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PUBLIC HEALTH ADVISORY

To: Health Care Providers
From: Dr. Puthiery Va, Maine CDC Director
Subject: Recommendations Related to Infant Botulism Linked to Powdered Infant Formula
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Recommendations Related to Infant Botulism Linked to Powdered Infant Formula

This health alert is to remind all health care providers that all ByHeart Whole Nutrition Infant Formula products have been [recalled](#). This includes all unexpired lots of formula cans and single-serve “anywhere pack” sticks. Providers should advise patients and their families and caregivers that no one should consume any ByHeart infant formula products. Testing of infant formula associated with suspected cases in Maine may be performed by federal partners as appropriate and in consultation with the Maine Center for Disease Control and Prevention (Maine CDC).

The Maine CDC’s Health and Environmental Testing Laboratory (HETL) does not conduct tests for botulism. Suspect human botulism specimens should be sent directly to U.S. CDC after consultation with U.S. CDC and/or the Infant Botulism Treatment and Prevention Program (IBTPP) at the California Department of Public Health (if infant botulism is suspected). Providers should not wait for laboratory confirmation to initiate case management. If clinical consultation supports infant botulism, begin immediate treatment with BabyBIG®.

The Maine CDC is currently investigating one suspected botulism case in a Maine infant who consumed ByHeart infant formula. The suspected case is currently hospitalized and will be treated with BabyBIG®. Confirmatory testing is underway. As of November 14, 2025, this multi-state outbreak includes 23 infants with suspected or confirmed infant botulism from 13 states.

Health care providers should immediately report suspected cases of botulism to the Maine CDC at 1-800-821-5821. Additional information about the outbreak is available in the U.S. CDC Partners Email, below, and on the U.S. CDC’s and FDA’s websites. The Maine CDC’s updates to the letter are in italics.

- <https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html>
- <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025>

US CDC Partners Email (11/13/2025)

Following is the U.S. CDC Partners Email. Recent updates, added by the Maine CDC, appear in italics.

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. Laboratory confirmation for some cases is ongoing. For 22 cases with illness onset information available, illnesses started on dates ranging from August 9 to November 11, 2025. All 23 infants were hospitalized and treated with BabyBIG® (Botulism Immune Globulin Intravenous medication). No deaths have been reported.*

The U.S. 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 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.

U.S. 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 as 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 *Maine CDC at 1-800-821-5821*.

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, the Maine CDC 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 the Maine CDC, U.S. CDC and the FDA.

Why this Matters & Next Steps

U.S. 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 *Maine CDC at 1-800-821-5821*. 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.

Resources

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