

PENNSYLVANIA DEPARTMENT OF HEALTH
2025 – PAHAN – 813 – 11– 13 - ADV
Infant Botulism Outbreak Linked to Infant Formula



DATE:	November 13, 2025
TO:	Health Alert Network
FROM:	Debra L. Bogen, M.D., FAAP, Secretary of Health
SUBJECT:	Infant Botulism Outbreak Linked to Infant Formula
DISTRIBUTION:	Statewide
LOCATION:	N/A
STREET ADDRESS:	N/A
COUNTY:	N/A
MUNICIPALITY:	N/A
ZIP CODE:	N/A

This transmission is a “Health Advisory” which provides important information for a specific incident or situation; may not require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL; EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE; FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE; PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; LONG-TERM CARE FACILITIES: PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

Summary

- On November 11, 2025, ByHeart, Inc. recalled all lots of ByHeart Whole Nutrition Infant Formula in response to the U.S. Food and Drug Administration’s (FDA’s) ongoing investigation into a recent outbreak of infant botulism.
- According to the company’s website, ByHeart Whole Nutrition Infant Formula was sold through its website ByHeart.com and through retail stores nationwide, including Amazon, Kroger, Walmart, Whole Foods, Target, SamsClub.com and others.
- Infant botulism is a rare but potentially fatal paralytic illness that impacts babies less than one year old. Symptoms can include constipation, poor feeding, drooping eyelids, weak cry, and progressive muscle weakness.
- Health care providers (HCP) should call the [California Infant Botulism Treatment and Prevention Program](#) (IBTPP) **immediately** at 510-231-7600 for consultation of suspected case. Consultation is available 24/7. Treatment with botulism immune globulin, BabyBIG®, obtained from California Department of Health, is recommended for all suspected cases of infant botulism.
- Infant botulism is a reportable disease in PA; all suspected cases must be reported to the Pennsylvania Department of Health (DOH) at 1-877-PA-HEALTH or their local health department.

Background:

As of November 11, 2025, [15 infants with suspected or confirmed infant botulism](#) were reported from 12 states: Arizona, California (2), Illinois (2), Kentucky, Minnesota, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas (2), and Washington. Laboratory confirmation for some cases is ongoing. Illnesses started on dates ranging from mid-August to

November 2025. All 15 infants were hospitalized and treated with BabyBIG®. No deaths were reported. Infants ranged in age from 16 to 157 days. State and local public health officials are interviewing caregivers about the foods infants were fed in the month before they got sick. All 15 (100%) reported feeding ByHeart Whole Nutrition infant formula. This investigation is ongoing, and additional cases may be identified.

Infant botulism is the most common form of botulism in the United States and Pennsylvania. Even so, this is a rare condition. Recently published data reveal the highest incidence in counties in southeastern Pennsylvania, including Bucks, Chester, Delaware, and Montgomery Counties¹.

Infant botulism impacts babies less than a year of age, with most cases in babies younger than 6 months. Infants can present with constipation, poor feeding, weaker suck, choking when trying to feed, difficulty swallowing, eyelid drooping (ptosis), loss of head control, lack of facial expression, weak cry, weakness or decreased muscle tone, especially starting at the top of their body and limbs, making the baby feel “floppy”². If untreated, infants with infant botulism experience a progressive, flaccid paralysis that can lead to breathing difficulties and require weeks of hospitalization, or even death. Treatment is available from the Infant Botulism Treatment and Prevention Program³.

All ByHeart Whole Nutrition Infant Formula products were recalled. This includes all unexpired lots of formula cans and single-serve “anywhere” sticks (see picture below). The link to the recall is: <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025>.



According to the [FDA](#), ByHeart Whole Nutrition Infant Formula makes up less than 1 percent of all infant formula sales in the United States. Given this small market share, recall of these products is unlikely to create shortage concerns of infant formula for parents and caregivers.

Recommendations for Clinicians

Diagnosis, consultation, and treatment

- Be aware of signs and symptoms of infant botulism as early diagnosis and treatment can improve the outcome.
- If symptoms of infant botulism are present, ask parents/caregivers about infant formula and check for lot code and “use by” date. The lot code and “Use by” date are located on the bottom of the infant formula can. Follow instructions provided by the [FDA](#) on how to handle remaining product.

- Consultation with the California Department of Health's Infant Botulism Treatment and Prevention Program ([IBTPP](#))³ is available for suspected cases. If you suspect your infant patient has botulism, **immediately call 510-231-7600** for case consultation. Consultation is available 24/7.
- If clinical consultation supports infant botulism, begin treatment with botulism immune globulin, BabyBIG®, obtained from California Department of Health as soon as possible. Do not wait for laboratory confirmation.
- The IBTPP is the only source of BabyBIG®, an orphan drug of human-derived botulism antitoxin approved (licensed) by the FDA for the treatment of infant botulism. Use of BabyBIG® significantly reduces the length of hospital stay and associated hospital costs in patients with infant botulism.
- For a definitive diagnosis, a stool or enema specimen is required for botulinum toxin testing. Enema should be performed with sterile, non-bacteriostatic water, preferably not glycerin. Stool specimens can be collected before or after antitoxin administration. Additional information on specimen collection can be found on [IBTPP site](#).
- Infant botulism is a reportable disease in PA; all suspected cases must be reported to DOH at 1-877-PA-HEALTH or your local health department.

Recommendations for Laboratories

Diagnostic testing for suspected botulism may be done through DOH Bureau of Laboratories when BabyBIG® has been approved for treatment. Please call DOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department for approval prior to submitting specimens.

- Laboratory confirmation of botulism is done by demonstrating the presence of botulinum toxin through either mouse bioassay or mass spectrometry.

Recommendations for Public

- Parents and caregivers should stop using All ByHeart Whole Nutrition Infant Formula products. Please see the [FDA website](#) for information on what to do with formula.
- Wash items and surfaces that may have touched the recalled formula using hot soapy water or a dishwasher.
- 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 any of ByHeart infant formula.

For More Information

CDC: [Investigation update: Infant Botulism Outbreak November 2025](#)

CDC: [Clinical guidelines for diagnosis and treatment of botulism, 2021](#)

FDA: [In response to a broader FDA investigation, ByHeart initiates a voluntary recall of two batches of infant formula.](#)

FDA: [Outbreak investigation of infant botulism: Infant formula \(November 2025\)](#)

References

1. Dabritz HA, Friberg IK, Payne JR, Moreno-Gorin C, Lunquest K, Thomas D, Newman AP, Negrón EA, and Drohan PJ. Elevated incidence of infant botulism in a 17-county area of the Mid-Atlantic region in the United States, 2000–2019, including association with soil types. *Appl Environ Microbiol*. 2024 Oct 31;90(11):e01063-24. doi: 10.1128/aem.01063-24. <https://pmc.ncbi.nlm.nih.gov/articles/PMC11577774/>
2. CDC. [Infant Botulism Outbreak Linked to Infant Formula, November 2025 | Botulism | CDC](#), accessed November 10, 2025.
3. California Department of Public Health. [Welcome to the Infant Botulism Treatment and Prevention Program](#), accessed November 10, 2025.

If you have any questions, please call DOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department.

Individuals interested in receiving future PA-HANs can register at:
<https://ondemand.mir3.com/han-pa-gov/login/>.

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of November 13, 2025 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.
