HEALTH ADVISORY #232

Infant Botulism Associated with Recalled Infant Formula

TO:

FROM: Shannon McBee, MPH, CHES State Epidemiologist, West Virginia Department of Health, Bureau for Public Health

DATE: November 20, 2025

LOCAL HEALTH DEPARTMENTS: Please distribute to community health providers, hospital-based physicians, infection control preventionists, laboratory directors, and other applicable partners

OTHER RECIPIENTS: Please distribute to association members, staff, etc.

Summary:
The Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), Infant Botulism Treatment and Prevention Program (IBTPP), and state and local public health departments are investigating a multistate outbreak of infant botulism lined to recalled powdered infant formula. Epidemiologic data shows that 40% of formula-fed infants that received treatment for infant botulism consumed ByHeart brand powdered infant formula. Epidemiologic data show that ByHeart Whole Nutrition formula might be contaminated with *Clostridium botulinum* and is making infants sick. ByHeart Inc. has voluntarily recalled all lots of ByHeart Whole Nutrition Infant Formula cans and single-serve packets nationwide. Parents and caregivers should immediately stop using all ByHeart Whole Nutrition infant formula cans or single-serve packets.

As of November 19, 2025, 31 cases of suspected or confirmed infant botulism who consumed ByHeart powdered infant formula have been reported to the CDC across 15 states: Arizona (3), California (4), Idaho (1), Illinois (2), Kentucky (1), Maine (1), Michigan (1), Minnesota (2), North Carolina (2), New Jersey (1), Oregon (3), Pennsylvania (1), Rhode Island (1), Texas (6), and Washington (2). All 23 infants were hospitalized and treated with BabyBIG®. No deaths have been reported. **At this time there are no cases of infant botulism from West Virginia linked to this outbreak.**

Clinical Characteristics:
Infant botulism occurs when the *Clostridium botulinum* spores are ingested and colonize the infant's large intestines. These spores produce botulinum neurotoxin leading to symptoms of botulism. Symptoms can develop up to 30 days after *Clostridium botulinum* spores are ingested and typically include constipation, difficulty feeding with diminished suck and gag reflexes, a weak and altered cry, weak facial expression, and loss of head control. Prompt recognition and treatment is necessary to prevent the progression of illness possibly leading to life-threatening symptoms including respiratory arrest.

Recommendations for Clinicians:
The West Virginia Bureau for Public Health (BPH) is requesting healthcare providers to consider infant botulism as a clinical diagnosis in any infant presenting with unexplained weakness, poor feeding, decreased head control, or difficulty swallowing, especially that has been fed ByHeart infant formula in the past 30 days. Initial

diagnosis should be made based on the patient's clinical presentation. Laboratory testing must be coordinated with the Office of Epidemiology and Prevention Service's epidemiologist on-call and the West Virginia Office of Laboratory Services Bioterrorism Laboratory (WV OLS BT). If you suspect your infant patient has botulism:

- Contact the Infant Botulism Treatment and Prevention Program (IBTPP) at 510-231-7600 for a no-cost clinical consultation. The IBTPP will release BabyBIG® treatment if the patient's clinical findings indicate infant botulism. The IBTPP is available 24 hours a day, 7 days a week.
- Report all suspected cases of infant botulism to the local health department in the patient's county of residence.
- Request laboratory testing for botulism at the point of reporting suspected botulism cases.
- Collect laboratory specimens for testing prior to the administration of BabyBIG® treatment.
- Do not wait for laboratory confirmation to start treatment. Early recognition and treatment are critical.

Testing:

Infant Botulism Specimen Collection and Shipping Guidelines		
Specimen	**Stool**	**Enema**
Quantity	10 grams	≥ 5 mL
Collection Instructions	Stool specimens should be raw in a sterile container prior to BabyBIG® treatment.	Collect specimen in a sterile container prior to BabyBIG® treatment.
Storage Instructions	Refrigerate all specimens promptly after collection. Maintain specimens at (2-8ºC) until shipment.	
Shipping Instructions	• Ship on frozen cold packs. • Label packages for biological hazards as: UN3373 biological substance, Category B. • Provide the local health department with the FedEx tracking number. • Call the WV OLS BT at 304-205-8917 for additional instructions.	
Required Forms	Complete the following forms listed below and include with the specimen shipment: • WV OLS Bioterrorism Clinical Sample Submission Form • CDC Specimen Submission Form 50.34	

Reporting Cases of Botulism:
Suspected or confirmed Botulism is a Category I reportable disease. Healthcare providers and laboratories should **immediately report all suspected cases of infant botulism** to the local health department serving the patient's county of residence. Healthcare providers should not wait for laboratory confirmation to report suspected cases.

Resources:

- CDC Infant Botulism Outbreak Linked to Infant Formula Updates
- FDA Outbreak Investigation of Infant Botulism
- Infant Botulism Treatment and Prevention Program

For any questions, please contact the Office of Epidemiology and Prevention Service's epidemiologist on-call at: (304) 558-5358, extension 1.