and Editor • Dec. 1, 2025



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- 37 confirmed U.S. cases; all powdered ByHeart formula recalled
- Botulism detected in unopened cans; international risk under review
- BabyBIG treatment effective but hard to access outside the U.S.

Federal health officials are urging families to check their pantries after 37 U.S. infants were diagnosed with infant botulism linked to ByHeart-brand powdered infant formula—an outbreak that has rapidly become one of the largest recorded in the United States. While all known cases remain domestic, the formula was shipped to 21 other countries, and public health authorities say it is still unclear whether infants overseas have also been affected.



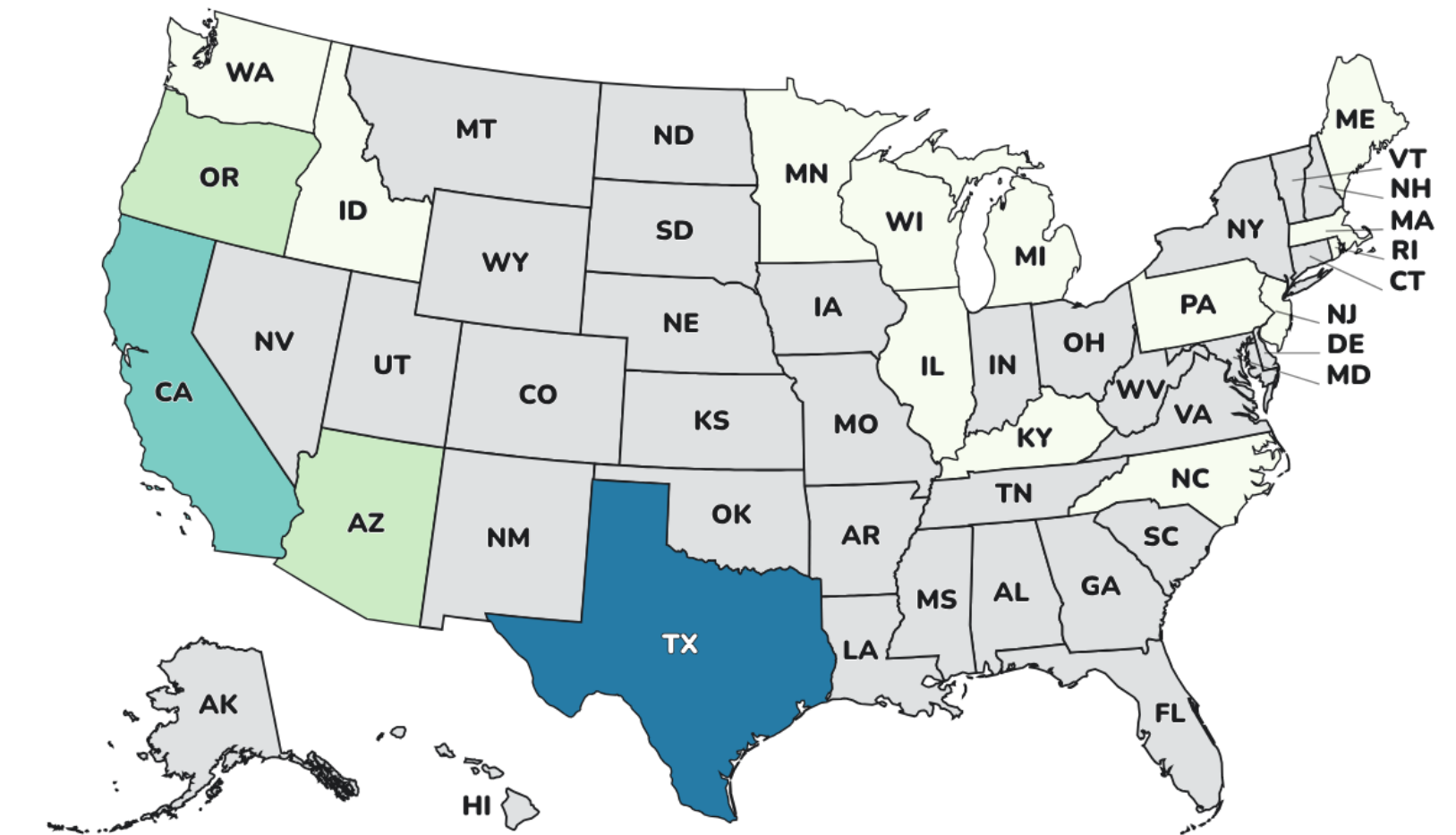
Image (c) ConsumerAffairs. A major recall of ByHeart formula linked to 37 infant botulism cases prompts health warnings and prevention tips for parents.

Infant Botulism

- Infant botulism is a rare but serious condition where *Clostridium botulinum* spores grow in an infant's intestines and produce a toxin that causes muscle weakness and paralysis.
- Symptoms include constipation, poor feeding, loss of head control, and a weak cry.
- Symptoms typically appear between 3 and 30 days after the baby swallows the bacteria's spores.
- Treated with a botulism immune globulin (BabyBIG), which halts the toxin's progression, and supportive care like ensuring proper nutrition and breathing support.
- Treatment must typically begin prior to laboratory confirmation as testing takes several days.

Current

- Cases have a link to ByHeart formula consumption.
- Testing has confirmed the presence of *C. bot* type A bacteria in some formula samples.
- All 37 infants have been hospitalized.
- No deaths have been reported to date.
- Illnesses started on dates ranging from 8/9 to 11/19/2025.
- For 35 infants with age and sex information available:
 - Range in age from 16 to 264 days
 - 15 (43%) are female
- 1 case in PA
- Distributed to 21 countries, with unknown number of international cases.



Number of Sick People

1 to 2

5 to 6

3 to 4

7 to 8

Case count as of 11/26/2025

Map Provided by CDC

Recall Timeline

- **November 7, 2025:** ByHeart initiated a voluntary recall of two specific batches of infant formula (Batch Codes 251261P2 and 251131P2) in response to an FDA investigation into infant botulism cases.
- **November 11, 2025:** The recall was expanded to include all ByHeart infant formula products, both cans and single-serve "Anywhere Pack™" sticks, nationwide due to laboratory tests showing the presence of *Clostridium botulinum* bacteria in some samples.
- **November 19, 2025:** The FDA provided an update on the outbreak, stating that 31 infants in 15 states had been reported with suspected or confirmed infant botulism after exposure to ByHeart formula.
- **November 26, 2025:** The CDC reported that 37 infants had been hospitalized in total, with the last reported illness onset on November 19, 2025.

Recall Timeline – DCHD Response

- **November 17, 2025:** PA Department of Agriculture held emergency call for all Act 315 Jurisdictions and began Recall Audits
 - No information could be shared with jurisdictions without 20.88 Agreements with the FDA prior to this time. Voluntary agreement made with manufacturer to share.
- **November 17, 2025:** Environmental Health alerted all Environmental Health Specialists of Recall Audits
- **November 18, 2025:** Recall Audits completed of 12 confirmed retailers and 18 retailers that sell infant formula or infant food
- **November 19-21, 2025:** Recall Audits completed of 51 retailers that sell infant formula or infant food
 - No recalled product was found on shelves at any retailers in DCHD jurisdiction
 - Any retailer that had received the product had it removed prior to Recall Audit

Additional Actions - DCHD

- Visited all retailers known to sell infant formula or infant food
 - Concerns raised regarding liquidation of products following initial voluntary recall
 - Ensure no accidental reintroduction of product into retail environment
- Alerted known food pantries in Delaware County
- Coordinated with WIC regarding infant formula retailers

Recall Audits - PA

- PA Department of Agriculture reported on 11/24/2025 that 154 additional Recall Audits were conducted in PA.
 - Recalled product was found at:
 - 1 Warehouse
 - 6 Retail Stores
 - 1 Distribution Center (DE) found to still be distributing product to PA
- All food pantries receiving State Food Purchase Program funding were alerted.
- Reading, PA manufacturing has not been in operation since September 2023..

Key Public Messaging

On November 11, 2025, ByHeart Inc. recalled all infant formula products.

Parents and caregivers are urged to stop using any ByHeart Whole Nutrition infant formula immediately. This includes:

- All lot numbers
- All sizes of cans and single serve packets

ByHeart Whole Nutrition Infant Formula was available for sale online and at major retailers nationwide.

Key Public Messaging – Parents & Caregivers

- Seek immediate medical care if your infant has consumed ByHeart Whole Nutrition Infant Formula and has any of these symptoms:
 - Poor feeding
 - Loss of head control
 - Difficulty swallowing
 - Decreased facial expression
- Symptoms of infant botulism can take as long as several weeks to develop, so parents should remain vigilant if they used ByHeart Whole Nutrition infant formula.
- To report a complaint or adverse event (illness or serious allergic reaction), visit FDA's Safety Reporting Portal. If your child has signs or symptoms of infant botulism, seek medical attention before using the portal.

Key Public Messaging – Retailers

- Do not sell or use recalled ByHeart Whole Nutrition infant formula.
 - Do not sell for liquidation.
 - Mark-out UPCs in point-of-sale systems to prevent accidental purchasing.
- Wash and sanitize items and surfaces that may have touched recalled formula.

Product Images

