



**To: CAHAN San Diego Participants**

**Date: November 12, 2025**

**From: Public Health Services**

**Health Alert: Outbreak of Infant Botulism Linked to ByHeart Infant Formula**

#### **Key Messages**

- As of November 10, 2025, 15 infants with suspected or confirmed infant botulism linked to ByHeart Infant Formula have been identified in multiple states including California, none of these were in San Diego County.
- Infant botulism is most common in infants younger than 6 months old. Signs and symptoms can include constipation and neurologic symptoms including poor feeding, hypotonia (floppy baby syndrome), and a weak or altered cry. The incubation period is typically 10 to 30 days but has been reported as short as 3 days.
- Botulism can be fatal. Infant botulism antitoxin immunoglobulin (BabyBIG®) should be administered to suspected cases but is only available through California Department of Public Health (CDPH) Infant Botulism Treatment and Prevention Program (IBTPP).
- Clinicians should call the CDPH IBTPP directly for consultation when infant botulism is suspected: 510-231-7600 (available 24/7).
- Health care providers should immediately report suspected cases of infant botulism to the San Diego County Epidemiology Unit by calling 619-692-8499 (8 am to 5 pm, Monday through Friday); 858-565-5255 (after hours and holidays).

#### **Situation**

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), in collaboration with California Department of Public Health (CDPH) and other state and local partners, are investigating a multistate outbreak of infant botulism. Epidemiologic and laboratory data show that ByHeart Whole Nutrition infant formula might be contaminated with *Clostridium botulinum*, which is causing infant illness in multiple regions of the country. A voluntary recall was initially issued November 8, 2025, for specific lots and then expanded to all ByHeart products on November 11. The Food and Drug Administration (FDA) is working to ensure all implicated products are removed from the market. ByHeart Infant Formula was available through multiple retail stores and online purchase.

As of November 10, 2025, fifteen infants ranging in age from 2 weeks to 5 months have been identified with suspected or confirmed infant botulism, including two in California (none in San Diego County). Illness onset dates range from August 9 to November 10, 2025. All 15 infants were hospitalized; no deaths have been reported. This is the first outbreak of infant botulism linked to infant formula in the United States.

#### **Background**

Infant botulism is caused by gut colonization with *Clostridium spp.* (*C. Botulinum*, toxigenic *C. baratii* or *C. butyricum*) following ingestion of spores in contaminated food or dust. The spores germinate and then may produce botulinum neurotoxin, the causative agent of botulism. Due to their low bile acid levels and immature gut microbiota, infants younger than 6 months are at highest risk. The incubation period is typically 10 to 30 days, but signs and symptoms have been reported as early as 3 days after exposure.

Constipation is often the earliest sign followed by poor feeding (weak suck, difficulty swallowing), hypotonia (floppy baby syndrome), weak or altered cry, loss of head control, facial weakness (e.g., diminished facial expression), ptosis, progressive, symmetric, descending flaccid paralysis, and respiratory compromise in severe cases. Diagnosis is based on clinical history, physical exam, and testing for botulinum neurotoxin in stool. Confirmatory testing includes detection of botulinum toxin in stool, or isolation of *C. Botulinum*, toxigenic *C. baratii* or *C. butyricum* from stool. If suspected, treatment with BabyBIG® (Human Botulism Immune Globulin Intravenous) should not be delayed for laboratory confirmation but is only available through the CDPH's Infant Botulism Treatment and Prevention Program (IBTPP). BabyBIG® can reduce severity of symptoms and shorten hospitalization [by more than 3 weeks](#), if administered early.

According to IBTPP, since August 1, 2025, through November 10, 2025, 84 infants nationwide have received treatment for infant botulism. Among them, 36 (43%) had any powdered infant formula exposure. Notably, more than 40% (15) infants who had powdered infant formula exposure consumed ByHeart Whole Nutrition infant formula.

### Actions Requested

1. **Maintain** a high index suspicion for infant botulism and ask parents about the use of ByHeart Whole Nutrition infant formula in any suspected cases.
  - a. Parents of children with suspected infant botulism are encouraged to retain opened containers and save lot numbers and expiration dates of any infant formula consumed by the child and report to their local health department.
2. **Consult** the [CDPH Infant Botulism Treatment and Prevention Program](#) (IBTPP) immediately at 510-231-7600. Consultation is available 24/7 when infant botulism is suspected.
  - a. BabyBIG® should be administered as soon as possible but is only available through IBTPP. Do not wait for laboratory confirmation.
3. **Report** all suspected cases of infant botulism immediately to San Diego County Epidemiology Unit by calling 619-692-8499 (8 am to 5 pm, Monday through Friday); 858-565-5255 (after hours and holidays).

### Resources

- [Infant Botulism Outbreak Linked to Infant Formula, November 2025 | Botulism | CDC](#)
- [Investigation Update: Infant Botulism Outbreak, November 2025 | Botulism | CDC](#)
- [Clinical Overview of Infant Botulism | Botulism | CDC](#)
- [Outbreak Investigation of Infant Botulism: Infant Formula \(November 2025\) | FDA](#)
- [CDPH Infant Botulism Treatment and Prevention Program | CDPH](#)
- [Outbreak of Infant Botulism Linked to ByHeart Infant Formula | CDPH](#)
- [Report: Botulism in San Diego County | CoSD](#)

Thank you for your participation.

### CAHAN San Diego

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