

Dear Partners,

The Centers for Disease Control and Prevention (CDC) would like to inform our medical and public health partners about a current multistate outbreak of infant botulism linked to ByHeart powdered infant formula. This communication is intended to help you prepare, identify cases early, manage suspected cases, and implement appropriate reporting and [public health actions](#).

Background

A multistate outbreak of infant botulism has been identified in the United States. As of November 11, 2025, this outbreak includes fifteen (15) infants with suspected or confirmed infant botulism from 12 states (Arizona, California (2), Illinois (2), Kentucky, Minnesota, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas (2), and Washington). All 15 infants were hospitalized and treated with BabyBIG® (Botulism Immune Globulin Intravenous medication). No deaths have been reported.

The CDC National Botulism Surveillance System records approximately 150-180 infant botulism cases each year. In 2024, over half of infants with infant botulism were exclusively breastfed and 43% were receiving powdered infant formula before becoming ill.

According to information shared by the [Infant Botulism Treatment and Prevention Program \(IBTPP\)](#), since August 1, 2025, through November 10, 2025, 84 infants nationwide have received BabyBIG® treatment.

Data from IBTPP have demonstrated a concerning association between consumption of ByHeart infant formula and botulism. Among the 84 infants recently receiving BabyBIG® treatment, 36 (43%) had any powdered infant formula exposure. Notably, more than 40% (15) consumed ByHeart Whole Nutrition infant formula. This information shows that ByHeart brand formula is disproportionately represented among sick infants in this outbreak, especially given Food and Drug Administration's (FDA) data that ByHeart represents an estimated 1% of all infant formula sales in the United States. Investigations are ongoing but have not identified any other infant formula brands or shared exposures that pose a risk to infants at this time.

CDC and FDA recommend that parents and caregivers immediately stop use of all ByHeart Whole Nutrition infant formula, including cans and single serve packets. On November 11, ByHeart Inc. recalled all ByHeart Whole Nutrition infant formula products. FDA does not anticipate any formula shortages as a result of this outbreak.

What is Infant Botulism

Infant botulism occurs when an infant ingests spores from a type of bacteria called *Clostridium botulinum*, which then grows in the large intestine and produces toxin that blocks the neuromuscular junction by inhibiting the release of acetylcholine. Initial signs and symptoms often include constipation, difficulty feeding (difficulty sucking or swallowing), loss of head control, weak facial expression, and reduced muscle tone. Without prompt recognition and treatment, descending paralysis may progress and involve the respiratory muscles, potentially leading to life-threatening respiratory failure. The time from ingestion to symptom presentation can be up to 30 days.

Recommendations for Clinicians & Public Health Partners

Consider infant botulism a clinical diagnosis in any infant presenting with unexplained weakness, poor feeding, decreased head control, or difficulty swallowing — especially if the infant has consumed ByHeart formula.

Immediate actions when suspecting a case:

- **Do not wait** for laboratory confirmation to initiate case management. Early recognition and treatment are critical.
- Arrange for consultation with the [Infant Botulism Treatment & Prevention Program \(IBTPP\)](#) at 510-231-7600 for evaluation and treatment guidance. Consultation is available 24 hours a day, 7 days a week.
- If clinical consultation supports infant botulism, begin treatment with BabyBIG® without delay. Do not wait for laboratory confirmation.
- Infant botulism is a notifiable disease. Report all suspected cases immediately to your [state or local health department](#).

Patient/caregiver guidance when ByHeart formula was used:

- **Do not use any ByHeart Whole Nutrition infant formula.** This includes formula sold in cans and single serve packets.
 - If possible, take a picture or record the lot number and best by date.
 - If you have leftover ByHeart powdered formula, label it "**DO NOT USE**" and keep it stored in a safe place for at least a month.
 - If your infant develops symptoms of infant botulism, your state health department may want to collect it for testing. If no symptoms appear after a month, throw the leftover formula away.
- Monitor for symptoms of botulism such as poor feeding, loss of head control, difficulty swallowing, or decreased facial expression, seek medical care **immediately** if symptoms appear. Early intervention is critical.
- Wash items and surfaces that may have touched the formula using hot soapy water or a dishwasher.

Institutions, hospitals, clinical labs, and public health partners:

- Do **not** use or distribute any of the recalled ByHeart Whole Nutrition infant formula. Remove it from inventory and inform relevant staff.
- Clean and [sanitize](#) feeding areas and equipment that may have been exposed.
- Ensure clinical labs and pathology services are aware that infant botulism is a reportable condition and laboratory confirmation is critical for case investigation; ensure timely specimen collection and consultation with the state or local health departments for information on specimen collection and confirmatory testing.
- Participate in trace-back, leftover product collection, and laboratory testing as requested by state health departments, CDC and the FDA.

Why this Matters & Next Steps

CDC and FDA, along with state and local health departments, are working to determine the contamination source and to issue further guidance as information becomes available. For clinicians and health-care systems, preparedness means:

- recognizing the signs and symptoms of infant botulism promptly
- having protocols in place for consultation and treatment
- ensuring awareness of case notification procedures
- providing caregivers with clear instructions when feeding concerns arise

We appreciate your support and partnership in addressing this outbreak. Please report suspect cases immediately to your state and local health department. For clinical questions about suspected infant botulism cases and release of BabyBIG® please contact the [Infant Botulism Treatment & Prevention Program \(IBTPP\)](#) at 510-231-7600. For health departments, CDC's Division of Foodborne, Waterborne, and Environmental Diseases at botsurveillance@cdc.gov is available to answer questions and receive case reports. For public health and investigation inquiries, please contact the CDC Emergency Operations Center at 770-488-7100 (after hours) or your [state or local health department](#).

Best regards,

U.S. Centers for Disease Control and Prevention (CDC)

Resources

- Infant Botulism Outbreak Linked to Infant Formula, Nov 2025 — [CDC](#)
- FDA Outbreak Investigation: Infant Botulism—Infant Formula, Nov 2025 — [U.S. Food and Drug Administration](#)
- [Infant Botulism Treatment and Prevention Program](#)