

	Louisiana Health Alert Message 25-6: Multi-State Outbreak of Infant Botulism Linked to ByHeart Infant Formula
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The Louisiana Department of Health (LDH) is issuing this health advisory to alert clinicians about a **multi-state outbreak of infant botulism** and assist in identification and management of suspected cases. **To date, no cases have been identified in Louisiana.**

Background

A [multistate outbreak of infant botulism](#) has been identified in the United States. As of November 14, 2025, this outbreak includes 23 infants with suspected or confirmed infant botulism from 13 states ([see map](#)). All 23 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 Healthcare Professionals

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 LDH's Infectious Disease Epidemiology 24/7 Clinician hotline at 800-256-2748.**

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.

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](#)

